

Nämnd för folkhälsa och sjukvård

Tid: 2026-03-31 13.00

Plats: Regionens hus, Ängen

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Nämnd för folkhälsa och sjukvård

Tid: 2026-03-31 13.00

17 Granskning: Hantering av dygnsvila

460 -

489

18 Initiativärende: Tillnyktringsenheten

490 -

496

Övrigt

19 Övriga frågor

Nämnd för folkhälsa och sjukvård

Tid: 2026-03-31 13.00

Kallade*Ledamöter*

Thomas Gustafsson (S), ordförande
Martin Nedergaard-Hansen (VD), 1:a vice ordförande
Monica Samuelsson (KD), 2:a vice ordförande
Eva Eliasson (S)
Karsten Offenbartl (S)
Annki Stark (S)
Kerstin Hammar (M)
Lisbeth Andersson (M)
Carina Källman (M)
Camilla Lundgren (VD)
Peter Iveroth (KD)
Razvan Nichitelea (C)
Andrea Stjärne (L)
Maria Högberg (SD)
Vibecke Hvidsten (SD)

Övriga

Bengt-Ove Eriksson (V), adjungerad
Jane Ydman, regiondirektör
Mats Bojestig, hälso- och sjukvårdsdirektör
Viktoria Karlsson, nämndsekreterare
Anette Peterson, hälso- och sjukvårdsstrateg
Jonatan Vincent, chefscontroller
Annika Bengtsson, jurist
Linda Löfgren sektionschef
Urban Funck, HR-direktör
Marcus Lundgren, utvecklingschef HR
Sofia Persson, utvecklingsledare
Elin Fröding Saric, chefläkare
Agneta Ståhl, sjukvårdsdirektör
Fatmir Zogaj, personalrepresentant Vårdförbundet
Ann-Christin Rydberg, personalrepresentant Kommunal
Anette Sandström, personalrepresentant Vision

För kännedom*Ersättare*

Erik Wågman (S)
Cristina Nichta (S)
Hans Oscarsson (S)
Linda Danielsson (S)
Senada Sacic (M)
Anders Jarl (M)
Gun Lusth (M)
Frida Aronsson (VD)
Emma Hörberg Butler (VD)
Zeljka Axelsson (KD)
Lina Johannesson (C)
Evelina Romhagen (L)
Leontina Aurell (SD)
Rebecca Lindgren (SD)

Regionråd

Rachel De Basso (S)
Tommie Ekered (M)
Per Eriksson (C)
Jimmy Ekström (L)
Stina Sinclair (KD)
Håkan Karlsson Nyborg (SD)
Mikael Ekvall (V)

Nämnd för folkhälsa och sjukvård

Tid: 2026-03-31 13.00

	NFS 2026-03-31	Föredragande/ansvarig
	Plats: Regionens hus, Ängen	
13.00	Upprop och val av protokollsjusterare Fastställande av dagordning Anmälan av delegationsbeslut Övriga anmälningsärenden Kurser och konferenser	Thomas Gustafsson, ordförande Viktoria Karlsson, nämndsekreterare
13.05	Årsrapport för dataskyddsarbete 2025	Annika Bengtsson, jurist Linda Löfgren, sektionschef
13.35	Granskning: Hantering av dygnsvila	Urban Funck, HR-direktör Marcus Lundgren, utvecklingschef HR
13.55	Kunskapsstyrning	Sofia Persson, utvecklingsledare
14.25	Paus	
14.40	Patientsäkerhetsberättelse	Elin Fröding Saric, chefläkare
15.10	Barnkliniken	Agneta Ståhl, sjukvårdsdirektör
15.30	Intern kontroll – Månadsrapport	Jonatan Vincent, enhetschef
15.45	Aktuell information	Mats Bojestig, hälso- och sjukvårdsdirektör
15.55	Frågor	Mats Bojestig, hälso- och sjukvårdsdirektör
16.00	Verksamhetsberättelse 2025 Nämnd för folkhälsa och sjukvård	Mats Bojestig, hälso- och sjukvårdsdirektör
16.05	Intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård	Jonatan Vincent, enhetschef
16.10	Transportambulans till ambulanssjukvård – steg 2	Mats Bojestig, hälso- och sjukvårdsdirektör
16.15	Remiss: Europeiska kommissionens förslag på förordning och direktiv om bioteknik – hälsa	Mats Bojestig, hälso- och sjukvårdsdirektör
16.20	Initiativärende: Tillnyktringsenheten	Mats Bojestig, hälso- och sjukvårdsdirektör
16.25	Övriga frågor	

Delegeringsbeslut

Utskriftsdatum: 2026-03-24 Utskriven av: Viktoria Karlsson

Diarieenhet:	Region Jönköpings län
Beslutsfattare:	Alla
Riktning:	Alla
Kategori:	Alla
Beslutsinstans:	Nämnd för folkhälsa och sjukvård
Sammanträdesdatum:	2026-03-31
Sekretess:	Visas ej

Id	Beskrivning	Paragraf
Datum	Avsändare/Mottagare	Beslutsfattare
Ärendenummer	Ärendemening	Kategori
		Ansvarig
2026.2415	Anmälan av personuppgiftsincident	FS 4.5.4 §17/2026
2026-02-11	Integritetsskyddsmyndigheten	Sofia Sund
RJL 2026/553	Personuppgiftsincident	FS 4.5.4
		Sofia Sund
2026.2480	Anmälan av personuppgiftsincident	FS 4.5.4 §18/2026
2026-02-11	Integritetsskyddsmyndigheten	Sofia Sund
RJL 2026/605	Personuppgiftsincident	FS 4.5.4
		Sofia Sund
2026.2875	Anmälan av personuppgiftsincident	FS 4.5.4 §19/2026
2026-02-18	Integritetsskyddsmyndigheten	Sofia Sund
RJL 2026/727	Personuppgiftsincident	FS 4.5.4
		Sofia Sund
2026.2896	Anmälan av personuppgiftsincident	FS 4.5.4 §21/2026
2026-02-19	Integritetsskyddsmyndigheten	Sofia Sund
RJL 2026/724	Personuppgiftsincident	FS 4.5.4
		Sofia Sund
2026.3054	Anmälan av personuppgiftsincident	FS 4.5.4 §20/2026
2026-02-20	Integritetsskyddsmyndigheten	Sofia Sund
RJL 2026/788	Personuppgiftsincident	FS 4.5.4
		Sofia Sund
2026.3166	Anmälan av personuppgiftsincident	FS 4.5.4 §22/2026
2026-02-23	Integritetsskyddsmyndigheten	Sofia Sund
RJL 2026/821	Personuppgiftsincident	FS 4.5.4
		Sofia Sund
2026.3242	Anmälan av personuppgiftsincident	FS 4.5.4 §23/2026
2026-02-24	Integritetsskyddsmyndigheten	Sofia Sund
RJL 2026/823	Personuppgiftsincident	FS 4.5.4
		Sofia Sund
2026.3650	Anmälan av personuppgiftsincident	FS 4.5.4 §24/2026
2026-02-27	Integritetsskyddsmyndigheten	Sofia Sund

RJL 2026/911	Personuppgiftsincident	FS 4.5.4 Sofia Sund
2026.3946	Anmälan av personuppgiftsincident	FS 4.5.4 §25/2026
2026-03-05	Integritetsskyddsmyndigheten	Sofia Sund
RJL 2026/965	Personuppgiftsincident	FS 4.5.4 Sofia Sund
2026.4333	Anmälan av personuppgiftsincident	FS 4.5.4 §26/2026
2026-03-10	Integritetsskyddsmyndigheten	Sofia Sund
RJL 2026/1038	Personuppgiftsincident	FS 4.5.4 Sofia Sund

Handlingar

Utskriftsdatum: 2026-03-02

Utskriven av: Monica Sandsvik Svensson

Diarienummer: Region Jönköpings län
Datum: 2026-02-02 - 2026-02-27
Riktning: Alla
Status: Alla
Handlingstyp: REMISS
Notering:
Sekretess: Visas ej

Id	I/U/K	Beskrivning	Ansvarig
Datum		Avsändare/Mottagare	Avdelning
Ärendenummer		Notering	Handlingstyp
		Ärendemening	
2026.1900	I	Remiss - Europeiska kommissionens förslag på förordning och direktiv om bioteknik - hälsa	Anette Peterson
2026-02-03		Socialdepartementet	Regionledningskontoret
RJL 2026/494		S2026/00180	REMISS
		Svar senast 2026-04-07	
		Remiss - Europeiska kommissionens förslag på förordning och direktiv om bioteknik - hälsa	
2026.1902	I	Remiss - Europeiska kommissionens förslag på förordning och direktiv om bioteknik - hälsa	Anette Peterson
2026-02-03		Socialdepartementet	Regionledningskontoret
RJL 2026/494		S2026/00180	REMISS
		Svar senast 2026-04-07	
		Remiss - Europeiska kommissionens förslag på förordning och direktiv om bioteknik - hälsa	
2026.1982	I	Remiss - Planbeskrivning Listen 21 granskning	Karin Hermansson
2026-02-04		Vetlanda kommun	Regionledningskontoret
RJL 2026/501		Vetlanda kommuns diarienummer KLF 2025/214	REMISS
		Svarstid 2026-02-12--2026-03-01	
		Remiss - Detaljplan för ändring av Brogårds industriområde, Listen 21, Vetlanda kommun	
2026.2482	I	Remiss - Regionalt serviceprogram Halland 2026-2030	Karin Hermansson
2026-02-13		Region Halland	Regionledningskontoret
RJL 2026/636		Remissversion RS260092	REMISS
		Svar senast 2026-04-02	
		Remiss - Regionalt serviceprogram Halland 2026-2030	
2026.2604	I	Remiss- Pilonidalcysta	Evelina Örn
2026-02-16		Nationellt system för kunskapsstyrning hälso- och sjukvård	Regionledningskontoret

RJL 2026/678		Svar senast 2026-04-14 Remiss- Pilonidalcysta	REMISS
2026.2609	I	Remiss- Perinalabscess	Evelina Örn
2026-02-16		Nationellt system för kunskapsstyrning hälso- och sjukvård	Regionledningskontoret
RJL 2026/679		Svar senast 2026-04-14 Remiss- Perinalabscess	REMISS
2026.2614	I	Remiss- Fecesinkontinens	Evelina Örn
2026-02-16		Nationellt system för kunskapsstyrning hälso- och sjukvård	Regionledningskontoret
RJL 2026/681		Svar senast 2026-04-14 Remiss- Fecesinkontinens	REMISS
2026.2619	I	Remiss- Analfistel	Evelina Örn
2026-02-16		Nationellt system för kunskapsstyrning hälso- och sjukvård	Regionledningskontoret
RJL 2026/688		Svar senast 2026-04-14 Remiss- Analfistel	REMISS
2026.2629	I	Remiss- Analfissur	Evelina Örn
2026-02-16		Nationellt system för kunskapsstyrning hälso- och sjukvård	Regionledningskontoret
RJL 2026/690		Svar senast 2026-04-14 Remiss- Analfissur	REMISS
2026.2641	I	Remiss- Matallergi och annan matöverkänslighet hos barn och vuxna, icke IgE-förmedlad	Evelina Örn
2026-02-16		Nationellt system för kunskapsstyrning hälso- och sjukvård	Regionledningskontoret
RJL 2026/692		Svar senast 2026-04-14 Remiss- Matallergi och annan matöverkänslighet hos barn och vuxna, icke IgE-förmedlad	REMISS
2026.2646	I	Remiss- Matallergi, kostbehandlad	Evelina Örn
2026-02-16		Nationellt system för kunskapsstyrning hälso- och sjukvård	Regionledningskontoret
RJL 2026/694		Svar senast 2026-04-14 Remiss- Matallergi, kostbehandlad	REMISS
2026.2650	I	Remiss- Matallergi, IgE-förmedlad, hos vuxna	Evelina Örn
2026-02-16		Nationellt system för kunskapsstyrning hälso- och sjukvård	Regionledningskontoret
RJL 2026/695		Svar senast 2026-04-14 Remiss- Matallergi, IgE-förmedlad, hos vuxna	REMISS
2026.2525	I	Remiss- Vägledningsdokument om 3D utskrivna medicintekniska produkter inom hälso- och sjukvården och tandvården	Evelina Örn
2026-02-16		Nationellt system för kunskapsstyrning hälso- och sjukvård	Regionledningskontoret
RJL 2026/650		öppen remiss mellan 16 februari och 14 april Remiss- Vägledningsdokument om 3D utskrivna medicintekniska produkter inom hälso- och sjukvården och tandvården	REMISS
2026.2655	I	Remiss- Matallergi, IgE-förmedlad, hos barn	Evelina Örn

2026-02-16		Nationellt system för kunskapsstyrning hälso- och sjukvård	Regionledningskontoret
RJL 2026/696		Svar senast 2026-04-14	REMISS
		Remiss- Matallergi, IgE-förmedlad, hos barn	
2026.2659	I	Remiss- Astma	Evelina Örn
2026-02-16		Nationellt system för kunskapsstyrning hälso- och sjukvård	Regionledningskontoret
RJL 2026/697		Svar senast 2026-04-14	REMISS
		Remiss- Astma	
2026.2540	I	Remiss – Nationellt vårdprogram för bröstcancer	Evelina Örn
2026-02-16		Nationellt system för kunskapsstyrning hälso- och sjukvård	Regionledningskontoret
RJL 2026/660		Svar senast 2026-04-14	REMISS
		Remiss – Nationellt vårdprogram för bröstcancer	
2026.2543	I	Remiss – Nationellt vårdprogram för cancerrehabilitering	Evelina Örn
2026-02-16		Nationellt system för kunskapsstyrning hälso- och sjukvård	Regionledningskontoret
RJL 2026/661		Svar senast 2026-04-14	REMISS
		Remiss – Nationellt vårdprogram för cancerrehabilitering	
2026.2546	I	Remiss- Matstrups- och magsäckscancer	Evelina Örn
2026-02-16		Nationellt system för kunskapsstyrning hälso- och sjukvård	Regionledningskontoret
RJL 2026/662		Svar senast 2026-04-14	REMISS
		Remiss- Matstrups- och magsäckscancer	
2026.2549	I	Remiss- Nationellt vårdprogram och standardiserat vårdförlopp (SVF) för peniscancer	Evelina Örn
2026-02-16		Nationellt system för kunskapsstyrning hälso- och sjukvård	Regionledningskontoret
RJL 2026/663		Svar senast 2026-04-14	REMISS
		Remiss- Nationellt vårdprogram och standardiserat vårdförlopp (SVF) för peniscancer	
2026.2552	I	Remiss- Nationellt vårdprogram för tumörer i centrala nervsystemet	Evelina Örn
2026-02-16		Nationellt system för kunskapsstyrning hälso- och sjukvård	Regionledningskontoret
RJL 2026/664		Svar senast 2026-04-14	REMISS
		Remiss- Nationellt vårdprogram för tumörer i centrala nervsystemet	
2026.2556	I	Remiss- Stöddokument för bedömning och hantering av biverkningar vid behandling med checkpointhämmare	Evelina Örn
2026-02-16		Nationellt system för kunskapsstyrning hälso- och sjukvård	Regionledningskontoret
RJL 2026/665		Svar senast 2026-04-14	REMISS
		Remiss- Stöddokument för bedömning och hantering av biverkningar vid behandling med checkpointhämmare	
2026.2562	I	Remiss- Min vårdplan akuta leukemier	Evelina Örn
2026-02-16		Nationellt system för kunskapsstyrning hälso-	Regionledningskontoret

		och sjukvård	
RJL 2026/668		Svar senast 2026-04-14	REMISS
		Remiss- Min vårdplan akuta leukemier	
2026.2583	I	Remiss- Skärpta villkor för friskolesektorn (SOU 2025:123)	
2026-02-16		Regeringskansliet	Regionledningskontoret
RJL 2026/674		Svar senast 2026-05-18	REMISS
		Remiss - Skärpta villkor för friskolesektorn (SOU 2025:123)	
2026.2584	I	Remiss – Tarmtömningssvårigheter	Evelina Örn
2026-02-16		Nationellt system för kunskapsstyrning hälso- och sjukvård	Regionledningskontoret
RJL 2026/675		Svar senast 2026-04-14	REMISS
		Remiss – Tarmtömningssvårigheter	
2026.2590	I	Remiss - Rektalprolaps	Evelina Örn
2026-02-16		Nationellt system för kunskapsstyrning hälso- och sjukvård	Regionledningskontoret
RJL 2026/677		Svar senast 2026-04-14	REMISS
		Remiss - Rektalprolaps	
2026.2637	I	Remiss - Riktlinjer för bostadsförsörjning 2026-2029 (Habo kommun)	Nathalie Bijelic Eriksson
2026-02-17		Habo Kommun	Regionledningskontoret
RJL 2026/691		Svar senast 2026-04-17	REMISS
		Dnr KS23/338	
		Remiss - Riktlinjer för bostadsförsörjning 2026-2029 (Habo kommun)	
2026.3201	I	Remiss- Remittering av Europeiska kommissionens förslag till förordning om digitala nät KOM(2026)16	Karin Hermansson
2026-02-17		Finansdepartementet	Regionledningskontoret
RJL 2026/705		Svar senast 2026-04-20 Fi2026/00350	REMISS
		Remiss- Remittering av Europeiska kommissionens förslag till förordning om digitala nät KOM(2026)16	
2026.2928	I	Samråd del av Rosenlund 2: 1	John Wilhelmsson
2026-02-19		Jönköpings kommun	Länstrafiken
RJL 2023/4125		Svar senast 2026-04-02	REMISS
		Detaljplan för idrottsanläggning på del av Rosenlund 2:1 och Äminne 2, Jönköpings kommun	
2026.3116	I	Remiss- Remittering av promemorian Samling runt barnet- en likvärdig och kvalitativ vård inom den sociala barn- och ungdomsvården (Ds 2026:5)	Nathalie Bijelic Eriksson
2026-02-20		Socialdepartementet	Regionledningskontoret
RJL 2026/810		S2026/00313	REMISS
		Svar senast 2026-05-20	
		Remiss- Remittering av promemorian Samling runt barnet- en likvärdig och kvalitativ vård inom den sociala barn- och	

2026.3389	I	Remiss - Rektor i fokus, förutsättningar för ett pedagogiskt ledarskap	Nathalie Bijelic Eriksson
2026-02-25		Regeringskansliet	Regionledningskontoret
RJL 2026/881		SOU 2026:4 Svar senast 2026-05-25 Remiss - Rektor i fokus, förutsättningar för ett pedagogiskt ledarskap	REMISS
2026.3539	I	Missiv: Begäran om yttrande - uppvisning på väg motorcykelkortege	John Wilhelmsson
2026-02-26		Länstrafiken	Länstrafiken
RJL 2026/902		2026-03-16 Ansökan om tillstånd till uppvisning på väg motorcykelkortege 29 maj 2026	REMISS
2026.3582	I	Remiss - ansökan om tillstånd till uppvisning på väg motorcykelkortege	Jessica Sjöström
2026-02-26		Länsstyrelsen i Jönköpings län	Länstrafiken
RJL 2026/902		Svar senast 2025-03-28 Ansökan om tillstånd till uppvisning på väg motorcykelkortege 29 maj 2026	REMISS

Handlingar

Utskriftsdatum: 2026-03-02

Utskriven av: Monica Sandsvik Svensson

Diarienummer: Region Jönköpings län
Datum: 2026-02-02 - 2026-02-27
Riktning: Alla
Status: Alla
Handlingstyp: MOTION
Notering:
Sekretess: Visas ej

Id	I/U/K	Beskrivning	Ansvarig
Datum		Avsändare/Mottagare	Avdelning
Ärendenummer		Notering	Handlingstyp
		Ärendemening	
2026.2577	I	Motion - Det är dags att ta itu med tystnadskulturen	Linda Byman
2026-02-16		Vänsterpartiet	Regionledningskontoret
RJL 2026/673		Motion - Det är dags att ta itu med tystnadskulturen	MOTION

Ärenden

Utskriftsdatum: 2026-03-02

Utskriven av: Monica Sandsvik Svensson

Diarienummer: Region Jönköpings län

Sekretess: Visas ej

Makulerade: Visas ej

Beskrivning av sökning:

Ärendenummer	Ärendemening	Ansvarig
Datum	Avsändare/Mottagare	Avdelning
2026/721	Uppföljning av granskning Informationssäkerhet	Linda Löfgren
2026-02-17	Regionrevisionen	Regionledningskontoret
2026/722	Uppföljning av granskning av kollektivtrafiken	Ulrika Rosander
2026-02-17	Regionrevisionen	Länstrafiken
2026/910	Granskning av regionstyrelsens styrning och ledning med utgångspunkt i strategier och andra övergripande styrande dokument	Linda Byman
2026-02-26	Regionrevisionen	Regionledningskontoret

Handling	Dnr + rubrik/innehåll
Inkomna handlingar	
– Regeringsbeslut	
– Beslut från Inspektionen för vård och omsorg (IVO)	RJL 2024/4266 Patientärende RJL 2024/2093 Patientärende RJL 2025/4476 Patientärende, lex Maria RJL 2026/201 Patientärende, lex Maria RJL 2024/635 Patientärende RJL 2024/1113 Personalärende RJL 2026/139 Patientärende, lex Maria RJL 2026/77 Patientärende, lex Maria RJL 2026/138 Patientärende, lex Maria
– Beslut från Sveriges kommuner och regioner (SKR)	
– Skrivelser från invånare	RJL 2026/319 Skrivelse om behov av riktade insatser för patienter med komplex traumatisering, DID och CPTSD
– Skrivelser från organisationer	
– Övrigt	RJL 2026/698 Information gällande ny EU-förordning om humanmaterial RJL 2026/6 Beslut RS 2026-03-04 Direktiv budget med verksamhetsplan 2027 och flerårsplan 2028–2029
Upprättade handlingar	
– Protokoll	Protokoll Nämnd för folkhälsa och sjukvård 2026-02-18 Protokoll Nämnd för folkhälsa och sjukvård – presidium 2026-03-17
– Svar på skrivelser från invånare	RJL 2026/319 Svar på skrivelse om behov av riktade insatser för patienter med komplex traumatisering, DID och CPTSD
– Svar på skrivelser från organisationer	
– Övrigt	

2026-03-17

§ 43**Kurser och konferenser****Beslut**

Presidiet beslutar följande.

Inbjudan: Utvecklingskraft – Primärvårdsdagen 6 maj 2026
– Två förtroendevalda från den politiska ledningen och två förtroendevalda från oppositionen erbjuds att delta på nämndens bekostnad.

Inbjudan: Kunskapsträff – Långsiktig planering som en del i det förebyggande arbetet
– Nämnden står inte för kostnader kopplade till inbjudan.

Inbjudan: Lunchwebbinarium 15 april om Hjärnskadekoordinator
– Nämnden står inte för kostnader kopplade till inbjudan.

Inbjudan: Jämställdhetskongressen 20 maj på Spira
– Nämnden står inte för kostnader kopplade till inbjudan.

Inbjudan: Communities that Care (CTC) – en samverkansprocess där närområdet engageras
– Nämnden står inte för kostnader kopplade till inbjudan.

Inbjudan: Framåtblick Sverige om politisk polarisering
– Nämnden står inte för kostnader kopplade till inbjudan.

Beslutsunderlag

- Inbjudan: Utvecklingskraft – Primärvårdsdagen 6 maj 2026
- Inbjudan: Kunskapsträff – Långsiktig planering som en del i det förebyggande arbetet
- Inbjudan: Lunchwebbinarium 15 april om Hjärnskadekoordinator
- Inbjudan: Jämställdhetskongressen 20 maj på Spira
- Inbjudan: Communities that Care (CTC) – en samverkansprocess där närområdet engageras
- Inbjudan: Framåtblick Sverige om politisk polarisering

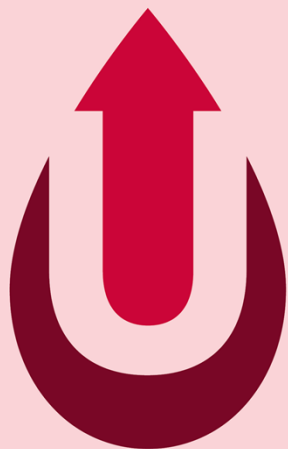
Beslutet skickas till

Nämnden för folkhälsa och sjukvård

From: "Bijelic Eriksson Nathalie" <nathalie.bijelic.eriksson@rjl.se>
Sent: 2026-02-20 14:52:20
To: "Karlsson Viktoria" <viktorias.karlsson@rjl.se>
Subject: VB: Utvecklingskraft 2026 - Anmälan öppen!

Från: Utvecklingskraft <esmaker.survey@entergate.se>
Skickat: den 20 februari 2026 13:23
Till: Regionledningskontoret Kansli <regionledningskontoret.kansli@rjl.se>
Ämne: Utvecklingskraft 2026 - Anmälan öppen!

Om e-postmeddelandet inte visas korrekt, kan det ses i sin helhet via följande länk: [Visa webbbversion](#)



Utvecklingskraft

Primärvårdsdagen 6 maj 2026

Tema: Tillsammans med invånaren i en föränderlig tid

Invitation till Utvecklingskraft - Primärvårdsdagen, 6 maj 2026!

På den 6 maj samlas vi för en dag helt tillägnad primärvården inom ramen för Utvecklingskraft 2026. Det är en dag som drivs av utveckling, förbättringsarbete och framtidens nära vård – oavsett roll eller utmaning. Tema: Tillsammans med invånaren i en föränderlig tid.

Information och program - utvecklingskraft.se

Vi är glada att få välkomna **Anders Vege**, senior rådgivare vid
Helse Nordregionen i Norge och en av Nordens starkaste röster inom
integrerad vård.

Utgångspunkt i den avgörande frågan "Vad är viktigt för dig – just nu?" visar
hur vi kan förändra både mötet med patienten och hur vi planerar, leder och
utför vården. Vad kan vi lära av varandra över landsgränserna?

Upp med dig hem?

Ena exemplet från 40 vårdcentralers pågående utvecklingsarbeten
utifrån perspektivet på hur invånare och närstående kan bli verkliga partners
och till tidigare projekt och resultat att bygga vidare på
utmaningar i aktuella teman via lärandestationer
och motivation från kollegor som gör samma resa



Är du med?

Plats redan idag – antalet fysiska platser på Qulturum i Jönköping är begränsat. Digitalt deltagande
erbjöds också.

Vi ser fram emot att träffa dig den 6 maj på **Utvecklingskraft 2026!**



Mer nytt för framtiden!

2026 tar vi avstamp mot ett nytt Utvecklingskraft. Vi bygger om och utvecklar konferensen för att ska
den ännu bättre speglar dagens behov och framtidens möjligheter. Ambitionen är att mötas våren 20
nästa – med mer samskapande, mer lärande och mod att testa, utveckla och tänka nytt tillsammans.

År 2026 fokuserat på den uppskattade arenan: Primärvårdsdagen. Det är en dag utformad särskilt
inriktad inom primärvården, fylld av praktiskt lärande, inspiration och konkreta exempel på förbättrings
ambitionen.

Inget - Följ oss i sociala medier!

På resan fram till konferensen startar – Vi kommer bjuda på inspiration och kunskap även inför dagen. Följ oss på sociala medier så missar du inget @qulturum och #ukraft.



Utvecklingskraft arrangeras av Qulturum, Region Jönköpings läns utvecklingsenhet.

Information om anmälan kommer via epost, i sociala medier och på konferenswebben, utvecklingskraft.se.

Visa gärna dina kollegor – sprid ordet och låt fler upptäcka kraften i Utvecklingskraft!

Utvecklingskraft 2026!



Du får detta nyhetsbrev eftersom du är kund hos oss eller för att du har registrerat dig för att få vårt nyhetsbrev. [Skulle du vilja avsluta din prenumeration, klicka här](#)

From: "Colliander Josefine" <regionledningskontoret.kansli@rjl.se> on behalf of "Regionledningskontoret Kansli" <regionledningskontoret.kansli@rjl.se>
Sent: 2026-02-16 10:18:17
To: "Karlsson Viktoria" <viktor.karlsson@rjl.se>
Subject: VB: Välkommen till Kunskapsträff: Långsiktig planering som en del i det förebyggande arbetet

Från: SKR Evenemang <evenemang@skr.se>

Skickat: den 16 februari 2026 07:01

Till: Region Jönköpings län <regionen@rjl.se>

Ämne: Välkommen till Kunskapsträff: Långsiktig planering som en del i det förebyggande arbetet

Viktig Information: Detta e-postmeddelande kommer från en avsändare utanför Region Jönköpings län. Klicka aldrig på länkar och öppna aldrig bifogade filer om du är osäker på avsändaren eller innehållet.

Om du misstänker att meddelandet är skadligt, vidarebefordra meddelandet till natfiske@rjl.se



Sveriges
Kommuner
och Regioner

Evenemang från SKR

För vidarebefordran till förtroendevalda och tjänstepersoner som jobbar med äldreomsorgsfrågor.

Kunskapsträff: Förebyggande och främjande äldreomsorg – att lyckas med hälsosamtal

Datum: 22 maj 2026

Tid: 10:00-11:30

Plats: Webbsändning

Kostnad: Kostnadsfritt, men anmälan krävs

Anmälan: [Kunskapsträff: Förebyggande och främjande äldreomsorg – att lyckas med hälsosamtal](#)

Träffarna spelas inte in men visst material som presenteras kommer att publiceras i SKRs samarbetsrum Ny socialtjänstlag fokus äldreomsorg.

Vid detta tillfälle lyfter vi den långsiktiga planeringen och hur denna kan bidra till att kommunens olika förvaltningar men även region, civilsamhälle och invånare involveras i arbetet för att främja äldre personers trygghet, hälsa och självständighet. Vi gästas av företrädare från två kommuner, Camilla Andersson, ledningsstöd på Socialförvaltningen i Vingåkers kommun och Ann-Charlotte Jansson, strateg för en äldrevänlig kommun, från enheten för Social Hållbarhet i Gävle kommun.

Du som deltar får möjlighet att dela med dig av hur din kommun just nu resonerar, och förstås lyssna på hur andra kommuner gör.

Välkommen!

Sanna Juhlin

sanna.juhlin@skr.se

Sveriges Kommuner och Regioner

Vid frågor, kontakta SKR:s kontaktcenter:

info@skr.se 08-452 70 00

[Läs mer om hur vi behandlar personuppgifter](#)

Från: Hjärnkraft Jönköping <jonkoping@hjarnkraft.se>

Skickat: den 1 mars 2026 17:29

Till: Region Jönköpings län <regionen@rjl.se>

Ämne: Inbjudan till lunchwebbinarium

Viktig Information: Detta e-postmeddelande kommer från en avsändare utanför Region Jönköpings län. Klicka aldrig på länkar och öppna aldrig bifogade filer om du är osäker på avsändaren eller innehållet.

Om du misstänker att meddelandet är skadligt, vidarebefordra meddelandet till natfiske@rjl.se

Hej,

Vi ber att nedanstående inbjudan vidarebefordras till ledamöterna i Nämnden för Folkhälsa och sjukvård, samt till verksamhetscheferna för rehabmedicinska klinikerna i Jönköping, Värnamo och Nässjö.

Vi tackar på förhand för hjälpen!

Vänligen,

Hjärnkraft Jönköpings län

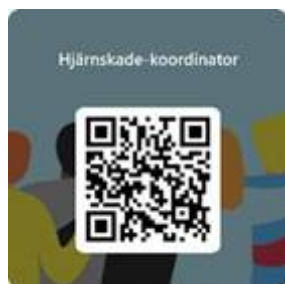
Inbjudan till lunchwebbinarium 15 april om Hjärnskadekoordinator

Ett stort antal personer drabbas årligen av **förvärvad hjärnskada**, de vanligaste anledningarna är traumatiska hjärnskador och stroke. Konsekvenserna är ofta omfattande och långvariga. Efter en förvärvad hjärnskada kan det behövas många olika kontakter med vård, kommun och myndigheter. För den person som har fått en hjärnskada kan detta vara svårt att klara på egen hand. Forskning visar tex att personer med förvärvad hjärnskada hör till de grupper som har allra störst svårigheter att klara digitala tjänster. Personer med förvärvad hjärnskada har därför ett särskilt behov av stöd och hjälp, något som inte finns i tillräcklig utsträckning i region Jönköping idag. Det behovet skulle en **hjärnskadekoordinator** fylla. Hjärnkraft Jönköpings län bjuder in till webbseminarium om hur region Skåne med stor framgång arbetat med hjärnskadekoordinatorer sedan över 20 år. **Hjärnskadekoordinator Ingela Ljunggren Törnblad, region Skåne**, berättar om koordinators roll och hur den bidrar till förbättrad rehabilitering efter hjärnskada, till gagn för såväl patient som samhälle.

Tid: Onsdag 15 april kl 12.30-13.30

Plats: webbseminarium via Teams. Länk skickas ut i vecka 16.

Anmälan:



Kontakt: jonkoping@hjarnkraft.se

Skicka gärna inbjudan vidare till intresserade kollegor.

Varmt välkomna!

Hjärnkraft Jönköpings län



Kort om hjärnskadekoordinatorer

Hjärnskadekoordinatören är en resursperson och ett stöd till personer med förvärvade hjärnskador och deras närstående och ger information, stöd och samordning. Koordinatören har som sin viktigaste funktion att se till att samverkan genom hela vårdkedjan fungerar, över huvudmannagränser i kontakten med vårdgivare och myndigheter.

Patienter med förvärvad hjärnskada och deras anhöriga har EN kontinuerlig kontakt med råd och stöd genom både det akuta förloppet och genom den ibland långa rehabiliteringen. Förutsättningarna att snabbare komma tillbaka till ett självständigt liv ökar genom den hjälp hjärnskadekoordinatören ger. Hjärnskadekoordinatorns arbete inte bara till gagn för den enskilde utan kommer också samhället i stort tillgodo.

Hjärnskadeförbundet Hjärnkraft verkar för att hjärnskadekoordinatorer ska finnas i landets samtliga regioner.

Hjärnkraft Jönköpings län * jonkoping@hjarnkraft.se * www.hjarnkraft.se

Från: Länsstyrelsen i Jönköpings län <noreply@jonkoping.lansstyrelsen.se>

Skickat: den 18 februari 2026 08:13

Till: Götesson Ola <ola.gotesson@rjl.se>

Ämne: [*Newsletter*] Nyhetsbrev För ett jämställt Jönköpings län 2026 nr.1

Viktig Information: Detta e-postmeddelande kommer från en avsändare utanför Region Jönköpings län. Klicka aldrig på länkar och öppna aldrig bifogade filer om du är osäker på avsändaren eller innehållet.

Om du misstänker att meddelandet är skadligt, vidarebefordra meddelandet till natfiske@rjl.se

[Visa i webbläsare](#)

För ett jämställt Jönköpings län



Välkommen till vårt nya nyhetsbrev!

Länsstyrelsen i Jönköpings län ger dig regionala och nationella nyheter på jämställdhetsområdet. Längst ner finns en länk för andra som vill börja prenumerera – tipsa gärna dina kollegor!

NYHETER



Välkommen på Jä-j-konferens 2026: Har vi råd att vänta?

Löneskillnader mellan kvinnor och män ökar, föräldrar sparar mindre till flickor än till pojkar, vid skilsmässor utnyttjas bodelningsprocessen för att bibehålla kontroll. Ekonomin är en central del av både individens liv och samhället i stort, och kopplat till jämställdhet går utvecklingen åt fel håll. Har vi råd att vänta på en jämställd ekonomi?

Under dagen kommer forskare, myndigheter och civilsamhället djupdyka i temat från olika perspektiv och erbjuda både teoretiska förklaringar och praktiska exempel med syfte att utveckla, utmana och kunskapshöja deltagarnas bild av ekonomisk jämställdhet och ekonomiskt våld.

Konferensen riktar sig till dig som arbetar med social hållbarhet, brottsförebyggande arbete, barn och unga, men också politiker, beslutsfattare, chefer och strateger inom offentlig förvaltning, näringsliv och civilsamhälle.

När: 20 maj, kl. 08:30 - 15:00

Var: Kulturhuset Spira, Jönköping

Arrangör: Länsstyrelsen i Jönköping län och Region Jönköpings län

[Läs mer och anmäl dig till konferensen](#)



Årets unga ledande kvinna - listan över årets förebilder

Nu är listan över årets förbilder 2025 klar. [Här kan du se alla nominerade](#)

Priser delas ut i kategorierna Årets ledarförebild, Årets entreprenör och Årets blivande styrelsetalang.

Den 4 mars kl. 17:30 - 20:30 går prisceremonin av stapeln på Science Park Towers i Jönköping. På kvällen hyllas de nominerade och tre koras till vinnare. [Du kan amäla dig till och med 1 mars.](#)

Får de jämställdhetspolitiska delmålen önskad effekt?

Senast den 29 maj i år ska en särskild utredning vara färdig gällande de jämställdhetspolitiska delmålen 1 - 5. Utredningen tillsattes 2024 och syftet är att den ska sammanfatta måluppfyllelsen, föreslå hur styrningen för att uppfylla dessa delmål kan bli mer effektiva och analysera om indikatorerna för delmålen är ändamålsenliga. I utredningen ska man också ta ställning till om det finns behov av en mer sammanhållen, kostnadseffektiv och ändamålsenlig styrning av statliga myndigheters arbete för att uppnå de jämställdhetspolitiska målen och vid behov lämna författningsförslag eller andra förslag på hur det kan uppnås.

[Läs mer om utredningen här](#)

KALENDER

6

mars

Digitalt frukostseminarium: Vad kan vi i Sverige lära av hur andra länder har arbetat med jämställdhet och mänskliga rättigheter i internationella fredsinsatser?

I ett tuffare säkerhetspolitiskt läge behöver Sverige ta höjd för att den beredskap som byggs upp säkerställer skydd för hela civilbefolkningen. Därför måste jämställdhet och mänskliga rättigheter beaktas på ett systematiskt sätt. Med anledning av Internationella kvinnodagen 8 mars bjuder länsstyrelserna in till ett digitalt frukostseminarium.

Tillfället riktar sig till funktioner inom offentlig sektor, civilsamhället och statliga myndigheter som hanterar och/eller är intresserad av frågor som rör civilt försvar, social hållbarhet och skydd av civilbefolkning i händelse av kris och krig.

[Anmäl dig här](#)

22

april

Digitalt frukostseminarium: Att integrera jämställdhet i övning och utbildning

Välkommen till en föreläsning som erbjuder dig kunskap och konkreta tips om hur jämställdhet kan beaktas och integreras i utbildning och övning av olika aktörer inom totalförsvaret. När aktörer inom totalförsvaret utvecklar och övar inom sin verksamhet är det nödvändigt att beakta kvinnor och män, flickor och pojkars olika behov, förutsättningar och riskutsatthet. Men hur gör vi det? Och vad händer om vi inte gör det?

Föreläsningen riktar sig till dig som arbetar inom offentlig sektor eller civilsamhället och som på olika sätt kommer i kontakt med frågor om krisberedskap, civilt försvar eller totalförsvaret.

[Anmäl dig här](#)

NYHETER OCH RAPPORTER

Maskulinitet - överblick, kontritiserings och framåtblick

Jämställdhetsmyndigheten gav Jesper Fundberg, som har lång erfarenhet och

Räkna med kvinnor - Global Media Monitoring Project 2025

Kvinnor utgör halva världens befolkning men syns bara i en fjärdedel av det globala

Hon vill bara att tiden ska gå

En kartläggning av profiler och webbplatser som marknadsför sexuella handlingar mot betalning.

gedigen kunskap inom detta kunskapsfält, att ta fram en lättillgänglig artikel om maskulinitet. Slutsatserna i artikeln är hans egna. Vi hoppas artikeln leder till respektfulla samtal om maskulinitet, ökad kunskap som kan bidra till att fler män vill bli delaktiga och tillsammans med kvinnor ta ansvar för ett jämställt samhälle fritt från våld.

[Läs rapporten hos jämställdhetsmyndigheten](#)

nyhetsflödet visar The Global Media Monitoring Project (GMMP) 2025. Sverige hör till länderna som placerar sig i topp men med 37 procent kvinnor i nyheterna inom press, radio och tv så finns det fortfarande mycket jobb kvar att göra.

[Läs nyhetsartikeln hos Jämställdhetsmyndigheten](#)

Idag kan alla led i människohandel och exploatering ske digitalt. Allt ifrån rekrytering och kontroll - till annonsering och betalning. Rapporten bidrar till att kartlägga kunskapsläget om webbplatser vars uttalade syfte är att marknadsföra fysiska sexuella handlingar mot betalning.

[Läs rapporten hos Jämställdhetsmyndigheten](#)

Länsstyrelsen i Jönköpings län

Besöksadress: Hamngatan 4, Jönköping

Postadress: 551 86 Jönköping

Telefon växel: 010-223 60 00

E-post: jonkoping@lansstyrelsen.se

Copyright: Länsstyrelsen i Jönköpings län och respektive fotograf.

[Så hanterar vi dina personuppgifter](#)

[Avregistrera dig från nyhetsbrevet Ett jämställt Jönköpings län](#)



Länsstyrelsen
i Jönköpings län



Region
Jönköpings län



Från: SKR Evenemang <evenemang@skr.se>

Skickat: den 13 mars 2026 09:01

Till: Region Jönköpings län <regionen@rjl.se>

Ämne: Påminnelse: Communities that Care (CTC) - en samverkansprocess där närområdet engageras

Viktig Information: Detta e-postmeddelande kommer från en avsändare utanför Region Jönköpings län. Klicka aldrig på länkar och öppna aldrig bifogade filer om du är osäker på avsändaren eller innehållet.

Om du misstänker att meddelandet är skadligt, vidarebefordra meddelandet till natfiske@rjl.se



Sveriges
Kommuner
och Regioner

Evenemang från SKR

Vänligen vidarebefordra till tjänstepersoner och förtroendevalda inom kommun och region, berörda inom Polismyndigheten, Länsstyrelsen, näringslivet och civilsamhället.

Communities that Care (CTC) - en samverkansprocess där närområdet engageras

Communities that Care (CTC) är ett system för ett långsiktigt, brett förebyggande arbete i det lokala såväl offentliga som civilsamhälle och näringsliv. Det är ett systematiskt tillsammansarbete för att säkerställa goda uppväxtvillkor för barn och unga.

Datum: 22 april 2026.

Tid: Klockan 10:00-11:00.

Plats: Webbsändning.

Kostnad: 500 kr exklusive moms.

Sista anmälningdag: 21 april 2026.

Målgrupp: Tjänstepersoner och förtroendevalda inom kommun och region, berörda inom Polismyndigheten, Länsstyrelsen, näringslivet och civilsamhället.

Praktisk information:

Evenemanget kommer att spelas in och vara tillgänglig för anmälda deltagare i 14 dagar i efter seminariet.

För mer information och anmälan:

[Communities that Care \(CTC\) - En samverkansprocess där närområdet engageras | SKR](#)

Communities that Care (CTC) är ett system för ett långsiktigt, brett förebyggande arbete i det lokala, som genomförs av lokala aktörer, såväl offentliga som civilsamhälle och näringsliv. Genom CTC får lokalområdet ett verktyg att aktivt "rekrytera" barn och unga till ett prosocialt sammanhang. CTC kan även förebygga problem med ANDT, ungdomsbrottslighet, våld och psykisk ohälsa.

Vad är CTC och hur kan man jobba med styrsystemet? Vad finns det för stöd att få och hur används CTC i Sverige? Detta är några frågor du kommer att få svar på i detta seminarium om Communities that Care (CTC).

Varmt välkommen!

Greta Berg

Avdelningen för tillväxt och samhällsbyggnad

Sveriges Kommuner och Regioner

Vid frågor, kontakta SKR:s kontaktcenter:

info@skr.se 08-452 70 00

Läs mer om hur vi behandlar personuppgifter

Från: LF Forskningsstiftelse <lforskningsstiftelse@medietjanst.se>

Skickat: den 11 mars 2026 08:49

Till: Region Jönköpings län <regionen@rjl.se>

Ämne: [*Newsletter*] Anmäl dig till Framåtblick Sverige om politisk polarisering

Viktig Information: Detta e-postmeddelande kommer från en avsändare utanför Region Jönköpings län. Klicka aldrig på länkar och öppna aldrig bifogade filer om du är osäker på avsändaren eller innehållet.

Om du misstänker att meddelandet är skadligt, vidarebefordra meddelandet till natfiske@rjl.se



Välkommen till Framåtblick Sverige den 16 april

Seminarium:

Valår i en polariserad värld – hur håller vi ihop?

Runt om i världen syns tydliga tecken på att samhällskontraktet är under press. I flera länder har geografiska klyftor mellan stad och land blivit grogrund för misstro och missnöje. Invånare i landsbygds- och glesbygdsområden upplever sig ofta förbisedda och förfördelade av politiska och ekonomiska eliter. Något som i flera länder kommit till uttryck genom stöd till antietablissemangsrörelser och populistiska partier. Välkommen till Framåtblick Sverige om politisk polarisering!

Anmäl dig till seminariet – digitalt eller på plats

Framåtblick Sverige tar denna gång utgångspunkt i aktuell forskning om geografisk polarisering som finansierats av LF Forskningsstiftelse. Seminariet genomförs i samarbete med Centrum för Kommunstrategiska Studier vid Linköpings universitet.

Politisk polarisering belyses ur flera perspektiv: Hur ser de värderingsmässiga och attitydmässiga skiljelinjerna mellan stad och land ut i Sverige? Hur kan polariseringen påverka valutgången och valrörelsen? Hur hanterar media och civilsamhälle problematiken och kan de bidra till sammanhållning? Tillsammans utforskar vi hur polariseringen i Sverige ser ut, hur den kan påverka valet och vad vi kan göra för att hålla ihop i en orolig tid.

Varmt välkommen!

Peter Griepenkerl Lööf
Forskningschef, LF Forskningsstiftelse

Datum och tid

Den 16 april klockan 9.00–10.00 (frukost och mingel från klockan 8.30)

Plats

Kulturhuset gatuplan, lokal Lilla Studion, T-centralen Stockholm. Eller digitalt.

Medverkande

- Gissur Ó Erlingsson, professor i statsvetenskap, Linköpings universitet
- Henrik Ekengren Oscarsson, professor i statsvetenskap, SOM- institutet, Göteborgs universitet
- Anne Lagercrantz, vd SVT
- Stefan Holmgren, stabschef MUCF

Moderator

Elin Ahldén

Anmäl dig här

Seminariet är kostnadsfritt, men platserna är begränsade. Anmäl dig [här](#) om du vill delta på plats på Kulturhuset eller få en länk för att delta digitalt. Anmäl dig senast 14 april.

Om seminariet

Framåtblick Sverige är en seminarieserie från LF Forskningsstiftelse som ställer aktuella frågor på sin spets. Här möts forskare och beslutsfattare för att under 60 minuter diskutera de bästa vägvalen för ett tryggt och hållbart samhälle.

Läs inbjudan i en [webbläsare](#).

Du får denna inbjudan eftersom vi bedömer att seminariet utgör ett berättigat intresse i din roll som beslutsfattare i eller nära offentlig sektor. Om du vill avregistrera dig från utskick från LF Forskningsstiftelse kan du [klicka här](#).

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§ 29**Årsrapport för dataskyddsarbete 2025**

Diarienummer: RJL 2025/3516

Beslut

Presidiet beslutar att

- nämnden ska informeras om årsrapport för dataskyddsarbete 2025 vid nämndsammanträdet den 31 mars 2026.

Beslutsunderlag

- Årsrapport för dataskyddsarbete 2025
-

2026-03-09

Dataskyddsombudet
Annika BengtssonRegionstyrelsen
Nämnden för arbetsmarknad, näringsliv och
attraktivitet
Nämnden för folkhälsa och sjukvård
Nämnden för trafik, infrastruktur och miljö
Parlamentariska nämnden
Patientnämnden
Regionrevisionen

Dataskyddsombudets årsrapport för år 2025

1. Inledning

I denna årsrapport redogörs för de delar av dataskyddsarbetet inom Region Jönköpings län under kalenderåret 2025 som dataskyddsombudet bedömer är väsentliga att uppmärksamma. Dataskyddsombudet gör också en del iakttagelser avseende risker inom dataskyddsområdet samt lämnar ett antal rekommendationer.

Uppgifter om antal ärenden, incidenter, konsekvensbedömningar m.m. har dataskyddsombudet inhämtat från Diarium och nämndadministration och Sektionen för informationssäkerhet och juridik.

2. Förklaring av grundläggande begrepp

Personuppgifter: All slags information som direkt eller indirekt kan knytas till en person som är i livet. Exempel på personuppgifter är namn, personnummer, uppgifter om hälsa, foto på person, röstinspelning, IP-adress.

Personuppgiftsbehandling: Behandling är ett vidsträckt begrepp och innefattar allt som kan göras med personuppgifter. Till exempel insamling, registrering, organisering, lagring, bearbetning eller ändring, utlämnande, spridning eller annat tillhandahållande av uppgifter, sammanställning eller samkörning, blockering, utplåning eller förstöring av personuppgifter.

Den registrerade: Den person vars personuppgifter behandlas.

Personuppgiftsansvarig: Den organisation (till exempel aktiebolag, stiftelse, förening eller myndighet) som bestämmer för vilka ändamål uppgifterna ska behandlas och hur behandlingen ska gå till. Det är alltså inte chefen på en arbetsplats eller en medarbetare som är personuppgiftsansvarig.

Personuppgiftsbiträde: Den som behandlar personuppgifter för den personuppgiftsansvariges räkning.

Personuppgiftsincident: En säkerhetsincident som leder till oavsiktlig eller olaglig förstöring, förlust eller ändring av personuppgifter. Den kan också leda till ett obehörigt röjande av eller obehörig åtkomst till personuppgifter.

3. Sammanfattning

Med tanke på det försämrade säkerhetsläget i Sverige och omvärlden är skyddet för personuppgifter viktigare än någonsin. Cyberincidenter orsakade av angrepp och andra typer av oönskade händelser fortsätter att drabba Sveriges kommuner och regioner. Samhällets säkerhetsskydd ökar med ett väl implementerat integritetsskydd. Det finns också ett direkt samband mellan arbetet med informations- och cybersäkerhet, dataskydd och säkerhetsskydd varför ett systematiskt och effektivt samarbete dessa funktioner emellan är av stor vikt.

I årsrapporten rekommenderar dataskyddsombudet bland annat Region Jönköpings län att under 2026 prioritera frågan om införande av mottagare/kontaktpersoner i regionens olika verksamheter. Ett sådant införande skulle ge verksamhetsansvariga ett bra stöd i det operativa dataskyddarbetet vid till exempel konsekvensbedömning eller hantering av personuppgiftsincidenter. Andra områden som behöver prioriteras är en översyn av registerförteckningen, konsekvensbedömningar samt kunskapshöjande åtgärder beträffande rutiner för rapportering av personuppgiftsincidenter.

4. Rättslig bakgrund

Det är främst EU:s dataskyddsförordning, The General Data Protection Regulation (GDPR), samt den kompletterande nationella dataskyddslagen med kompletterande bestämmelser till EU:s dataskyddsförordning som reglerar den personuppgiftsbehandling som sker inom Region Jönköpings läns olika verksamheter. Det finns också ytterligare reglering från EU, praxis från EU-domstolen, nationell lag och förordning så som patientdatalagen och kamerabevakningslagen samt bindande föreskrifter och beslut om behandling av personuppgifter som tillsammans utgör tillämplig dataskyddslagstiftning.

Dataskyddsförordningen är till för att skydda grundläggande rättigheter och friheter, särskilt enskildas rätt till skydd av sina personuppgifter. Dataskyddsförordningen gäller i hela EU/EES och har också som syfte att skapa en enhetlig och likvärdig nivå för skyddet av personuppgifter så att det fria flödet av uppgifter inom EU/EES inte hindras.

Inom Region Jönköpings läns olika verksamheter behandlas stora mängder personuppgifter. Ansvariga för att personuppgiftsbehandlingen sker i enlighet med tillämplig dataskyddslagstiftningen är regionstyrelsen och övriga nämnder,

var och en för de behandlingar som sker i den egna verksamheten. Det är alltså respektive nämnd/styrelse som är personuppgiftsansvarig, inte den juridiska personen Region Jönköpings län. I vissa fall agerar nämnderna som personuppgiftsbiträde.

Dataskyddslagstiftningen tar också sikte på att ge den registrerade kontroll över hur dennes personuppgifter behandlas. Denna kontroll kan bland annat utövas genom ett antal lagstadgade rättigheter, till exempel rätten att begära ut ett registerutdrag.

Efterlevnaden av regelverket övervakas av Integritetsskyddsmyndigheten (IMY) och överträdelser kan leda till bland annat sanktionsavgifter och/eller skadeståndskrav från de registrerade personerna. IMY genomför också så kallade regulatoriska sandlådor, en metod för att kunna ge fördjupad vägledning inom ett visst område samt publicerar allmänna vägledningar och mallar.

5. Dataskydd – en värdegrundsfråga i tiden

Dataskydd är ett begrepp för allt det som gör att människors personuppgifter hanteras tryggt och säkert när de samlas in, bearbetas, delas, lagras eller hanteras på annat sätt. Det handlar om allt från ordning och reda med hjälp av rutiner och administrativa processer till att sätta upp tekniska skyddsåtgärder i system och digitala verktyg. Det handlar också om att personalen behöver kunskap att upprätthålla dataskyddet - både i den dagliga verksamheten och när verksamheten utvecklas.

Dataskydd kan upplevas som ett komplext område med ett detaljerat regelverk, men också tekniskt och abstrakt eftersom det många gånger handlar om hur personuppgifter hanteras i olika tekniska funktioner och verktyg. Regelverket ska dock ses i ljuset av att skyddet av personuppgifter är en grundläggande värdegrundsfråga som kommit att bli högaktuell tack vare den snabba innovativa och datadrivna teknikutvecklingen. Även mot bakgrund av hoten i vår omvärld har skyddet för den personliga integriteten aldrig varit viktigare att värna än idag.

Rätten till integritet är många gånger ett led i att tillvarata andra fri- och rättigheter som människor har i demokratiska samhällen. Till exempel rörelsefriheten, rätten att fritt bilda åsikter och rätten att inte bli diskriminerad. Det är i det ljuset som GDPR ska förstås. Utan GDPR vore det ”fritt fram” att använda personuppgifter för sådant som profilering, åsiktsregistrering eller försök att negativt påverka våra uppfattningar och vår tillit till samhället. Möjligheterna att följa, kartlägga och påverka människor ökar med den nya tekniken.

GDPR sätter ramarna så att tekniken inte ska leda till en insamling och användning av personuppgifter som äventyrar människors grundläggande fri- och

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rättigheter i ett demokratiskt samhälle. Att hålla sig inom reglerna blir därför centralt, framförallt eftersom det inte är tekniken som sätter gränserna.

6. Dataskyddsombudets arbetsuppgifter

Dataskyddsombudets ställning och uppdrag är särskilt reglerade i dataskyddsförordningen. De övergripande och viktigaste uppgifterna är att informera och ge råd till verksamheterna, oberoende övervaka att verksamheterna efterlever tillämplig dataskyddslagstiftning samt att samarbeta med IMY. Dataskyddsombudet ska också ge råd om konsekvensbedömningar.

Dataskyddsombudet är kontaktperson för såväl IMY som de registrerade.

Dataskyddsombudet ska vid utförande av sina uppgifter arbeta riskbaserat. Vidare ska dataskyddsombudet rapportera direkt till den personuppgiftsansvariges högsta förvaltningsnivå, vilket inom Region Jönköpings län är de politiska nämnderna och Regionstyrelsen.

Varje år lämnar dataskyddsombudet en årsrapport. Årsrapporten är avsedd att komplettera annan rapportering för att ge nämnderna och Regionstyrelsen en ökad medvetenhet och bredare insyn i det dataskyddsarbete som bedrivs inom regionen.

Dataskyddsombudet är inte ansvarig i händelse av bristande efterlevnad av dataskyddsregelverket. Ansvar för behandling av personuppgifter åligger istället respektive personuppgiftsansvarig politisk nämnd.

7. Rapporteringsområden samt dataskyddsombudets iakttagelser och rekommendationer

7.1 Ansvarsfördelning och systematiskt dataskyddsarbete

Under året har Sektionen för informationssäkerhet och juridik inom Regionkontoret stöttat regionens verksamheter med att uppfylla kraven i dataskyddsregelverket. Det löpande arbetet har i huvudsak bestått i att ge råd i olika frågor samt att utreda och anmäla personuppgiftsincidenter. Bedömningen av Sektionen för informationssäkerhet och juridik är att antalet frågor från verksamheterna ökat något under året jämfört med föregående år.

Under året har Sektionen för informationssäkerhet och juridik också haft rollen som Region Jönköpings läns dataskyddsombud.

Dataskyddsombudet har i tidigare årsrapporter konstaterat att det saknas mottagare ute i verksamheterna som arbetar aktivt med dataskyddsfrågor.

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Dataskyddsbudet och har också konstaterat att Sektionen för informationssäkerhet och juridik inte bedriver något operativt dataskyddsarbete - det ansvaret åvilar verksamheterna.

Beslut om att anställa ett dataskyddsbud fattades under tidig höst och det nya dataskyddsbudet påbörjade sin anställning i januari 2026.

Dataskyddsbudets iakttagelser och rekommendationer

Dataskyddsbudet vill även i denna årsrapport framhålla att ett införande av en mottagare/kontaktperson, placerade i regionens olika verksamheter skulle förbättra möjligheterna till ett mer systematiskt och effektivt dataskyddsarbete. En sådan mottagare/kontaktperson är också viktig för att förbättra möjligheterna till att dataskyddsfrågor kan identifieras och adresseras i ett tidigt skede. Uppdraget kommer sannolikt inte att kräva lika mycket resurser i alla regionens verksamheter men dataskyddsbudet vill framhålla vikten av att de personer som utses till mottagare/kontaktpersoner ges tillräckligt med tid och kompetensutveckling för att utföra sitt uppdrag.

7.2 Registerförteckning

Av Dataskyddsbudets årsrapport för dataskyddsarbete 2024 framgår att det vid tidpunkten för rapporten fanns personuppgiftsbehandlingar som borde registrerats i registerförteckningen samt att det inom vissa verksamheter saknades fastställda rutiner för hur dessa löpande skulle kunna hålla registret uppdaterat.

Under våren 2025 pausades registreringarna i Region Jönköpings läns registerförteckning under en tid. Anledningen var att många registreringar i förteckningen var gjorda utifrån system och register – inte med utgångspunkt i verksamheternas processer. Under hösten har ett mindre antal registreringar i förteckningen skett och ett nytt systemstöd för registerförteckning köpts in.

Dataskyddsbudets iakttagelser och rekommendationer

Personuppgiftsansvariga och personuppgiftsbiträden är skyldiga att föra ett register över sina behandlingar av personuppgifter. Register över behandlingar ska upprättas skriftligen, vara tillgängliga i elektroniskt format och hållas uppdaterade. På begäran ska registret göras tillgängligt för IMY. Vad som ska finnas med i registret beskrivs i artikel 30 i dataskyddsförordningen.

Dataskyddsbudet konstaterar att Region Jönköpings län planerar en översyn av aktuell registerförteckning i samband med att det nya systemstödet tas i bruk. Dataskyddsbudet välkomnar översynen och rekommenderar att den utgår från en kartläggning av både regiongemensamma och verksamhetsspecifika arbetsprocesser. På så sätt kan en struktur med utgångspunkt i personuppgiftsbehandlingarnas ändamål/syfte åstadkommas.

7.3 Konsekvensbedömning

En konsekvensbedömning är ett verktyg som har till syfte att identifiera, bedöma och minimera risker för den registrerades rättigheter och friheter, dvs risker som kan resultera i negativa konsekvenser. Konsekvenserna kan vara av materiell, fysisk eller psykisk karaktär.

En konsekvensbedömning är obligatorisk om en typ av personuppgiftsbehandling sannolikt leder till en hög risk för fysiska personers rättigheter och friheter.

Av dataskyddsombudets årsrapport för år 2024 framgår att få konsekvensbedömningar genomförs inom Region Jönköpings län. Riktlinje konsekvensbedömning och förhandssamråd samt mall för konsekvensbedömning för forskning finns tillgängliga på regionens intranät. Mall för konsekvensbedömning för personuppgiftsbehandling för andra ändamål kan efterfrågas hos Sektionen för informationssäkerhet och juridik.

Enligt Sektionen för informationssäkerhet och juridik har det även under 2025 genomförts eller påbörjats endast ett fåtal konsekvensbedömningar. Diarium och nämndadministration hittar, vid sökning i de mappar som de har tillgång till en (1) konsekvensbedömning som godkänts under 2025. Det är dock troligt att flera verksamheter hanterar dessa dokument i sina egna verksamhetsmappar.

Dataskyddsombudets iakttagelser och rekommendationer

Enligt dataskyddsombudets bedömning uppfyller inte Region Jönköpings län kraven beträffande genomförande av konsekvensbedömningar. Bedömningen baseras på tidigare bedömning av dataskyddsombudet, att endast en konsekvensbedömning går att hitta i diariet samt det faktum att Region Jönköpings län i många verksamheter utför personuppgiftsbehandling som sannolikt leder till hög risk (till exempel behandlas känsliga personuppgifter i stor omfattning avseende personer i beroendeställning).

Bristen på konsekvensbedömningar är allvarlig och innebär ökade risker för att personuppgifter behandlas utan att de legala kraven efterlevs, till exempel att personuppgifter behandlas utan rättslig grund eller att uppgifterna inte skyddas av erforderliga tekniska och organisatoriska säkerhetsåtgärder.

Dataskyddsombudet rekommenderar att arbetet med att genomföra konsekvensbedömningar prioriteras. Ett förslag till första steg i arbetet är att kartlägga vilka personuppgiftsbehandlingar som sannolikt leder till en hög risk för fysiska personers rättigheter och friheter. En sådan kartläggning kan med fördel ske i samband med det planerade arbetet med översynen av registerförteckningen.

Dataskyddsombudet rekommenderar också att riktade utbildningsinsatser till de verksamhetsansvariga och andra medarbetare som berörs av arbetet med

konsekvensbedömningar genomförs. Utbildningen bör ge kunskap om när en konsekvensbedömning är obligatorisk, på vilket sätt den tillför nytta inom dataskyddsarbetet och hur den genomförs.

7.4 Personuppgiftsincidenter

En personuppgiftsincident är en incident som leder till förstöring, förlust eller ändring av personuppgifter. Den kan också leda till ett obehörigt röjande av eller obehörig åtkomst till personuppgifter. Det spelar ingen roll om det har skett oavsiktligt eller med avsikt.

Alla personuppgiftsincidenter ska rapporteras som avvikelser i Region Jönköpings läns avvikelshanteringssystem. Enligt Region Jönköpings läns rutin görs därefter en bedömning av händelsen och regionjurist beslutar om incidenten ska anmälas till IMY eller inte.

I denna årsrapport presenteras siffror avseende kalenderåret 2025.

Under aktuell tidsperiod har det rapporterats in 912 avvikelser som efter bedömning har konstaterats inte vara några personuppgiftsincidenter.

Under året hade Region Jönköpings län 468 registrerade personuppgiftsincidenter. 114 av dessa bedömdes så allvarliga att de anmäldes till IMY. Samtliga personuppgiftsincidenter som anmäldes till IMY under 2025 har avslutats med motiveringen att "IMY beslutar att för närvarande inte vidta några åtgärder med anledning av anmälan".

Personuppgiftsincidenter per resultatområde i avvikelshanteringssystemet:

Verksamhetsområde	Antal incidenter	Antal anmälda incidenter	Antal incidenter där man underrättat de registrerade
Folktandvården	22	3	2
IT-centrum	5	1	0
Kirurgisk vård	115	33	23
Kommunal utveckling	0	0	0
Länstrafiken	2	1	1
Medicinsk vård	122	24	15
Psykiatri, rehabilitering och diagnostik	138	37	22
Regionens åtagande	0	0	0
Regionledningskontoret och Verksamhetsnära funktion	22	3	4
Utbildning och kultur	0	0	0
Utbildning och kultur naturbruk	4	0	0
Verksamhetsstöd och service	4	1	0
Vårdcentralerna Bra Liv	34	11	7
Totalt	468	114	74

Bild 1: Tabellen visar antal personuppgiftsincidenter, antalet anmälda incidenter och antal incidenter där man informerat de berörda registrerade. Områdena följer indelningen av resultatområden i avvikelshanteringssystemet.

Det kan noteras att verksamhetsområdena Kommunal utveckling, Regionens åtagande och Utbildning och kultur inte rapporterat några

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personuppgiftsincidenter under året. Det kan också noteras att Länstrafiken och Utbildning och kultur naturbruk, som båda hanterar större mängder personuppgifter, endast rapporterat två respektive fyra personuppgiftsincidenter under året.

Personuppgiftsincidenter per personuppgiftsansvarig nämnd

Personuppgiftsansvarig nämnd	Antal incidenter	Antal anmälda incidenter
Nämnd för arbetsmarknad, näringsliv och attraktivitet	4	0
Nämnd för folkhälsa och sjukvård	433	108
Nämnd för trafik, infrastruktur och miljö	2	1
Parlamentarisk nämnd	0	0
Patientnämnd	0	0
Regionrevisionen	0	0
Regionstyrelsen	29	5
Krisledningsnämnd	0	0
Totalt	468	114

Bild 2: Tabellen visar antal personuppgiftsincidenter per personuppgiftsansvarig nämnd/styrelse.

Det kan noteras att Patientnämnd, Parlamentarisk nämnd och Regionrevisionen inte rapporterat några personuppgiftsincidenter.

I vissa fall ska de berörda registrerade underrättas om den inträffade personuppgiftsincidenten. Inom Region Jönköpings län är det enligt rekommendation på intranätet regionjurist i samråd med ansvarig inom berörd verksamhet som fattar beslut om huruvida information ska ges eller ej.

Av rapporteringen från Sektionen för informationssäkerhet och juridik framkommer att 86 personuppgiftsincidenter bedömdes innebära en sådan risk för de registrerades fri- och rättigheter att underrättelse skulle göras. Vid 74 incidenter informerades de registrerade. Av de återstående 12 incidenterna valde berörd verksamhet i sju fall att inte informera bland annat med hänvisning till att man inte visste vem den registrerade var eller att den registrerades hälsotillstånd inte tillät att informationen gavs. Vid fem incidenter saknas information.

Av Region Jönköpings läns rutin ” Rutiner för rapportering av personuppgiftsincident (GDPR-lagstiftningen)” framkommer att alla anställda inom Region Jönköpings län ska anmäla personuppgiftsincidenter i avvikelshanteringssystemet senast två timmar efter att de har upptäckts. Under året har 116 personuppgiftsincidenter rapporterats inom två timmar. 352 rapporterades senare än inom två timmar.

Anmälan till IMY ska ske inom 72 timmar från upptäckten av incidenten. Under året har tre personuppgiftsincidenter anmälts för sent. En av förseningarna orsakades av att den initiala bedömningen av incidenten visade sig felaktig. De andra två förseningarna orsakades av att ansvariga medarbetare inte var i tjänst.

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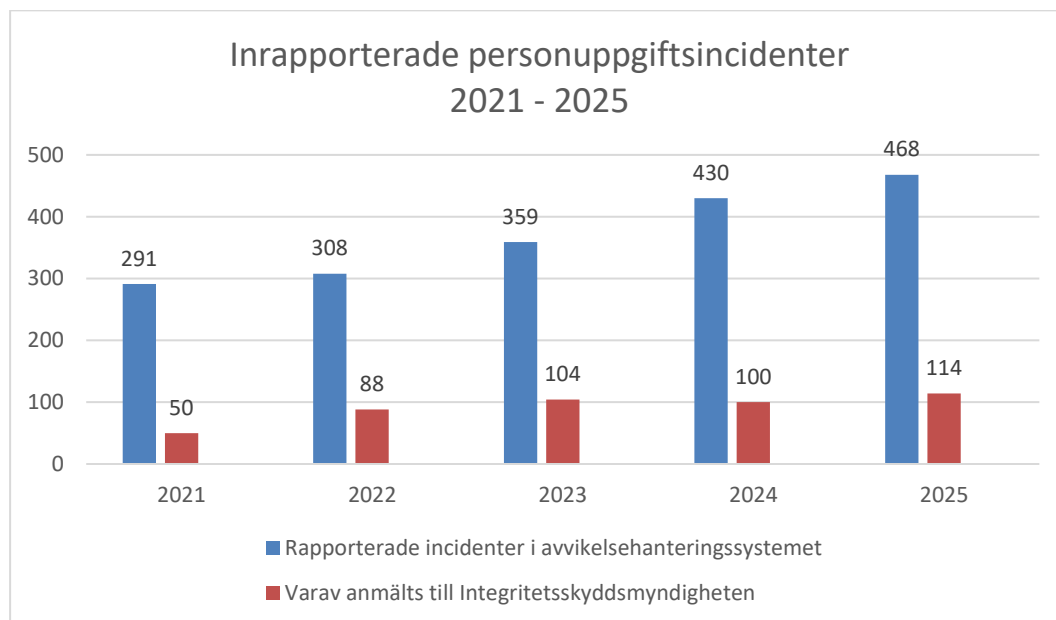


Bild 3: Diagrammet visar antal personuppgiftsincidenter som rapporterats inom Region Jönköpings län samt antal incidenter som anmäls till IMY under år 2021 till år 2025.

Diagrammet ovan visar antalet inrapporterade personuppgiftsincidenter under åren 2021 till 2025. En ökning av antalet rapporterade personuppgiftsincidenter har skett varje år, framförallt från år 2023 (359) till år 2024 (430). Diagrammet visar också antalet personuppgiftsincidenter som anmäls till IMY. Andelen som anmäls har minskat något från år 2023 (28 %) till år 2024 (23 %) och år 2025 (24 %).

Dataskyddsombudets iakttagelser och rekommendationer

Det samlade antalet rapporterade personuppgiftsincidenter har ökat de senaste fem åren. Orsaken är inte känd men en anledning skulle kunna vara en högre medvetenhet om vikten av att rapportera personuppgiftsincidenter hos verksamheterna. Trots detta bedömer dataskyddsombudet att ett mörkertal föreligger. Det finns verksamheter som inte rapporterat några personuppgiftsincidenter alls och det finns verksamheter som har ett lågt antal incidenter vid en jämförelse med andra verksamheter. Det totala antalet personuppgiftsincidenter är inte heller särskilt högt i förhållande till Region Jönköpings läns storlek.

Dataskyddsombudet rekommenderar att samtliga verksamheter säkerställer att rutiner för rapportering av personuppgiftsincidenter följs samt att alla medarbetare har relevant kunskap om vad som ska rapporteras och när.

Antalet felregistreringar är fortfarande högt. Det är förvisso positivt att incidenter rapporteras in men det är samtidigt viktigt för regionens arbete med säker hantering av personuppgifter att det finns kunskap om vad som är en

personuppgiftsincident så att resurser utnyttjas på ett ändamålsenligt och effektivt sätt.

7.5 Klagomål

En registrerad, som anser att behandling av personuppgifter som avser henne eller honom strider mot dataskyddsförordningen, har rätt att lämna in ett klagomål till IMY.

Region Jönköpings län har under året mottagit två klagomål som skickats in till IMY. Klagomålen har handlat om personuppgiftsbehandling som skett inom Nämnden för folkhälsa och sjukvård. Båda klagomålen avslutades utan några vidare åtgärder förutom att IMY informerade Nämnden för folkhälsa och sjukvård om klagomålet i det ena ärendet.

7.6 De registrerades rättigheter

Enligt dataskyddsförordningen har de registrerade ett antal rättigheter som på olika sätt ska garantera bland annat insyn i hur dennes personuppgifter hanteras. Rättigheterna innebär skyldigheter för den personuppgiftsansvarige att vidta vissa åtgärder, till exempel att ge den registrerade tillgång till sina personuppgifter genom ett så kallat registerutdrag eller att radera eller rätta vissa uppgifter.

I Region Jönköpings län förekommer framförallt begäran om registerutdrag. Under 2025 inkom 41 begäranden om registerutdrag. Någon begäran om radering eller rättelse inkom inte till Region Jönköpings län under året.

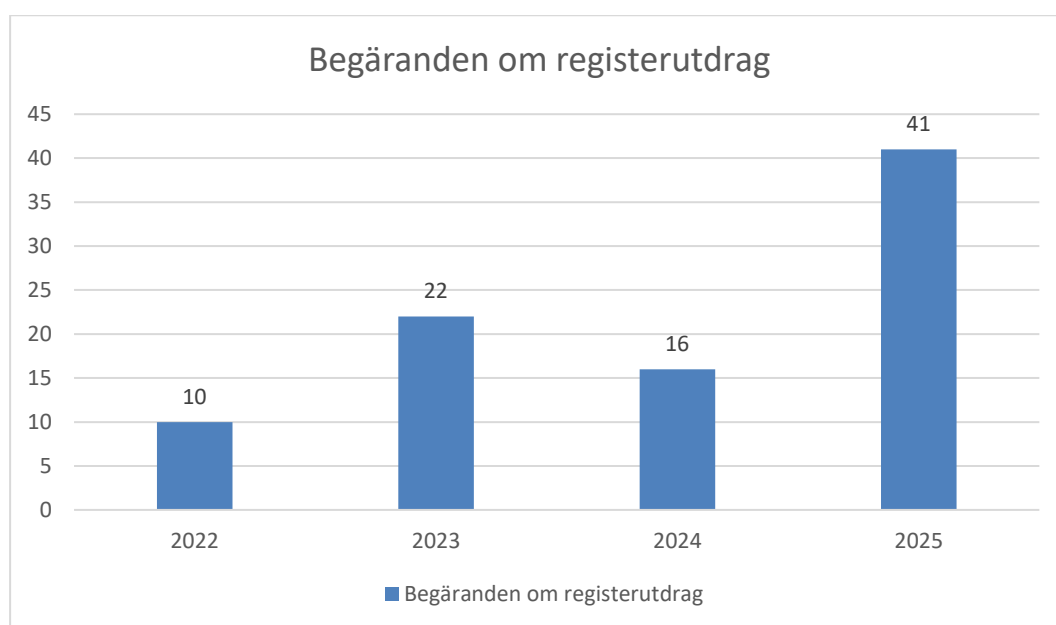


Bild 4: Diagrammet visar antal begäranden om registerutdrag som diarieförts i Region Jönköpings län under år 2022 till år 2025.

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Det kan noteras att antalet begäran om registerutdrag mer än fördubblades under år 2025.

Dataskyddsombudets iakttagelser och rekommendationer

Även om det är relativt få registrerade som vänder sig till Region Jönköpings län för att utöva sina rättigheter är det viktigt att verksamheterna vet hur de ska gå tillväga om en registrerad till exempel begär ett registerutdrag.

Dataskyddsombudet rekommenderar därför att rutiner och processer avseende registrerades rättigheter utvärderas kontinuerligt. Vidare rekommenderar dataskyddsombudet att verksamheterna kontinuerligt utbildas i de registrerades rättigheter, särskilt de verksamheter som arbetar nära allmänheten.

7.7 Personuppgiftsbiträdesavtal

Region Jönköpings läns verksamheter anlitar ofta ett personuppgiftsbiträde som utför hela eller delar av en personuppgiftsbehandling. Enligt dataskyddsförordningen ska personuppgiftsansvarig och personuppgiftsbiträde reglera sina relationer genom ett avtal. Mall för personuppgiftsbiträdesavtal finns tillgänglig via regionens intranät

Enligt Region Jönköpings läns rutin ska alla delar av ett avtal, inklusive eventuella bilagor, registreras i avtalskatalogen. Av dataskyddsombudets årsrapport 2024 framkommer emellertid att det förefaller saknas ett antal personuppgiftsbiträdesavtal i avtalskatalogen och att det inte heller finns någon fullständig förteckning av personuppgiftsbiträden med tillhörande personuppgiftsbiträdesavtal.

Dataskyddsombudets iakttagelser och rekommendationer

Det är av avgörande betydelse att berörda verksamheter har kunskap om i vilka situationer ett personuppgiftsbiträdesavtal ska tecknas alternativt att man vet i vilka situationer man ska kontakta regionjurist för hjälp med bedömningen. Dataskyddsombudet rekommenderar därför att rutiner och processer avseende personuppgiftsbiträdesavtal utvärderas kontinuerligt. Vidare rekommenderar dataskyddsombudet att berörda verksamheter kontinuerligt utbildas i frågor om när ett personuppgiftsbiträdesavtal ska tecknas och vad som ska regleras i avtalet.

Dataskyddsombudet konstaterar också, att verksamheterna behöver säkerställa att personuppgiftsbiträdesavtal registreras tillsammans med huvudavtalet i avtalskatalogen alternativt diarieförs i diariet.

7.8 Tredjelandsoverföringar

Behandlas personuppgifter på ett sätt som innebär att någon utanför EU/EES har tillgång till uppgifterna kallas detta för att överföra personuppgifter till tredjeland. Sådana överföringar är endast tillåtna under vissa förutsättningar.

Tredjelandsoverföring kan bli aktuellt bland annat i samband med att Region Jönköpings län anlitar en leverantör som tillhandahåller en molntjänst. För att säkerställa legalitet vid den här typen av överföringar tillämpar regionen en intern molntjänstriktnlinje, "Hantering av molntjänster, Riktlinjer informationssäkerhet. Av årsrapport för 2024 framkommer att riktlinjen kommer ses över och eventuellt revideras under 2025. Arbete med revidering av riktlinjen pågår.

Dataskyddsombudets iakttagelser och rekommendationer

Det är viktigt att berörda verksamheter har kunskap om i vilka situationer en tredjelandsoverföring är tillåten och hur detta regleras alternativt att man vet i vilka situationer man ska kontakta regionjurist för hjälp med bedömningen. Dataskyddsombudet rekommenderar därför att berörda verksamheter kontinuerligt utbildas i frågor om när tredjelandsoverföring är tillåten och vilka avtal som ska tecknas i anledning av detta.

7.9 Informera och ge råd

Rådgivning och utbildning är två av dataskyddsombudets centrala uppgifter. Dataskyddsombudet har lämnat råd och stöd till regionens olika verksamheter under året. Några särskilda, riktade utbildningsinsatser har inte genomförts, dataskyddsfrågor har dock tagits upp i andra utbildningssammanhang.

7.10 Omvärldsbevakning

Under året har IMY avgjort ett antal ärenden. Bland annat fattade IMY beslut att ge Sjukhusstyrelsen i Region Uppsala en reprimand eftersom Sjukhusstyrelsen behandlat personuppgifter utan att ha vidtagit lämpliga tekniska och organisatoriska åtgärder för att säkerställa en säkerhetsnivå som är lämplig i förhållande till riskerna med behandlingen av patienters personuppgifter i verksamhetens e-posttjänst (Outlook).

IMY utfärdade också sanktionsavgifter mot Aktiebolaget Storstockholms Lokaltrafik och mot Waxholms Ångfartygs AB. Orsaken var att bolagen behandlat personuppgifter i samband med utandningsprov utan rättslig grund.

I september meddelade EU-domstolen dom i ett mål som bland annat handlade om frågan om när pseudonymiserad data (pseudonymisering innebär att uppgifter om en person görs mindre igenkännbara, till exempel genom att ersätta namn eller personnummer med en kod eller ett alias) ska anses vara personuppgifter. Den 19 november 2025 presenterade EU-kommissionen ett förslag på omfattande ändringar i dataskyddsförordningen, den så kallade digitala omnibus-förordningen. En av de föreslagna ändringarna rör definitionen av begreppet personuppgift. Genom läckta dokument finns en bild av hur EU:s medlemsstater, genom ministerrådet, ställer sig till kommissionens förslag men någon reviderad officiell version finns ännu inte. Det kommer vara dock vara viktigt för Region

Jönköpings län att bevaka utvecklingen samt innebörden av de föreslagna förändringarna.

2026-03-17

§ 30**Kunskapsstyrning****Beslut**

Presidiet beslutar att

- nämnden ska informeras om kunskapsstyrning vid nämndsammanträdet den 31 mars 2026.
-

2026-03-17

§ 32**Patientsäkerhetsberättelse****Beslut**

Presidiet beslutar att

- nämnden ska informeras om patientsäkerhetsberättelse vid nämndsammanträdet den 31 mars 2026.
-

2026-03-17

§ 33**Barnkliniken****Beslut**

Presidiet beslutar att

- nämnden ska informeras om barnkliniken vid nämndsammanträdet den 31 mars 2026.
-

2026-03-17

§ 34**Intern kontroll – Månadsrapport februari 2026 Nämnd
för folkhälsa och sjukvård**

Diarienummer: RJL 2026/27

Beslut

Presidiet beslutar att

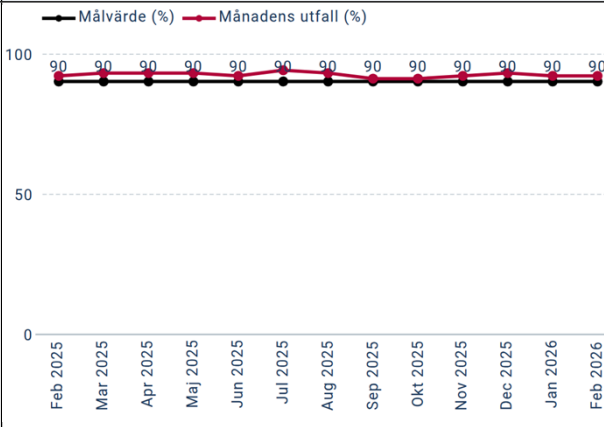
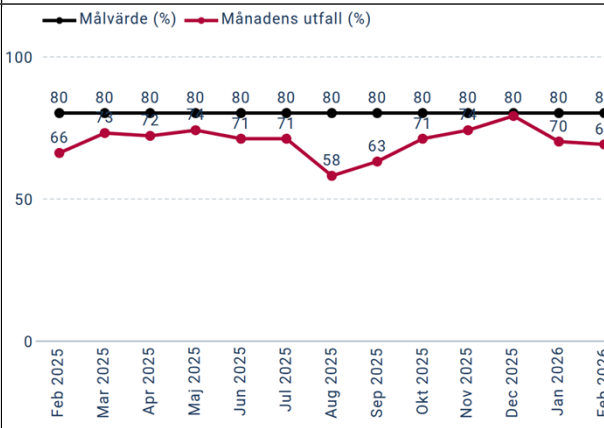
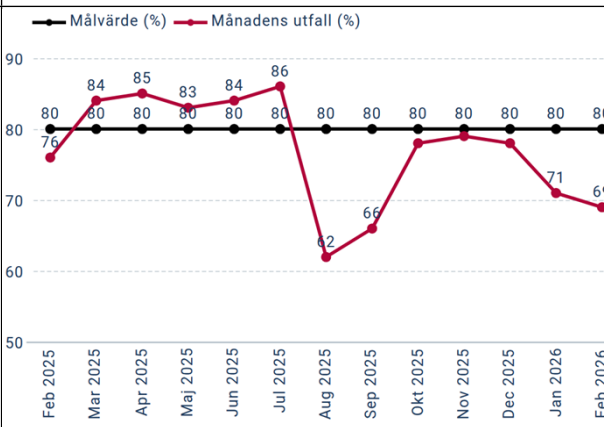
- nämnden ska informeras om intern kontroll – månadsrapport februari vid nämndsammanträdet den 31 mars 2026.

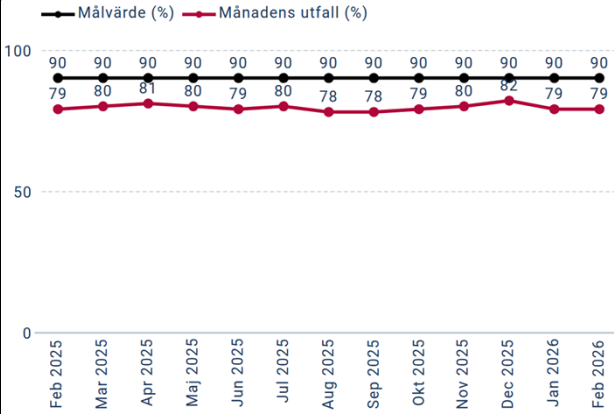
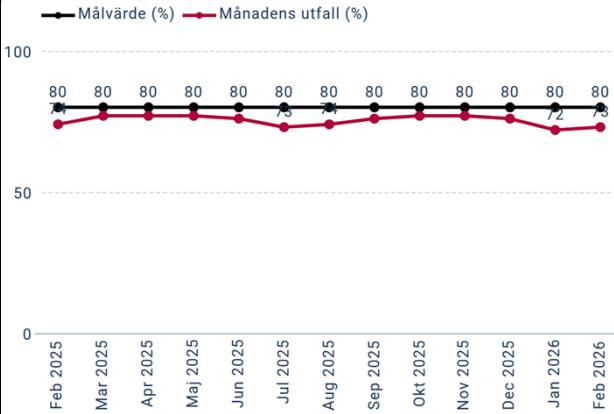
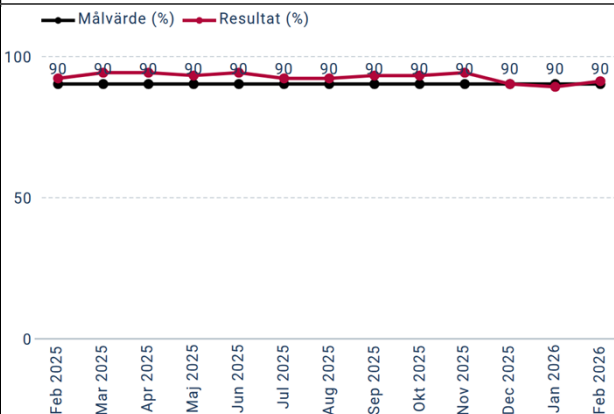
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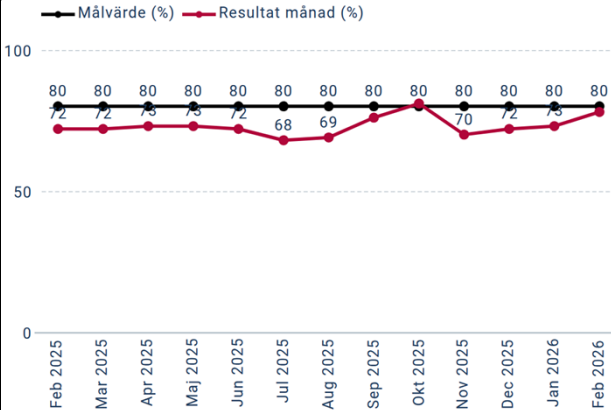
- Intern kontroll – Månadsrapport februari 2026 Nämnd för folkhälsa och sjukvård
-

Intern kontroll- Månadsrapport februari 2026 - Nämnden för folkhälsa och sjukvård

6 ■ 6 ◆ 5 ● 2 — av 19 Mätetal

Mätetal	Resultat	Analys	Diagram																																										
 Medicinsk bedömning i primärvården inom tre dagar.	92 % 	Fortsatt över målnivån. Står sig väl vid nationell jämförelse, ett bra resultat.	 — Målvärde (%) — Månadens utfall (%) <table><tr><th>Månad</th><th>Målvärde (%)</th><th>Månadens utfall (%)</th></tr><tr><td>Feb 2025</td><td>90</td><td>90</td></tr><tr><td>Mar 2025</td><td>90</td><td>90</td></tr><tr><td>Apr 2025</td><td>90</td><td>90</td></tr><tr><td>Maj 2025</td><td>90</td><td>90</td></tr><tr><td>Jun 2025</td><td>90</td><td>90</td></tr><tr><td>Jul 2025</td><td>90</td><td>90</td></tr><tr><td>Aug 2025</td><td>90</td><td>90</td></tr><tr><td>Sep 2025</td><td>90</td><td>90</td></tr><tr><td>Okt 2025</td><td>90</td><td>90</td></tr><tr><td>Nov 2025</td><td>90</td><td>90</td></tr><tr><td>Dec 2025</td><td>90</td><td>90</td></tr><tr><td>Jan 2026</td><td>90</td><td>90</td></tr><tr><td>Feb 2026</td><td>90</td><td>90</td></tr></table>	Månad	Målvärde (%)	Månadens utfall (%)	Feb 2025	90	90	Mar 2025	90	90	Apr 2025	90	90	Maj 2025	90	90	Jun 2025	90	90	Jul 2025	90	90	Aug 2025	90	90	Sep 2025	90	90	Okt 2025	90	90	Nov 2025	90	90	Dec 2025	90	90	Jan 2026	90	90	Feb 2026	90	90
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 Faktisk väntetid till första besök inom 60 dagar i specialiserad vård nationell rapportering.	70 % 	Når inte upp till målnivån, och ligger ungefär i nivå med föregående år. Psykiatri, rehabilitering och diagnostik når nästan upp till målvärdet, medan medicinsk- och kirurgisk vård har ligger på 66-67 %. Störst utmaningar har hudkliniken, medicinkliniken på Ryhov, och ortopedklinikerna i Värnamo och Eksjö.	 — Målvärde (%) — Månadens utfall (%) <table><tr><th>Månad</th><th>Målvärde (%)</th><th>Månadens utfall (%)</th></tr><tr><td>Feb 2025</td><td>80</td><td>66</td></tr><tr><td>Mar 2025</td><td>80</td><td>78</td></tr><tr><td>Apr 2025</td><td>80</td><td>72</td></tr><tr><td>Maj 2025</td><td>80</td><td>78</td></tr><tr><td>Jun 2025</td><td>80</td><td>78</td></tr><tr><td>Jul 2025</td><td>80</td><td>78</td></tr><tr><td>Aug 2025</td><td>80</td><td>58</td></tr><tr><td>Sep 2025</td><td>80</td><td>63</td></tr><tr><td>Okt 2025</td><td>80</td><td>78</td></tr><tr><td>Nov 2025</td><td>80</td><td>78</td></tr><tr><td>Dec 2025</td><td>80</td><td>80</td></tr><tr><td>Jan 2026</td><td>80</td><td>70</td></tr><tr><td>Feb 2026</td><td>80</td><td>69</td></tr></table>	Månad	Målvärde (%)	Månadens utfall (%)	Feb 2025	80	66	Mar 2025	80	78	Apr 2025	80	72	Maj 2025	80	78	Jun 2025	80	78	Jul 2025	80	78	Aug 2025	80	58	Sep 2025	80	63	Okt 2025	80	78	Nov 2025	80	78	Dec 2025	80	80	Jan 2026	80	70	Feb 2026	80	69
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 Faktisk väntetid till operation/åtgärd inom 60 dagar i specialiserad vård nationell rapportering	70 % 	Tydligt sämre än februari 2025, långt ifrån målnivån.	 — Målvärde (%) — Månadens utfall (%) <table><tr><th>Månad</th><th>Målvärde (%)</th><th>Månadens utfall (%)</th></tr><tr><td>Feb 2025</td><td>80</td><td>76</td></tr><tr><td>Mar 2025</td><td>80</td><td>84</td></tr><tr><td>Apr 2025</td><td>80</td><td>85</td></tr><tr><td>Maj 2025</td><td>80</td><td>83</td></tr><tr><td>Jun 2025</td><td>80</td><td>84</td></tr><tr><td>Jul 2025</td><td>80</td><td>86</td></tr><tr><td>Aug 2025</td><td>80</td><td>62</td></tr><tr><td>Sep 2025</td><td>80</td><td>66</td></tr><tr><td>Okt 2025</td><td>80</td><td>78</td></tr><tr><td>Nov 2025</td><td>80</td><td>78</td></tr><tr><td>Dec 2025</td><td>80</td><td>78</td></tr><tr><td>Jan 2026</td><td>80</td><td>71</td></tr><tr><td>Feb 2026</td><td>80</td><td>69</td></tr></table>	Månad	Målvärde (%)	Månadens utfall (%)	Feb 2025	80	76	Mar 2025	80	84	Apr 2025	80	85	Maj 2025	80	83	Jun 2025	80	84	Jul 2025	80	86	Aug 2025	80	62	Sep 2025	80	66	Okt 2025	80	78	Nov 2025	80	78	Dec 2025	80	78	Jan 2026	80	71	Feb 2026	80	69
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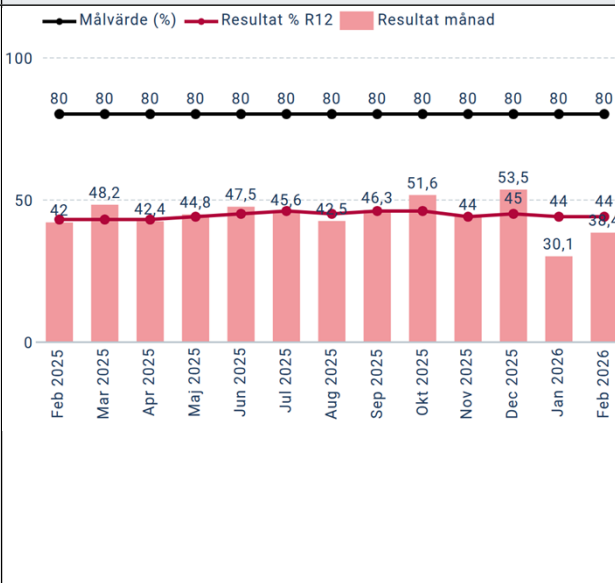
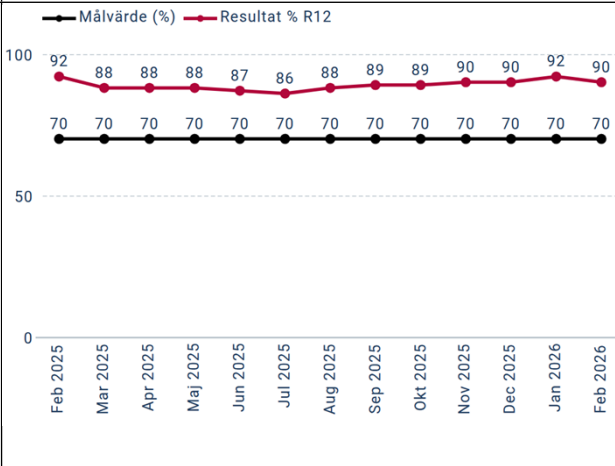
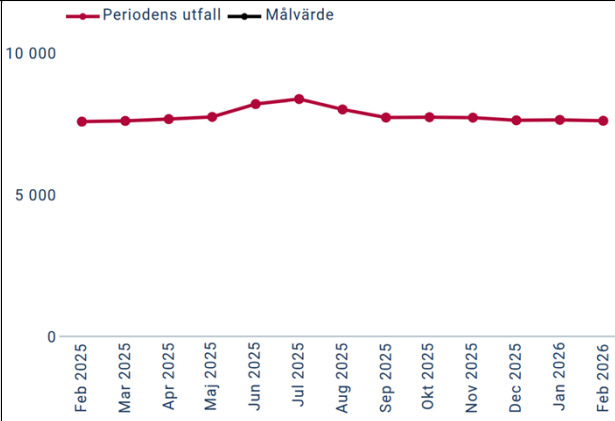
Mätetal	Resultat	Analys	Diagram																																										
 Genomförda återbesök inom medicinskt måldatum	79 % 	Fortsatt på en stabil nivå runt 80 procent.	 <table><tr><th>Månad</th><th>Målvärde (%)</th><th>Månadens utfall (%)</th></tr><tr><td>Feb 2025</td><td>90</td><td>79</td></tr><tr><td>Mar 2025</td><td>90</td><td>80</td></tr><tr><td>Apr 2025</td><td>90</td><td>81</td></tr><tr><td>Maj 2025</td><td>90</td><td>80</td></tr><tr><td>Jun 2025</td><td>90</td><td>79</td></tr><tr><td>Jul 2025</td><td>90</td><td>80</td></tr><tr><td>Aug 2025</td><td>90</td><td>78</td></tr><tr><td>Sep 2025</td><td>90</td><td>78</td></tr><tr><td>Okt 2025</td><td>90</td><td>79</td></tr><tr><td>Nov 2025</td><td>90</td><td>80</td></tr><tr><td>Dec 2025</td><td>90</td><td>82</td></tr><tr><td>Jan 2026</td><td>90</td><td>79</td></tr><tr><td>Feb 2026</td><td>90</td><td>79</td></tr></table>	Månad	Målvärde (%)	Månadens utfall (%)	Feb 2025	90	79	Mar 2025	90	80	Apr 2025	90	81	Maj 2025	90	80	Jun 2025	90	79	Jul 2025	90	80	Aug 2025	90	78	Sep 2025	90	78	Okt 2025	90	79	Nov 2025	90	80	Dec 2025	90	82	Jan 2026	90	79	Feb 2026	90	79
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 Tid till ambulans - andel prio 1 larm inom 20 minuter	72 % 	Tillgängligheten uppgick till och med februari till 72 procent. Föregående år motsvarande period 74 procent. Antalet prioritet 1 uppdrag har minskat med 9 procent jämfört med föregående år motsvarande period. Inom- och utomlänstransporter mellan vårdinrättning tar en stor del av ambulanssjukvårdens resurser, cirka 12 procent av totalt antal uppdrag. Totalt har antalet uppdrag är oförändrat jämfört med föregående år motsvarande period.	 <table><tr><th>Månad</th><th>Målvärde (%)</th><th>Månadens utfall (%)</th></tr><tr><td>Feb 2025</td><td>80</td><td>78</td></tr><tr><td>Mar 2025</td><td>80</td><td>79</td></tr><tr><td>Apr 2025</td><td>80</td><td>79</td></tr><tr><td>Maj 2025</td><td>80</td><td>79</td></tr><tr><td>Jun 2025</td><td>80</td><td>79</td></tr><tr><td>Jul 2025</td><td>80</td><td>78</td></tr><tr><td>Aug 2025</td><td>80</td><td>79</td></tr><tr><td>Sep 2025</td><td>80</td><td>79</td></tr><tr><td>Okt 2025</td><td>80</td><td>79</td></tr><tr><td>Nov 2025</td><td>80</td><td>79</td></tr><tr><td>Dec 2025</td><td>80</td><td>79</td></tr><tr><td>Jan 2026</td><td>80</td><td>78</td></tr><tr><td>Feb 2026</td><td>80</td><td>78</td></tr></table>	Månad	Målvärde (%)	Månadens utfall (%)	Feb 2025	80	78	Mar 2025	80	79	Apr 2025	80	79	Maj 2025	80	79	Jun 2025	80	79	Jul 2025	80	78	Aug 2025	80	79	Sep 2025	80	79	Okt 2025	80	79	Nov 2025	80	79	Dec 2025	80	79	Jan 2026	80	78	Feb 2026	80	78
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Allmäntandvård: Andel revisionspatienter i tid till undersökning och behandling	91 % 	Utfallet för februari 2026 ligger på 91 procent. Under 2025 har satsning pågått för att erbjuda tid till nya patienter som står på kö till Folktandvården. Trots detta är tillgängligheten för revisionspatienter mycket god.	 <table><tr><th>Månad</th><th>Målvärde (%)</th><th>Resultat (%)</th></tr><tr><td>Feb 2025</td><td>90</td><td>90</td></tr><tr><td>Mar 2025</td><td>90</td><td>90</td></tr><tr><td>Apr 2025</td><td>90</td><td>90</td></tr><tr><td>Maj 2025</td><td>90</td><td>90</td></tr><tr><td>Jun 2025</td><td>90</td><td>90</td></tr><tr><td>Jul 2025</td><td>90</td><td>90</td></tr><tr><td>Aug 2025</td><td>90</td><td>90</td></tr><tr><td>Sep 2025</td><td>90</td><td>90</td></tr><tr><td>Okt 2025</td><td>90</td><td>90</td></tr><tr><td>Nov 2025</td><td>90</td><td>90</td></tr><tr><td>Dec 2025</td><td>90</td><td>90</td></tr><tr><td>Jan 2026</td><td>90</td><td>90</td></tr><tr><td>Feb 2026</td><td>90</td><td>91</td></tr></table>	Månad	Målvärde (%)	Resultat (%)	Feb 2025	90	90	Mar 2025	90	90	Apr 2025	90	90	Maj 2025	90	90	Jun 2025	90	90	Jul 2025	90	90	Aug 2025	90	90	Sep 2025	90	90	Okt 2025	90	90	Nov 2025	90	90	Dec 2025	90	90	Jan 2026	90	90	Feb 2026	90	91
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Mätetal	Resultat	Analys	Diagram																																										
 Tillgänglighet specialisttandvård inom 60 dagar efter remiss	75 % 	Tillgängligheten till och med februari uppgår till 75 procent. Följande specialiteter klarar inte tillgänglighetsmålet om 80 procent: käkkirurgi, orofacial medicin, klinisk bettfysiologi samt pedodonti. Tillgängligheten för specialisttandvården har förbättrats avsevärt de senaste åren från 40 procent år 2022 till 64 procent 2024 och 72 procent 2025. Inom orofacial medicin är en övertandläkartjänst vakant, samtidigt som inflödet av remisser för äldre patienter ökar och en större andel patienter vårdas över längre tid. Bettfysiologi bedöms nå målvärdet under 2026. Sammantaget förbättras tillgängligheten inom specialisttandvården över tid och bedöms på totalen nå målvärdet under 2026. Under 2025 har ett enhetligt prioriteringssystem arbetats fram, som implementeras under 2026 där käkkirurgin är först ut. I samband med detta ser man över remisshanteringen för att säkerställa att endast de som står i kö till första tid räknas in samt särredovisning av patientvald väntan och medicinskt vald väntan, vilket i dagsläget inte återspeglats i tillgänglighetsmätningen.	Målvärde (%) Resultat månad (%) <table><thead><tr><th>Månat</th><th>Målvärde (%)</th><th>Resultat månad (%)</th></tr></thead><tbody><tr><td>Feb 2025</td><td>80</td><td>72</td></tr><tr><td>Mar 2025</td><td>80</td><td>72</td></tr><tr><td>Apr 2025</td><td>80</td><td>75</td></tr><tr><td>Maj 2025</td><td>80</td><td>75</td></tr><tr><td>Jun 2025</td><td>80</td><td>72</td></tr><tr><td>Jul 2025</td><td>80</td><td>68</td></tr><tr><td>Aug 2025</td><td>80</td><td>69</td></tr><tr><td>Sep 2025</td><td>80</td><td>75</td></tr><tr><td>Okt 2025</td><td>80</td><td>80</td></tr><tr><td>Nov 2025</td><td>80</td><td>70</td></tr><tr><td>Dec 2025</td><td>80</td><td>72</td></tr><tr><td>Jan 2026</td><td>80</td><td>75</td></tr><tr><td>Feb 2026</td><td>80</td><td>80</td></tr></tbody></table>	Månat	Målvärde (%)	Resultat månad (%)	Feb 2025	80	72	Mar 2025	80	72	Apr 2025	80	75	Maj 2025	80	75	Jun 2025	80	72	Jul 2025	80	68	Aug 2025	80	69	Sep 2025	80	75	Okt 2025	80	80	Nov 2025	80	70	Dec 2025	80	72	Jan 2026	80	75	Feb 2026	80	80
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Mätetal	Resultat	Analys	Diagram																																										
Faktisk väntetid till första besök inom 30 dagar till barn och ungdomspsykiatrisk vård	62 % 	Som förväntat ett tydligt bättre utfall i februari, i närheten av målnivån.	— Målvärde (%) — Månadens utfall (%) <table><thead><tr><th>Månad</th><th>Målvärde (%)</th><th>Månadens utfall (%)</th></tr></thead><tbody><tr><td>Feb 2025</td><td>90</td><td>85</td></tr><tr><td>Mar 2025</td><td>90</td><td>88</td></tr><tr><td>Apr 2025</td><td>90</td><td>90</td></tr><tr><td>Maj 2025</td><td>90</td><td>64</td></tr><tr><td>Jun 2025</td><td>90</td><td>71</td></tr><tr><td>Jul 2025</td><td>90</td><td>69</td></tr><tr><td>Aug 2025</td><td>90</td><td>59</td></tr><tr><td>Sep 2025</td><td>90</td><td>90</td></tr><tr><td>Okt 2025</td><td>90</td><td>90</td></tr><tr><td>Nov 2025</td><td>90</td><td>90</td></tr><tr><td>Dec 2025</td><td>90</td><td>90</td></tr><tr><td>Jan 2026</td><td>90</td><td>37</td></tr><tr><td>Feb 2026</td><td>90</td><td>90</td></tr></tbody></table>	Månad	Målvärde (%)	Månadens utfall (%)	Feb 2025	90	85	Mar 2025	90	88	Apr 2025	90	90	Maj 2025	90	64	Jun 2025	90	71	Jul 2025	90	69	Aug 2025	90	59	Sep 2025	90	90	Okt 2025	90	90	Nov 2025	90	90	Dec 2025	90	90	Jan 2026	90	37	Feb 2026	90	90
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Faktisk väntetid till behandling till barn- och ungdomspsykiatrisk vård inom 30 dagar	12 % 	Resultatet nu åter på den nivå som det varit under föregående år, långt ifrån målnivån. Eftersom mätningen enbart görs på vissa behandlingar är resultatet inte heltäckande för hur väntetiden till behandling ser ut.	— Målvärde (%) — Månadens utfall (%) <table><thead><tr><th>Månad</th><th>Målvärde (%)</th><th>Månadens utfall (%)</th></tr></thead><tbody><tr><td>Feb 2025</td><td>90</td><td>8</td></tr><tr><td>Mar 2025</td><td>90</td><td>40</td></tr><tr><td>Apr 2025</td><td>90</td><td>13</td></tr><tr><td>Maj 2025</td><td>90</td><td>36</td></tr><tr><td>Jun 2025</td><td>90</td><td>36</td></tr><tr><td>Jul 2025</td><td>90</td><td>28</td></tr><tr><td>Aug 2025</td><td>90</td><td>12</td></tr><tr><td>Sep 2025</td><td>90</td><td>7</td></tr><tr><td>Okt 2025</td><td>90</td><td>19</td></tr><tr><td>Nov 2025</td><td>90</td><td>16</td></tr><tr><td>Dec 2025</td><td>90</td><td>40</td></tr><tr><td>Jan 2026</td><td>90</td><td>14</td></tr><tr><td>Feb 2026</td><td>90</td><td>10</td></tr></tbody></table>	Månad	Målvärde (%)	Månadens utfall (%)	Feb 2025	90	8	Mar 2025	90	40	Apr 2025	90	13	Maj 2025	90	36	Jun 2025	90	36	Jul 2025	90	28	Aug 2025	90	12	Sep 2025	90	7	Okt 2025	90	19	Nov 2025	90	16	Dec 2025	90	40	Jan 2026	90	14	Feb 2026	90	10
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Faktisk väntetid till utredning till barn- och ungdomspsykiatrisk vård inom 30 dagar	2 % 	Fortsatt ingen rörelse i utfallet.	— Målvärde (%) — Månadens utfall (%) <table><thead><tr><th>Månad</th><th>Målvärde (%)</th><th>Månadens utfall (%)</th></tr></thead><tbody><tr><td>Feb 2025</td><td>90</td><td>4</td></tr><tr><td>Mar 2025</td><td>90</td><td>3</td></tr><tr><td>Apr 2025</td><td>90</td><td>4</td></tr><tr><td>Maj 2025</td><td>90</td><td>3</td></tr><tr><td>Jun 2025</td><td>90</td><td>4</td></tr><tr><td>Jul 2025</td><td>90</td><td>1</td></tr><tr><td>Aug 2025</td><td>90</td><td>1</td></tr><tr><td>Sep 2025</td><td>90</td><td>3</td></tr><tr><td>Okt 2025</td><td>90</td><td>2</td></tr><tr><td>Nov 2025</td><td>90</td><td>4</td></tr><tr><td>Dec 2025</td><td>90</td><td>6</td></tr><tr><td>Jan 2026</td><td>90</td><td>2</td></tr><tr><td>Feb 2026</td><td>90</td><td>2</td></tr></tbody></table>	Månad	Målvärde (%)	Månadens utfall (%)	Feb 2025	90	4	Mar 2025	90	3	Apr 2025	90	4	Maj 2025	90	3	Jun 2025	90	4	Jul 2025	90	1	Aug 2025	90	1	Sep 2025	90	3	Okt 2025	90	2	Nov 2025	90	4	Dec 2025	90	6	Jan 2026	90	2	Feb 2026	90	2
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Mätetal	Resultat	Analys	Diagram																																										
Disponibla vårdplatser	662 	Antal disponibla platser är sammantaget för hela regionen i nivå med motsvarande period som föregående år. Viss variation vad gäller enskilda kliniker förekommer dock och Infektionskliniken Jönköping är ett exempel på en klinik med fler platser under perioden. Då aktuellt behov till stor del styr antalet platser förutsätts en aktiv hantering av vårdplatskapacitet och organisatorisk samordning för att möta behov och beläggningsnivåer.	<table><thead><tr><th>Månad</th><th>Målvärde</th><th>Månadens utfall</th></tr></thead><tbody><tr><td>Feb 2025</td><td>662</td><td>665</td></tr><tr><td>Mar 2025</td><td>662</td><td>665</td></tr><tr><td>Apr 2025</td><td>662</td><td>671</td></tr><tr><td>Maj 2025</td><td>662</td><td>673</td></tr><tr><td>Jun 2025</td><td>662</td><td>603</td></tr><tr><td>Jul 2025</td><td>662</td><td>544</td></tr><tr><td>Aug 2025</td><td>662</td><td>593</td></tr><tr><td>Sep 2025</td><td>662</td><td>661</td></tr><tr><td>Okt 2025</td><td>662</td><td>666</td></tr><tr><td>Nov 2025</td><td>662</td><td>665</td></tr><tr><td>Dec 2025</td><td>662</td><td>659</td></tr><tr><td>Jan 2026</td><td>662</td><td>662</td></tr><tr><td>Feb 2026</td><td>662</td><td>663</td></tr></tbody></table>	Månad	Målvärde	Månadens utfall	Feb 2025	662	665	Mar 2025	662	665	Apr 2025	662	671	Maj 2025	662	673	Jun 2025	662	603	Jul 2025	662	544	Aug 2025	662	593	Sep 2025	662	661	Okt 2025	662	666	Nov 2025	662	665	Dec 2025	662	659	Jan 2026	662	662	Feb 2026	662	663
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Beläggning	84 % 	Beläggningen är i nivå med motsvarande period föregående år, och strax under uppsatt mål sett till hela regionen. Enskilda kliniker som kirurgkliniken, geriatriska kliniken Jönköping samt medicin- och geriatrikklíniken Eksjö är dock kliniker med en hög beläggningen, över 95% under månaden. Antal vårdtillfällen, inneliggande samt disponibla platser är i det närmaste oförändrat. Sammanfattningsvis en i många delar lägre beläggning än vad rådande kapacitet tillåter, dock med vissa undantag. Flera pågående förbättrings- och samordningsinsatser med syfte att bättre utnyttja resurser, förbättra vårdövergångar och anpassa vårdflöden pågår.	<table><thead><tr><th>Månad</th><th>Målvärde (%)</th><th>Månadens utfall (%)</th></tr></thead><tbody><tr><td>Feb 2025</td><td>85</td><td>85</td></tr><tr><td>Mar 2025</td><td>85</td><td>85</td></tr><tr><td>Apr 2025</td><td>85</td><td>85</td></tr><tr><td>Maj 2025</td><td>85</td><td>85</td></tr><tr><td>Jun 2025</td><td>85</td><td>85</td></tr><tr><td>Jul 2025</td><td>85</td><td>85</td></tr><tr><td>Aug 2025</td><td>85</td><td>85</td></tr><tr><td>Sep 2025</td><td>85</td><td>85</td></tr><tr><td>Okt 2025</td><td>85</td><td>85</td></tr><tr><td>Nov 2025</td><td>85</td><td>85</td></tr><tr><td>Dec 2025</td><td>85</td><td>85</td></tr><tr><td>Jan 2026</td><td>85</td><td>85</td></tr><tr><td>Feb 2026</td><td>85</td><td>85</td></tr></tbody></table>	Månad	Målvärde (%)	Månadens utfall (%)	Feb 2025	85	85	Mar 2025	85	85	Apr 2025	85	85	Maj 2025	85	85	Jun 2025	85	85	Jul 2025	85	85	Aug 2025	85	85	Sep 2025	85	85	Okt 2025	85	85	Nov 2025	85	85	Dec 2025	85	85	Jan 2026	85	85	Feb 2026	85	85
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Utlokalisera de	1,6 % 	Något fler utlokaliserade jämfört motsvarande period föregående år men sammantaget för hela regionen en förhållandevis låg nivå. Flest utlokaliseringar sker inom kirurgisk vård, där det stora flertalet utlokaliseras inom verksamhetsområdet. Orsaker som anges är exempelvis högt patientflöde och kommunens svårigheter att ta emot ortopedpatienter. Som tidigare mycket få utlokaliseringar inom psykiatrisk vård.	Målvärde (%)Månadens utfall (%) <table><thead><tr><th>Månat</th><th>Målvärde (%)</th><th>Månadens utfall (%)</th></tr></thead><tbody><tr><td>Feb 2025</td><td>0</td><td>0,8</td></tr><tr><td>Mar 2025</td><td>0</td><td>0,8</td></tr><tr><td>Apr 2025</td><td>0</td><td>0,9</td></tr><tr><td>Maj 2025</td><td>0</td><td>0,9</td></tr><tr><td>Jun 2025</td><td>0</td><td>0,9</td></tr><tr><td>Jul 2025</td><td>0</td><td>1,1</td></tr><tr><td>Aug 2025</td><td>0</td><td>1,1</td></tr><tr><td>Sep 2025</td><td>0</td><td>0,5</td></tr><tr><td>Okt 2025</td><td>0</td><td>0,6</td></tr><tr><td>Nov 2025</td><td>0</td><td>0,7</td></tr><tr><td>Dec 2025</td><td>0</td><td>0,6</td></tr><tr><td>Jan 2026</td><td>0</td><td>2</td></tr><tr><td>Feb 2026</td><td>0</td><td>1,2</td></tr></tbody></table>	Månat	Målvärde (%)	Månadens utfall (%)	Feb 2025	0	0,8	Mar 2025	0	0,8	Apr 2025	0	0,9	Maj 2025	0	0,9	Jun 2025	0	0,9	Jul 2025	0	1,1	Aug 2025	0	1,1	Sep 2025	0	0,5	Okt 2025	0	0,6	Nov 2025	0	0,7	Dec 2025	0	0,6	Jan 2026	0	2	Feb 2026	0	1,2
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Överbeläggningar	0,7 % 	Antalet överbeläggningar minskar något från 0,6 per 100 disponibla platser i jämförelse med 0,8 samma period föregående år. Fortsatt dock periodvis hög belastning särskilt under helger och vissa dygn. Flest överbeläggningar förekommer inom kirurgisk vård. Kapacitetsstyrning, planering samt kartläggning av administrativa rutiner rekommenderas för att hantera kvarstående toppar och undanröja felaktiga registreringar.	Målvärde (%)Månadens utfall (%) <table><thead><tr><th>Månat</th><th>Målvärde (%)</th><th>Månadens utfall (%)</th></tr></thead><tbody><tr><td>Feb 2025</td><td>0</td><td>0,8</td></tr><tr><td>Mar 2025</td><td>0</td><td>0,9</td></tr><tr><td>Apr 2025</td><td>0</td><td>0,6</td></tr><tr><td>Maj 2025</td><td>0</td><td>0,3</td></tr><tr><td>Jun 2025</td><td>0</td><td>0,8</td></tr><tr><td>Jul 2025</td><td>0</td><td>1</td></tr><tr><td>Aug 2025</td><td>0</td><td>0,8</td></tr><tr><td>Sep 2025</td><td>0</td><td>0,4</td></tr><tr><td>Okt 2025</td><td>0</td><td>0,4</td></tr><tr><td>Nov 2025</td><td>0</td><td>0,5</td></tr><tr><td>Dec 2025</td><td>0</td><td>0,3</td></tr><tr><td>Jan 2026</td><td>0</td><td>0,8</td></tr><tr><td>Feb 2026</td><td>0</td><td>0,6</td></tr></tbody></table>	Månat	Målvärde (%)	Månadens utfall (%)	Feb 2025	0	0,8	Mar 2025	0	0,9	Apr 2025	0	0,6	Maj 2025	0	0,3	Jun 2025	0	0,8	Jul 2025	0	1	Aug 2025	0	0,8	Sep 2025	0	0,4	Okt 2025	0	0,4	Nov 2025	0	0,5	Dec 2025	0	0,3	Jan 2026	0	0,8	Feb 2026	0	0,6
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 Standardise rade vårdförlopp - andel inom max ledtid	44 % 	Under den senaste 12-månadsperioden har behandlingsstart skett inom totalt 2021 cancerförlopp. Av dessa har 44 procent skett inom angiven ledtid vilket är i nivå med motsvarande period föregående år. Inget förlopp når uppsatt målvärde under perioden. För förlopp med mer än 300 startade behandlingar under perioden, SVF Prostatacancer samt SVF Bröstcancer är variationen 16,3- 63,5 procent.	 <table><thead><tr><th>Månat</th><th>Resultat månad (%)</th><th>Resultat % R12 (%)</th><th>Målvärde (%)</th></tr></thead><tbody><tr><td>Feb 2025</td><td>42</td><td>42</td><td>80</td></tr><tr><td>Mar 2025</td><td>48,2</td><td>42,2</td><td>80</td></tr><tr><td>Apr 2025</td><td>42,4</td><td>42,4</td><td>80</td></tr><tr><td>Maj 2025</td><td>44,8</td><td>44,8</td><td>80</td></tr><tr><td>Jun 2025</td><td>47,5</td><td>47,5</td><td>80</td></tr><tr><td>Jul 2025</td><td>45,6</td><td>45,6</td><td>80</td></tr><tr><td>Aug 2025</td><td>42,5</td><td>42,5</td><td>80</td></tr><tr><td>Sep 2025</td><td>46,3</td><td>46,3</td><td>80</td></tr><tr><td>Okt 2025</td><td>51,6</td><td>51,6</td><td>80</td></tr><tr><td>Nov 2025</td><td>44</td><td>44</td><td>80</td></tr><tr><td>Dec 2025</td><td>53,5</td><td>45</td><td>80</td></tr><tr><td>Jan 2026</td><td>30,1</td><td>44</td><td>80</td></tr><tr><td>Feb 2026</td><td>38,4</td><td>44</td><td>80</td></tr></tbody></table>	Månat	Resultat månad (%)	Resultat % R12 (%)	Målvärde (%)	Feb 2025	42	42	80	Mar 2025	48,2	42,2	80	Apr 2025	42,4	42,4	80	Maj 2025	44,8	44,8	80	Jun 2025	47,5	47,5	80	Jul 2025	45,6	45,6	80	Aug 2025	42,5	42,5	80	Sep 2025	46,3	46,3	80	Okt 2025	51,6	51,6	80	Nov 2025	44	44	80	Dec 2025	53,5	45	80	Jan 2026	30,1	44	80	Feb 2026	38,4	44	80
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 Standardise rade vårdförlopp - andel utredda patienter i SVF	90 % 	Målet är uppfyllt. Region Jönköpings län uppnår sammantaget vad som förväntas enligt det nationella beräkningsunderlaget för standardiserade vårdförlopp.	 <table><thead><tr><th>Månat</th><th>Resultat % R12 (%)</th><th>Målvärde (%)</th></tr></thead><tbody><tr><td>Feb 2025</td><td>92</td><td>70</td></tr><tr><td>Mar 2025</td><td>88</td><td>70</td></tr><tr><td>Apr 2025</td><td>88</td><td>70</td></tr><tr><td>Maj 2025</td><td>88</td><td>70</td></tr><tr><td>Jun 2025</td><td>87</td><td>70</td></tr><tr><td>Jul 2025</td><td>86</td><td>70</td></tr><tr><td>Aug 2025</td><td>88</td><td>70</td></tr><tr><td>Sep 2025</td><td>89</td><td>70</td></tr><tr><td>Okt 2025</td><td>89</td><td>70</td></tr><tr><td>Nov 2025</td><td>90</td><td>70</td></tr><tr><td>Dec 2025</td><td>90</td><td>70</td></tr><tr><td>Jan 2026</td><td>92</td><td>70</td></tr><tr><td>Feb 2026</td><td>90</td><td>70</td></tr></tbody></table>	Månat	Resultat % R12 (%)	Målvärde (%)	Feb 2025	92	70	Mar 2025	88	70	Apr 2025	88	70	Maj 2025	88	70	Jun 2025	87	70	Jul 2025	86	70	Aug 2025	88	70	Sep 2025	89	70	Okt 2025	89	70	Nov 2025	90	70	Dec 2025	90	70	Jan 2026	92	70	Feb 2026	90	70														
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 Faktiska årsarbetare	7 593 	Totalt sett en ökning av faktiska årsarbetare jämfört med motsvarande period föregående år med 31. Ökningen beror framför allt på en ökning av anställda som totalt sett har ökat i genomsnitt med 28 men då frånvaron minskat med motsvarande 3 årsarbetare så innebär det också fler i arbete. Folk tandvården har minskat jämfört med föregående år medan övriga verksamhetsområden inom nämndområdet har ökat.	 <table><thead><tr><th>Månat</th><th>Periodens utfall</th><th>Målvärde</th></tr></thead><tbody><tr><td>Feb 2025</td><td>7 593</td><td>7 593</td></tr><tr><td>Mar 2025</td><td>7 593</td><td>7 593</td></tr><tr><td>Apr 2025</td><td>7 593</td><td>7 593</td></tr><tr><td>Maj 2025</td><td>7 593</td><td>7 593</td></tr><tr><td>Jun 2025</td><td>7 593</td><td>7 593</td></tr><tr><td>Jul 2025</td><td>7 593</td><td>7 593</td></tr><tr><td>Aug 2025</td><td>7 593</td><td>7 593</td></tr><tr><td>Sep 2025</td><td>7 593</td><td>7 593</td></tr><tr><td>Okt 2025</td><td>7 593</td><td>7 593</td></tr><tr><td>Nov 2025</td><td>7 593</td><td>7 593</td></tr><tr><td>Dec 2025</td><td>7 593</td><td>7 593</td></tr><tr><td>Jan 2026</td><td>7 593</td><td>7 593</td></tr><tr><td>Feb 2026</td><td>7 593</td><td>7 593</td></tr></tbody></table>	Månat	Periodens utfall	Målvärde	Feb 2025	7 593	7 593	Mar 2025	7 593	7 593	Apr 2025	7 593	7 593	Maj 2025	7 593	7 593	Jun 2025	7 593	7 593	Jul 2025	7 593	7 593	Aug 2025	7 593	7 593	Sep 2025	7 593	7 593	Okt 2025	7 593	7 593	Nov 2025	7 593	7 593	Dec 2025	7 593	7 593	Jan 2026	7 593	7 593	Feb 2026	7 593	7 593														
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Mätetal	Resultat	Analys	Diagram
Kostnad för bemannings företag (hyrkostnad som andel av egna personalkos tnader)	2,0 %	Kostnaden för hyrpersonal som andel av personalkostnaden ligger på målnivån och har minskat jämfört med föregående år. Den ackumulerade kostnaden för bemanningsföretag har totalt sett minskat med ca 26 % jämfört med föregående år och ligger på ca 22,9 mnkr (31 mnkr, 2025). Kostnaden för hyrläkare har minskat med ca 29 % medan kostnaden för sjuksköterskor har ökat med ca 38 %. Ökningen av hyrsjuksköterskor är kopplad till bemanningsutmaningar på OP/IVA och Kvinnokliniken på Högländssjukhuset. Verksamheterna arbetar utifrån sina handlings- och kompetensplaner för att minska beroendet av hyrpersonal.	

Mätetal	Resultat	Analys	Diagram
		2,5 mnkr bättre. Allmäntandvårdens ackumulerade resultat uppgår till plus 2,1 mnkr. Specialisttandvårdens resultat uppgår till plus 0,9 mnkr. I samband med årsskiftet infördes tandvårdsreformen Tiotandvård, vilket gör fler äldre tandvård när behandlingen numera är subventionerad för patienten. Det är fortfarande så pass tidigt på året att det är svårt att dra några slutsatser kring hur det påverkar verksamheten. Medicinsk vård redovisar ett ackumulerat budgetunderskott till och med februari om -15,8 miljoner kronor. Budgetunderskott i perioden februari var -5,7 mnkr. Huvudsakliga orsaker till budgetavvikelsen: • Lönekostnaden har ökat (i fast pris) med 1,6 mnkr (0,5 procent) jämfört med föregående år motsvarande period. • Kostnaden avseende hyrbemanning (läkare) uppgick till 0,4 mnkr. Kostnaden har ökat med 0,3 mnkr jämfört med föregående år motsvarande period. • Övertidskostnaden har ökat med 1,5 mnkr (18 procent) jämfört med föregående år motsvarande period. • Minskade kostnader (i fast pris) avseende laboratorieprover med 1,2 mnkr (4 procent) jämfört med föregående år motsvarande period. • Budgetunderskott läkemedel 3.9 mnkr. Kirurgisk vård har ackumulerat en negativ budgetavvikelse på -27,6 miljoner kronor. Utfallet är högt på personalkostnader främst för OB kostnader. Utfallet är även högt för läkemedel och för material. Budgetavvikelsen påverkas även av att klinikerna budgeterat för intäkter för statsbidrag och dessa intäkter har inte fördelats eller betalats ut än. Utfallet bemanningsföretag är lägre än förra året. Psykiatri, rehab och diagnostik har en ackumulerad avvikelse budgetavvikelse till och med februari på -12,8 miljoner kronor. Psykiatriverksamheterna är i balans, verksamheterna inom habilitering och rehabilitering visar sammantaget en positiv budgetavvikelse med 1,1 mnkr, medan diagnostikverksamheterna har en negativ budgetavvikelse på -15,3 mnkr. Laboratoriemedicin redovisar en betydande negativ budgetavvikelse med -10,4 mnkr. Intäkterna ligger cirka 3,7 mnkr under budget och personalkostnaderna cirka 1,0 mnkr över budget. Kostnader för köpt verksamhet och material överstiger budget med cirka 3,6 mnkr, främst avseende labtjänster och reagenser. Även övriga verksamhetskostnader visar negativa avvikelser. Åtgärdsplan finns, men avvikelsen är till stor del kopplad till minskade intäkter och volymvariationer. Arbete pågår med prisjusteringar, bemanningsanpassning genom naturlig avgång samt effektivisering av arbetssätt. Röntgenkliniken redovisar en negativ budgetavvikelse om -5,1 mnkr trots att intäkterna ökat med 8 mnkr jämfört med föregående år, bland annat till följd av prisjusteringar, förändrad produktionsmix, ökad PET-CT-volym och försäljning av utrustning. Kostnadsutvecklingen påverkas av ökade kostnader för reparation och underhåll, distansgranskning samt inköp av isotoper som ännu inte fullt ut täcks av pris. Samtidigt har kostnaderna för hyrpersonal minskat.	

Mätetal	Resultat	Analys	Diagram
		FS centralt har en positiv budgetavvikelse till och med februari på 13,3 miljoner kronor. Köpt vård har ett budgetunderskott på 20,3 mnkr. Underskottet är i linje med tidigare år, och beror på att den köpta högspecialiserade vården konstant har en högre kostnadsutveckling än index. Underskottet vägs bland annat upp av ej utfördelade budgetposter.	

2026-03-17

§ 36**Frågor****Beslut**

Presidiet beslutar att

- följande fråga, som lämnades vid nämndsammanträdet den 18 februari 2026, ska besvaras vid nämndsammanträdet den 31 mars 2026.

– Fråga 2026-02-18 Förändring av ledningsorganisationen för kirurgiverksamheten

Presidiet beslutar att

- eventuella frågor ska tas emot vid nämndsammanträdet den 18 februari 2026.

Beslutsunderlag

- Fråga 2026-02-18 Förändring av ledningsorganisationen för kirurgiverksamheten
-

Förändring av ledningsorganisationen för kirurgiverksamheten

Med anledning av nämndens beslut från sammanträde 2025-10-14 (diarienummer: RJL 2025/3138) om att utreda en förändrad ledningsorganisation för kirurgiverksamheten i Region Jönköpings län vill jag fråga hur utredningsarbetet fortskrider.

Finns det en tidsplan för när utredningen beräknas vara färdig och när nämnden kan förvänta sig att få den presenterad?

Razvan Nichitelea
Centerpartiet

2026-03-17

§ 37**Verksamhetsberättelse 2025 Nämnd för folkhälsa och sjukvård**

Diarienummer: RJL 2025/25

Beslut

Presidiet föreslår nämnden för folkhälsa och sjukvård att

- godkänna Verksamhetsberättelse 2025 Nämnden för folkhälsa och sjukvård.

Sammanfattning

I oktober 2024 antog nämnden för folkhälsa och sjukvård sin verksamhetsplan för 2025 samt godkände förslag till budgeterade anslag 2025 för nämndens centrala anslag samt för verksamhetsområden privata vårdgivare, vårdcentralerna Bra Liv, folktandvården, medicinsk vård, kirurgisk vård och psykiatri, rehab och diagnostik. Verksamhetsberättelse 2025 ger återslag av verksamhetsplan och budget.

Beslutsunderlag

- Tjänsteskrivelse: Verksamhetsberättelse 2025 – Nämnden för folkhälsa och sjukvård
- Verksamhetsberättelse 2025 – Nämnden för folkhälsa och sjukvård

Beslutet skickas till

Nämnden för folkhälsa och sjukvård

Verksamhetsberättelse 2025 Nämnd för folkhälsa och sjukvård

Förslag till beslut

Nämnd för folkhälsa och sjukvård

- godkänner Verksamhetsberättelse 2025 Nämnden för folkhälsa och sjukvård.

Sammanfattning

I oktober 2024 antog nämnden för folkhälsa och sjukvård sin verksamhetsplan för 2025 samt godkände förslag till budgeterade anslag 2025 för nämndens centrala anslag samt för verksamhetsområden privata vårdgivare, vårdcentralerna Bra Liv, folktandvården, medicinsk vård, kirurgisk vård och psykiatri, rehab och diagnostik. Verksamhetsberättelse 2025 ger återslag av verksamhetsplan och budget.

Ärendebeskrivning

Regionfullmäktiges beslutade budget med verksamhetsplan 2025 anger utgiftsramar och verksamhetsmål som ska nås för Region Jönköpings län samlade åtagande, oavsett vem som utför verksamheten. I oktober 2025 antog nämnden för folkhälsa och sjukvård sin verksamhetsplan för 2025 samt godkände förslag till budgeterade anslag 2025 för nämndens centrala anslag samt för verksamhetsområden privata vårdgivare, vårdcentralerna Bra Liv, folktandvården, medicinsk vård, kirurgisk vård och psykiatri, rehab och diagnostik. Verksamhetsberättelse 2025 ger återslag av verksamhetsplan och budget.

Regiondirektören är ytterst verkställande tjänsteman som på regionstyrelsens och nämndernas uppdrag leder verksamheten i enlighet med fastställd verksamhetsplan och budget för regionstyrelsen och respektive nämnd. Operativt ansvar fördelas vidare till verksamhetsområdesdirektör som rapporterar till regiondirektören.

Verksamhetsberättelserna utgör tillsammans regiondirektörens återslag av förvaltningens verksamhet och resultat för 2025. De är också en del av Region Jönköpings län interna kontroll. Verksamhetsberättelserna är även ett viktigt underlag för regionledningskontorets arbete med Region Jönköpings län årsredovisning som utgör regionstyrelsens återslag till regionfullmäktige.

I verksamhetsberättelsen för 2025 lämnas en slutlig redovisning av hur verksamheten har utvecklats och om regionfullmäktiges mål har uppnåtts. Av de 37 mål för en ändamålsenlig och kostnadseffektiv verksamhet som fullmäktige och nämnden har angivit och som mäts för 2025 har 31 mål (cirka 84 procent) helt eller delvis uppnåtts.

Vid årets slut redovisar nämnden en negativ budgetavvikelse motsvarande 189 miljoner kronor. Verksamhetsområdena (inklusive privata vårdgivare) redovisar en negativ avvikelse motsvarande 164 miljoner kronor medan centralt budgeterade anslag redovisar ett underskott på 25 miljoner kronor.

Beslutsunderlag

- Tjänsteskrivelse: Verksamhetsberättelse 2025 – Nämnden för folkhälsa och sjukvård
- Verksamhetsberättelse 2025 – Nämnden för folkhälsa och sjukvård

Beslutet skickas till

Regionledningskontoret – Ekonomi

Regionledningskontoret – Folkhälsa och sjukvård

Mats Bojestig
Hälso- och sjukvårdsdirektör

Verksamhetsberättelse Styrelse/nämnd 2025

Nämnden för folkhälsa och sjukvård (FS)

Dnr RJL 2025/25

Mats Bojestig, hälso- och sjukvårdsdirektör

Nämnden för folkhälsa och sjukvård (FS)

Region Jönköpings län, Box 1024, 551 11 Jönköping

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Inledning

Nämnden för folkhälsa och sjukvård omfattar uppdrag inom verksamhetsområdena medicinsk vård, kirurgisk vård, psykiatri, rehabilitering och diagnostik, vårdcentralerna Bra liv, Folk tandvården samt det arbete som sker inom avdelningen för folkhälsa och sjukvård som är placerat på Regionledningskontoret.

Verksamhetsområde Medicinsk vård har verksamhet inom akutsjukvård, ambulanssjukvård, barnhälsovård, barnsjukvård, barn- och ungdomshälsa, geriatrik, hudsjukvård, infektion och medicin. Verksamhet bedrivs på sjukhusen i Eksjö, Jönköping och Värnamo, ambulanser runt om i länet, barn- och ungdomsenheter i Eksjö, Jönköping och Värnamo samt på länets familjecentraler. Medicinsk vård har även en mottagning för hudverksamhet i Nässjö samt mottagning för barn- och ungdomshälsa även i Huskvarna och Nässjö. Infektionskliniken som finns i Jönköping har även mottagning för sprututbytesverksamhet i Jönköping, Nässjö och Värnamo. Antalet faktiska årsarbetare uppgick i genomsnitt under 2025 till närmare 1 900.

Verksamhetsområde Kirurgisk vård bedriver verksamhet inom kirurgi, kvinnohälsa och kvinnosjukvård, onkologi, operations- och intensivvård, ortopedi, smärtbehandling, urologi, ögonsjukvård samt öron-, näs- och halssjukvård. Verksamheten bedrivs i huvudsak på sjukhusen i Eksjö, Jönköping och Värnamo samt på länets familjecentraler och ungdomsmottagningar. Kirurgisk vård har cirka 2 700 medarbetare.

Verksamhetsområde Psykiatri, rehabilitering och diagnostik består av länsklinikerna barn och ungdomspsykiatri (BUP), habiliteringscentrum, klinisk fysiologi, laboratoriemedicin, rehabiliteringscentrum, rehabiliteringsmedicin och röntgen. De tre vuxenpsykiatriska klinikerna utgår från respektive länsdel. Inom habiliteringscentrum finns förutom barn- och vuxenhabilitering även tolkcentral, syncentral och hörselhabilitering. Laboratoriemedicin är samlingsbegrepp för klinisk kemi, mikrobiologi, immunologi, patologi och transfusionsmedicin. Faktiska årsarbetare är knappt 2040.

Vårdcentralerna Bra liv finns med 28 vårdcentraler och flera filialer spridda i länet. Vid dessa enheter är cirka 276 000 invånare listade, vilket är 74 procent av länets befolkning. Verksamheten har cirka 1000 årsarbetare.

Det finns även ett antal privata vårdcentraler och privata ögonmottagningar i länet.

Folk tandvårdens allmäntandvård omfattar 26 kliniker i länets samtliga kommuner. Specialisttandvården bedrivs med tyngdpunkt i Jönköping, där nio odontologiska specialiteter finns. Därutöver bedrivs ortodont (tandreglering) i Nässjö. I Värnamo bedrivs verksamhet med tandreglering, rotbehandling, specialistbarntandvård samt orofacial medicin (sjukhustandvård). Folk tandvården har runt 570 faktiska årsarbetare.

Folkhälsa och sjukvårds verksamhet inom Regionledningskontoret arbetar med uppdrag bland annat inom nära vård, kunskapsstyrning, läkemedel, patienträttigheter och avgifter. Primärvård och rehabilitering inklusive vårdval, patientsäkerhet, Smittskydd och vårdhygien, Folkhälsa, E-hälsa samt Bedömning tandvård är andra områden. Avdelningen har omkring 110 medarbetare.

Strategin för att möta framtidens behov av hälso- och sjukvård 2020-2030 har under året uppdaterats, men innehåller fortfarande samma sex delstrategier. I arbetet ingår "Bästa platsen att leva på" som är ett samarbete med kommunerna i länet. Även det förebyggande folkhälsoarbetet har fortsatt med införande av Hälsocenter. De olika hälsocentren arbetar aktivt med att främja de fyra dimensionerna av hälsa: fysisk, psykisk, social och existentiell, genom en rad olika individanpassade aktiviteter och program. Hälsocentren lägger stor vikt vid personligt anpassade planer och stöd. Arbetet med riktade insatser för elevhälsocentraler och förstärkt lokal samverkan inklusive arbetet med dashboardar har också fortsatt. Rutinen kring konsultstöd från sjukhusens specialistvård till primärvården genom sömlösa vårdövergångar följs upp kontinuerligt.

Kapacitets- och produktionsstyrning (KPS) har fortsatt med inkludering av fler kliniker. Region Jönköpings län har bland de bästa resultaten i landet vad gäller tillgänglighet. Trots detta behöver arbetet med att förbättra tillgängligheten till vården fortsätta. Exempelvis fortsätter neuropsykiatriska frågeställningar att öka hos både barn och vuxna.

Arbete med att öka användningen av digitala tjänster och digitala arbetssätt har fortsatt. Bokningsbara

tider via webbtidbok har ökat, fler patienter bokar eller avbokar tiden via 1177. Arbete pågår för mer ändamålsenliga vårdtjänster med avsikt att underlätta för fler utlagda tider. Antal meddelanden skickade av invånare till vården har ökat med 20 procent jämfört med föregående år. Antal meddelanden skickade av vården till invånarna har ökat med över 100 procent från föregående år varav de flesta meddelanden innebär en kallelse till vården. Även antal skickade formulär via formulärtjänsten har ökat från 23 000 formulär 2024 till 184 000 under 2025. Detta har lett till snabbare hantering och bättre kunskap om patienters behov och tillstånd, och portokostnaderna har minskat.

Under året har även arbetet med en säker, jämlik och kostnadseffektiv läkemedelsbehandling fortsatt, även tillsammans i sydöstra sjukvårdsregionen och nationellt. Flera olika aktiviteter och exempelvis läkemedelsdialoger genomförs kontinuerligt.

Vaccination mot influensa och covid-19 har givits som höstdos och mot covid-19 som vårdos. Även pneumokockvaccin har givits i samband med höst- och vårdoserna. Alla över 75 år kallas till vaccination för influensa och covid-19. De mellan 65 och 74 får ett meddelande i 1177. Siffror från Nationella vaccinationsregistret har under året visat att Region Jönköpings län har högst vaccinationstäckning i landet. Intresset för TBE vaccination har under 2025 varit något lägre än 2024.

Arbetet med rationell antibiotikaanvändning har senaste året utgått utifrån konceptet Antibiotikasmart. Trettiofyra av 40 vårdcentraler och 19 av 25 sjukhuskliniker diplomerades under 2025, vilket är en ökning från föregående år.

Även arbetet med det akuta flödet har fortsatt under året och kan nu visa goda resultatet på bland annat förkortad tid på akutmottagningen.

Nämnden för folkhälsa och sjukvård redovisar för helåret 2025 ett underskott på 189,2 miljoner kronor, vilket motsvarar en avvikelse på -1,5 procent i förhållande till budget för perioden.

Måluppfyllelse ändamålsenlig och kostnadseffektiv verksamhet

	2025	Andel	2024	Andel
Antal mätetal som är uppfyllda	17	46%	14	35%
Antal mätetal som är delvis uppfyllda	14	38%	16	40%
Antal mätetal som inte är uppfyllda	6	16%	10	25%
Antal mätetal som mäts	37	100%	40	100%

Nämnden för Folkhälsa och sjukvård följer flera system- och nämndsmätetal. Resultat finns för 37 mätetal. Bland annat finns inget resultat för självskattad hälsa i befolkningen för 2025.

I 46 procent av mätetalen uppnås målen. Vilken är en tydlig ökning jämfört med föregående år. Målen nås exempelvis inom: patienttillfredsställelse, patientens delaktighet och på frågorna om våra invånare har tillgång till den hälso- och sjukvård som de behöver och förtroendet för hälso- och sjukvården. Målet nås även för standardiserade vårdförlopp - andel utredda patienter i SVF och antal hembesök av läkare. Hel- och delvisa måluppfyllelsen är sammanlagt 84 procent vilket också är en tydlig ökning i jämförelse med föregående år.

I 6 mätetal (16 procent) nås inte måluppfyllelsen vilket är färre än föregående år. Exempel på mätetal där måluppfyllelse inte nås är standardiserade vårdförlopp inom max ledtid, inom väntetid till utredning och behandling inom barn- och ungdomspsykiatri, andel berättigad till nödvändig tandvård som fått den utförd samt ekonomi i balans.

Medborgare och kund

Strategiska mål: Bästa plats att växa upp, leva, verka och åldras på

Framgångsfaktorer: Nöjda kunder och intressenter

Uppdrag	Analys
Införa gemensam dokumenterad överenskommelse mellan patient och vårdgivare.	Antal patienter som har en dokumenterad överenskommelse fortsätter att öka. Särskilt viktig är överenskommelsen för patienter med kroniska sjukdomar. Arbetet fortsätter med egengranskningar för att stärka kvalitet och innehåll i dokumenterade överenskommelser. En kartläggning har gjorts som visar att personer med kroniska sjukdomar har flera parallella överenskommelser. Syftet var att titta på innehållet i dessa överenskommelser. Arbetet förväntas bidra till ett mer sammanhållet och effektivt arbetssätt med patientöverenskommelser.
Öka patientens kunskap om sin sjukdom.	Arbetet med patientens kunskapsstöd samordnas med flera andra utvecklingsområden, exempelvis dokumenterad överenskommelse, digitala kallelser, digital patientinformation, gemensam digital servicenivå. Kommunikation har skett vid olika forum, såsom storgrupp sjukvård, utvecklingskraft och nätverksträffar. Utveckling och spridning av fler mötesplatser och hälsocaféer likt hjärtats hus i länet pågår också. På Folkhälsa och sjukvårdswebben finns nu en samlad sida för vilka hälsofrämjande stöd som finns.
Ett treårigt projekt med en samordnare för omställningen till nära vård startas under 2024.	Den operativa ledningsgruppen för ledning, styrning och uppföljning av verksamhetsplanen för Folkhälsa och sjukvård inklusive förflyttningen mot nära vård har fortsatt sitt arbete. Syftet med gruppen är att stödja och stärka samverkan kring olika uppdrag och aktiviteter utifrån verksamhetsplanen. I uppdraget ingår att följa upp aktiviteter, mål och mätningar. Kartlägga aktiviteter och resultat utifrån förflyttningen mot nära vård och stödja spridning av goda exempel.

Mätetal	Målvärde	Resultat	Analys
Nämnd Patientupplevd delaktighet och kontinuitet (NPE)	80 %	82 % 	I de genomförda undersökningarna under året inom ramen för Nationell patientenkät, andel nöjda/mycket nöjda, i dimensionerna delaktighet och kontinuitet. Somatisk vård (öppenvård) 88,4 procent Somatisk vård (slutenvård) 81,5 procent Primärvård 76,65 procent Genomsnittliga resultatet blir då 82,2 procent

Mätetal	Målvärde	Resultat	Analys
Nämnd Överenskommelse, utvalda kroniska sjukdomsgrupper	60 %	85 % 	Andel patienter med en kronisk sjukdom som har en dokumenterad överenskommelse har under hela 2025 legat på ca 85 procent. Nästa steg är att kvalitetssäkra innehållet i överenskommelserna. I patientgrupperna hjärtsvikt, höftledsartros, kronisk obstruktiv lungsjukdom, hypertoni och diabetes typ 2 har mellan 83 procent och 89 procent av patienterna en dokumenterad överenskommelse. En stadig förbättring jämfört med föregående år. För patientgruppen med diabetes typ 1 är andelen 72 procent, även det en klar förbättring.
 Patienttillfredsställelse - andel nöjda patienter	90 %	84,9 	I de genomförda undersökningarna under året inom ramen för Nationell patientenkät, andel nöjda/mycket nöjda med helhetsupplevelsen (medelvärde samtliga frågor) Somatisk vård (öppenvård) 89 procent Somatisk vård (slutenvård) 86,1 procent Primärvård 79,5 procent Genomsnittliga resultatet blir då 84,9 procent
 Jag har tillgång till den hälso- och sjukvård jag behöver - Instämmer helt/delvis.	90 %	92 % 	Hälso- och sjukvårdsbarometern 2025 visar att 92 procent av befolkningen i vårt län uppfattar att de har tillgång till den hälso- och sjukvård de behöver. Detta är en förbättring från föregående år med 1 procentenhet, fortsatt över målnivån. Resultatet är delat högst i landet. Medel i riket är 87 procent. I denna undersökning tillfrågas slumpvis utvalda invånare och de behöver inte ha haft någon kontakt med vården.
 Andel i befolkningen som har stort/mycket stort förtroende för hälso- och sjukvården i sin helhet i sin region	75 %	77 % 	Hälso- och sjukvårdsbarometern 2025 visade att 77 procent av befolkningen i Region Jönköpings län har stort eller mycket stort förtroende för hälso- och sjukvården i sin helhet (snitt för riket 62 procent). Detta är en försämring med 5 procentenheter jämfört med föregående år både för genomsnittet i riket och för Region Jönköpings län. Resultatet är högst i landet för fjärde året i rad. I denna undersökning tillfrågas invånare slumpvis utvalda och behöver inte ha haft någon kontakt med vården.

Framgångsfaktorer: God tillgänglighet

Uppdrag	Analys
Förbättra tillgängligheten till sjukvårdsrådgivning.	1177 på telefon har lämnat avtalet med Östergötland och Örebro den 2 juni. Under våren genomfördes också en utredning kring tillgängligheten på 1177 på telefon. Arbetet med att förbättra tillgängligheten har pågått under hösten. Exempelvis har helgbemanning och utökning av hemarbetsplatser införts. Resultatet har under hösten successivt förbättrats. En

Uppdrag	Analys
	viss nedgång i december då vårdcentralerna varit stängda.
Under 2025 genomförs en utredning kring 1177 på telefon	Utredningen kring 1177 på telefon genomfördes under våren 2025. Den har rapporterats till nämnd för folkhälsa och sjukvård och till sjukvårdens ledningsgrupp. Rapporten ger ett antal förslag till förbättringar. Denna rapport är tillsammans med andra uppdrag och initiativ i budget och verksamhetsplan ett underlag till det fortsatta arbetet med "Ingångar i vården - del 2" som startar i januari 2026.
Översyn av ingångar till vården	Förstudien av ingångar till vården genomfördes under våren och är rapporterad till sjukvårdens ledningsgrupp. Denna rapport föreslår ett antal förbättringsförslag och förtydliganden av vägarna in till vården med vårdcentralen som navet. Rapporten är tillsammans med utredningen av 1177 på telefon och förslag till digital servicenivå ett underlag för det fortsatta arbetet med ingångar i vården - del 2, som startas i januari 2026.
Förbättra tillgängligheten till vården och tandvården utifrån systemmätetal och mål för verksamheterna.	Tillgängligheten till vården ligger stabilt och inom de flesta verksamheter på en bra nivå. Region Jönköpings län ligger i en nationell jämförelse fortsatt bland de bästa i landet. Det pågår ett stort antal aktiviteter för att fortsatt förbättra tillgängligheten, exempelvis digitala besök, teambesök, kapacitets och produktionsstyrning, andra exempel är teambedömningar i tvärprofessionella team, triagering till rätt yrkeskategori, kortare behandlingsserier, kortare besökstider och mer individualiserad vård. Patienternas egen kraft och ansvar för sin sjukdom tas på ett systematiskt sätt tillvara.
Erbjuda fast vårdkontakt och enkla kontaktvägar in till vårdcentralerna för patienter med stora vårdbehov.	Vårdcentralerna arbetar aktivt med att nå målsättning om att alla patienter med kronisk sjukdom och/eller komplexa sjukvårdsbehov ska ha en dokumenterad överenskommelse i journalen, vilket inkluderar en tid i handen och fast vårdkontakt.
Arbeta aktivt med att uppnå bemanningsmålet inom primärvården.	Fyra vårdcentraler har valts ut att delta i satsningen på 1 100 listade per ordinarie heltidsanställd läkare. På kort sikt medför detta ett ökat behov av hyrläkare. På helår 2025 motsvarar det ca 3,5 hyrläkare extra. På lång sikt ska det skapa en attraktiv arbetsmiljö med ökad möjlighet till ordinarie rekrytering. Satsningen påverkar det ekonomiska resultatet med merkostnader på ca 12 miljoner kronor.
Förbättra tillgängligheten och omhändertagandet av barn och ungdomars psykiska hälsa.	Tillgängligheten till första besök ligger nära målvärdet. Habiliteringscentrum når målet och Barn- och ungdomspsykiatrien större delen av året, men sommaren påverkar negativt. Antalet besök är i nivå

Uppdrag	Analys
	med föregående år, och en ökad andel remisser till Barn- och ungdomspsykiatri drivs av fler neuropsykiatriska frågeställningar. Tillgängligheten till behandling inom 30 dagar är fortsatt en utmaning inom Barn- och ungdomspsykiatri, medan habiliteringscentrum sedan september uppfyller målet. Väntetiden till utredning är fortsatt lång trots att fler utredningar genomförts. Ökat inflöde och rekryteringsutmaningar påverkar kapaciteten, men åtgärder pågår. Arbetet med En väg in och triageringsmodellen fungerar väl och möjliggör insatser på rätt vårdnivå, men den höga andelen remisser till specialistnivå, särskilt Barn- och ungdomspsykiatri, innebär fortsatt belastning och behov av att stärka den primära nivån.
Under mandatperioden ska Region Jönköpings län säkra akutvårdkedjan för att patienter ska få ett snabbare och säkrare omhändertagande i hela länet.	Förbättringsarbetet med akutflödesprocessen har fortsatt under 2025. Samtliga sjukhus har arbetsgrupper som utvecklar arbetssätt för att hantera högt patientinflöde, komplexa vårdbehov och smidiga övergångar mellan akutmottagning och vårdavdelning. Målet är ökad patientsäkerhet, kortare ledtider och bättre patientupplevelse. Sjukhusen arbetar med förbättrad överrapportering, samverkan mellan akutmottagning och andra enheter, samt test av nya arbetssätt för att effektivisera inläggning och utflöde. Region Jönköpings läns akutmottagningar fortsätter att ligga i topp nationellt, med cirka 80 procent av patienterna färdigbehandlade inom fyra timmar. Dessutom visar senaste nationella patientenkäten att akutmottagningarna har mest nöjda patienter och har förbättrat sig i alla dimensioner.
Tillse att det finns vårdplatser efter behov på de tre akutsjukhusen.	Antalet disponibla platser styrs av aktuellt behov och kan därför variera över tid. Under året har det skett en ökning av disponibla platser. Beläggningen är totalt sett något lägre vid jämförelse med föregående år. Antalet överbeläggningar minskar och är betydlig färre jämfört samma period, januari-december föregående år. Relativt oförändrat antal inneliggande samt en utökning av disponibla platser bidrar till det aktuella resultatet.

Mätetal	Målvärde	Resultat	Analys
Nämnd Telefonkontakt med vårdcentralen samma dag	100 %	90 % 	Resultatet visar en förbättring under året jämfört med föregående år.
 Medicinsk bedömning i	90 %	92 % 	Fortsatt över målnivån. Står sig väl vid nationell jämförelse, ett bra resultat.

Mätetal	Målvärde	Resultat	Analys
primärvården inom tre dagar.			
 Faktisk väntetid till första besök inom 60 dagar i specialiserad vård nationell rapportering.	80 %	70 % 	Resultatet är fortsatt en bit från målet på totalen, även om resultatet i december var väldigt nära. Resultatet är dock bland de bästa vid nationell jämförelse.
 Faktisk väntetid till operation/åtgärd inom 60 dagar i specialiserad vård nationell rapportering	80 %	78 % 	Resultatet ligger nära målet och är bland de bästa vid nationell jämförelse.
 Genomförda återbesök inom medicinskt måldatum	90 %	79 % 	Resultatet är det bästa månadsresultatet på många år.
Nämnd Fått hjälp och lämnat akutmottagningen inom 4 timmar	90 %	79 % 	Resultatet ligger på en jämn nivå under 2025. Det finns fortfarande en bit kvar till målet, men i nationell jämförelse är resultatet i topp. Utvecklingsarbetet på akutmottagningarna har fortsatt under året.
 Tid till ambulans - andel prio 1 larm inom 20 minuter	80 %	76 % 	Tillgängligheten uppgick under 2025 till 76 procent. Föregående år 72 procent. Antalet prioritet 1 uppdrag har minskat med 15 procent jämfört med motsvarande period föregående år. Inom- och utomlänstransporter mellan vårdinrättning tar en stor del av ambulanssjukvårdens resurser, cirka 11 procent av totalt antal uppdrag. Ambulansverksamheten har under 2025 startat upp en verksamhet (transportfordon) som ska ta hand om inom- och utomlänstransporter mellan vårdinrättningar. Förväntad effekt är ökad tillgänglighet för prioritet 1 uppdrag. Totalt har antalet uppdrag minskat med 650 uppdrag (1,5 procent) jämfört med föregående år.
Nämnd Kontinuitetsmått – primärvård	0,4 index	0,36 index 	För perioden är variationen 0,18 till 0,63 i index för den vårdcentral med lägst respektive högst index. Flera vårdcentraler exempelvis Skillingaryd VC, Tenhults VC, Wasa VC samt Vårdcentralen Tranan Tranås redovisar en förbättring jämfört årets början. Som tidigare är Tenhults VC och Landsbro VC vårdcentraler med högt index.
 Täckningsgrad för den uppsökande verksamheten (munhälsobedömningar)	90 %	92 % 	Av de personer som har "Intyg om nödvändig tandvård" och som önskat få en munhälsobedömning utförd (4 398 personer) har 90 procent (4 060 personer) fått det. Målet är därmed uppfyllt.
Nämnd Andel berättigade till nödvändig tandvård som fått den utförd	80 %	64 % 	Av 6 852 berättigade personer har 4 357 fått nödvändig tandvård utförd (64 procent). Behandlingarna utförs av både privat- och Folk tandvård varför mätetalet inte specifikt mäter Folk tandvårdens måluppfyllnad. Folk tandvården har god tillgänglighet att ta emot alla patienter, det centrala teamet för den uppsökande verksamheten har

Mätetal	Målvärde	Resultat	Analys
			utökats och därmed ökat andelen munhälsobedömningar, vilket dock inte får genomslag i detta mätetal. Folktandvården har i dagsläget inte tillgång till information om vilka invånare som är berättigade till nödvändig tandvård, eller vilka av de berättigade patienterna som har tackat nej till vård, vilket heller inte tas hänsyn till i målet.
Nämnd Allmäntandvård: Andel revisionspatienter i tid till undersökning och behandling	90 %	90 % 	Utfallet för december 2025 ligger på 90 procent, men resultat är gult då utfallet är 89,84. Under 2025 har satsning pågått för att erbjuda tid till nya patienter som står på kö till Folktandvården. Satsningen på att ta emot nya patienter medför tillfälligt att tillgängligheten för revisionspatienter är något under 90 procent. Trots detta håller Folktandvården en mycket god tillgänglighet för revisionspatienter i nationell jämförelse.
Nämnd Allmäntandvård: Möjlighet att ta emot nya patienter, mäts genom minskning av kö	-10 %	-84 % 	Sedan årsskiftet 2025 har allmäntandvården minskat antalet patienter i kö till första tid med ca 5100 patienter. Antalet personer i kö var 8150 personer i december 2023, 6402 personer i kö december 2024 och 1342 i december 2025.
 Tillgänglighet specialisttandvård inom 60 dagar efter remiss	80 %	72 % 	Tillgängligheten för specialisttandvården har förbättrats avsevärt jämfört med tidigare år. Från 40 procent år 2022 till 64 procent under 2024 till 2025 års nivå om 72 procent. Följande specialiteter klarar inte tillgänglighetsmålet: käkkirurgi, orofacial medicin, klinisk bettfysiologi samt pedodonti. En utmaning finns inom Orofacial medicin där inremitterade patienter ofta blir revisionspatienter vilket gör att patienterna aldrig slussas vidare till annan vårdnivå. Eftersom det är en relativt ny specialitet samtidigt som befolkningen blir äldre och tandhälsan oftast försämras i högre ålder så ökar patientinflödet. Liknande problematik med "revisionspatienter" finns på Pedodonti. Bettfysiologi bedöms nå målvärdet under 2026 i takt med att ST-tandläkare blir mer erfarna. Utifrån trenden de senaste två åren, bedöms specialisttandvården på totalen nå målvärdet under 2026. Under året har det tagits fram ett enhetligt prioriteringssystem inom specialisttandvården. Detta har implementerats på 2 kliniker, målsättningen är att samtliga kliniker inför detta i början av 2026.
Nämnd Faktisk väntetid till första besök inom 30 dagar till barn och ungdomspsykiatrisk vård	90 %	78 % 	Mätetalet visar väntetid till både Barn - och ungdomspsykiatri och habiliteringscentrum. Resultat för hela 2025 är en bit ifrån målvärdet, men senaste fyra månaderna har målet nåtts och är ett bra resultat i nationell jämförelse. Under 2025 fick 1661 barn ett första besök till barn- och ungdomspsykiatrisk vård,

Mätetal	Målvärde	Resultat	Analys
			vilket är i nivå med föregående år.
Nämnd Faktisk väntetid till behandling till barn- och ungdomspsykiatrisk vård inom 30 dagar	90 %	19 % 	Resultatet är något bättre än tidigare. För Barn och ungdomspsykiatri är genomförda behandlingar vid slutet av året enligt tillgänglighetsmätning: 22 procent inom 30 dagar, 56 procent inom 60 dagar och 67 procent inom 90 dagar. Antal väntande är totalt 570 patienter, varav 34 stycken är egen vald väntan. De flesta (423 patienter) väntar på insatser efter genomförd NP-utredning. Det är variationer över tid då insatser startas upp med visst intervall på grupp-nivå. På habiliteringscentrum har alla barn erbjudits behandling inom 30 dagar sedan september månad.
Nämnd Faktisk väntetid till utredning till barn- och ungdomspsykiatrisk vård inom 30 dagar	90 %	4 % 	Mätetalet visar tillgänglighet till utredning för barn och unga som väntar på utredning på BUP och habiliteringscentrum. Resultatet är långt ifrån målvärdet och på samma nivå vi sett under en längre tid. Under 2025 har 1244 barn fått en neuropsykiatrisk utredning vilket är 71 fler än föregående år. Utmaningar finns bland annat med rekrytering av specialistpsykologer och andra nyckelresurser. Glädjande kan konstateras att det inom barn- och ungdomspsykiatri har kunnat anställas flera psykologer under utbildning, PTP och enstaka specialist. Under 2026 förväntas habiliteringscentrum utöka antalet skickade utredningar till externa leverantörer.
Nämnd Disponibla vårdplatser		646 	Antalet disponibla platser baseras på aktuellt behov och varierar därför något över tid. Jämfört samma period föregående ökar samtliga verksamhetsområden antalet disponibla platser.
Nämnd Beläggning	<85 %	81 % 	Beläggningen är i snitt under året något lägre än föregående år och sammantaget för hela regionen under uppsatt mål. Relativt oförändrat antal inneliggande samt en utökning av disponibla platser bidrar till det aktuella resultatet. Geriatriska kliniken Jönköping samt Medicin- och geriatrikliniken Eksjö är exempel på kliniker med fortsatt hög beläggning.
Nämnd Utlokaliserade	0 %	0,8 % 	Antalet utlokaliserade patienter kan variera något månad för månad men sett till hela perioden januari-december sker en minskning jämfört med föregående år. Flest patienter utlokaliseras inom verksamhetsområde Kirurgisk vård och då från Kirurgkliniken. Inom Psykiatri rehabilitering och diagnostik sker utlokalisering i mycket liten omfattning. Arbetet med att minimera antalet utlokaliseringar pågår ständigt.

Mätetal	Målvärde	Resultat	Analys
Nämnd Överbeläggningar	0 %	0,6 % 	Antalet överbeläggningar minskar och är betydlig färre jämfört samma period, januari-december föregående år. Relativt oförändrat antal inläggande samt en utökning av disponibla platser bidrar till det aktuella resultatet.
Nämnd Återinläggningar inom 30 dagar vård dygn	15 %	16 % 	Resultatet fortsätter ligga på samma nivå som de senaste tre åren, med väldigt liten variation.
Nämnd Utskrivningsklara	2	2,3 % 	Målet för hur länge en utskrivningsklar patient ska vara inläggande på vårdavdelning uppgår till 2 dygn. Det genomsnittliga antalet dygn är 2,3. Framförallt är det under det första tertialet 2025 målet inte uppnås. Resultatet är något sämre än 2024, men på samma nivå som 2023.

Framgångsfaktorer: God och jämlik hälsa

Uppdrag	Analys
Förbättra folkhälsan hos länets invånare.	Arbetet har fortsatt med samverkan mellan Region Jönköpings län och 13 kommuner bland annat genom Hälsocenter, familjecentraler. Utbildning sker inom exempelvis More to life, interkulturell hälsokommunikation, HBTQI, levnadsvanor, Hälso guider mm. Det pågår ett arbete med införandet av Elevhälsocentraler eller arbetet som benämns tidiga samordnade insatser. Arbetet ska leda till att det ska gå snabbare att få den hjälp man behöver och att underlätta för föräldrar att ha kontakt med flera aktörer. Arbetet finns med i Strategigrupp barns handlingsplan och inkluderar samtliga 13 kommuner i samverkan med Region Jönköpings län. Arbetet ska leda till att det ska gå snabbare att få den hjälp man behöver och att underlätta för föräldrar att ha kontakt med flera aktörer.
Arbeta för en mer jämlik hälsa hos utrikesfödda invånare.	Region Jönköpings läns hälsokommunikatörer tillsammans med hälsoguider har under 2025 arbetat med riktad hälsokommunikation, hälsofrämjande gruppinsatser, verksamhetsstöd och personalutbildningar. Tillsammans har insatserna från hälsokommunikatörer och hälsoguider resulterat i 4891 migrantinteraktioner vid hälsofrämjande gruppinterventioner eller hälsokommunikation genom föreläsning eller samtal. Insatser från hälsokommunikatörerna och hälsoguider har erbjudits och skett i länets alla 13 kommuner men fokuserats mest till kommunerna med flest utrikesfödda och störst socioekonomiskt utsatta områden. Under året har hälsokommunikatörerna genomfört vägledande samspelegrupper, föräldraskapsstödgrupper på föreningar eller

Uppdrag	Analys
	familjecentraler, Hälsoškolor, More to life-grupper, Diabetes- och Smärtskolor Region Jönköpings läns arbete för att öka medvetenheten om socioekonomiska och kulturella faktorerens påverkan på patientsäkerhet och kliniska resultat har stärkts. Personalutbildningar och verksamhetsstöd till Region Jönköpings läns och kommunernas verksamheter har genomförts kring interkulturell hälsokommunikation, hälsolitteracitet och inkluderande bemötande i vården för att bidra till mer hälsolitterata organisationer. Totalt har 1985 personal deltagit.
Förbättra barn och ungas hälsa.	Processledare är tillsatta under året för att driva arbetet med konceptet kring elevhälsocentraler. Inom länet pågår arbete med goda erfarenheter kring det man benämner som tidiga samordnade insatser. Men för att lyckas utifrån de utmaningar som finns för många barn och unga idag, krävs arbete tillsammans i samverkan över gränser på helt nya sätt. Målsättningen är att tillsammans bygga en gemensam struktur utifrån lokala förutsättningar, för tidiga samordnade insatser mellan skola, socialtjänst, fritids samt hälso- och sjukvård. Arbetet fortsätter under 2026 och 2027 Ett annat arbete är det som påbörjats från barn- och ungdomsenheten, rehabiliteringscentrum, habiliteringen, barntandvården och barnkliniken med att ta fram arbetssätt för ett obesitas team. Ett första steg har varit att möta de barn som har obesitas och typ 2 diabetes i team.
Förebyggande insatser som stöd till nyblivna föräldrar.	Familjecentraler och barnhälsovården (BHV) i länet har arrangerat tematräffar och gruppaktiviteter för blivande och nyblivna föräldrar. Exempel på teman som tagits upp är vara ny förälder (vardag, samspel och anknytning), kost, sömn och barns utveckling, utmaningar och vardagsliv med små barn, relationer och föräldrarollens förändringar. Dessa träffar leds ofta av BHV-sjuksköterska, kurator, pedagog eller barnmorska. Syftet är att ge ett tidigt och tryggt stöd i hemmiljön, samtala om barns utveckling och familjens behov samt skapa en relation till vårdpersonal redan i början av föräldraskapet. Sammanställning har även gjorts av det samlade behovet av familjecentraler under året. Det finns stor samsyn gällande behovet av utbudsplatser och antal familjecentraler mellan barnhälsovården och kvinnohälsovården.
Främja äldres hälsa.	Insatser för att främja fysisk aktivitet och motverka stillasittande hos seniorer 65+ inklusive utrikesfödda 60+ har genomförts under året. Exempel är konceptet

Uppdrag	Analys
	"Walk and talk" som har lett till ökad fysisk aktivitet, minskat stillasittande och stärkt social gemenskap hos målgruppen utrikesfödda seniorer. Genom Walk and Talk har deltagarna fått regelbunden rörelse, social samvaro och möjlighet att samtala om hälsa, vilket ger omedelbara effekter i form av ökad aktivitet och minskad ensamhet. Dansaktiviteter på äldreboenden har bidragit till rörelseglädje och ökad social interaktion hos äldre, med tydliga positiva effekter under aktivitetstillfällena. Totalt har 131 personer deltagit. Samverkan med Bauer Endurance Club har påbörjat ett arbete för att främja kondition, balans och rörlighet hos personer 60+. Omtag har initierats inför 2026 med nytillkomna aktörer. Resultaten förväntas bli tydligare i takt med fortsatt genomförande. Simskolan för utrikesfödda seniorer har lett till förbättrad simkunnighet och till att verksamheten nu lever vidare i ordinarie föreningsregi, vilket visar på ett hållbart resultat exempelvis deltagarna har fått en större vattenvana och trygghet i att vistas i vatten.
Arbeta målinriktat med att skapa trygg och säker vård och omsorg.	Utvecklingen med förstärkt lokal samverkan fortsätter i hela länet. Dashboard är framtagen för att följa resultat på läns- och kommunnivå. Arbetet innefattar att förstärka både på chefsnivå och i den nära samverkan mellan kommunal hälso- och sjukvård och vårdcentral kring gemensamma patienter. Den förstärkta lokala samverkan i Jönköpings kommun har visat sig ha speciella utmaningar, med flera olika vårdcentraler i centrala Jönköping och kommunernas hemsjukvårdsteam som inte helt matchar. Därför pågår i Jönköping kommun sedan oktober 2025 en förskjutning av kommunens hemsjukvårdspatienter från den valda vårdcentralen till den geografiskt närmaste. Ett annat arbete som pågår är att konstruera och testa Invånarteam på tre vårdcentraler pågår.
Fortsätta arbeta för en jämlik geriatrisk vård i länet	Arbetet pågår för att utveckla forsknings- och kompetensutvecklings aktiviteter för geriatrik, samt att utveckla och prova metoder för äldreanpassat sjukhus. Exempelvis planeras att kvalitativt utvärdera "digitala kompisar", där seniorer lär varandra om digital teknik och e-hälsa. Arbetet fortsätter 2026 bland annat med att planera och genomföra olika seminarium. Forum Geriatrikum som digital föreläsningsserie har fortsatt med en föreläsning per månad. Inom programmet bästa platsen att åldras på, pågår arbete med att skapa ett äldrevänligt samhälle,

Uppdrag	Analys
	baserat på världshälsoorganisationens åtta domäner. En av dessa domäner är utvecklingen av ett äldrevänligt hälso- och sjukvårdssystem. Bland annat har en tjänstedesign-workshop med seniorer genomförts.
Förbättra tandvården för patienter med särskilda behov.	Äldretandvårdssamordnaren har under året kontinuerligt varit ute hos kommunerna och informerat aktörer inom äldreomsorgen kring äldres munhälsa och vikten av att utföra och upprätthålla en god munhygien. Arbete pågår för att munnen ska ses som en del av kroppen i hela sjukvården. Ny samverkan har även startat med fokus på patienternas behov vad gäller nödvändig tandvård.
Riktade insatser genomförs inom områden där kariesförekomsten ökar i förskola, fritidshem och skola.	Under året har arbetet med att förbättra och effektivisera det preventiva arbetet utifrån risk och socioekonomi tagit fart. Ett nytt team har bildats som är ute i skolor under delar av våren och hela hösten. Teamet är fullbemannat från januari 2026.
Säkerställa att verksamheter som är centraliserad inom Region Jönköpings län, når länets invånare jämnt.	Arbete pågår inom de olika verksamhetsområdena. Analyser och kartläggningar har gjorts. Kapacitets- och produktionsstyrning används för att planera, prioritera och fördela patienter inom länet utifrån den samlade kapaciteten vid de tre sjukhusen. Exempel på områden som analyserats är heldygnsvården och anorexienheten inom Barn- och ungdomspsykiatri, som mynnat ut i handlingsplaner med identifierade åtgärder att arbeta vidare med. Andra kliniker som arbetar med detta är reumatologen, barnkliniken och infektionskliniken. Den rehabiliteringsmedicinska kliniken arbetar kontinuerligt med att se över rehabiliteringens innehåll och tillgång till personalresurs. Jämförelse av resultat för patienterna görs kontinuerligt. I dagsläget finns skillnader avseende tillgänglighet, med längre väntan i Jönköping.

Mätetal	Målvärde	Resultat	Analys
Nämnd Självskattad hälsa i befolkningen	72 %		Redovisningen bygger på frågor i Nationella folkhälsoenkäten och det finns inget resultat för 2025 eftersom det inte genomförts någon undersökning. För 2024 visade resultatet att 70,9 procent (konfidensintervall 68,3 - 73,5 procent) av befolkningen i vårt län upplever/skattar sin hälsa som bra eller mycket bra. Resultatet var 8:e högst i landet. Medel i riket är 71,0 procent (konfidensintervall 70,5 - 71,5 procent). Kommande undersökning genomförs under 2026.

Mätetal	Målvärde	Resultat	Analys
 Andel approximant kariesfria 19-åringar	70 %	74 % 	Resultatet ligger stabilt sedan några år tillbaka. Folk tandvården ligger i övre halvan vid nationell jämförelse. Dock skiljer det sig mycket på individuell klinisk nivå, där utsatta områden har en betydligt lägre kariesfrihet. Utökade satsningar på preventiv vård i framförallt utsatta områden krävs för att bibehålla och förbättra en god munhälsa i regionen.

Process och produktion

Strategiska mål: Enklare vardag för invånare och medarbetare

Framgångsfaktorer: Utveckling av arbetssätt och digitala tjänster

Uppdrag	Analys
Öka användningen av digitala tjänster och system för vård, hälsa och prevention.	Fortsatt arbete med stöd för ökad digitalisering pågår. Exempelvis har inspirationstillfällen för kliniska verksamheter gällande nationella e-tjänster, 1177 och vårdstöd genomförts under året. Under hösten har extra fokus legat på arbete med digital patientinformation som förberedelse inför införandet och breddning av digitala kallelser. Effekter och lärdomar kring att arbeta med Insight har sammanställts. Inför införande av NLL, nationell läkemedelslista, genomfördes utbildningstillfällen för användare. Planering pågår för upphandling, införande och förvaltning av egenmonitorering har påbörjats under hösten men försenats. Planering och upphandlingsunderlag för kommande upphandling under 2026 finns.
1177.se utvecklas till att bli en viktig digital ingång till vården och samlingsplats för nödvändig information om hälsa, vård och tandvård.	Utbildningar har genomförts riktade till medarbetare som vill nyttja 1177 e-tjänster. Enklare vardag har flera pågående utvecklingsarbeten med verksamheter som vill använda tjänster på 1177.se. Bokningsbara tider via webbtidbok har ökat, fler patienter bokar eller avbokar tiden via 1177. Antal meddelande skickade av invånare till vården har ökat med 20 procent jämfört med föregående år. Antal meddelande skickade av vården till invånarna har ökat med 123 procent med en dubbel ökning från föregående år. De flesta meddelande innebär en kallelse till vården. Detta har lett till en enklare och mer effektiv kommunikation mellan personal och patient. Antal startade Stöd- och behandlingsprogram har ökat måttligt jämfört med föregående år och fler behandlingsprogram erbjuds i Region Jönköpings län jämfört med föregående år. Antal skickade formulär via formulärtjänsten har ökat från 23 000 formulär 2024 till 184 000 under 2025. Detta har lett till snabbare hantering och bättre kunskap om patienters behov och tillstånd. Portokostnader har minskat. Inom till exempel neurologin har användning av formulär lett till att patienter med epilepsi sluppit vissa sjukvårdsbesök.
Förbättra dialogen mellan sjukhusens specialistvård och primärvården genom sömlös vård och övergångar.	Begreppet sömlös vård är känt på kliniker och vårdcentraler, och arbetet fortskrider. Syftet är att minska glapp mellan vårdnivåer, undvika felaktiga

Uppdrag	Analys
	överföringar och skapa snabbare, tryggare och mer ändamålsenliga vårdkedjor. Arbete pågår kontinuerligt med att säkerställa att konsult on demand finns tillgänglig. Alla avvikelser där det inte upplevs ha fungerat följs upp. Det saknas dock fortfarande bra uppföljningssystem. Inom ramen för forskningsprojekt kring processer och processutveckling har kvalitativ analys av processarbete, inklusive vårdens övergångar, genomförts.

Strategiska mål: Bästa möjliga kvalitet

Framgångsfaktorer: Hälsofrämjande och sjukdomsförebyggande

Uppdrag	Analys
Stödja invånare att främja hälsosamma levnadsvanor med minskad klimatpåverkan.	Genom att tidigt identifiera och stödja förändring kan det förebygga framtida sjukdom och förbättra livskvaliteten hos patienter. Samverkan mellan Läns gemensamt programområde (LPO) levnadsvanor och LPO cancersjukdomar pågår. Syftet är att samla olika professioner i och kring cancervården till ett forum för att dela kunskap, lyfta goda exempel och stärka arbetet med hälsosamma levnadsvanor genom hela vårdförloppet - före, under och efter cancerbehandling. Forumet ska leda till att ge inspiration, kunskap och konkreta verktyg för att utveckla arbetet med levnadsvanor i cancervården. En länsarbetsgrupp (LAG) för fysisk aktivitet på recept (FaR) har tillsatt och startat ett arbete med att uppdatera nuvarande receptblankett. Syftet är att göra ordinationen mer anpassad till patientens behov, förutsättningar och diagnos samt förenkla och underlätta för förskrivaren. Fakta dokument <i>Riskbruk av alkohol</i> och <i>Sexuell hälsa</i> har reviderats. Uppdateringen av dokumenten ska leda till att beslutsstöden i det grundläggande medicinska arbetet - att utreda, behandla och följa upp patienter - överensstämmer med nationella kunskapsstödet. <i>Hälsocenter</i> i länet är lokalt anpassade men vilar på en gemensam grund i uppdrag, arbetssätt och mål. Verksamheterna har under året utvecklats i takt med lokala behov och visar tydliga resultat i form av förbättrat välmående, ökad delaktighet och stärkt livskvalitet hos deltagarna. Det finns skillnader i förutsättningar mellan kommunerna, främst kopplat till bemanning, lokaler och tillgång till långsiktiga resurser.

Uppdrag	Analys
Stödja kommunernas rehabiliteringspersonal med specialistkompetens och följa upp hela rehabiliteringsprocessen.	"Konsultera en rehabkollega" är ett nytt arbetssätt som infördes hösten 2024 för att förenkla kommunikation och bidra till kompetensöverföring mellan vårdnivåer. Det nya arbetssättet är en utveckling av sömlös vård-konceptet. Under 2025 har arbetet följts upp fortlöpande. Dietist och logoped har föreläst för sjuksköterskor och läkare på "SÄBO-dagar" i syfte att öka kunskap, bidra med inspiration och få ett erfarenhetsutbyte.
Samordna arbetet kring suicidprevention i länet.	Uppdatering av den gemensamma handlingsplanen pågår. Det finns ett behov i Jönköpings län att bli mer samstämmiga när det gäller suicidprevention och att alla har förbättringsområden. Den regionala handlingsplanen för suicidprevention bygger på ett strategiskt och långsiktigt arbetssätt i linje med nationella riktlinjer. Under vecka 37 genomfördes "En vecka för livet" – en bred informations- och utbildningskampanj som genomförs årligen i samband med suicidpreventiva dagen (10 september). Syftet är att öka kunskap, minska stigma och visa att suicid kan förebyggas. K Under 2024–2025 har en kartläggning genomförts för att undersöka kommunernas behov av efterlevandestöd och vård- och insatsförlopp för suicidprevention. Kartläggningen visade att behov finns av tydligare samordning och gemensamma strukturer. Planeringen för 2026 fokuserar på att uppdatera och implementera den regionala handlingsplanen i linje med nationella strategin. Målet är att stärka förutsättningarna för samverkan, kompetenshöjning, efterlevandestöd samt säkra vårdövergångar. Det finns även fortsatt behov av stärkt samverkan mellan angränsande strategiska områden, såsom samsjuklighet, psykisk hälsa hos äldre, och narkotikautredning. Ett gemensamt angreppssätt över strategierna är avgörande för att långsiktigt minska suicid i länet.
Arbeta för en hög vaccinationstäckning bland äldre.	Pneumokockvaccin kan ges året runt, men flest doser ges i samband med vaccination mot influensa och covid-19. Även i år gavs främst doser i samband med vårdosen mot covid-19 och höstens vaccinationer mot influensa och covid-19. Siffror från Nationella vaccinationsregistret har under året visat att Region Jönköpings län har högst vaccinationstäckning i landet.
Stödja arbetet med att vaccinera mot TBE.	Under 2025 gavs totalt 17 540 doser gratis TBE-vaccin till barn i åldern 3-18 år som är folkbokförda i regionen. Ca 3 500 barn tog sin första dos under året, vilket kan jämföras med 8 400 barn som

Uppdrag	Analys
	nyvaccinerades under 2024. Antalet barn som valde att påbörja en vaccination mot TBE under året sjönk påtagligt från 2024 till 2025 vilket var som förväntat. De flesta doser som gavs under 2025 var påfyllnadsdoser och då framför allt dos 3 till barn som tagit dos 1 och 2 under 2024. Detta innebär att vi kan förvänta oss att betydligt färre doser kommer ges under 2026 eftersom antalet personer som fortfarande är ovaccinerade, men ändå är intresserade av vaccin, sannolikt är än färre. Dessutom ska nästa påfyllnadsdos (dos 4) för de som nyvaccinerades under 2024 ges först 2028. Totalt har ca 12 000 barn 3-18 år valt att påbörja vaccination mot TBE sedan erbjudandet infördes 2024
Hälsofrämjande arbete i socioekonomiskt utsatta områden - tilläggsuppdrag till primärvården.	Ett omtag har gjorts i uppdraget kring satsningar på vårdcentraler i socioekonomiskt utsatt områden. Exempel på aktiviteter som pågår för att möta invånarnas behov i CNI tunga områden är arbetet med Hälsoguiderna som förklara det svenska sjukvårdssystemet och Hälsokommunikatörer som stödjer på vårdcentraler. Erbjudande om stöd till vårdcentraler i socioekonomiskt utsatta områden har fördjupats för 2026-2028. Vårdcentraler har erbjudits projektmedel och sex vårdcentraler har inkommit med ansökan. Sammanlagt stärks dessa vårdcentraler med 3,0 miljoner kronor per år.

Framgångsfaktorer: Säker verksamhet

Uppdrag	Analys
Stärka hälso- och sjukvårdens och dess stödfunktioners förmåga vid fredstida kriser, höjd beredskap och krig.	I arbetet ingår att planera och organisera kompetensutveckling och utbildning/övning som stärker hälso- och sjukvården och andra aktörers förmåga. En överskådlig utbildnings- och övningsplan har tagits fram. Den tydliggör utbildnings- och övningsinsatser inom beredskap och säkerhet, riktade till både verksamheterna och politiken, och stödjer att rätt målgrupper får de kunskaper och färdigheter som behövs. Kunskapshöjande föreläsningar inom beredskap och säkerhet har genomförts för flera av Region Jönköpings läns verksamheter. Innehållet anpassas efter verksamheternas behov och omfattar bland annat omvärldsläge, totalförsvar, kontinuitetshantering samt kris- och katastrofmedicinsk beredskap. Inom säkerhetsområdet ingår hantering av hot och våld, inklusive pågående dödligt våld (PDV). Under 2025 har CBRNE-utbildningar (kemiska, biologiska, radiologiska, nukleära och explosiva)

Uppdrag	Analys
	genomförts för personal vid akutmottagningar vid alla tre sjukhus. Syftet är att stärka förmågan att identifiera och hantera händelser med farliga ämnen på ett säkert och strukturerat sätt. Fyra övningar har genomförts för lokal särskild sjukvårdsledning (LSSL) med fokus på att stärka ledning och samordning vid allvarliga händelser. Varje sjukhus genomför en övning per år. En av dessa är en större övning, enligt ett treårigt rullande schema mellan de tre sjukhusen. Övriga två sjukhus genomför mindre övningar under samma år. Flera övningar har även genomförts inom ramen för F-samverkan. Sjukvården har tillsammans med räddningstjänst och polis tränat gemensam hantering av komplexa händelser.
Arbeta med rätt antibiotikaförskrivning och att minska vårdrelaterade infektioner.	Stramas stöd till verksamheterna för rationell antibiotikaanvändning har senaste året utgått utifrån konceptet Antibiotikasmart. Trettiofyra av 40 vårdcentraler och 19 av 25 sjukhuskliniker diplomerades under 2025, vilket är en ökning från föregående år. En grupp för Strama i tandvård har etablerats och koncept för Antibiotikasmart Tandvård kommer utvecklas under 2026. Detta systematiska patientsäkerhetsarbete bidrar till att Region Jönköpings län förskriver näst minst antibiotika i landet på recept och fortsatt använder minst antibiotika på totalen av alla regioner. Dock ses fortsatt brister i kvalitet på diagnostik och följsamhet till riktlinjer vilket visar betydelsen av fortsatt arbete. Riktlinjer för antibiotikabehandling är lättillgängliga för läkare inom slutenvård och primärvård via den nationella Strama-appen, som uppdateras och utvecklas kontinuerligt. Dessa riktlinjer implementeras sedan i journalsystemets läkemedelsmallar.
Under planperioden anpassas Region Jönköpings läns patientsäkerhetsarbete till Socialstyrelsens nationella handlingsplan för ökad patientsäkerhet, Agera för säker vård.	Flera aktiviteter pågår. Exempelvis har årets patientsäkerhetsronder genomförts. Arbetssättet med Patientsäkerhetsronder i realtid i (PiR) har genomförts på de tre orterna i triagering inom ögonsjukvården i syfte att stärka samverkan och det proaktiva patientsäkerhetsarbetet. Utvärdering av arbetssätt visar på att önskemål om att ha ronder årligen samt PiR på fler enheter vilket planering för pågår. Patientsäkerhetsdialoger och uppföljning av patientsäkerhetsarbetet har genomförts integrerat med höstens verksamhetsuppföljningar enligt årshjul för patientsäkerhet. Denna gång med fokus på arbetssätt för ökad riskmedvetenhet och beredskap (fokusområde 5 i den nationella handlingsplanen för ökad patientsäkerhet 2025-2030).

Uppdrag	Analys
Agera för en säker läkemedelsanvändning.	Arbetet med att ta fram rutiner för läkemedelslista i kommunal hälso- och sjukvård fortsätter. Länsövergripande rutin kring läkemedel i vårdens övergångar har uppdaterats. I november skedde Region Jönköpings läns anslutning till Nationella läkemedelslistan, vilket kan underlätta arbetet med att se vilka läkemedel patienten har förskrivits och hämtat ut. Fokus under 2025 har varit på antikoagulantia, koncentrerade kaliumlösningar samt samverkan mellan olika enheter för att hantera immunorelaterade allvarliga biverkningar inom Region Jönköpings län. Det har även pågått ett arbete med att uppdatera och implementera riktlinjer gällande läkemedel i samband med operation/undersökning hos patienter med diabetes.

Mätetal	Målvärde	Resultat	Analys
Nämnd Vårdrelaterade infektioner	<7	7 st. 	Vårdrelaterade infektioner i Region Jönköpings län är stabil runt 7 fall/ 1000 inv. Postoperativ infektion dominerar följt av urinvägsinfektion och lunginflammation. Vårdhygien har under 2025 arbetat med riktat stöd till Kirurgkliniken som en pilot i processen "Stöd i enheternas arbete för att förebygga VRI". Erfarenheter från det kommer användas när vi riktar oss till övriga kliniker under 2026. Arbetet med att förebygga VRI får också stark draghjälp av konceptet "Antibiotikasmart klinik".
 Vårdprevention - upprättad vårdplan	90 %	88 % 	Riskbedömningar för fall, trycksår, munhälsa och undernäring följs nu via Cosmic. Detta är ett samlat värde för samtliga 4 riskbedömningar. När risk har identifierats startas vårdplaner i nästan 90 procent av fallen. Det finns alltjämt behov av ytterligare kommunikation och förankring med berörda verksamheter kring de nya mätetalen och arbetssätten avseende riskbedömning, korrekt registrering i Cosmic samt analys av resultat.

Framgångsfaktorer: Ändamålsenliga, resurseffektiva och hållbara processer

Uppdrag	Analys
Fortsätta implementering och utveckling av kunskapsstyrning med syfte att erbjuda god och jämlik vård.	Samtliga Läns gemensamma programgrupper (LPO) har startat, eller har ett planerat startdatum. Målsättningen var att samtliga LPO skulle vara uppstartade under 2025. Det återstår dock fyra LPO att starta upp varav ett har ett planerat uppstartsdatum i början av 2026. Två dagar med ledningsdialoger i form av LPO-forum har genomförts, med fokus på uppföljning och

Uppdrag	Analys
	dialog kring det pågående arbetet med kunskapsstöd. Utvärderingen av dessa mötesplatser visar på stor nytta och lärande. LPO-forum kommer att återkomma under hösten 2026. Det fortsatta arbetet kommer att ha fokus på integrering av FAKTA-grupper i LPO, fortsatt utveckling av mät- och analysstöd, sammanhållen kunskapsstyrningskedja med Regionala programområden (RPO) och Nationella programområden (NPO) samt tillgängliggörande av kunskapsstöd.
Utökning av intensivvården i länet.	Utökning av intensivvårdsplatser har genomförts på Länssjukhuset Ryhov. Förstärkning har även skett av bemanning av undersköterskor på intensivvården på Höglandssjukhuset och Värnamo sjukhus. Förstärkning av bemanning av sjuksköterskor sker under 2024 och 2025 primärt via utbildningsanställningar.
Utifrån utredningen av intermediärvårdplatser under 2024 besluta om fortsättning.	En utredning om behov av intermediärvårdplatser inom Region Jönköpings län har genomförts och avrapporterats till sjukvårdens ledningsgrupp. Beslut om nästa steg är ännu inte fattat.
Fortsatt utveckling av cancervården.	Uppföljning av screeningprogram sker i de verksamheter som hanterar utfallet. Organiserad prostatacancertestning har fortsatt med att erbjuda nya åldersgrupper. Kvinnor födda mellan 1994 och 1998 har erbjudits självprov HPV och gratis vaccination. En processororienterad uppföljningsmodell har utvecklats. Arbete för att visualisera del-ledtider sker via en omstart av arbetet med tjock- och ändtarmscancerprocessen, med förhoppning om spridning till andra cancerprocesser. I nuläget har melanom-processen startat upp arbete och fler förlopp har anmält intresse. Det kan på sikt bidra till kunskap om hur resultat i en process som går över olika enheter kan följas upp. Utvecklings- och implementeringsarbetet inom cancerrehabilitering pågår inom flera olika vårdprogram.
Region Jönköpings län ska sammantaget bli en av de bästa i Sverige när det gäller standardiserade vårdförlopp för cancer.	Region Jönköpings län har ett väletablerat cancerråd som fungerar som LPO för cancerfrågor. Kontinuerligt arbete fortgår och stöd från regionala processledare och lokala processledare inom varje processområde skapar samsyn och värnar om kontinuerlig utveckling inom området. Uppdraget med halverat gap för ledtidsmåttet inom SVF har uppdaterats och förlängts även för 2026. De processer som nått sitt mål under 2025 har fått nytt mål inför 2026. Flera verksamheter och processer

Uppdrag	Analys
	arbetar aktivt i frågan, vilket märks på resultatet.
Erbjuda avancerad läkemedelsbehandling nära patienten.	En utveckling och design av att erbjuda avancerade läkemedelsbehandlingar personcentrerat i hemmet eller på länets tre sjukhus pågår. Vissa patientgrupper som är bosatta i södra länsdelen får nu sin cancerbehandling på behandlingsenheten i Värnamo. En antitumoral behandlingsenhet startade på Högländssjukhuset i Eksjö under 2025 i samarbete mellan medicin- och geriatrikklíniken Eksjö och onkologen Jönköping.
Utforma den palliativa vården så att alla länsinvånare har jämlik tillgång till palliativ vård dygnet runt.	Ett nytt personcentrerat vårdförlopp inom palliativ vård har startats. Samverkan med kommunal hemsjukvård sker kontinuerligt. Behovet av utbildning och stöd till primärvården är stort.
För att uppnå en mer jämställd vård och jämlik hälsa genomförs en flerårig satsning för förbättrad förlossningsvård och stärkta insatser för kvinnors hälsa.	Strukturerat arbete pågår inom de tre kvinnoklinikerna inklusive kvinnohälsovård för att gemensamt skapa jämlikt utbud och stöd under hela vårdkedjan, från graviditet till förlossning och eftervård. Det finns goda förutsättningar för en sammanhållen vårdkedja genom det etablerade samarbetet med familjecentraler samt samverkan med socialtjänst, öppen förskola och barnhälsovård. Detta möjliggör ett mer sammanhållet och personcentrerat stöd till gravida och nyblivna familjer. Även ett nära samarbete inom sydöstra sjukvårdsregionen är etablerat. Under året har olika utbildningsinsatser genomförts för att säkra att personer utsatta för sexuellt våld och könsstympning får tillgång till en god vård baserad på bästa möjliga kunskap. Utbildningsinsatserna har bidragit till ökad medvetenhet, förbättrade rutiner och stärkt professionell trygghet hos medarbetare, vilket i sin tur bedöms ha haft en positiv effekt på patientsäkerhet, bemötande och kvalitet i vården.
Arbeta med särskilda utvecklingsområden för patienter med psykisk sjukdom.	Det länsgemensamma programområdet är etablerat och arbetar med bland annat vårdförloppen för nyinsjuknande i schizofreni samt ADHD, inom vilka arbetsgrupper med sakkunniga formerats och startats upp. Specialistpsykiatrien har fått ett uppdrag att ta fram ett utbildningsmaterial riktat till den somatiska vården. Parallellt undersöks hur utbildningen kan nå ut till aktuella målgrupper samt vilka dessa är. Målsättningen är att kunna genomföra en pilotomgång av utbildningen under 2026.
Tillhandahålla en rationell och hållbar läkemedelsförsörjning.	Rest- och bristsituationer av läkemedel är ett ökande problem i Sverige och globalt. Kontinuerligt arbete med rest- och bristsituationer av läkemedel, bedrivs i nära samarbete med Hälso- och sjukvårdsfarmaci. FAKTA-grupper involveras för att ge förslag till

Uppdrag	Analys
	alternativ behandling. Information om restnoteringar publiceras på Folkhälsa sjukvårdswebben samt i Cosmic läkemedelsmallar. Under 2025 har det varit flera akuta bristsituationer av läkemedel, till exempel infusionsvätskor, Pegasys och astma-sprayer. Under 2025 har ett arbete bedrivits för att ta fram ett inventerings- och analysverktyg för att möjliggöra digital journalföring av narkotiska läkemedel. Verktöget är nu i drift och används på de enheter som haft digital journalföring sedan tidigare. Under 2026 kommer arbetet med att ta fram rutiner och instruktioner samt involvera fler enheter i arbetssättet fortgå.
Arbeta för en kostnadseffektiv och jämlik läkemedelsbehandling.	Under 2025 har läkemedelsdialoger genomförts löpande med fokus på kvalitet och kostnadseffektivitet, främst med läkemedelstunga verksamheter. Totalt har cirka 30 dialoger genomförts under året. Verksamheterna har haft tillgång till uppdaterad läkemedelsstatistik för kontinuerlig uppföljning och jämförelser kan göras inom länet, med sydöstra sjukvårdsregionen samt med riket som helhet. Gemensamma läkemedelsrekommendationer för Sydöstra Sjukvårdsregionen tas fram löpande och dessa publiceras både på lokal webbplats samt på Sydöstragemensam webbplats. Benchmarking för Sydöstra sjukvårdsregionen gentemot riket och övriga regioner har genomförts under året. Aktivt arbete med att identifiera möjligheter till kostnadsbesparingar i samband med tex patentutgångar och introduktion av biosimilarer pågår ständigt. Senior inköpare har anställts under året och ett aktivt strategiskt arbete avseende inköp av läkemedel för att optimera upphandlingsunderlag, implementering och uppföljning av upphandlade läkemedel är påbörjat. Under 2025 har även arbetet med behandlingsrekommendationer, läkemedelsstatistik och kostnadsbesparingar bedrivits, bland annat vid introduktion av biosimilarer och patentutgångar. Nationella och storregionala läkemedelsrekommendationer har tagits fram och ett mer strukturerat arbetssätt via Cosmic ordinationsmallar har utvecklats i samverkan med Fakta. Samverkan inom Sydöstra sjukvårdsregionen har stärkts genom bland annat etablering av RAG Obesitas och genom att en gemensam träff för förskrivare av biologiska läkemedel har anordnats.
Skapa förutsättningar för patientdelaktighet i läkemedelsbehandling.	Arbeta pågår för att förbättra överenskommelsen mellan vård och patient kring fortsatt

Uppdrag	Analys
	läkemedelsbehandling. Medicinsk plan för fortsatt läkemedelsbehandling och överenskommelse, är två olika delar som hänger ihop. Strukturen i journalen behöver konkretiseras under 2026 för att bli tydlig för patient (Information om din vårdtid/ ditt besök) och vård, och för att undvika dubbeldokumentation. Arbetet med att öka patienters delaktighet genom successiv övergång till självmedicinering för patienter som har lång vårdtid har påbörjats i liten skala.
Följa alla delar i överenskommelsen ”Riktlinjer för länskliniker”.	Alla verksamheter arbetar för att erbjuda sitt vårdutbud jämlikt i länet. Två länskliniker som endast har verksamhet på en ort är barnkliniken och infektionskliniken. Båda verksamheterna har mätetal och/eller aktiviteter som inkluderar de fyra fokusområden som riktlinjen anger. Barnklinikens samarbete med barn- och ungdomsmedicinsk mottagningen bidrar till att säkra ansvaret för den nära vården, den fasta bemanningen och kompetensutveckling. Andra exempel är kvinnohälsovården och onkologiska behandlingsenheter som fördelar resurser efter behov till olika områden. All kompetens kan inte finnas överallt när volymerna är små. I vissa fall kan distanskontakt med patienter eller andra verksamheter underlätta. Andra lösningar kan vara stöd för rotationstjänster, digitala lösningar och samarbete mellan orter. För den nära vården i alla länsdelar pågår arbete med att stärka jämlik tillgång till vård och diagnostik, skapa bättre samverkan mellan vårdnivåer och utveckla stöd för vårdcentraler och kommuner. Vissa verksamheter har professionsansvar över länet, medan andra utvecklar nya arbetssätt och samverkansformer för att stödja den nära vården.
Åstadkomma bästa möjliga resultat till lägsta möjliga kostnad varje gång.	Arbetet med kloka kliniska val har fortsatt lokalt i alla verksamhetsområden och primärvården. Exempel är röntgen som har definierat sex prioriterade områden och arbetar både regionalt och nationellt med implementering tillsammans med remitterter. Laboratoriemedicin har ett pilotprojekt där mikrobiologer deltar i IVA-ronder för att stödja i diagnostiska beslut. Inom Bra Liv jämförs exempelvis förskrivningsmönster och utredningskostnader mellan vårdcentraler. Goda exempel sprids genom ledningsgrupper, verksamhetsutvecklar- och verksamhetschefsnätverk.
Arbeta med övergången från barn till vuxna i vården.	Arbetssätt för tryggt och säkert mottagande i övergången från barnverksamheter till specialistvård för vuxna finns etablerade i många verksamheter. Analys av nuvarande arbetssätt och gap har

Uppdrag	Analys
	genomförts främst inom och mellan Barn och ungdomspsykiatri och de vuxenpsykiatriska klinikerna samt inom barn- och ungdomshabiliteringen. Inom Region Jönköpings län har en arbetsgrupp bildats med fokus på implementering av relevanta och möjliga åtgärder utifrån rapporten "Vägledning för övergång från barn- till vuxensjukvård för unga med medfödd eller tidigt förvärvad funktionsnedsättning". Habiliteringscentrum har fått i uppdrag att ta fram ett förslag på hur stöd till patientgrupperna skulle kunna se ut, både sett till hälso- och sjukvård men också andra kontakter i samhället. Förslaget ska presenteras under våren 2026.
En utvärdering av behovet av tillnyktringsenheten (TNE) genomförs.	Utvärderingen av tillnyktringsenheten är klar. Uppföljningen visar att det finns behov av en tillnyktringsenhet, att den bemanning och kostnadsfördelning som gjordes vid omorganisationen stämmer med nuvarande beläggning, att de rutiner och flöden som finns fungerar och kontinuerligt uppdateras vid behov. Samarbete internt fungerar väl och dialogmöten genomförs kontinuerligt. Förbättringspotential finns i informationsflöde hos externa aktörer för att nå ut till samtliga kommuner och socialtjänst. Finns också behov att revidera samverkansrutin, där ett utkast finns klart.

Mätetal	Målvärde	Resultat	Analys
 Indikatorer i öppna jämförelser	60 %	67,5 % 	Målet är uppfyllt. Det finns en jämförelse framtagen av Sveriges Kommuner och regioner över ett större antal mått som påminner om tidigare års öppna jämförelser. Det går inte riktigt att jämföra helt med tidigare år eftersom måtten i flera fall är både nya och fler. Av måtten är Region Jönköpings län bättre än hälften av landets regioner på 27 av 40 mått topp 3 på 15 mått, vilket är på samma nivå som 2024 Exempel på mått med goda resultat är andelen med trycksår, tillgänglighet till vård, få överbeläggningar/utlokaliserade och nöjdhet hos invånarna. Områden där förbättringsbehov ses är exempelvis strokevården, dödlighet efter hjärtinfarkt, oplanerad återinskrivning hos äldre och läkemedelsbehandlingen för nyinsjuknade hjärtsviktpatienter.
 Standardiserade vårdförlopp - andel inom max ledtid	80 %	45 % 	Under den senaste 12-månadsperioden har behandlingsstart skett inom totalt 2011 cancerförlopp. Av dessa har 45 procent skett inom angiven ledtid vilket är en förbättring jämfört med

Mätetal	Målvärde	Resultat	Analys
			motsvarande period föregående år. Inget förlopp når uppsatt målvärde under perioden. För förlopp med mer än 300 startade behandlingar under perioden, SVF Prostatacancer, SVF Bröstcancer, SVF Tjock- och ändtarmscancer är variationen 17,1 - 65,1 procent.
 Standardiserade vårdförlopp - andel utredda patienter i SVF	70 %	90 % 	Målet är uppfyllt. Region Jönköpings län uppnår sammantaget vad som förväntas enligt det nationella beräkningsunderlaget för standardiserade vårdförlopp.
Nämnd Antal hembesök läkare	8 644	8 965 	Arbetsätt med tillgänglighet till läkarbesök i hemmet finns vid samtliga vårdcentraler vilka ofta sker i samverkan med den kommunala hemsjukvården. Sker en successiv ökning av hembesöken från år till år, ca 3,5 procent fler 2025 jämfört föregående år.
Nämnd Antal vårdplaneringar enligt SiP	3 502	3 320 	Antalet vårdplaneringsbesök fortsätter att minska. Minskningen sker framförallt inom Bra Liv, privata vårdgivare i nivå med föregående år. Finns dock en variation mellan vårdcentralerna. Rydaholms VC, Smålandsstenars VC, Bräcke Diakoni VC Nyhälsan samt Wetterhälsan är exempel på vårdcentraler som dokumenterat fler SIP jmf föregående år

Verksamhetsstatistik

Primärvård

Egenproducerad vård (inkl såld vård)	2024	2025	Förändring % 2025-2024
Antal besök, läkare	414 670	400 115	-4 %
Antal besök, annan personalkategori	640 595	630 345	-2 %
-varav distansbesök utomlänare	796	780	-2 %
-varav distansbesök länsbor	28 880	26 613	-8 %
Andel distansbesök länsbor	2,5 %	2,3 %	
Länets vårdkonsumtion			
Antal besök, läkare	449 455	432 805	-4 %
Antal besök, annan personalkategori	706 160	701 198	-1 %

Antalet besök inom primärvården minskar såväl vad gäller läkarbesök som besök av annan personalkategori. Även antal distansbesök minskar, och det är fortsatt en liten andel jämfört med totala antalet besök.

Specialiserad somatisk vård

Egenproducerad vård (inkl såld vård)	2024	2025	Förändring % 2025-2024
Antal disponibla vårdplatser	528	541	2 %

Vårdtid i dagar	159 658	160 727	1 %
Antal vårdtillfällen	44 831	45 230	1 %
Medelvårdtid, dagar	3,6	3,6	0 %
Antal läkarbesök	358 737	364 623	2 %
Antal besök annan personalkategori	356 418	364 154	2 %
Varav distansbesök	8 604	10 222	19 %
Andel distansbesök	1,20 %	1,40 %	
Länets vårdkonsumtion			
Vårdtid i dagar	173 646	175 779	1 %
Antal vårdtillfällen	47 128	47 425	1 %
Antal läkarbesök	377 117	376 434	0 %
Antal besök annan personalkategori	354 978	363 762	2 %

Inom den somatiska vården är det i det närmaste oförändrat på totalen vad gäller besök jämfört med 2024. Antal disponibla vårdplatser har ökat något. Andelen distansbesök har ökat med 19 procent jämfört med 2024, men i jämförelse med totala antalet besök är distansbesök fortfarande en mycket liten del.

Läkarbesök köpt vård minskar med 9 procent vilket till största del beror på att Bäckalyckans läkarmottagning samt Dr Nords öron, näsa och halsmottagning har cirka 3000 besök färre jämfört med 2024.

Specialiserad psykiatrisk vård

Egenproducerad vård (inkl såld vård)	2024	2025	Förändring % 2025-2024
Antal disponibla vårdplatser	101	105	4 %
Vårdtid i dagar	29 954	28 667	-4 %
Antal vårdtillfällen	3 789	4 117	9 %
Medelvårdtid, dagar	8	7	-12 %
Antal läkarbesök	35 328	35 012	-1 %
Antal besök annan personalkategori	114 089	114 966	1 %
Varav distansbesök	7 946	8 188	3 %
Varav andel distansbesök	5,32 %	5,46 %	
Länets vårdkonsumtion			
Vårdtid i dagar	41 288	39 869	-3 %
Antal vårdtillfällen	4 062	4 390	8 %
Antal läkarbesök	35 089	34 497	-2 %
Antal besök annan personalkategori	117 665	117 429	0 %

Även inom den psykiatriska vården är det i det närmaste oförändrat på totalen vad gäller besök jämfört med 2024. Vårdtillfällen ökar något inom psykiatrin samtidigt som vårdtiden minskar, dvs fler men kortare vårdtillfällen. Såld vård ökar inom psykiatrin men det är förhållandevis små volymer totalt sett.

Tandvård

	2024	2025	Förändring % 2025-2024
Antal listade barn 3-23 år (2024) och 3-19 år (2025), genomsnitt under året i länet 1)	92 830	76 006	-18,1 %
Antal behandlade barn hos folktandvården 3-23 år (2024) och 3-19 år (2025) 2)	69 706	64 160	- 8,6 %
Antal behandlande (undersökta) barn hos privata (3-19 år) 3)	1 497	1 396	-6,7 %
Allmäntandvård vuxna (folktandvården): Antal behandlade patienter 4)	79 177	85 277	7,7 %
Specialisttandvård: Antal behandlade patienter	22 792	22 514	-1,2 %
Tandvård för patienter med rätt till tandvårdsstöd, N- och F-tandvård. 5)	8 000	8 542	6,8 %
Antal behandlade; N- och F-patienter	5 037	5 676	12,7 %
Antal behandlade S-patienter	1 048	979	-6,6 %

1) Mellan 2024 och 2025 ändrades regelverket för gratis tandvård för barn. 2024 gäller det till och med det år man fyller 23 år. 2025 är det till och med det år man fyller 19 år.

2) Antal behandlade barn 3-19 år 2024 var 60 394.

3) Antalet som undersökts, åtgärd 101, 111 eller 112, i indikatoråldrarna (3, 6, 12, 19).

4) 2024 räknas man som vuxen från och med det år man fyller 24, medan 2025 räknas man som vuxen från det år man fyller 20.

5) Tandvårdsstöd:

N-tandvård - tandvård för personer med stort omvårdnadsbehov i dagliga livet

F-tandvård- tandvård för personer med stora behov pga långvarig sjukdom eller funktionsnedsättning

S-tandvård - tandvård som led i en sjukdomsbehandling, den har man inte rätt till, utförs på remiss ofta från läkare

Antalet listade och behandlade barn minskar i länet jämfört med 2024. Det beror på att regelverket för när man räknas som barn som får subventionerad tandvård sänktes från 23 till 19 år mellan åren. Antal behandlade barn 3-19 år har däremot ökat mellan åren. Det beror till stor del på att barntandvårdsprogrammet uppdaterats under perioden, med tätare kallelseintervall för vissa grupper. Antal vuxna som fått behandling inom allmäntandvården har samtidigt ökat, och det beror dels på de ändrade åldrarna, dels på att folktandvården tagit emot fler patienter.

Inom det regionfinansierade tandvårdsstödet har antalet behandlade patienter inom N- och F-tandvård ökat med 12,7 procent.

1177 – e-tjänster

	2020	2021	2022	2023	2024	2025
Antal bokade tider (webbtidbok)	0	105 758	124 877	154 606	194 787	238 448
Antal inkomna ärenden via e-tjänster	181 383	216 985	235 421	266 799	317 780	381 740
Antal skickade meddelanden	6 184	15 059	26 279	63 438	221 055	493 002
Antal startade program (stöd och behandling)	2 120	2 983	3 246	4 193	4 914	5 127
Antal skickade formulär	0	19	1 154	4 833	48 221	186 089
Andel besvarade formulär	-	58 %	50 %	59 %	85 %	95 %

Utvecklingen visar att hälso- och sjukvården i allt större utsträckning använder digitala arbetssätt för kommunikation och vård. Samtidigt visar invånarna en ökande vilja att hantera sina vårdärenden via digitala tjänster.

Lärande och förnyelse

Strategiska mål: Bäst på att förbättra och förnya

Framgångsfaktorer: Förbättringskunskap

Uppdrag	Analys
Kortare ledtider från kontakt till utförd vårdåtgärd.	Det finns en regiongemensam gruppering som arbetar med effektiv datadriven verksamhetsutveckling och med flera olika initiativ. En AI-kompetensgrupp och implementering av visualiseringsstöd för akutprocessen pågår, men även ett arbete med att ta fram beslutsunderlag gällande datalager och de kompetenser som krävs för att tillgängliggöra data. Dashboard möjliggör en verksamhetsnära och engagerad uppföljning i realtid för chefer och medarbetare som stöd för utveckling och förbättring. Verksamheterna använder i olika utsträckning Cosmic Insight för att följa sin verksamhet och identifiera risker, brister och utvecklingsbehov kopplat till sina patientflöden Inom akutflödesarbetet är informationsdriven verksamhetsutveckling väl etablerat. Det finns en portal Diver online som används dagligen för dialog om förbättringar. Kapacitet- och produktionsstyrning använder data i Astrada för planering och utveckling av verksamheten. Flera verksamheter har väl utvecklade dashboards i Diver.

Framgångsfaktorer: Professionell kunskap

Uppdrag	Analys
Arbeta aktivt med kompetensutveckling, samt erbjuda utbildnings- och forskningsmöjligheter.	Arbetet med att utreda stöd till universitetssjukvårdsenheter (USV)/samverkansavtal för universitetssjukvård pågår. Ett avtal om samverkan inom Sydöstra sjukvårdsregionen om läkarutbildning och forskning (RALF) finns sedan juni 2025. I detta avtal regleras hur stöd till universitetssjukvård kan se ut. Det fortsatta arbetet får fokusera hur regionen praktiskt skall stödja våra USV-enheter.
Region Jönköpings län ska kunna bidra med lärarresurser i Jönköping Universitys tandläkarutbildning.	Jönköping University har för tredje gången ansökt hos regeringen om tillstånd att utfärda tandläkarexamen. Universitetskanslersämbetet har yttrat sig och föreslår avslag. Mot bakgrund av detta bedöms förutsättningarna för att erhålla examensrätt inom överskådlig tid som begränsade. I stället planeras ett fortsatt arbete där Jönköping University, tillsammans med Region Jönköpings län och samverkande regioner, vidareutvecklar Centrum för odontologi och oral hälsa (COO).

Framgångsfaktorer: Forskning

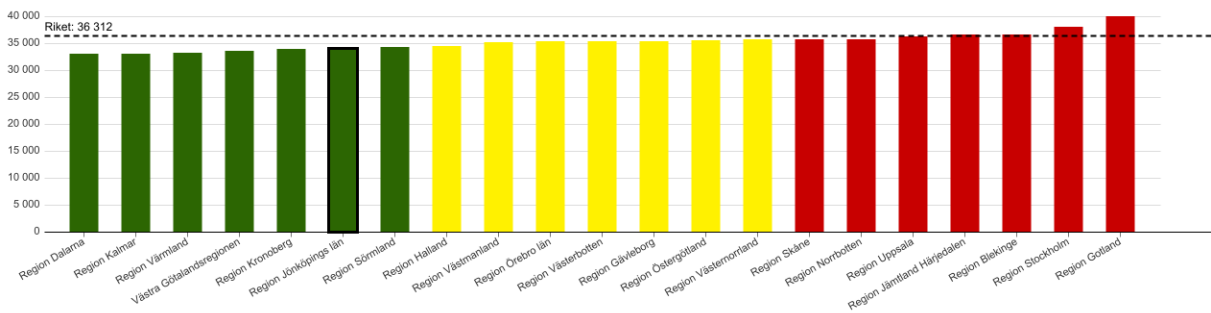
Uppdrag	Analys
Identifiera, kartlägga, samordna och stödja strategiska forskningsområden och kunskapsunderlag i arbetet med nära vård.	Det pågår ett antal forskningsprojekt inom området. Futurum stödjer dessa på olika sätt. Diskussion förs tillsammans med Jönköping University och Kommunal Utveckling hur man kan utveckla forskningen.

Mätetal	Målvärde	Resultat	Analys
 Antal forskarutbildade medarbetare	>125	177 	Antalet forskar utbildade medarbetare har ökat med 10 under året.
 Antal publikationer	>150 st.	181 	Under året har 181 vetenskapliga artiklar publicerats vilket är en ökning jämfört med förra året.

Ekonomi

Region Jönköpings län har som inriktningsmål att ligga i nedre kvartilen avseende strukturjusterad hälso- och sjukvårdskostnad per invånare. Region Jönköpings län klarar inte målet 2024, som är det senaste resultatåret. Region Jönköpings län har den 6:e lägsta kostnaden 2024 vilket är en försämring jämfört med 2023 då Region Jönköpings län hade en 5:e placering.

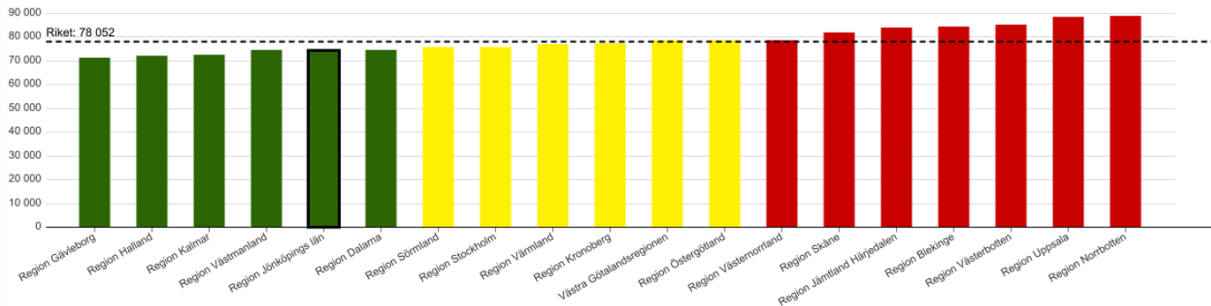
Strukturjusterad hälso- och sjukvårdskostnad 2024, kronor per invånare



Källa: Kolada. Strukturjusterad hälso- och sjukvårdskostnad anger regionernas kostnadsnivå för hälso- och sjukvård sedan hänsyn tagits till strukturella faktorer som regionen inte kan påverka. Kostnader för privat vård och den vård som befolkningen konsumerar i annan region ingår. De strukturella faktorerna definieras som standardkostnaden i kostnadsutjämnings hälso- och sjukvårdsmodell där hänsyn till glesbygd, skillnader i befolkningen vad gäller ålder, sysselsättning, inkomster och boende ingår.

Ett annat sätt att beskriva hälso- och sjukvårdens kostnadseffektivitet är att jämföra kostnad per producerad DRG poäng. En låg kostnad per producerad DRG poäng indikerar en hög produktivitet där regionen levererar mycket vård för insatta resurser. 2024 låg Region Jönköpings län på femte plats. Uppgifter för 2025 är ännu inte klara för jämförelse med övriga regioner.

Kostnad per producerad DRG-poäng i sluten och öppen sjukhusvård 2024



Källa: Kolada. DRG står för diagnosrelaterade grupper och bedömer resursåtgången och vårdtyngden för vårdkontakter.

Strategiska mål: God och hållbar hushållning

Framgångsfaktorer: Kostnadseffektiv verksamhet

Uppdrag	Analys
Följa omställningen och förstärkningen av den nära vården.	Omställningen följs och analyseras löpande som en del av ett pågående arbete. FS-nämnden fick i maj en presentation med fokus på omställningen och förstärkningen av den nära vården. Presentationen hade bland annat fokus på resursförstärkningen inom primärvården, utvecklingen av antalet medarbetare inom Bra Liv, tillgänglighet och kontakter i primärvården, utvecklingen av överenskommelser vid

Uppdrag	Analys
	kronisk sjukdom samt befolkningens uppfattning om vården. En fortsatt utmaning är att identifiera ändamålsenliga mått som på ett heltäckande sätt fångar begreppet nära vård.
Se över att resurserna har en jämlig fördelning utifrån länsinvånarnas behov av vård.	Region Jönköpings län använder sedan flera år kostnad per patient (KPP) för att jämföra produktivitet mellan regioner. Många kliniker arbetar också med kapacitet- och produktionsstyrning (KPS). Genom att väga samman produktivitet och behov av produktion för att nå tillgänglighetsmålen kan en ekonomisk styrmodell användas för att styra mot önskade resultat och vid behov omfördela resurser mellan kliniker och verksamhetsområden. Under hösten har modellen uppdaterats med nya data tillsammans med verksamhetsområdena medicinsk och kirurgisk vård. Under året har en mall för så kallad nyttoanalys tagits fram. Nyttanalysen syftar till att vara ett stöd i arbetet med att värdera ett investerings-, utvecklings- eller förbättringsinitiativs nyttor och den insats som krävs för att nå nyttorna. Verktuget ska även belysa ett antal frågeställningar och perspektiv som behöver beaktas när man bestämmer sig för att driva initiativet.

Mätetal	Målvärde	Resultat	Analys
 Ekonomi i balans	0 tkr	-189 178 tkr 	Nämnden för folkhälsa och sjukvård redovisar för helåret 2025 ett underskott på 189,2 miljoner kronor (mnkr), vilket motsvarar en avvikelse på -1,5 procent i förhållande till budget för perioden.
Nämnd Kostnad per DRG Öppenvård		79 000 kr 	Total kostnad per DRG (alltså slutenvård+ öppen vård) minskar med 0,4 procent år 2025 i RJL. Minskningen beror på en förändring i redovisningsprinciperna och gör årets resultat svåranalyserat. Förändringen innebär att besök som leder till oplanerad inskrivning i slutenvården numera redovisas som egna kontakter. Tidigare togs dessa kontakter bort från KPP och kostnaden flyttades till vårdtillfället. Jämfört med 2024 redovisas fler kontakter i KPP, och kostnaden per kontakt blir därför lägre. I slutenvården minskar kostnaderna. I öppenvården ökar kostnaderna och antalet kontakter ökar. Kostnad per DRG kan utvecklas åt olika håll beroende på vilken DRG och vikt en kliniks akuta kontakter landar i. Kostnad per DRG inom öppen somatisk vård ökar med 2,6 procent jämfört med 2024. Exklusive principförändringen ökar kostnaden per DRG dock med ca 1,2 procent. Här har Kirurgisk vård både en högre kostnadsutveckling och sämre

Mätetal	Målvärde	Resultat	Analys
			volymutveckling än Medicinsk vård.
Nämnd Kostnad per DRG slutenvård		83 000 kr —	Total kostnad per DRG (alltså sluten+ öppen vård) minskar med 0,4 procent år 2025 i RJL. Minskningen beror på en förändring i redovisningsprinciperna och gör årets resultat svåranalyserat. Förändringen innebär att besök som leder till oplanerad inskrivning i slutenvården numera redovisas som egna kontakter. Tidigare togs dessa kontakter bort från KPP och kostnaden flyttades till vårdtillfället. Jämfört med 2024 redovisas fler kontakter i KPP, och kostnaden per kontakt blir därför lägre. I slutenvården minskar kostnaderna. I öppenvården ökar kostnaderna och antalet kontakter ökar. Kostnad per DRG kan utvecklas åt olika håll beroende på vilken DRG och vikt en kliniks akuta kontakter landar i. Kostnaden per DRG minskar med 3,5 procent mellan 2024 och 2025. Om man exkluderar effekten av principförändringen så ökar dock kostnad per DRG med ca 3 procent i slutenvården. Störst är ökningen inom Medicinsk vård där antalet vårdtillfällen och DRG-poäng minskar, trots en ökad kostnad. Inom Kirurgisk vård ökar både kostnad och produktionsvolym.

Avvikelse mot budget i miljoner kronor

Verksamhetsområde	Utfall	Budget	Avvikelse
Privata vårdgivare	-49,2	-59,4	10,2
Vårdcentralerna Bra Liv	9,6	0,0	9,6
Folktandvården	-147,3	-154,1	6,8
Medicinsk vård	-3 247,1	-3 244,7	-2,4
Kirurgisk vård	-3 499,9	-3 414,7	-85,2
Psykiatri rehab o diagnostik	-1 621,6	-1 518,9	-102,7
Summa verksamhetsområde inkl privata	-8 555,4	-8 391,7	-163,7
Regionövergripande FS	-3 929,8	-3 904,4	-25,5
Totalt	-12 485,3	-12 296,1	-189,2

Bokslut, budgetavvikelse i miljoner kronor

Verksamhetsområde	Bokslut 2023	Bokslut 2024	Bokslut 2025	Skillnad mot 2024
Privata vårdgivare	-21,1	-4,8	10,2	14,9
Vårdcentralerna Bra Liv	-45,7	-28,3	9,6	37,9
Folktandvården	-2,4	4,4	6,8	2,3

Medicinsk vård	-98,9	6,4	-2,4	-8,7
Kirurgisk vård	-78,8	-105,7	-85,2	20,5
Psykiatri rehab o diagnostik	-105,6	-181,1	-102,7	78,4
Summa verksamhetsområde inkl privata	-352,5	-309,0	-163,7	145,3
Regionövergripande FS	30,7	84,5	-25,5	-110,0
Totalt	-321,7	-224,5	-189,2	35,4

Privata vårdgivare är i balans.

Bra Liv har en positiv avvikelse mot budget på 9,6 miljoner kronor, vilket är 37,9 miljoner kronor bättre än 2024. Bra Livs intäkter har ökat med 9 procent jämfört med föregående år och kostnaderna har ökat med 6 procent. Den ackumulerade budgetavvikelsen beror på överskott när för läkemedel (läkemedelsersättningen minus kostnader för läkemedel), statsbidrag för tillgänglighet. På minussidan finns fortfarande ett fortsatt hyrläkarbehov.

Folktandvården redovisar ett positivt resultat på 6,8 miljoner kronor. Jämfört med föregående år är resultatet 2,3 miljoner kronor bättre. Allmäntandvårdens ackumulerade resultat uppgår till plus 5,7 miljoner kronor. Specialisttandvårdens resultat uppgår till plus 1,1 miljoner kronor.

Inför 2025 sänktes åldern för avgiftsfri tandvård vilket bidrar till att Folktandvården tappat en fast intäkt utan att helt kunna ersätta patienttiden med vuxna patienter, vilket drabbat intäktssidan. Flera kliniker inom Folktandvården upplever en försämrad ekonomi då Folktandvården byggt upp en god bemanning, nått en god tillgänglighet och tagit ikapp köer. Kommande tandvårdsreform Tiotandvård gör att äldre under 2025 avstått från tandvård, medan reformen under 2026 förväntas innebära ökad vårdkonsumtion som Folktandvården behöver vara dimensionerade för. Under året har Folktandvården erhållit retroaktiv finansiering för nationella ST-platser samt tilläggsbudget för ökade läkemedelskostnader vilket bidragit till det positiva resultatet.

Medicinsk vård redovisar ett resultat för helår 2025 på -2,4 miljoner kronor. Det är 8,7 miljoner kronor sämre än 2024.

Huvudsakliga orsaker till budgetavvikelsen:

- Budgetöverskott läkemedel 9,9 miljoner kronor.
- Ökade lönekostnader (i fast pris) om 31 miljoner kronor (2 procent) jämfört med föregående år.
- Kostnaden avseende hyrbemanning (läkare) uppgick till 3,5 miljoner kronor. Ökade med 1,5 miljoner kronor jämfört med föregående år.
- Övertidskostnaden ökade med 7,7 miljoner kronor (15 procent) jämfört med föregående år.
- Minskade kostnader (i fast pris) avseende klinisk fysiologiska undersökningar och laborieprover med 11 miljoner kronor (3 procent) jämfört med föregående år motsvarande period.
- Ökade statliga bidrag om 5,1 miljoner kronor jämfört med föregående år. Statliga bidrag uppgår under 2025 till 31 miljoner kronor.

Kirurgisk vård har i bokslut 2025 en negativ budgetavvikelse på 85,2 miljoner kronor. Det är 20,5 miljoner kronor bättre än 2024.

Verksamhetsområdet har fått ersättning för ökat antal höft- och framfallsoperationer med 17 miljoner kronor. I november har verksamhetsområdet haft höga kostnader för reglering av läkarjourer. Detta behöver analyseras mer. De största budgetavvikelserna är för personalkostnader med 39 miljoner kronor, bemanningsföretag 21 miljoner kronor (bemanningsföretag är nollbudgeterat), lab och röntgen med 11,5 miljoner kronor, material 26 miljoner kronor. Kostnader för läkemedel har ökat med 14 miljoner kronor jämfört med 2024.

Antal skickade remisser enligt vårdgaranti har minskat kraftigt inom ortopedi men ökat inom kirurgi främst för att hantera stort antal väntande på skopier. För minskad köpt vård har verksamhetsområdet fått en ersättning på 9 miljoner kronor och för ökad såld vård med 8 miljoner kronor.

Kostnader för hyrbemanning fortsätter att minska. Kostnadsutvecklingen för personal har bromsat in och antal faktiska årsarbetare är färre än 2024.

Ögonklinikernas resultat inom vårdval specialiserad ögonsjukvård är ett överskott med 0,6 miljoner kronor.

Handlingsplaner för ekonomi i balans finns för såväl Kirurgisk vård totalt som för kliniker med ekonomisk obalans. Planen syftar till att minska kostnader för personalkostnader och övertid, lab och röntgen, för materialkostnader samt för köp av bemanningsföretag. Verksamhetsområdet arbetar även för att maximera intäkter för tillgänglighet och minska kostnader för köpt vård inom vårdgaranti.

Verksamhetsområdets arbete med kapacitet och produktionsstyrning (KPS) har lett till förbättrad tillgängligheten bland annat via ökat antal operationer. Arbetet med KPS fortsätter som en viktig del i arbete för ekonomi i balans

Psykiatri, rehab och diagnostik har för 2025 en avvikelse för området på -102,7 miljoner kronor, vilket är 78,4 miljoner kronor bättre än 2024. Det samlade ekonomiska utfallet visar en blandad bild mellan klinikerna. Flera verksamheter redovisar fortsatt underskott, främst kopplat till ökade personalkostnader och minskade intäkter, medan några kliniker uppvisar positiva avvikelser tack vare statsbidrag och tillgänglighetsersättningar. Den totala budgetavvikelsen för diagnostiken (röntgen, laboriemedicin och klinisk fysiologi) är 99 miljoner kronor. Resterande del av områdets verksamhet har en samlad budgetavvikelse på -3,5 miljoner kronor, och är alltså nära ekonomi balans totalt sett.

De största negativa avvikelserna återfinns inom Laboriemedicin (budgetavvikelse -49 miljoner kronor) och Röntgen (budgetavvikelse -47 miljoner kronor). Inom Laboriemedicin förklaras avvikelsen till största del av lägre intäkter mot budget, medan kostnaderna för personal och verksamhet varit stabila. Röntgen uppvisar högre intäkter än föregående år tack vare regioninterna kompensationsmedel för tillgänglighet och ST-läkare (40 miljoner kronor för helår 2025) men också en ökad produktion. Satsningar på ST-läkare, och därmed högre personalkostnader, tynger resultatet. Ökade kostnader för material och reparationer påverkar också negativt. Klinisk fysiologi har en ekonomi i huvudsak i balans, med ett mindre negativt resultat som bedöms kunna återhämtas genom ökad produktion framöver.

Barn- och ungdomspsykiatriska kliniken redovisar en budgetavvikelse på -4,8 miljoner kronor, drivet av ökade personalkostnader och fortsatt behov av hyrläkare. Extra ersättningar för tillgänglighet och överbeläggningar har delvis kompenserat resultatet. Psykiatriska kliniken Jönköping visar ett positivt resultat på +10,9 miljoner kronor, främst genom minskad användning av hyrpersonal och ökade intäkter från statsbidrag.

Psykiatriska kliniken Värnamo redovisar ett underskott på -5,7 miljoner kronor, en förbättring jämfört med föregående år, med ökade kostnader för egen personal och hyrpersonal men stärkt intäktssida genom statsbidrag och tillgänglighetsmedel.

Rehabiliteringscentrum och Rehabiliteringsmedicinska kliniken redovisar positiva resultat genom höga patientintäkter och tillgänglighetsersättningar. Habiliteringens budgetavvikelse är -16,7 miljoner kronor och förklaras framförallt av underskott i personalbudgeten, men också av kostnader för inköp till de nya lokalerna i Värnamo.

Regionövergripande FS har ett resultat för 2025 på -25,5 miljoner kronor, vilket är 110 miljoner kronor sämre än 2024.

Regionövergripande FS innehåller bland annat kostnader för köpt vård och intäkter för såld vård. Här finns även finansieringen av vårdval primärvård och vårdval ögon. Vårdvalen har en kostnadsbudget, men den brukar normalt matchas mot en kostnad som är den ersättning som går ut till vårdvalen. Viss tandvård (uppsökande/nödvändig tandvård, finansiering underskottskliniker och nyexade tandläkare) finns också här.

Köpt vård har ett budgetunderskott på 203 miljoner kronor. De höga kostnaderna beror delvis på att ca 25 miljoner kronor härrör från 2024, men fakturerats först under våren 2025. Då vissa regioner kan ha ett eftersläp på upp till sex månader till fakturering är det svårt att vid ett givet tillfälle veta hur mycket vård som utförts av andra men som inte fakturerats ännu. Den totala kostnaden för köpt vård över länsgränserna är 1,2 miljarder kronor. Räknar man bort de 25 miljoner kronor som egentligen hör

till 2024 så har kostnaden ökat med 9 procent jämfört med 2024. Kostnadsökningarna handlar om avancerad högspecialiserad vård, främst från fem regioner.

- Västra Götalandsregionen: En väsentlig del av kostnadsökningen kan hänföras till vård av två nyfödda barn som erhållit läkemedelsintensiva engångsbehandlingar med potentiellt livsförbättrande effekt. Därutöver noteras en ökning av högspecialiserad och resurskrävande vård, inklusive transplantationer och lång psykiatrisk slutenvård, vilket sammantaget bidrar till den ökade kostnadsnivån.
- Region Stockholm: Kostnadsökningen förklaras i stor utsträckning av vård av extremt för tidigt födda barn samt en tydlig ökning av både antalet patienter och vårdtyngden. Utvecklingen drivs främst av fler vårdtillfällen inom intensiv, resurskrävande och högspecialiserad vård, vilket ger betydande kostnadseffekter även vid begränsade volymförändringar.
- Region Skåne: Kostnadsökningen drivs av en kombination av nya kostnadstyngda vårdområden och ökade volymer inom högspecialiserad vård. Stora bidrag kommer från rehabilitering, hjärt- och lungkirurgi samt transplantationsvård, samtidigt som både ökade patientvolymer och ökad vårdtyngd per individ bidrar till den samlade kostnadsutvecklingen.
- Region Östergötland: Kostnadsökningen är främst kopplad till hjärt- och lungkirurgi, neonatalvård och ortopedisk kirurgi. Utvecklingen präglas av både ökade volymer och mer avancerade vårdförlopp, där hög vårdtyngd per patient ger stora kostnadseffekter även vid små förändringar i patientantal.
- Region Uppsala: Kostnadsökningen drivs huvudsakligen av avancerad kirurgisk och onkologisk vård, särskilt inom buk- och bäckenkirurgi. Även rikssjukvård och högspecialiserade behandlingar bidrar tydligt, med långa vårdtider och höga resursbehov som centrala kostnadsdrivare.

Det är svårt att påverka kostnaderna för den köpta högspecialiserade vården. Region Jönköpings län kan inte utföra detta i egen regi, utan är beroende av universitetssjukhusen produktion. Under året har särskilt kirurgisk vård arbetat med att minska antalet patienter som behöver remitteras till andra regioner för vård inom vårdgarantin. Där har antalet remisser minskat avsevärt, men kostnadsmässigt så motsvarar de bara 1-2 av de dyraste patienterna inom den högspecialiserade vården.

Tandvård centralt har en negativ avvikelse på 16,1 miljoner kronor. De större poster som påverkar är - 6,7 miljoner kronor i finansiering av N-sats-platser och övergångsregler, -4,6 miljoner kronor underskottskliniker (där budgeten är 2,8 miljoner kronor, och underskottet uppgår till 7,4 miljoner kronor), och -3,4 miljoner kronor i mindre momsintäkter när Folktandvården belastas för momskostnader de hade haft om de varit en privat klinik. Anledningen till den stora avvikelsen är främst att förväntad intäkt bygger på historiska värden, och att inköp varit lägre i år (främst baserat på tidigare höga inköp av digitala scannrar).

Budgetavvikelsen inom köpt vård vägs upp främst av statsbidrag, ej utfördelad budget, samt ett överskott inom den sålda vården.

Nettokostnad inom nämnden för folkhälsa och sjukvård per område

Område	Utfall 2025	Andel av total	Budget	Avvikelse mot budget
Primärvård	-2 748,7	22,0%	-2 817,6	68,8
Specialiserad somatisk vård	-6 299,4	50,5%	-6 239,1	-60,3
Specialiserad psykiatrisk vård	-1 241,7	9,9%	-1 172,3	-69,4
Tandvård	-327,6	2,6%	-304,7	-22,9
Övrig hälso- och sjukvård	-560,3	4,5%	-551,3	-9,0
Politisk verksamhet	-1,5	0,0%	-1,5	0
Medicinsk service	-1 313,5	10,5%	-1 196,6	-116,9

Allmän service	7,5	-0,1%	-13,1	20,6
Summa	-12 485,3		-12 296,1	-189,2

Utökningar 2025

Förändring jämfört med budget 2024, totalt

Miljoner kronor	2025	Kommentar/hänvisning till uppdrag
Primärvård	-40	Utfördelad. Ingår i ramen för vårdval primärvård.
Vårdplatser rättspsykiatri	-8	Utfördelad till verksamheten.
Barn och ungdomshälsan/BUP	-10	Utfördelad till verksamheten.
Vårdplatser	-10	Ej utfördelat.
Intensivvården	-10	Utfördelad till verksamheten.
Vuxenpsykiatri	-5	Utfördelad till verksamheten.

2026-03-17

§ 38**Intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård**

Diarienummer: RJL 2025/4394

Beslut

Presidiet föreslår nämnden för folkhälsa och sjukvård att

- besluta att kompletterande kontrollmoment om köpt vård ska utföras enligt bifogad beskrivning.

Sammanfattning

Regionledningskontoret fick i januari i uppdrag att komplettera intern kontrollplan 2026 med ett kontrollmoment om köpt vård. Förvaltningens förslag är att kontrollmomentet ska granska volym och kostnad av köpt specialiserad vård över tid, samt utvärdera om det finns vård som regionen köper som vi skulle kunna hantera själva.

Förslag till beslut

Förslag av ordföranden:

Presidiet föreslår nämnden för folkhälsa och sjukvård att

- besluta att kompletterande kontrollmoment om köpt vård ska utföras enligt bifogad beskrivning.

Förslag av Monica Samuelsson (KD):

Presidiet föreslår nämnden för folkhälsa och sjukvård

- att nytt kontrollmoment om köpt vård kompletteras att även inkludera såld vård för att ge svar på:

Vilken vård säljer vi idag?

Till vilka intäkter (och ev. extra kostnader)?

Finns det sådant vi kunde sälja mer av?

Vad? Till vem?

Beslutsgång

Ordföranden frågar om presidiet beslutar enligt hans förslag och finner att presidiet gör så.

Beslutsunderlag

- Tjänsteskrivelse: Komplettering till intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård
- Beslut NFSP 2026-02-04 Intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård

2026-03-17

- Beslut NFS 2026-01-20 Intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård
- Beslut NFSP 2026-01-09 Intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård
- Tjänsteskrivelse: Intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård
- Intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård

Beslutet skickas tillNämnden för folkhälsa och sjukvård

Komplettering till intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård

Förslag till beslut

Nämnd för folkhälsa och sjukvård

- fastställer att kompletterande kontrollmoment gällande köpt vård ska utföras enligt bifogad beskrivning.

Sammanfattning

Regionledningskontoret fick i januari i uppdrag att komplettera intern kontrollplan 2026 med ett kontrollmoment om köpt vård. Förvaltningens förslag är att kontrollmomentet ska granska volym och kostnad av köpt specialiserad vård över tid, samt utvärdera om det finns vård som regionen köper som vi skulle kunna hantera själva.

Ärendebeskrivning

Den 20 januari 2026 gav nämnden i uppdrag åt förvaltningen att komplettera den interna kontrollplanen för år 2026 med ett kontrollmoment om köpt vård.

Regionledningskontoret föreslår att intern kontrollplan 2026 kompletteras med följande kontrollmoment av köpt vård.

Kontrollmoment

Uppföljning av vilken typ av vård Region Jönköpings Län köper från andra regioner. Vad skulle vi kunna utföra själva?

Vad kontrolleras och hur kontrolleras det?

Undersöka vilka olika typer av vård Region Jönköpings län köper från andra regioner, dels i volym, dels i kostnad. Hur ser utvecklingen ut över tid? Vad är vård som vi måste köpa, och vad skulle vi kunna göra själva? Finns det några andra åtgärder som kan göras för att minska kostnadsutvecklingen?

Kontrollmomentet genomförs i två delar; dels genom genomgång av statistik utifrån fakturaunderlagen, dels genom intervjuer av remitterande verksamheter. Utredningen avgränsas till specialiserad somatisk och psykiatrisk vård.

Berörda verksamhetsområden

Regionledningskontoret, medicinsk vård, kirurgisk vård, samt psykiatri, rehabilitering och diagnostik.

Beslutsunderlag

- Tjänsteskrivelse: Komplettering till intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård
- Beslut NFSP 2026-02-04 Intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård
- Beslut NFS 2026-01-20 Intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård
- Beslut NFSP 2026-01-09 Intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård
- Tjänsteskrivelse: Intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård
- Intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård

Beslutet skickas till

Regionledningskontoret – Folkhälsa och sjukvård

Regionledningskontoret – Kansli

Mats Bojestig
Hälso- och sjukvårdsdirektör

Anette Peterson
Bitr. hälso- och sjukvårdsstrateg

2026-02-04

§ 24**Intern kontrollplan 2026 Nämnd för folkhälsa och
sjukvård**

Diarienummer: RJL 2025/4394

Sammanfattning

Den 20 januari 2026 gav nämnden i uppdrag åt förvaltningen att komplettera den interna kontrollplanen för år 2026 med ett kontrollmoment om köpt vård.

Presidiet ger information till förvaltningen om uppdraget, och man kommer fram till att en utredning avseende köpt vård ska genomföras inom ramen för intern kontroll.

Förvaltningen ska som första steg ta fram ett underlag som beskriver hur utredningen ska genomföras.

Beslutsunderlag

- Beslut NFS 2026-01-20 Intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård
-

§ 16

Intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård

Diarienummer: RJL 2025/4394

Beslut

Nämnden för folkhälsa och sjukvård

1. fastställer Intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård
2. ger förvaltningen i uppdrag att komplettera planen med ett kontrollmoment om köpt vård.

Sammanfattning

Region Jönköpings läns riktlinjer för intern kontroll gäller för Region Jönköpings läns verksamhet i sin helhet samt för regionens helägda bolag.

I Kommunallagen 6 kap 6§ fastställs att nämnderna ska, var och en inom sitt område, se till att verksamheten bedrivs i enlighet med de mål och riktlinjer som fullmäktige har bestämt samt de bestämmelser i lag eller annan författning som gäller för verksamheten. De ska också se till att den interna kontrollen är tillräcklig för att förebygga fel och oegentligheter i verksamheten, och att verksamheten bedrivs på ett i övrigt tillfredsställande sätt.

Detsamma gäller när skötseln av en kommunal angelägenhet med stöd av 10 kap. 1 § har lämnats över till någon annan.

Förslag till beslut

Ordföranden föreslår att förslaget om Intern kontrollplanen 2026 Nämnd för folkhälsa och sjukvård kompletteras med ett kontrollmoment om köpt vård.

Beslutsgång

Ordföranden frågar om nämnden fastslår Intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård, och finner att nämnden gör så.

Ordföranden frågar om nämnden bifaller hans förslag om tillägg av kontrollmoment och finner att nämnden gör så.

Beslutsunderlag

- Beslut NFSP 2026-01-09 Intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård

- Tjänsteskrivelse: Intern kontrollplan 2026 Nämnd för Folkhälsa och sjukvård
- Intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård

Beslutet skickas tillRegionledningskontoret – Folkhälsa och sjukvård

2026-01-09

§ 12

Intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård

Diarienummer: RJL 2025/4394

Beslut

Presidiet föreslår Nämnd för folkhälsa och sjukvård att

- fastställa intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård.

Sammanfattning

Region Jönköpings läns riktlinjer för intern kontroll gäller för Region Jönköpings läns verksamhet i sin helhet samt för regionens helägda bolag.

I Kommunallagen 6 kap 6§ fastställs att nämnderna ska, var och en inom sitt område, se till att verksamheten bedrivs i enlighet med de mål och riktlinjer som fullmäktige har bestämt samt de bestämmelser i lag eller annan författning som gäller för verksamheten. De ska också se till att den interna kontrollen är tillräcklig för att förebygga fel och oegentligheter i verksamheten, och att verksamheten bedrivs på ett i övrigt tillfredsställande sätt.

Detsamma gäller när skötseln av en kommunal angelägenhet med stöd av 10 kap. 1 § har lämnats över till någon annan.

Beslutsunderlag

- Tjänsteskrivelse: Intern kontrollplan 2026 Nämnd för Folkhälsa och sjukvård
- Intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård

Beslutet skickas till

Nämnden för folkhälsa och sjukvård

Intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård

Förslag till beslut

Nämnd för folkhälsa och sjukvård

- fastställer intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård.

Sammanfattning

Region Jönköpings läns riktlinjer för intern kontroll gäller för Region Jönköpings läns verksamhet i sin helhet samt för regionens helägda bolag.

I Kommunallagen 6 kap 6§ fastställs att nämnderna ska, var och en inom sitt område, se till att verksamheten bedrivs i enlighet med de mål och riktlinjer som fullmäktige har bestämt samt de bestämmelser i lag eller annan författning som gäller för verksamheten. De ska också se till att den interna kontrollen är tillräcklig för att förebygga fel och oegentligheter i verksamheten, och att verksamheten bedrivs på ett i övrigt tillfredsställande sätt.

Detsamma gäller när skötseln av en kommunal angelägenhet med stöd av 10 kap. 1 § har lämnats över till någon annan.

Ärendebeskrivning

Syftet med riktlinjen är att systematisera arbetet med intern kontroll samt beskriva hur Region Jönköpings län ska arbeta för att upprätthålla en tillräcklig intern kontroll.

Intern kontroll ingår i styrningen och är en del av ledningssystemet. Utöver de årliga intern kontrollplanerna som beslutas av styrelse, nämnder och bolag sker styrning och intern kontroll bl.a. via månadsuppföljningar, delårsrapporter och årsredovisning. Genom dessa kontrolleras att:

- tjänster produceras som uppnår och tillgodoser de behov som fullmäktige och styrelse/nämnder angivit i budget/verksamhetsplan i form av verksamhetsmål och ekonomiska ramar.
- verksamheten håller en hög kvalitet och produktivitet i förhållande till jämförbara organisationer i omvärlden.

Enligt styrelsens och nämndernas reglementen ska respektive styrelse och nämnd tillse att den interna kontrollen är tillräcklig för att förebygga fel och oegentligheter i verksamheten, och att verksamheten bedrivs på ett i övrigt tillfredsställande sätt. Styrelse och nämnder ansvarar för att ha en process för intern kontroll samt att de följer fastställda riktlinjer för arbetet med intern kontroll. Styrelse och nämnder är även skyldiga att åtgärda brister som framkommer i den interna kontrollen.

Intern kontrollplanen för styrelse, nämnder och bolag ska bygga på riskanalyser som genomförts för de verksamhetsområden som ingår i respektive styrelses/nämnds/bolags ansvarsområden. Regionstyrelse, nämnder och bolag beslutar årligen om sina egna intern kontrollplaner enligt gällande riktlinje.

Kontrollmomenten i årets internkontrollplan genomförs och avrapporteras löpande till ansvarig direktör. Rapporter avseende genomförda kontrollmoment lämnas även löpande under året till nämnden som informationsärendet. En sammanfattande presentation över genomförda kontrollmoment enligt denna intern kontrollplan sker till nämnden senast i mars året efter enligt gällande riktlinje.

Förslag till intern kontrollplan 2026 för parlamentariska nämnden framgår av bilaga.

Beslutsunderlag

- Tjänsteskrivelse: Intern kontrollplan 2026 Nämnd för Folkhälsa och sjukvård
- Intern kontrollplan 2026 Nämnd för folkhälsa och sjukvård

Beslutet skickas till

Regionledningskontoret – Folkhälsa och sjukvård

Regionledningskontoret – Kansli

Mats Bojestig
Hälso- och sjukvårdsdirektör

Anette Peterson
Hälso- och sjukvårdsstrateg

Intern kontrollplan 2026

Nämnden för folkhälsa och sjukvård (FS)

Dnr RJL 2025/4394
Mats Bojestig, Hälso- och sjukvårdsdirektör
Nämnden för folkhälsa och sjukvård (FS)
Region Jönköpings län, Box 1024, 551 11 Jönköping
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Innehållsförteckning

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1 Inledning

I enlighet med Region Jönköpings läns riktlinje för intern kontroll ska varje styrelse/nämnd/helägda bolag besluta om en årlig intern kontrollplan.

1.1 Lagstiftning

Enligt Kommunallagen (2017:725) 6 kap. § 6 ska nämnderna, var och en inom sitt område, se till att verksamheten bedrivs i enlighet med de mål och riktlinjer som fullmäktige har bestämt samt de bestämmelser i lag eller annan författning som gäller för verksamheten.

De ska också se till att den interna kontrollen är tillräcklig för att förebygga fel och oegentligheter i verksamheten, och att verksamheten bedrivs på ett i övrigt tillfredsställande sätt.

1.2 Riktlinje

Region Jönköpings län har en riktlinje gällande intern kontroll som gäller för verksamheten i sin helhet samt för regionens helägda bolag. Syftet med riktlinjen är att systematisera arbetet med intern kontroll samt beskriva hur Region Jönköpings län ska arbeta på ett enhetligt sätt för att upprätthålla en tillräcklig intern kontroll.

1.3 Definition och syfte

Med begreppet intern kontroll avses de strukturer, system och processer som bidrar till tydlighet och ordning och som säkerställer att verksamheten bedrivs i enlighet med beslutade mål, uppdrag och övriga styrdokument. En bra och tillräcklig intern kontroll förebygger, upptäcker och åtgärdar fel och brister som hindrar att organisationen kan nå sina mål på ett säkert och effektivt sätt.

Intern kontroll bidrar till:

- Att verksamheten når sina mål – med effektivitet, säkerhet och stabilitet
- Att informationen och rapporteringen om verksamheten och ekonomin är tillförlitlig och rättvisande.
- Att verksamheten efterlever lagar, regler, avtal m.m.

Intern kontroll ingår i styrningen och är en del av ledningssystemet.

Utöver de årliga intern kontrollplanerna som beslutas av styrelse, nämnder och bolag sker styrning och intern kontroll via månadsuppföljningar, delårsrapporter och årsredovisning. Genom dessa kontrolleras att:

- tjänster produceras som uppnår och tillgodoser de behov som fullmäktige och styrelse/nämnder angivit i budget/verksamhetsplan i form av verksamhetsmål och ekonomiska ramar.
- verksamheten håller en hög kvalitet och produktivitet i förhållande till jämförbara organisationer i omvärlden.

Region Jönköpings läns styrmodell Balanced Scorecard är ett hjälpmedel för både planering, uppföljning och återkoppling och innehåller bl.a. strategiska mål, framgångsfaktorer och

systemmätetal. Utifrån resultatet formuleras handlingsplaner för förbättringar och eventuella behov av resursförändringar. Systemmätetalen redovisas och följs upp i månadsuppföljningar, i delårsrapporter och i årsredovisningen.

Regionstyrelsen ska genom sin uppsiktsplikt följa övriga nämnders verksamhet och ekonomi. Nämnd med låg måluppfyllelse avseende systemmätetal, oavsett perspektiv inom Balanced Scorecard, ska i samband med att delårsrapport per april respektive augusti i protokollet till ärendet beskriva vilka åtgärder nämnden vidtagit eller avser att vidta i syfte att nå förbättrad måluppfyllelse.

1.4 Ansvar och arbetssätt

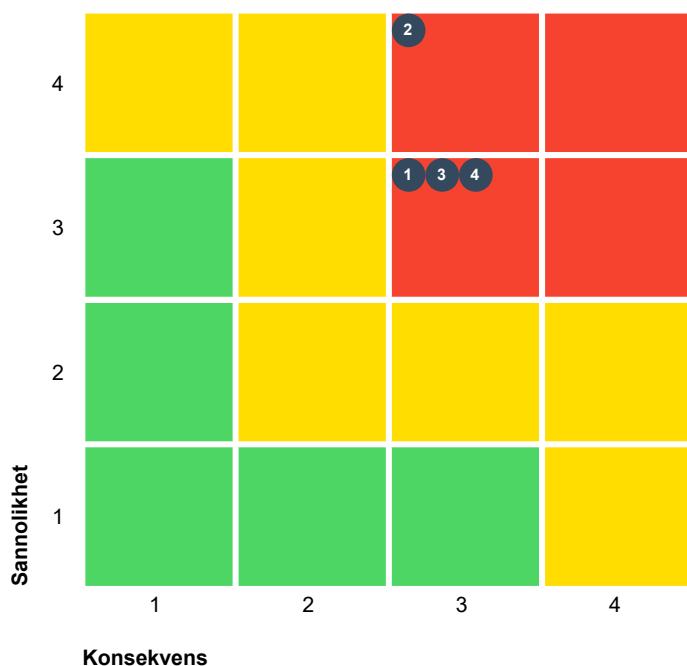
Enligt gällande reglementen ska respektive styrelse och nämnd tillse att den interna kontrollen är tillräcklig för att förebygga fel och oegentligheter i verksamheten, och att verksamheten bedrivs på ett i övrigt tillfredsställande sätt. Styrelse och nämnder ansvarar för att ha en process för intern kontroll samt att de följer fastställda riktlinjer för arbetet med intern kontroll. Styrelse och nämnder är även skyldiga att åtgärda brister som framkommer i den interna kontrollen.

Denna interna kontrollplan har tagits fram utifrån genomförda riskanalyser som har sin utgångspunkt i varje styrelses/nämnds/bolags mål, uppdrag, ansvarsområden, resultat av tidigare genomförda kontrollmoment och övergripande diskussioner, omvärldsbevakning m.m.

2 Riskanalys

Som utgångspunkt för styrelsens/nämndens/bolagets arbete med intern kontroll genomförs varje år en riskanalys enligt gällande riktlinje. En risk är en möjlig händelse eller omständighet som kan göra det svårare att uppnå verksamhetens mål eller utföra verksamhetens uppdrag och att detta sker på ett avsett och säkert sätt. Riskanalysen genomförs i flera steg där risker identifieras, värderas, prioriteras och hanteras.

Nedan redovisas de risker som framkom under riskanalysarbetet och som bör prioriteras till att ingå i intern kontrollplan för kommande verksamhetsår, samt vilken värdering risken har fått.



4 Hög Totalt: 4

Hög
Medel
Låg

	Sannolikhet	Konsekvens
4	Sannolik (Sannolikheten är så stor att det är en fråga om när det inträffar och i vilken omfattning)	Allvarlig (Mycket allvarlig skada. Omfattande och allvarliga konsekvenser för verksamheten. Kan orsaka mycket stora skador för tredje part)
3	Möjlig (Kan mycket väl inträffa men troligtvis inte särskilt frekvent)	Kännbar (Allvarlig skada. Stora störningar i verksamheten. Kan medföra betydande skada för tredje part)
2	Mindre sannolik (Inträffar inte under normala omständigheter eller i alla fall inte frekvent)	Lindrig (Betydande skada men konsekvensen kan hanteras i det löpande arbetet. Kan få bekymmersamma konsekvenser för tredje part)
1	Osannolik (Obefintlig eller liten risk)	Försumbar (Liten skada. Möjlig påverkan på verksamheten. Konsekvensen för tredje part är begränsad)

Område	Risk	Risk-värdering	Risk-värde	Vad kan hända?
Verksamhets-specifika risker utifrån nämndens ansvarsområden	 Brister i den dokumenterade överenskommelsen mellan patient och vården	Sannolikhet 3. Möjlig Konsekvens 3. Kännbar	 9	Utgångspunkten i överenskommelsen är patientens behov, resurser och erfarenheter som tillsammans med vårdens kompetenser ger individuella överenskommelser som stöd för en god hälsa. Om överenskommelser inte finns tillgänglig för patienten, eller inte innehåller den information som ska finnas där kanske patienten inte upplever sig ha fått information, blir osäker på vad som gäller eller agerar fel kopplat till medicinering, egenvård eller återbesök.
	 Medarbetarna har inte tillräcklig kunskap om vårdhygieniska rutiner eller arbetssätt.	Sannolikhet 4. Sannolik Konsekvens 3. Kännbar	 12	Vid bristande vårdhygienisk standard ökar risken för smittspridning av vårdrelaterade infektioner (VRI) både till patienter och bland personal. VRI är förenat med stora risker och stort lidande för våra patienter. Utöver detta orsakar VRI kraftigt förlängda vårdtider, höga kostnader och mycket merarbete för vården. VRI är även kopplat till ökad användning av bredspektrumantibiotika vilket driver utvecklingen av antibiotikaresistens.
Administrativa rutiner	 Registrerar inte rätt i IT-systemen vilket ger fel utdata. tex tillgänglighet, SVF-förlopp	Sannolikhet 3. Möjlig Konsekvens 3. Kännbar	 9	Om data rapporteras felaktigt kan t ex tillgänglighetsdata och statistik av standardiserade vårdförlopp i cancer leda till att beslut tas på felaktig grund. Även rapporteringen till nationella jämförelser kan bli felaktig, vilket kan leda till att förtroendet för nationella jämförelser minskar.
	 Uppföljning av tidigare genomförda kontrollmoment	Sannolikhet 3. Möjlig Konsekvens 3. Kännbar	 9	Identifierade åtgärder är inte genomförda

3 Kontrollmoment

3.1 Område: Verksamhetsspecifika risker utifrån nämndens ansvarsområden

Risk-värde	Kontrollmoment	Vad kontrolleras och hur kontrolleras det?	Berörda verksamhetsområden
■ 9	Hur fungerar dokumentationen av överenskommelse? Finns den tillgänglig och innehåller den rätt information?	Hur ser innehållet i överenskommelserna ut? Används det stödmaterial som finns för att följa upp innehållet i dokumenterad överenskommelsen? Syftet med uppföljning är att säkerställa att överenskommelserna håller hög kvalitet och fyller sitt syfte: att säkerställa delaktighet, samordning, tillgänglighet och samverkan, med patientens perspektiv som utgångspunkt. Kontrollen genomförs med stickprov inom ett antal verksamheter.	Alla verksamhetsområden inom Folkhälsa och sjukvård
■ 12	Kontroll och analys av hur vårdhygienisk egenkontroll efterföljs.	Vårdhygienisk egenkontroll (VEK) är en egenkontroll som varje verksamhet/enhet rekommenderas göra årligen. Den är utformad som en checklista som täcker in de flesta punkterna i definitionen av God hygienisk standard. Arbete med implementering har pågått under 2025. Kontrollmomentet ska undersöka om och hur vårdhygienisk egenkontroll används, i vilken omfattning och om förbättringsområden har identifierats. Kontrollen görs via rapporterna i Stratsys.	Alla verksamhetsområden inom Folkhälsa och sjukvård

3.2 Område: Administrativa rutiner

Risk-värde	Kontrollmoment	Vad kontrolleras och hur kontrolleras det?	Berörda verksamhetsområden
■ 9	Rätt registrering av data i journalsystem	Undersöka om data registreras på rätt sätt i journalsystemet för att ge rätt utdata t ex för SVF-förlopp, tillgänglighet och om rätt data rapporteras nationellt. Stickprov görs inom olika områden och verksamheter.	Alla verksamhetsområden inom Folkhälsa och sjukvård
■ 9	Uppföljning av 2024 års kontrollmoment	2024 års kontroller med åtgärdsplaner följs upp.	Berörda verksamheter inom Folkhälsa och sjukvård

4 Rapportering av kontrollmoment

Varje kontrollmoment ska rapporteras skriftligt enligt fastställd intern kontrollplan. I rapporten ska resultat/iakttagelser och åtgärdsförslag framgå. Rapporten ska överlämnas till ansvarig direktör/VD. Till rapporten ska det även överlämnas en åtgärdsplan. Rapporter avseende genomförda kontrollmoment lämnas även löpande till berörd styrelse/nämnd/bolag som informationsärendet. En sammanfattande presentation av årets genomförda kontrollmoment presenteras för styrelse/nämnd/bolag senast under mars månad efterföljande år.

2026-03-17

§ 39**Transportambulans till ambulanssjukvård – steg 2**

Diarienummer: RJL 2026/1104

Beslut

Presidiet

- lämnar ärendet till nämnden för folkhälsa och sjukvård utan eget förslag till beslut.

Sammanfattning

En utredning av transportorganisation för sekundärtransporter inom ambulanssjukvården genomfördes under 2022 och gav förslag på utveckling i tre steg. Steg 1 är genomfört genom att ambulanssjukvården har en egen sjuksköterska på SOS, ISL (inre sjukvårdsledning) och från mars 2025 startade en transportambulans sitt uppdrag.

Förslaget är nu att gå vidare med steg 2. Eftersom resultatet av transportambulansen fått större effekt än beräknat är ett omarbetat förslag för steg 2 framtaget. De 2 transportambulanserna som fanns med i ursprungsförslaget för steg 2 ersattes av en akutambulans kvällstid måndag till söndag i område Norr.

Som en del i steg 2 skapas även en ny samlad transportorganisation för sekundärtransporter med ny områdeschef, administrativ resurs, ambulanschef i beredskap samt utökning av inre sjukvårdsledning (ISL) på SOS Alarm.

Beslutsunderlag

- Tjänsteskrivelse: Transportambulans till ambulanssjukvård – steg 2
- Utredningsuppdrag – Förslag till alternativ transportorganisation inom ambulanssjukvården Region Jönköpings län – Version 2.0 slutversion inklusive utvärdering av steg 1
- Utredningsuppdrag – Förslag till alternativ transportorganisation inom ambulanssjukvården Region Jönköpings län

Beslutet skickas till

Nämnden för folkhälsa och sjukvård

Transportambulans till ambulanssjukvård – steg 2

Förslag till beslut

Nämnd för folkhälsa och sjukvård

- godkänner genomförande av omarbetat förslag avseende steg 2, med vissa justeringar, och för detta en budgetförstärkning på 9 150 000 kronor.

Sammanfattning

En utredning av transportorganisation för sekundärtransporter inom ambulanssjukvården genomfördes under 2022 och gav förslag på utveckling i tre steg. Steg 1 är genomfört genom att ambulanssjukvården har en egen sjuksköterska på SOS, ISL (inre sjukvårdsledning) och från mars 2025 startade en transportambulans sitt uppdrag.

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Ärendebeskrivning

En utredning av transportorganisation för sekundärtransporter inom ambulanssjukvården genomfördes under 2022 och gav förslag på utveckling i tre steg. Steg 1 är genomfört genom att ambulanssjukvården har en egen sjuksköterska på SOS, ISL (inre sjukvårdsledning) och från mars 2025 startade en transportambulans sitt uppdrag.

Resultatet av transportambulansen har fått större effekt än beräknat och därför har ett omarbetat förslag för steg 2 tagits fram. De 2 transportambulanserna som fanns med i ursprungsförslaget för steg 2 ersätts av en akutambulans kvällstid måndag till söndag i område Norr. Akutambulansen kvällstid, förslagsvis kl. 17-01 skulle med alla sannolikhet minska beläggningen på övriga ambulanser, öka redundansen och öka tillgängligheten för hela länet. Som kvällsambulans används

dagbilen, vilket betyder att inget inköp av ytterligare ambulans behövs. Se bilaga med omarbetat förslag för steg 2.

Utöver detta ger förslaget vissa justeringar av arbetstider för exempelvis enkelbemannade fordon, utökning av ISL funktionen på SOS Alarm, samt en utökning med även en ambulanschef i beredskap. I förslaget ligger det 1 sjuksköterska SOS Alarm för att täcka kvällar vardagar. Det finns dock behov av ISL funktion även på helger, varför det vore önskvärt med ytterliga 0,5 sjuksköterskeresurs till SOS alarm.

I steg 2 finns det medräknat att organisationen förstärks med en ansvarig områdeschef som placeras i Öster, detta för att nå målet mindre än 35 medarbetare per chef. Område Öster, som har över 100 medarbetare, behöver också förstärkas med en schemaläggare/bemanningsansvarig. I utredningens alla steg för transportorganisationen är det beräknat till totalt 17 tjänster. I steg 1 och steg 2 ingår 13 nya medarbetare.

Beslutsunderlag

- Tjänsteskrivelse: Transportambulans till ambulanssjukvård – steg 2
- Utredningsuppdrag – Förslag till alternativ transportorganisation inom ambulanssjukvården Region Jönköpings län – Version 2.0 slutversion inklusive utvärdering av steg 1
- Utredningsuppdrag – Förslag till alternativ transportorganisation inom ambulanssjukvården Region Jönköpings län

Beslutet skickas till

Regionledningskontoret – Folkhälsa och sjukvård

Mats Bojestig
Hälso- och sjukvårdsdirektör

Anette Peterson
Bitr. hälso- och sjukvårdsdirektör

Utredningsuppdrag

Förslag till alternativ transportorganisation inom ambulanssjukvården Region
Jönköpings län

Version 2.0 slutversion inklusive utvärdering av steg 1

Uppdaterad 2026-02-05

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Uppdragsbeskrivning och bakgrund

Ambulanssjukvården har under en längre tid sett ett ökat behov av transporter med kompetens och utrustning som vårdnivåmässigt ligger mellan en akutambulans och en sjukresa med Serviceresor.

Serviceresor kan i dagsläget inte erbjuda sjukvårdskompetens, vilket patientansvarig avsändande läkare allt oftare kräver vid överflyttning mellan vårdinrättning. Om patienten har ett vårdbehov så finns idag endast fullt utrustade akutambulanter samt en lättvårdsambulans. Detta försämrar ambulansens akutberedskap och tillgänglighet negativt.

Sekundärtransporter mellan sjukvårdsinrättningar har ökat både inom länet och utanför länet. Merparten av dessa transporter genomförs med akutambulanter. I många av dessa fall är patientens vårdbehov av den karaktären att en alternativ transportorganisation med sjukvårdskompetens bättre svarar mot behovet.

Uppdrag

Uppdraget innebär att utreda och lämna förslag på en alternativ transportorganisation för sekundärtransporter. Transportorganisationen föreslås finnas inom ambulanssjukvårdens regi och skall innehålla sjukvårdskompetens som motsvarar det behov som krävs, och som också skall beskrivas i utredningen. En omvärldsanalys skall göras och nödvändig statistik som kan stödja ett behov av alternativa transportsätt inom ambulanssjukvården i Region Jönköpings län skall redovisas.

Tilläggsuppgift hösten 2025

Utreda om steg 2 fortfarande är aktuellt i ursprungligt förslag efter införandet av transportambulansen i steg 1 eller om verksamheten ser förändrat behov.

Omvärldsanalys

Utredningen har tittat på både närliggande regioners organisation för sekundärtransporter men även Västra Götalands region samt Värmland.

Region Östergötland

I Östergötland är både ambulansverksamhet samt sjukresor upphandlat via privat vårdgivare. Länet har idag akutambulanter, transportambulanter, IVA-ambulans vid behov samt liggande sjuktransport.

Transportambulanterna utför tidsbestämda överflyttningar mellan vårdinrättning vardag som helg. Kompetensen är sjuksköterska plus undersköterska och tar en liggande patient. Fordonen är i stort lika som en akutambulans men saknar diverse utrustning för fixation.

Avtalet som benämns liggande sjuktransport bygger på tidskrav, därav har leverantören i uppdrag att erhålla det antal fordon som krävs. I dagsläget finns det i länet 10 fordon men alla är inte i drift samtidigt. Fordonen är aktiva både dag, kväll och natt.

Fordonen är både enkel och dubbelbemannade. Fordon med enkelbemanning tar högst en patient åt gången, dubbelbemannade fordon tar en liggande och flera sittande patienter.

Kompetensen är lägst undersköterska, finns inget krav på sjuksköterska men vårdgivaren får själv bestämma vilken kompetens som behövs. Fordonen innehåller sjukvårdsutrustning i form av defibrillator, förbandsväska och möjlighet att ge syrgas.

Region Värmland

Länet har idag en ambulansverksamhet med flera vårdnivåer. Som grund finns liggande sjuktransport som består av 11 fordon och utför sekundärtransporter. Fordonen kan transportera flera liggande patienter men ingen sittande. Bemanningen varierar från 1-2 medarbetare och kompetensen är lägst undersköterska. Fordonen är utrustade med defibrillator, möjlighet att mäta vitalparametrar samt syrgas.

Transportnivå över grund är en buss som går linjetrafik mellan sjukhus och är fullt utrustad med övervakningsutrustning, defibrillator samt läkemedel och tar både flera liggande, sittande och rullstolsburna patienter. Bussen bemannas av sjuksköterska och ambulanssjukvårdare.

Utöver detta finns flera bedömningsbilar som är fullt utrustade och bemannas av sjuksköterska som komplement till ordinarie akutambulanser.

Region Kalmar

Regionen har en lättvårdsambulans som likt Kronoberg tar en liggande och en sittande patient och fordonet bemannas av sjuksköterska. Utöver den så finns det en buss av modell större som tar en sängtransport plus upp till 29 sittande patienter. Bussen går på linje mellan sjukhusen och upp till Linköpings universitetssjukhus. Bussen bemannas av en undersköterska samt en chaufför och sköts av länstrafiken. Det finns ingen möjlighet till övervakning på bussen.

Region Kronoberg

Regionen har idag två lättvårdsambulanser utöver ordinarie akutambulanser. Liggande sjuktransport utförs av sjukresor.

Lättvårdsambulansen tar en liggande och en sittande patient och bemannas av en specialistsjuksköterska. Fordonet är utrustat i stort som en akutambulans med möjlighet till EKG-övervakning, läkemedel och syrgas. Enheterna används också som första insats då akutambulans saknas. Vårdnivån är att jämföra med vårdavdelning, likt lättvårdsambulansen i vår egen region förutom att Kronobergs fordon tar flera patienter.

Västra Götalandsregionen NU-sjukvården och Skaraborg

NU-sjukvården är i storlek på antal ambulansuppdrag och även antal akutambulanser att jämföra med Region Jönköpings län. Utöver detta har länet fyra bedömningsfordon/single responder med kompetens sjuksköterska samt sju fordon för sjuktransport för sekundäruppdrag mellan vårdinrättningar med lägst kompetens undersköterska.

Skaraborg är till antal uppdrag mindre än Region Jönköpings län och har utöver akutambulanser sex stycken fordon för sjuktransport med lägst kompetens undersköterska. Fordonen tar maximalt två patienter varav en liggande.

Västra Götalandsregionen Storgöteborg

Sahlgrenska Universitetssjukhuset driver ambulanssjukvården i storgöteborg och även om Göteborg är en storstad så är antal uppdrag drygt 1,5 gånger storleken av Region Jönköpings län med ungefärligt lika antal medarbetare. I organisationen finns en imponerande skala av vårdnivåer utöver akutambulans:

- Sjuktransport som bemannas av undersköterska

- Lättvårdstransport – undersköterska med akuterfarenhet
- Lättvårdsambulans – specialistsjuksköterska
- Bedömningsbil – specialistsjuksköterska
- Läkarstödsbil- anestesi-läkare

Region Västmanland

Startade sommaren 2023 transportambulanser med bemanning undersköterska, som ska utföra sekundärtransporter mellan länets sjukhus och därmed avlasta akutambulanser. Den nystartade organisationen är väldigt lik förslaget i denna utredning. Till sommaren 2025 gjordes konceptet om och ambulanserna gjordes om till lättvårdsambulanser för att om möjligt kunna transportera lite svårare sjuka patienter. Idag är det omväxlande undersköterskor och sjuksköterskor som bemannar. Arbetsbeskrivningen skiljer sig beroende på vilken kompetens som bemannar för dagen. De 3 bilarna går 08-17, 10-19 samt helg 9-18.

Region Halland

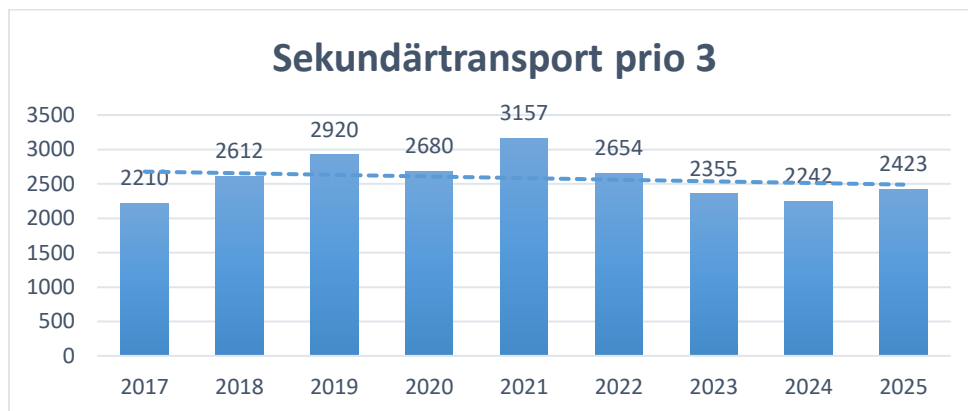
Regionen har utöver akutambulanser två stycken lättvårdsambulanser som bemannas av sjuksköterska. För liggande sjuktransport finns 5 stycken fordon som har sjukvårdsutbildad personal, de flesta av dem undersköterskor, och de tar en liggande och några sittande patienter.

Statistik och patientunderlag

Utredningen har analyserat statistik av sekundärtransporter för alla prioriteter men fokus och grundunderlag för analysen gäller transporter med prioritet 3 – tidsplanerade icke brådskande uppdrag. Dessa uppdrag kommer ligga till grund för en ny transportorganisation.

Tidsperioden för analys är från 2017 till 2025. Antal sekundärtransporter prioritet 3 har mellan 2017-2022 ökat med över 600 uppdrag eller motsvarande 27 procent, se tabell 1 nedan med trendlinje. Mellan åren 2022 till 2025 har de däremot minskat med 9 procent.

Tabell 1

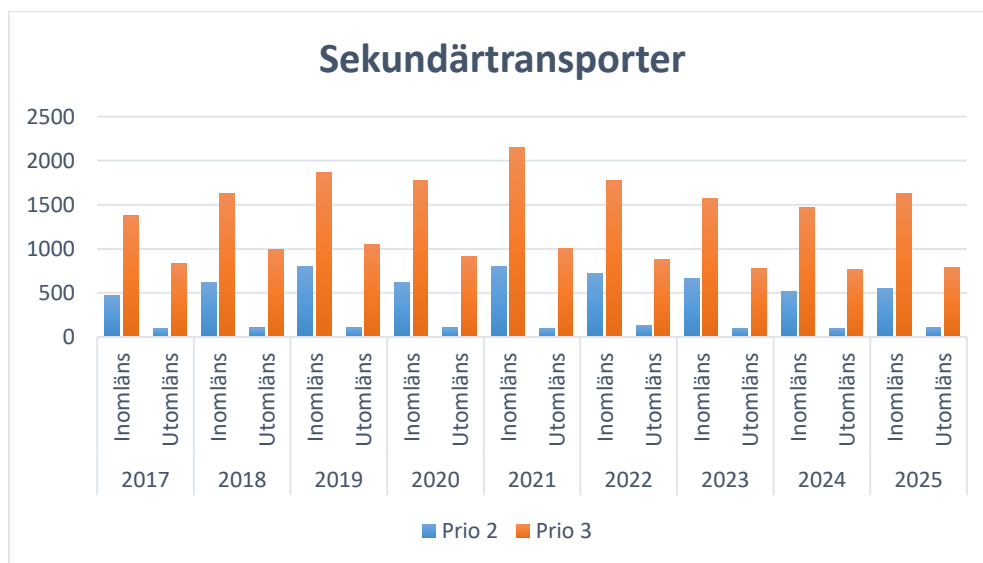


Störst ökning av totala antalet sekundärtransporter (prioritet 1-3) är inom länet som har ökat med cirka 1000 uppdrag eller 45 procent under femårsperioden 2017-2022, utomlänstransporter har ökat med 23 procent.

Om vi även tittar på sekundärtransporter med prioritet 2, vilket i högsta grad kan vara aktuella uppdrag även för en transportorganisation, så ökar underlaget ytterligare. Transporter prioritet två är

exempelvis vårdnivå som kräver lättare EKG övervakning, mellan sjukhus eller från vårdcentral till sjukhus. Tabell 2 nedan visar även uppdelning mellan inom- och utomlänstransporter.

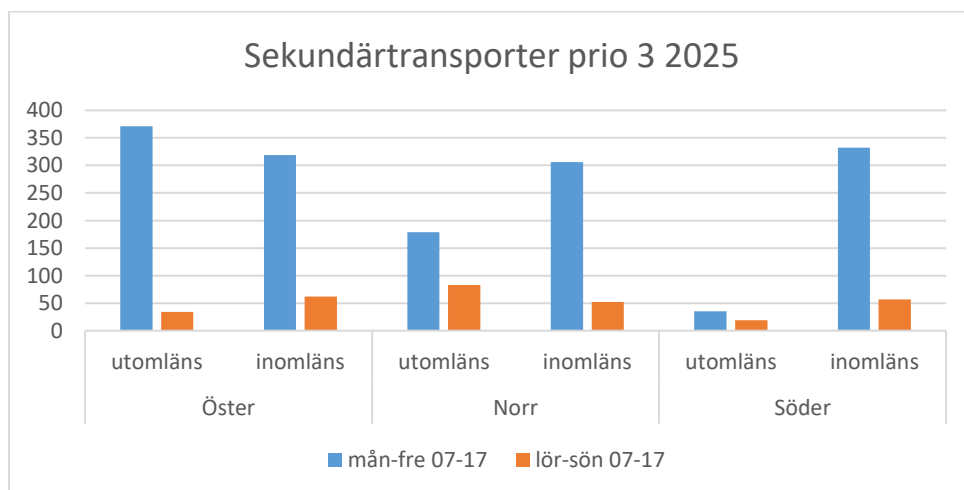
Tabell 2



En djupare analys av sekundärtransporter prioritet 3 är gjord för 2025 och uppdelat på ambulansområde norr, öster och söder. Område Norr består av Jönköping, Habo och Mullsjö. Område Öster av hela Höglandsregionen och till söder räknas Vaggeryd, Värnamo och Gislaved.

Majoriteten av uppdragen infaller dagtid vardagar samt helger. I tabell 3 nedan visas antal sekundärtransporter totalt, och prioritet 3 för respektive område samt för givna klockslag.

Tabell 3



En sammanställning av statistiken för åren 2017-2022 ger ett snitt på drygt 8 sekundärtransporter prioritet 3 per dag veckans alla dagar, både inom och utomläns. Vardagar är det betydligt fler, helger färre. Varje uppdrag inom länet tar i snitt 2,5 timmar, utomlänsuppdrag cirka 4,5 timmar.

Gruppen sekundärtransporter prioritet 2 innehåller också en andel som potentiellt kan överflyttas med transportambulans. I denna grupp finns exempelvis överflyttning mellan vårdcentral/särskilt boende och sjukhus. Snittet är cirka 2 uppdrag per dag.

Ytterligare en grupp patienter som kan överflyttas med transportambulans är de patienter som bedöms och triageras av akutambulans i hemmet. Efter genomförd undersökning så kan akutambulansen beställa transportambulans för vidare transport till sjukhus eller vårdcentral. Här finns det stor potential för att frigöra tid. Som exempel kan en patient i Smålandsstenar undersökas av en akutambulans, efter bedömning beställs en transport till sjukhus i Värnamo, och akutambulansen kan sedan vara tillgänglig i samma område och återgå till Gislaved, en tidsbesparing på ca 2 timmar.

Sammantaget finns det ett stort patientunderlag som är aktuella för denna organisation.

KPS – kapacitets och produktionsstyrning

Ambulanssjukvården har sedan 2022 implementerat arbetssättet kapacitets- och produktionsstyrning och analyserat behovet av personal och resurser kopplat till ekonomiska ramar. I analysen framkommer att varje ambulansområde har olika utmaningar relaterat till geografi och befolkningens mängd. Område Öster och Söder har stora avstånd som gör att varje uppdrag som kan avlastas av en transportambulans är till stor nytta för tillgängligheten.

Område norr har kortare avstånd men betydligt fler uppdrag och högre beläggning eftermiddag/kväll. I tabell 4 nedan är de fordon med högst beläggning rödmarkerade, vilket visar på fordon i Jönköping samt Nässjö och Vaggeryd. Den enkla förklaringen här är att kringliggande stationer som Nässjö och Vaggeryd utför många uppdrag i Jönköpingsområdet.

I ett övergripande perspektiv sett över länet så finns det en ort som klarar den målsättning i tillgänglighet på 80 procent inom 20 minuter på prio1 som råder idag, och det är Tranås med omnejd. Om vi tittar på beläggningsstatistiken för Tranås så visar den i snitt 45 procent, vilket föranleder slutsatsen att Tranås är rätt dimensionerat med rätt redundans för att hålla en bra tillgänglighet. Samma resonemang ger att när beläggningen går över 50 procent så försämras tillgängligheten och redundansen minskar.

En sammanställande analys av resonemanget är att Jönköpingsområdet behöver förstärkas framförallt kvällstid för att höja tillgängligheten. Detta skulle kunna göras på olika sätt. Ett alternativ kan vara att införa transportambulans som tjänstgör något senare på kvällen. Ett annat alternativ kan vara att införa en akutambulans kvällstid som kan avlasta med alla typer av uppdrag då vi ser att beläggningen enligt tabell 4 är som högst i område Norr mellan 17-24. En akutambulans kvällstid veckans alla dagar i Jönköping skulle få en positiv synergieffekt på närliggande ambulansstationer i Nässjö och Vaggeryd och innebär sannolikt att tillgängligheten ökar inte bara i Norr utan även i Öster och Söder.

Transportambulansens införande och resultatet

I mars 2025 startade transportambulansen sitt uppdrag med att gå på linje mellan Högländssjukhuset, Ryhov och Universitetssjukhuset i Linköping. Effekten blev omedelbar och har avlastat akutambulanser i hög grad för alla tre sjukhusområden. Tillgängligheten har ökat och steg med 3,6 procent i länet mellan åren 2024 och 2025. I tabell 4 nedan redovisas statistiken för transportambulansen mellan 1 mars 2025 till 31 december 2025. Om semesterperioden räknas bort så ligger snittet på runt 2,5 patienter per arbetspass.

Tabell 4 antal patienter på transportambulansen

Från	Till	Antal
Eksjö	Ryhov och Linköping	192
Ryhov	Eksjö och Linköping	155
Linköping	Eksjö	72
Linköping	Ryhov	169
Värnamo	Ryhov	26
Ryhov	Värnamo	47

När utredningen gjordes 2022 så lades förslaget upp i tre steg varav mindre fordon i steg 2.

Resultatet av transportambulansen som tar upp till fyra patienter samtidigt fick dock större effekt än beräknat. Ledningsgruppen har nu i början av 2026, tillsammans med fackliga representanter diskuterat om steg 2 i utredningen fortfarande är mest resurseffektiv och delvis kommit fram till ett annat behov.

I tabell 5 nedan så ser vi en betydligt högre beläggning under sen eftermiddag/kväll i alla områden men som högst i Jönköping av naturliga skäl som en storstad. Det är också tydligt att behovet av transporter till hemsjukhus inom länet från hjärtvården Ryhov är stort på sena eftermiddagar.

Nytt omarbetat förslag för steg 2

Diskussionen har varit om steg 2 bör omorganiseras och att de 2 transportambulanserna istället ersattes av en akutambulans kvällstid måndag till söndag i område Norr. Akutambulansen kvällstid, förslagsvis kl. 17-01 skulle med alla sannolikhet minska beläggningen på övriga ambulanser, öka redundansen och öka tillgängligheten för hela länet. Här är ledningsgrupp och fackliga organisationer överens. Kvar finns 2 transportambulanser i steg 3 om organisationen behöver förstärkas ytterligare.

Synergieffekten av en kvällsambulans i område Norr bör vara tydlig då statistiken visar att ambulanser från framförallt Nässjö och Vaggeryd har mycket uppdrag i Jönköping både vardag som helg.

Om kvällsambulansen schemaläggs som en förlängd dagbil mellan kl. 17-01 kan i princip inköpet av ytterligare ambulans utebli vilket sparar stora kostnader för steg 2 då inget nyinköp av fordon behövs. En fysisk dagambulans kan förlängas och användas för ändamålet både kvällar och helger.

Som ett bakre ledningsstöd i kris och krig men även vid hot och vålds- situationer samt på grund av ett ökat tryck från samverkanspartners som polis, räddningstjänst och larmcentral att kunna nå ambulanssjukvårdens chef, föreslår utredaren en ambulanschef i beredskap. Se utförligare text under ambulanschef i beredskap sid 15.

Tabell 5

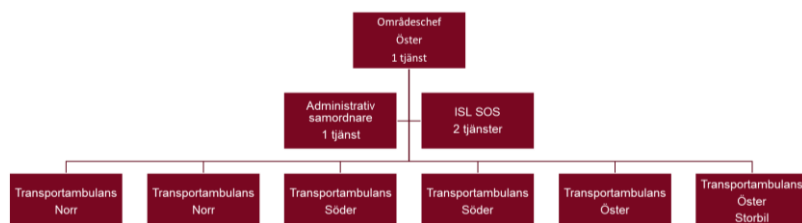
Öster														
2023 %	07-17	17-24	00-07		2024 %	07-17	17-24	00-07		2025 %	07-17	17-24	00-07	
Nässjö	9210	53	62,7	38,1	Nässjö	9210	50,3	54,5	33	Nässjö	9210	46,3	52,8	22,9
	9220	49,3	60,9	20		9220	46,4	56,2	20,4		9220	43,9	49,3	24,3
Sävsjö	9250	45,1	46,2	23,4	Sävsjö	9250	41,3	42,8	20,9	Sävsjö	9250	39,8	41,9	21,9
Vetlanda	9410	51,1	51,5	32,8	Vetlanda	9410	42,7	47	29,9	Vetlanda	9410	43	45,4	19,7
	9420	47,6	49	16,6		9420	40,2	38,9	14,8		9420	38,2	41,8	20,6
Eksjö	9610	48,4	50,3	26,4	Eksjö	9610	48,3	47	24,8	Eksjö	9610	43,3	46,9	25,2
	9620					9620					9620			
	9630					9630					9630			
Söder														
2023 %	07-17	17-24	00-07		2024 %	07-17	17-24	00-07		2025 %	07-17	17-24	00-07	
Värnamo	9510	47,4	51,6	14,4	Värnamo	9510	41,6	42,4	13,6	Värnamo	9510	43,9	41,7	22,4
	9520	44,3	34,6	27,5		9520	37,6	31,6	24,7		9520	40,7	41,6	20,1
	9530					9530					9530			
Gislaved	9710	44,3	48,9	15,4	Gislaved	9710	41,6	47,1	16,7	Gislaved	9710	41,4	40,5	22,2
	9720	42,4	36,4	30,3		9720	39,4	38,4	30		9720	39,7	40,8	23,5
Vaggeryd	9850	44	53,3	22,5	Vaggeryd	9850	46,1	51,2	22,6	Vaggeryd	9850	42,1	48,8	22,8
Norr														
2023 %	07-17	17-24	00-07		2024 %	07-17	17-24	00-07		2025 %	07-17	17-24	00-07	
Jönköping	7110				Jönköping	7110				Jönköping	7110			
	9120					9120					9120			
	9130					9130					9130			
	9140	56,2	71,2	27,9		9140	53,8	66	24,4		9140	53,7	60,5	35,2
	9150	52,1	49	46		9150	52,2	54,2	43,7		9150	52	58,1	39,7
	9160	42,9	59,8	39,7		9160	48,6	55,2	43,9		9160	47,8	57,5	39,7
Habo	9810	38,3	49,8	21,5	Habo	9810	37,8	40,9	16,8	Habo	9810	39,6	43,7	22,4
Mullsjö	9830				Mullsjö	9830				Mullsjö	9830			

* De rödmarkerade siffrorna visar fordon med högst beläggning.

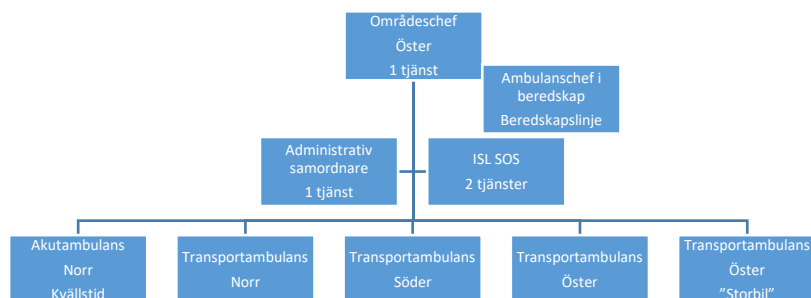
Organisationsförslag

Ledningsgruppen har tagit fram ett förslag på en organisationsstruktur baserat på statistikunderlag som redovisats i dokumentet. Nedan finns en schematisk bild över ursprungsförslaget (alternativ 1) samt det omarbetade förslaget (alternativ 2) i nya analysen från starten av 2026.

Alternativ 1 ursprungliga förslaget



Alternativ 2 omarbetat förslag



Område norr

Alternativ 1 ursprungligt förslag

Två stycken enkelbemannade mindre fordon inklusive den lättvårdsambulans som finns idag. Fordonen ska ta en liggande patient vardera. Arbetstider föreslås vara mellan kl. 7-17 samt 9-19 vardagar. Ett av fordonen arbetar helg enligt schema kl. 7-17.

Alternativ 2 nytt förslag

En lättvårdsambulans som finns redan idag vardagar samt en akutambulans kvällstid vardagar samt helg, förslagsvis kl. 16-24 eller 17-01, dvs. 8 timmars arbetstid.

Område söder

Alternativ 1 ursprungligt förslag

Två stycken enkelbemannade mindre fordon som tar en liggande patient vardera. Arbetstider föreslås likt område norr vara kl. 7-17 samt 8-18 vardagar. Ett av fordonen arbetar helg enligt schema kl. 7-17.

Alternativ 2 nytt förslag

Ett enkelbemannat mindre fordon som tar en liggande patient. Arbetstider föreslås likt område norr vara kl. 7-17 vardagar.

Område öster

Ett mindre enkelbemannat fordon som tar en liggande patient, vardagar kl. 9-18.

Ett större dubbelbemannat fordon som tar 1-2 liggande samt 1-2 sittande patienter. Detta fordon ska gå på linje vardagar mellan Eksjö- Ryhov- Linköpings universitetssjukhus, samt tillbaka samma väg på eftermiddagen. Av erfarenhet i ambulanssjukvården finns det stora vinster för länets avdelningar att ha fasta tider för transport av patienter mellan länets sjukhus, men även för avdelningar på sjukhuset i Linköping. Analys av patientunderlag ger att överlägset flest transporter beställs från Höglandssjukhuset tidig morgon, varför den fasta linjen bör utgå där från start.

Summering transportorganisation fullt utbyggd

Alternativ 1

- 6 fordon totalt i länet inklusive dagens lättvård
- Vardagar 6 aktiva, helger 2
- 2 fordon per område (varav 1 storbil öster)
- 1 tjänst områdeschef med placering i öster
- 1 tjänst bemanningskoordinator/administrativt
- 2 tjänster ISL (inre sjukvårdsledning, sjuksköterska) på SOS
- 2 tjänster sjuksköterska i fordon
- 11 tjänster undersköterska i fordon
- Totalt 17 tjänster (5+1 chef öster, 2 norr, 4 söder, 2 ISL, 1 administrativt)

Alternativ 2

- 5 fordon totalt i länet inklusive dagens lättvård
- Vardagar 5 fordon aktiva, helger 1
- 2 fordon i Norr, 2 i Öster och ett i Söder (varav 1 storbil Öster)
- 1 tjänst områdeschef med placering i Öster
- Ambulanschef i beredskap jourtid
- 1 tjänst schemaläggare/administrativt
- 2 tjänster ISL (inre sjukvårdsledning, sjuksköterska) på SOS
- 5 tjänster sjuksköterska i fordon
- 8 tjänster undersköterska i fordon
- Totalt 17 tjänster (5+1 chef Öster, 5 Norr, 3 Söder, 2 ISL, 1 administrativt)

Administration

En utökning av ny organisation förutsätter tillsättandet av en områdeschef som ska fungera som närmsta chef och sköta sedvanliga uppgifter för de nya medarbetarna. Ledningsgruppen anser inte att en utökning av organisationen kan påföras ordinarie chefslinjer med risk för betydligt sämre arbetsmiljö. Kopplat till en områdeschef behövs även en schemaläggare/administratör som kan sköta det administrativa kring organisationen tillsammans med övriga schemaläggare i kliniken.

Fordon

De enkelbemannade fordonen som föreslås kan vara av olika karaktär, men det finns betydande fördelar för både patient och vårdare/förare att kommunikationen underlättas genom en nära kontakt dem emellan. Lättvårdsambulansen som finns idag är ett bra exempel på en väl fungerande miljö för dessa typer av uppdrag.

Gällande upphandling och kostnadseffektivitet finns det fördelar med att ha samma typ av fordon och storlek för både de enkelbemannade samt det dubbelbemannade fordonet. Det ger även redundans vid service och andra relaterade problem.

Placeringsorter

Det mest önskvärda och logistiskt fördelaktiga är att fordonen kan placeras så nära som möjligt respektive sjukhus i länet, men inte nödvändigtvis på ambulansstationerna.

Det är av vikt att fordon finns i varje ambulansområde/sjukhusområde för att minimera transporttiden från uppställningsplats till sjukhus.

Utredningen visar på eventuella svårigheter att hitta uppställningsplatser och då framförallt garageplats till fordonen, men det bör finnas tid att undersöka detta under tiden mellan beslut och införandeprocess. Utredningen har fått förslag på möjliga garage i område norr och söder i närheten av sjukhusen. I öster är det i skrivande stund ett svårare läge, men projektledaren får undersöka detta vidare.

Sjuksköterska på SOS Alarm (ISL) och logistik

En grundläggande förutsättning för en transportorganisation är att ambulanssjukvården har en egen sjuksköterska på SOS, en så kallad ISL (inre sjukvårdsledning) funktion. Ett projekt med en sådan funktion prövas just nu under 2022-2023 och visar på stora vinster med att frigöra tid för akutambulanser. Under en 6 veckors period december-januari 2023 sparades motsvarande 153 timmars akutambulanstid, genom vårdnivåbedömning.

Ambulanssjukvårdens egen sjuksköterska kan bedöma patientens vårdbehov på helt andra grunder än en SOS operatör, vilket har visat sig under projektiden. Genom att ringa upp avsändande vårdavdelning kan patienter med lägre vårdbehov planeras med transportambulans och på det sättet frigöra tid för en akutambulans. Att bedöma vårdnivå kräver ambulanssjukvårdens kompetens och kan inte läggas på SOS Alarms operatörer, som endast prioriterar hur snabbt den vårdsökande behöver hjälp.

En ambulanssjuksköterska på SOS Alarm är också en förutsättning för vårdnivåstyrning i arbetet med god och nära vård, i en framtid med fler mobila team i sjukvården.

Utvärdering hösten 2025 visar att ISL har en betydande effekt på logistikplaneringen dagtid vardagar då behovet av transporter är som störst. ISL utför även vårdnivåbedömning för patienter med oklart vårdbehov och är en viktig faktor även i framtiden som möjlig sammanhållande funktion för regionens mobila team. En utökning och utbyggnad av funktionen skulle främst rekommenderas vardagkvällar samt eventuellt helg dagtid. Vardagkvällar är beläggningen som högst och troligen skulle ISL vara till nytta i vårdnivåbedömning där liksom helger dagtid då antal ambulanser är färre än vardagar.

Vinster i tillgänglighet

Omvärldsanalys och intervjuer visar att regioner med flera vårdnivåer inom ambulansorganisationen är bättre rustade för länsinvånarnas vårdbehov och får en effektivare patientstyrning. I statistikunderlaget för Region Jönköpings län visas att de tänkta transportambulanserna med föreslagna tider, täcker upp mot 85 procent av sekundäruppdragen prioritet 3, vardag som helg. Det innebär att fordonen tillsammans tar mellan 8-12 uppdrag per dag.

Varje uppdrag inomläns har i snitt en uppdragstid på 2,5 timmar. Utomlänsuppdrag ligger på snittet 4,5 timmar. Transportambulanserna beräknas ha en snittbeläggning på mellan 80-90 procent. Denna beläggning och antal uppdrag skulle innebära att tid motsvarande 5 akutambulanser/250 timmar skulle sparas vardagar.

Tidsbesparingen på helg skulle med samma räknesätt spara tid för 1,5-2 akutambulanser. Sammantaget kan tillgängligheten till akutambulans öka med minst 290 timmar varje vecka, vilket motsvarar samma sak som att regionen tillför 6 dagambulanser.

Region Jönköpings län mäter tillgänglighet i andel länsinvånare som nås inom 20 minuter på prioritet 1-larm. Snittet för 2022 blev cirka 68,5 procent. En grov uppskattning är att en alternativ transportorganisation, tillsammans med en utökad ISL-funktion kan öka andelen med cirka 5 procentenheter. Resultatet vid utgången av 2025 visar en andel på 75,7 procent dvs. en ökning med 7,2 procent.

Nationellt redovisas tillgänglighet via vården i siffror med data som tas från SOS Alarm. Tiden som redovisas är mediantid från besvarat samtal till första resurs på plats.

Med detta sätt att mäta når ambulanssjukvården alla kommuner i länet utom tre i dagsläget, inom 20 minuter i median. Med en alternativ transportorganisation i full drift och med detta mätesätt bör alla kommuner nås inom målsättningen.

Fordonsutrustning

Alla tänkta fordon ska vara utrustade med nödvändiga delar som behövs för de patienter som transporteras. En grunduppsättning är tänkt enligt följande:

- EKG-övervakning
- Defibrillator
- Syrgas,
- Eventuell luft för neonataltransporter
- Förbandsväska
- Pensi-bår med automatisk båruppdagare
- System för journaldokumentation, ärendehantering och navigering

Läkemedel kommer finnas tillgängligt om fordonet bemannas av sjuksköterska.

Personal och kompetens

Ingången i utredningsuppdraget är primärt att frigöra tid för de akutambulanser som finns idag, inte att tillföra mer akuta resurser. Dock har en ny analys i början av 2026 visat på ett förändrat behov i steg 2 varför ett alternativ 2 i steg 2 förordas.

För varje uppdrag som kan läggas på en transportambulans så ökar tillgängligheten av akutambulanser. Utredningen har i möten med framförallt hjärtvårdsavdelningen och PCI-enheten (Perkutan Coronar Intervention) som utnyttjar ambulanssjukvårdens resurser vanligtvis, efterfrågat vilken typ av övervakning och omvårdnadsbehov som de behöver för sina patienter. Denna kunskap tillsammans med analys av omvärldsbevakning har legat till grund för kompetensfrågan.

Region Östergötland har valt att avveckla sina lättvårdsambulanser med kompetens sjuksköterska till förmån för enkelbemannad liggande sjuktransport med undersköterska samt dubbelbemannade transportambulanser med kompetens undersköterska och sjuksköterska. De patienter som behöver mer avancerad vård transporteras med akutambulans.

Region Kalmar och Kronoberg har idag lättvårdsambulanser med sjuksköterska och tycker att detta koncept fungerar bra för dem, eftersom fordonen kan användas till fler typer av uppdrag. Dock saknar de en lägre vårdnivå för den stora delen av överflyttningsuppdrag.

Baserat på uppdragsbeskrivningen, analys av patientunderlag samt journalanalyser så anser ambulanssjukvårdens ledningsgrupp att det är mest resurs – och kostnadseffektivt att bemanna de mindre fordonen i första hand med lägst kompetens undersköterska. Den stora mängden av uppdrag kommer att kunna hanteras med bra omvårdnadskompetens av internutbildade undersköterskor eller ambulanssjukvårdare. Detta innebär att dagens lättvårdsambulans kan omvandlas till transportambulans vid behov.

I det större fordonet som är dubbelbemannat så ser dock utredningen att det kan finnas ett behov av sjuksköterska i kombination med undersköterska, för att kunna hantera patienter med mer omvårdnadsbehov framförallt till och från vårt regionsjukhus i Linköping.

Vilken kompetens fordonen bör bemannas med kan även vara en öppen fråga och kan förändras över tid beroende på samhällsutveckling och önskemål från avsändande kliniker.

Organisationen som beredskap

Händelser med många skadade är komplexa och innebär en rad utmaningar för hälso- och sjukvården. Det absoluta antalet skadade kan variera beroende på t.ex. geografi och händelsens art samt i vilken grad lokala eller regionala resurser inte räcker till för att möta vårdbehovet som uppstår. Hanteringen av masskadehändelser kräver ofta betydande mängder utrustning, personalresurser, sjuktransporter, vårdplatser, ledningsförmåga och rutiner.

”Vid händelser med många skadade eller sjuka samt vid katastrofer behöver sjukvården kunna mobilisera resurser för att möta de ökade vårdbehoven och samtidigt, så långt det är möjligt, upprätthålla annan vård som inte kan anstå”. Så skriver utredningen om hälso- och sjukvårdens beredskap i sitt slutbetänkande (SOU 2022:6).

Vidare sammanfattar utredningen: ”Regionerna ansvarar enligt hälso- och sjukvårdslagen för att det inom regionen finns en ändamålsenlig organisation för sjuktransporter.

Regionerna behöver, var och en för sig eller gemensamt, säkerställa att hälso- och sjukvården har kapacitet att hantera sina behov av sjuktransporter. Vissa myndigheter som normalt inte utför sjuktransporter kan under vissa förutsättningar bistå hälso- och sjukvården, men det kan inte tas för givet eftersom myndigheterna i första hand är skyldiga att upprätthålla sin egen verksamhet. Deras möjligheter att stödja hälso- och sjukvården är beroende av vad som händer i samhället i övrigt.”

Jönköpings länstrafik är Region Jönköpings läns trafikhuvudman och kan tillgodose transporter av oskadade patienter vid masskadesituationer. Det som Region Jönköpings län saknar idag är transportnivå/vårdsnivå mellan busstransport och akutambulans.

En transportambulans med specialutbildad personal skulle vid en masskadesituation kunna användas som exempelvis:

- Transportör av patienter med lättare skador till sjukhus, vårdcentral eller annan offentlig anvisad plats.
- Fungera som sjukvårdsassistans och stöd vid skadeplats och uppsamlingsplats.
- Fungera som stöd till stab och ledning.
- Transportera patienter mellan sjukhus för att frigöra vårdutrymme.
- Transport av sjukvårdspersonal till skadeplats.
- Höjd förmåga vid ökad belastning i vardagen.

Utredningen som nämns ovan föreslår lagändringar i hälso- och sjukvårdslagen (2017:30):

- Regionen ska planera sin hälso- och sjukvård så att en katastrofmedicinsk beredskap upprätthålls.
- Regionen ska vid planeringen särskilt beakta behovet av beredskap för att hantera händelser som medför ett stort antal skadade eller sjuka, katastrofer samt andra händelser som allvarligt kan inverka på regionens förutsättningar att fullgöra sina skyldigheter enligt 8 kap. eller andra föreskrivna krav som gäller för hälso- och sjukvård.

Enligt Hälso- och sjukvårdslag (2017:30) ska hälso- och sjukvård erbjudas och utföras i alla lägen, utföras enligt alla rättsliga krav, och inkludera även ambulanssjukvård. Detta gäller även när det

inträffar händelser eller uppkommer situationer som kan beskrivas som stor olycka, kris, krig, extraordinära händelser i fredstid eller mycket omfattande och svåra extraordinära händelser som allvarligt kan påverka regioners verksamhet.

I Socialstyrelsens föreskrifter (SOSFS 2009:10) framgår att varje region ska upprätta en plan för ambulanssjukvården inom sitt geografiska område. Av planen ska det framgå vilka mål som har fastställts, vilka resurser som ska finnas, och hur ambulanssjukvården ska vara organiserad. Regionen ska samordna planen för ambulanssjukvården med den fredstida katastrofmedicinska beredskapsplanen och planeringen inför höjd beredskap.

Vid ett stort skadepanorama kommer ambulanssjukvården utsättas för ett massivt tryck. Det visar erfarenheten av de händelser som inträffat historiskt. Det kommer inte finnas möjlighet att använda den avancerade sjukvården som en akutambulans ger till massan av oskadade/lättare skadade patienter.

Utredningen tror att en alternativ transportorganisation kan komplettera behovet av förhöjd beredskap, både i handling och enligt regelverk i hälso- och sjukvårdslagen.

Ambulanschef i beredskap

Civil beredskap och krisberedskap är en högaktuell fråga som länder, regioner, kommuner och samhällen rustar för och som tidigare nämnts så kommer ambulanssjukvården utsättas för ett massivt tryck vid ett stort skadepanorama. Trycket från ambulanssjukvårdens samverkansparter som polis, räddningstjänst och larmcentral likväl som från regionens egen beredskapsverksamhet har också ökat markant där man eftersöker en chef i beredskap som kontaktperson dygnets alla timmar och veckans alla dagar. Ambulanssjukvården ska dygnet runt snabbt kunna mobilisera beredskap, organisation och ledningsstruktur vilket då kräver en chef i beredskap som kontaktperson via alternativa kontaktvägar som telefon och RAKEL.

En omvärldsanalys ger att funktionen ambulanschef i beredskap finns i alla närliggande regioner samt även hos de allra flesta regioner i Sverige.

Funktionen hanterar alla frågor dygnet runt gällande logistik av ambulanser, patienttransporter, helikopter och flyg, kontakt med samverkansparter, samarbete med ISL samt inte minst ett stöd till ambulansens medarbetare vid hot och vålds händelser likt händelsen i Gävleborg hösten 2025 där en ambulanssjuksköterska avled. Funktionen är också viktig för att upprätthålla bemanning jourtid på länets ambulanser vid akut sjukdom eller andra påverkanshändelser.

En chef i beredskap är viktig för att stärka ambulanssjukvårdens beredskap i händelse av kris- och krig.

Med ovanstående som resonemang har utredaren föreslagit ett tillägg av ambulanschef i beredskap i steg 2 alternativ 2.

Implementering av organisation

Att starta en ny organisation kräver lång framförhållning och en noggrann planering. Fortlöpande utvärdering måste ske under resans gång, bland annat vilka effekter på tillgänglighet som införda resurser ger. Detta måste också balanseras mot behovet av beredskap enligt nationella lagkrav från Socialstyrelsen.

Organisationsförslaget kan införas fullt ut direkt, eller succesivt genom en 3-stegsmodell. Om 3-stegsmodell väljs så är det viktigt att sätta en tidsplan och arbeta proaktivt, eftersom upphandlingsfasen har mycket långa ledtider.

Steg 1

Baserat på utredningens organisationsförslag så är det mest naturliga och det som sannolikt ger effekt fortast, att som första åtgärd implementera en dubbelbemannad transportambulans på Höglandet som kan ta flera patienter. Fordonet ska gå på fast linje mellan Höglandssjukhuset, Ryhov och Linköpings universitetssjukhus måndag till fredag.

Steg 1 beräknas kunna införas utan att förstärka organisationen med områdeschef eller bemanningsplanering. Dock är ISL på SOS Alarm en förutsättning för att kunna avgöra vårdbehov och fullt ut belägga transportambulansen med rätt patientgrupp.

Behov och kostnad för steg 1

- 1 fordon
- 2 tjänster sjuksköterska
- 2 tjänster undersköterska
- 1 tjänst ISL SOS Alarm (måndag-fredag)
- Total kostnad/år **5 880 668 kr**

Steg 2

Som steg 2 i implementeringen för att möta upp behovet av sekundära överflyttningar enligt statistik och analys samt öka tillgängligheten föreslår utredningen implementering av ytterligare 2 transportambulanser i alternativ 1 eller 1 akutambulans kvällstid i område Norr i alternativ 2. I detta steg bör organisationen förstärkas med en ansvarig områdeschef som placeras i Öster, som får ansvar för medarbetare i alla steg, samt schemaläggare/administratör. Steg 2 innebär också en utökning av ISL samt införandet av en ambulanschef i beredskap.

Behov och kostnad för steg 2

Alternativ 1

- 2 fordon
- 1 tjänst områdeschef
- 5 tjänster undersköterska
- 1 tjänst ISL SOS Alarm (kvällstid eller lördag-söndag)
- 1 tjänst administrativ samordnare

Kostnad steg 2 alternativ 1: **10 629 351 kr**

Behov och kostnad för steg 2

Alternativ 2

- 1 tjänst områdeschef
- 2 tjänster ambulanssjukvårdare (undersköterska)
- 3 tjänster sjuksköterska
- 1 tjänst ISL SOS Alarm (kvällstid och/eller lördag-söndag)
- 1 tjänst administrativ samordnare
- Ambulanschef i beredskap jourtid

Kostnad steg 2 alternativ 2: **8 675 235kr**

Steg 3

Om utvärdering av tidigare steg visar att tillgänglighet och organisation fortfarande är i behov av förstärkning så föreslår utredningen ett sista steg till full implementation av organisationsförslaget.

Behov och kostnad för steg 3

- 2 fordon
- 4 tjänster undersköterska
- Total kostnad/år inkl. engångskostnad år 1:

Kostnad steg 3: **6 366 579 kr**

En preliminär uppskattad tidsaxel efter beslut i budget är 1 år och 4 månader tills fordonen är upphandlade, levererade och startklara, vilket gäller för alla steg.

Diskussion

I linje med Region Jönköpings läns ambitioner att styra patienter till rätt vårdnivå, inklusive transportnivå, så behöver ambulanssjukvården fler verktyg i verktygslådan. Nationellt har de allra flesta regioner olika vårdnivåer inom ambulanssjukvård, visar den omvärldsanalys som gjorts.

Statistiken visar att interna överflyttningar mellan länets sjukhus ökat kraftigt under en femårsperiod. även om det var en reduktion under 2022, och med ökad specialisering så lär trenden fortsätta. Avsändande läkare är av naturliga skäl restriktiva med att skicka inneliggande patienter med sjukresa(taxi) och alternativet som då återstår är akutambulans eller den lättvårdsambulans som finns idag. En väl dimensionerad transportorganisation med utbildad sjukvårdspersonal och fordon med medicinsk utrustning skulle fylla luckan som ambulanssjukvården och övrig länssjukvård idag saknar.

Utvärderingen av steg 1 i utredningen visar att effekten blev större än förväntat. Därför har ledningsgruppen tagit fram ett ytterligare alternativ 2 med en kvällsambulans i steg 2.

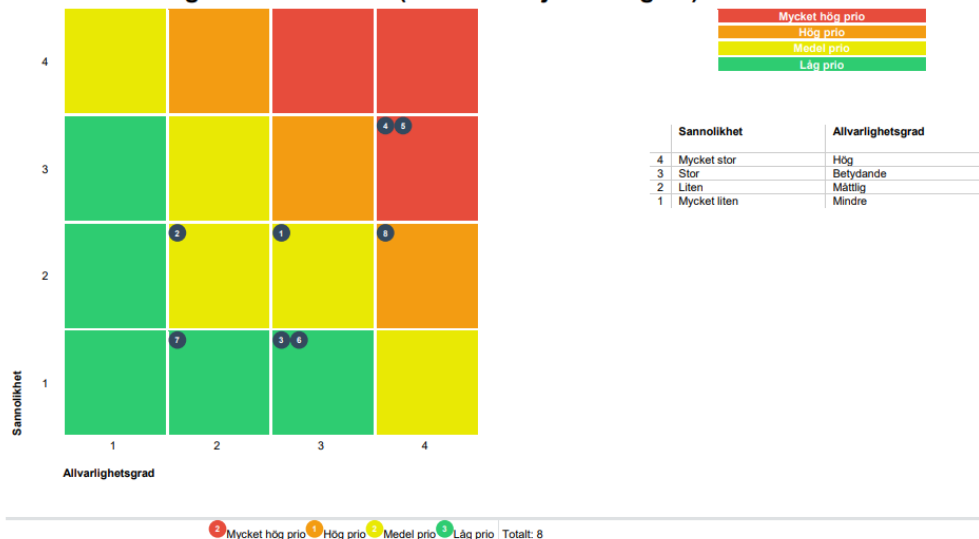
Bedömningen är att en akutambulans kvällstid i område Norr ger störst effekt på beläggning och tillgänglighet för hela länet, därför rekommenderar ledningsgruppen alternativ 2 i steg 2.

Bemanning	Antal	
Undersköterska	5	3 273 120 kr
Sjuksköterska	0	0 kr
Administratör	1	588 528 kr
IB SOS	1	727 315 kr
Områdeschef	1	1 001 376 kr
Kostnad bemanning		5 590 339 kr
OH-kostnad		1 677 102 kr
Övrig kostnad för personal		
Kläder		30 000 kr
Total övrig kostnad för personal		30 000 kr
Total kostnad inkl. OH-kostnad		7 297 441 kr
Fordon		
Småbil 1		1 649 395 kr
Småbil 2		1 649 395 kr
Småbil 3		0 kr
Total kostnad fordon		3 298 790 kr
Utbildning nyanställda steg 2		33 120
Kostnad steg 2		10 629 351 kr
Kostnad som följer med steg 1		5 995 309 kr
Total kostnad/år		16 624 660 kr

Bemanning	Antal	
Undersköterska	2	1 342 849 kr
Sjuksköterska	3	2 456 987 kr
Administratör	1	588 528 kr
ISL SOS Alarm	1	727 315 kr
Områdeschef	1	1 001 376 kr
Ambulanschef i beredskap	-	507 649 kr
Kostnad bemanning		6 624 704 kr
OH-kostnad		1 987 411 kr
Övrig kostnad för personal		
Kläder		30 000 kr
Total övrig kostnad för personal		30 000 kr
Total kostnad inkl. OH-kostnad		8 642 115 kr
Fordon		
Kvällsbil		0 kr
Total kostnad fordon		0 kr
Utbildning nyanställda steg 2		33 120
Kostnad steg 2		8 675 235 kr
Kostnad som följer med steg 1		5 995 309 kr
Total kostnad/år		14 670 544 kr

Bilaga 2 Risk och konsekvensanalys

Inför förändring i verksamheten (Ambulanssjukvård gem)



Förändring i verksamheten	Beskrivning av förändring	ID	Risk	Beskrivning av risk	Risken bedöms	Risken värderas	Friskfaktorer	Åtgärd	Beskrivning	Ansvaret för åtgärden	Skrivet klart	Tid för uppföljning	Status vid uppföljning
Alternativ transportorganisation i ambulanssjukvården	Uppdrag från sjukvårdsdirektör att undersöka förutsättningar för alternativ transportorganisation. Utredningen ger förslag på både enkelbemannade och dubbelbemannade fordon. Fordon placeras i varje ambulansområde.	1	Mycket hög prio	Ergonomi-lastning på bår	Risk för felaktiga lyft av patient vid ensamarbete	Liten	6		Vid lastning på vårdenheter eller sjukhus finns personal att tillgå för säker överflyttning. Transportambulans skall aldrig lasta patient ensam, exempelvis i bostad.		Slutdatum 2024-06-30		---
		2	Medel prio	Ergonomi- och urlastning i fordon	Risk för felaktiga lyft och snedbelastning	Liten	4		Automatisk uppdagare för Pensibär installeras i alla fordon som går att hantera för en personal.		Slutdatum 2024-06-30		---
		3	Låg prio	Hot och våld	Patient kan bli orolig under transport	Mycket liten	3		Rätt patienturval. larma ytterligare resurs vid akut händelse. Överfallsalarm i Rakel		Slutdatum 2024-06-30		---

Förändring i verksamheten	Beskrivning av förändring	ID	Risk	Beskrivning av risk	Riskbedömning	Riskvärde	Friskfaktorer	Åtgärd	Beskrivning	Ansv. ansvarig för åtgärden	Ska vara klart	Tid för uppföljning	Status vid uppföljning
		4	 Distraction vid bilkörning	Patient påkallar uppmärksamhet	Stor	12		Stanna fordonet vid närmsta tillfälle och ge patienten vård eller uppmärksamhet. Ett vanligt samtal ska kunna hållas även vid färd genom nära kontakt mellan patient och förare.			Slutdatum 2024-06-30		—
		5	 Distraction	Övervakningsutrustning larmar	Stor	12		Övervakningsutrustning placeras ej i primärt blickfång för bilkörning. Erfarenheter från lättvården tas i beaktning.			Slutdatum 2024-07-31		—
		6	 Patientsäkerhet	Patient blir sämre under färd	Mycket liten	3	Betydande	Ringklocka för patienten finns tillgänglig. Möjlighet finns att följa vitalparametrar under färd. Patienten kameraövervakas. Kontakta SOS Alarm för assistans om patienten blir sämre			Slutdatum 2024-06-30		—

Förändring i verksamheten	Beskrivning av förändring	ID	Risk	Beskrivning av risk	Riskbedömning	Riskvärde	Friskfaktorer	Åtgärd	Beskrivning	Ansv. ansvarig för åtgärden	Ska vara klart	Tid för uppföljning	Status vid uppföljning
		7	 Arbetsmiljö	Risk för långa arbetspass vilket kan medföra trötthet	Mycket liten	2		Schemaläggning med fokus på återhämtning mellan arbetspass			Slutdatum 2024-06-30		—
		8	 Arbetsmiljö	Risk för trötthet i samband med lång transportsträcka	Liten	8	Hög	Upprätta rutiner för maximala färdsträckor. Uppmana till pauser vid tillfälle			Slutdatum 2024-06-30		—

Ansvarig utredare

Rickard Joneman

Verksamhetschef

Ambulanssjukvården Region Jönköpings län

Utredningsuppdrag

Förslag till alternativ transportorganisation inom ambulanssjukvården Region
Jönköpings län

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Uppdragsbeskrivning och bakgrund

Ambulanssjukvården har under en längre tid sett ett ökat behov av transporter med kompetens och utrustning som vårdnivåmässigt ligger mellan en akutambulans och en sjukresa med Serviceresor.

Serviceresor kan i dagsläget inte erbjuda sjukvårdskompetens, vilket patientansvarig avsändande läkare allt oftare kräver vid överflyttning mellan vårdinrättning. Om patienten har ett vårdbehov så finns idag endast fullt utrustade akutambulanser samt en lättvårdsambulans. Detta försämrar ambulansens akuteredskap och tillgänglighet negativt.

Sekundärtransporter mellan sjukvårdsinrättningar har ökat både inom länet och utanför länet. Merparten av dessa transporter genomförs med akutambulanser. I många av dessa fall är patientens vårdbehov av den karaktären att en alternativ transportorganisation med sjukvårdskompetens bättre svarar mot behovet.

Uppdrag

Uppdraget innebär att utreda och lämna förslag på en alternativ transportorganisation för sekundärtransporter. Transportorganisationen föreslås finnas inom ambulanssjukvårdens regi och skall innehålla sjukvårdskompetens som motsvarar det behov som krävs, och som också skall beskrivas i utredningen. En omvärldsanalys skall göras och nödvändig statistik som kan stödja ett behov av alternativa transportsätt inom ambulanssjukvården i Region Jönköpings län skall redovisas.

Omvärldsanalys

Utredningen har tittat på både närliggande regioners organisation för sekundärtransporter men även Västra Götalands region samt Värmland.

Region Östergötland

I Östergötland är både ambulansverksamhet samt sjukresor upphandlat via privat vårdgivare. Länet har idag akutambulanser, transportambulanser, IVA-ambulans vid behov samt liggande sjuktransport.

Transportambulanserna utför tidsbestämda överflyttningar mellan vårdinrättning vardag som helg. Kompetensen är sjuksköterska plus undersköterska och tar en liggande patient. Fordonen är i stort lika som en akutambulans men saknar diverse utrustning för fixation.

Avtalet som benämns liggande sjuktransport bygger på tidskrav, därav har leverantören i uppdrag att erhålla det antal fordon som krävs. I dagsläget finns det i länet 10 fordon men alla är inte i drift samtidigt. Fordonen är aktiva både dag, kväll och natt.

Fordonen är både enkel och dubbelbemannade. Fordon med enkelbemanning tar högst en patient åt gången, dubbelbemannade fordon tar en liggande och flera sittande patienter.

Kompetensen är lägst undersköterska, finns inget krav på sjuksköterska men vårdgivaren får själv bestämma vilken kompetens som behövs. Fordonen innehåller sjukvårdsutrustning i form av defibrillator, förbandsväska och möjlighet att ge syrgas.

Region Värmland

Länet har idag en ambulansverksamhet med flera vårdnivåer. Som grund finns liggande sjuktransport som består av 11 fordon och utför sekundärtransporter. Fordonen kan transportera flera liggande patienter men ingen sittande. Bemanningen varierar från 1-2 medarbetare och kompetensen är lägst undersköterska. Fordonen är utrustade med defibrillator, möjlighet att mäta vitalparametrar samt syrgas.

Transportnivå över grund är en buss som går linjetrafik mellan sjukhus och är fullt utrustad med övervakningsutrustning, defibrillator samt läkemedel och tar både flera liggande, sittande och rullstolsburna patienter. Bussen bemannas av sjuksköterska och ambulanssjukvårdare.

Utöver detta finns flera bedömningsbilar som är fullt utrustade och bemannas av sjuksköterska som komplement till ordinarie akutambulanser.

Region Kalmar

Regionen har en lättvårdsambulans som likt Kronoberg tar en liggande och en sittande patient och fordonet bemannas av sjuksköterska. Utöver den så finns det en buss av modell större som tar en sängtransport plus upp till 29 sittande patienter. Bussen går på linje mellan sjukhusen och upp till Linköpings universitetssjukhus. Bussen bemannas av en undersköterska samt en chaufför och sköts av länstrafiken. Det finns ingen möjlighet till övervakning på bussen.

Region Kronoberg

Regionen har idag två lättvårdsambulanser utöver ordinarie akutambulanser. Liggande sjuktransport utförs av sjukresor.

Lättvårdsambulansen tar en liggande och en sittande patient och bemannas av en specialistsjuksköterska. Fordonet är utrustat i stort som en akutambulans med möjlighet till EKG-övervakning, läkemedel och syrgas. Enheterna används också som första insats då akutambulans saknas. Vårdnivån är att jämföra med vårdavdelning, likt lättvårdsambulansen i vår egen region förutom att Kronobergs fordon tar flera patienter.

Västra Götalandsregionen NU-sjukvården och Skaraborg

NU-sjukvården är i storlek på antal ambulansuppdrag och även antal akutambulanser att jämföra med Region Jönköpings län. Utöver detta har länet fyra bedömningsfordon/single responder med kompetens sjuksköterska samt sju fordon för sjuktransport för sekundäruppdrag mellan vårdinrättningar med lägst kompetens undersköterska.

Skaraborg är till antal uppdrag mindre än Region Jönköpings län och har utöver akutambulanser sex stycken fordon för sjuktransport med lägst kompetens undersköterska. Fordonen tar maximalt två patienter varav en liggande.

Västra Götalandsregionen Storgöteborg

Sahlgrenska Universitetssjukhuset driver ambulanssjukvården i storgöteborg och även om Göteborg är en storstad så är antal uppdrag drygt 1,5 gånger storleken av Region Jönköpings län med ungefärligt lika antal medarbetare. I organisationen finns en imponerande skala av vårdnivåer utöver akutambulans:

- Sjuktransport som bemannas av undersköterska
- Lättvårdstransport – undersköterska med akuterfarenhet
- Lättvårdsambulans – specialistsjuksköterska
- Bedömningsbil – specialistsjuksköterska
- Läkarstödsbil- anestesiläkare

Region Västmanland

Startar sommaren 2023 transportambulanser med bemanning undersköterska, som ska utföra sekundärtransporter mellan länets sjukhus och därmed avlasta akutambulanser. Den nystartade organisationen är väldigt lik förslaget i denna utredning.

Region Halland

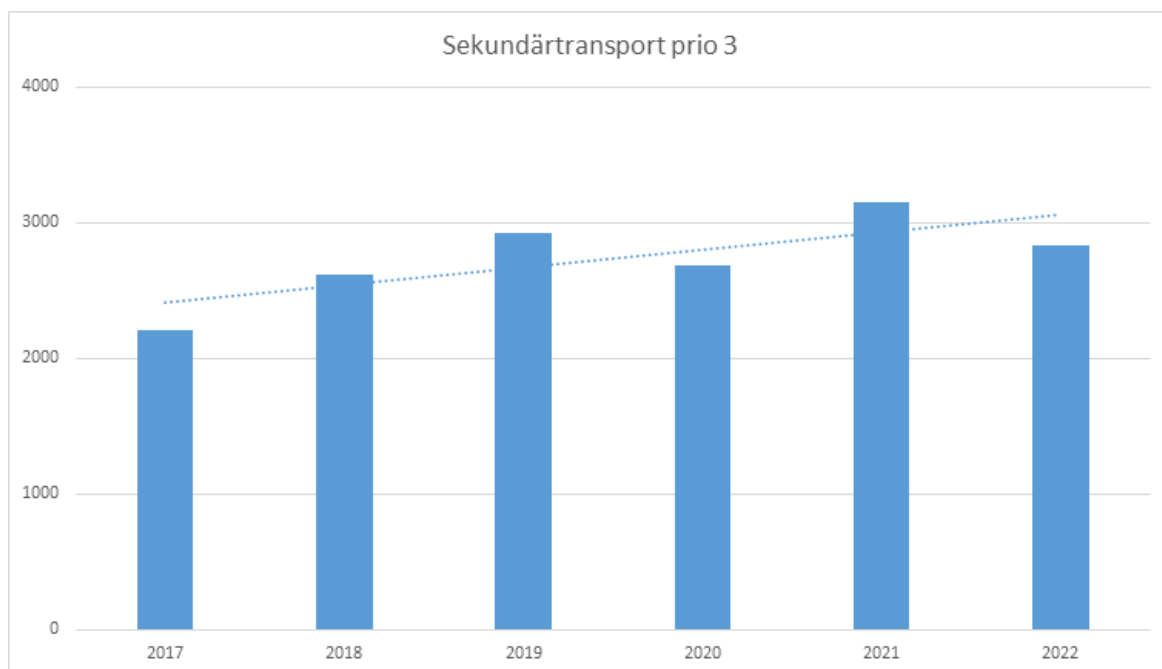
Regionen har utöver akutambulanser två stycken lättvårdsambulanser som bemannas av sjuksköterska. För liggande sjuktransport finns 5 stycken fordon som har sjukvårdsutbildad personal, de flesta av dem undersköterskor, och de tar en liggande och några sittande patienter.

Statistik och patientunderlag

Utredningen har analyserat statistik av sekundärtransporter för alla prioriteter men fokus och grundunderlag för analysen gäller transporter med prioritet 3 – tidsplanerade ej brådskande uppdrag. Dessa uppdrag kommer ligga till grund för en ny transportorganisation.

Tidsperioden för analys är senaste femårsperioden från 2017 till 2022. Antal sekundärtransporter prioritet 3 har här ökat med över 600 uppdrag eller motsvarande 27 procent, se tabell 1 nedan med trendlinje.

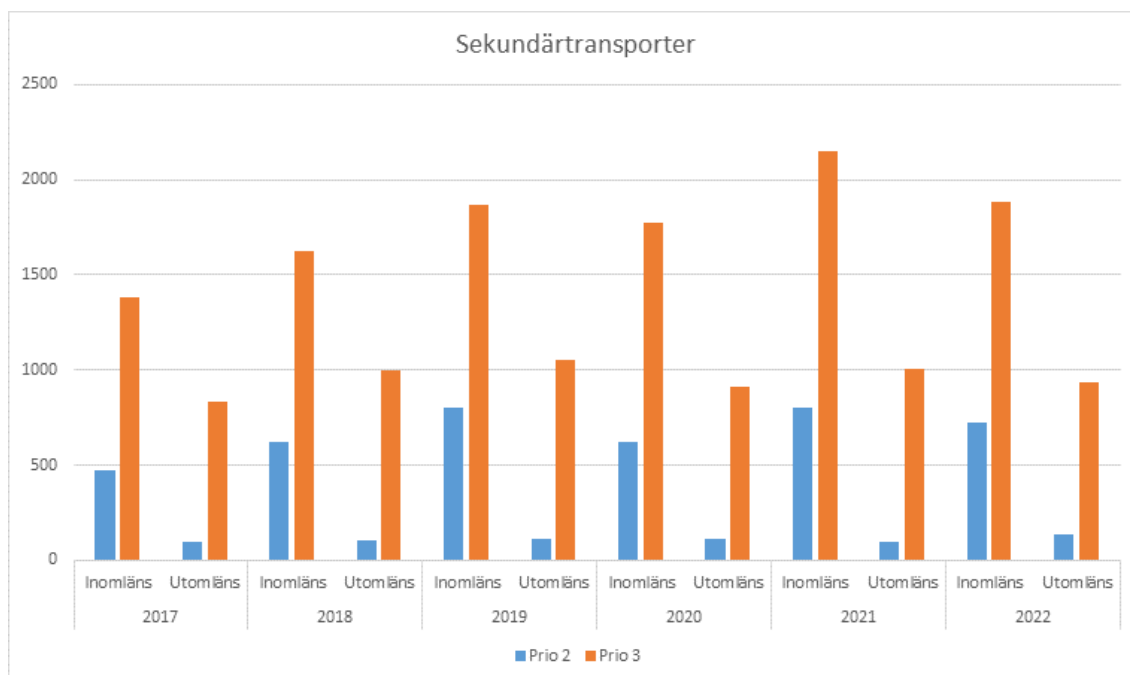
Tabell 1



Störst ökning av totala antalet sekundärtransporter (prioritet 1-3) är inom länet som har ökat med cirka 1000 uppdag eller 45 procent under femårsperioden. Utomlänstransporter har ökat med 23 procent.

Om vi även tittar på sekundärtransporter med prioritet 2, vilket i högsta grad kan vara aktuella uppdag även för en transportorganisation, så ökar underlaget ytterligare. Transporter prioritet två är exempelvis vårdnivå som kräver lättare EKG övervakning, mellan sjukhus eller från vårdcentral till sjukhus. Tabell 2 nedan visar även uppdelning mellan inom- och utomlänstransporter.

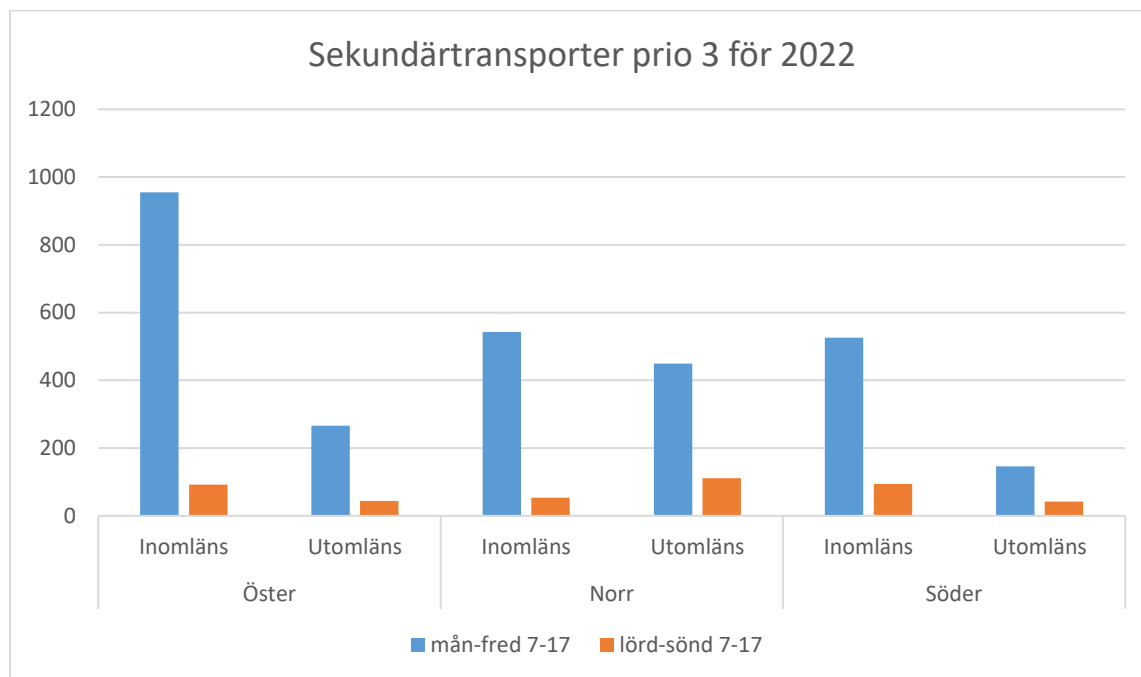
Tabell 2



En djupare analys av sekundärtransporter prioritet 3 är gjord för 2022 och uppdelat på ambulansområde norr, öster och söder. Område norr består av Jönköping, Habo och Mullsjö. Område öster av hela Höglandsregionen och till söder räknas Vaggeryd, Värnamo och Gislaved.

Majoriteten av uppdragen infaller dagtid vardagar samt helger. I tabell 3 nedan visas antal sekundärtransporter totalt, och prioritet 3 för respektive område samt för givna klockslag.

Tabell 3



En sammanställning av statistiken för åren 2017-2022 ger ett snitt på drygt 8 sekundärtransporter prioritet 3 per dag veckans alla dagar, både inom och utomläns. Vardagar är det betydligt fler, helger något färre. Varje uppdrag inom länet tar i snitt 2,5 timmar, utomlänsuppdrag cirka 4,5 timmar.

Gruppen sekundärtransporter prioritet 2 innehåller också en andel som potentiellt kan överflyttas med transportambulans. I denna grupp finns exempelvis överflyttning mellan vårdcentral/särskilt boende och sjukhus. Senaste två-års perioden är snittet cirka 2 uppdrag per dag.

Ytterligare en grupp patienter som kan överflyttas med transportambulans är de patienter som bedöms och triageras av akutambulans i hemmet. Efter genomförd undersökning så kan akutambulansen beställa transportambulans för vidare transport till sjukhus eller vårdcentral. Här finns det stor potential för att frigöra tid. Som exempel kan en patient i Smålandsstenar undersökas av en akutambulans, efter bedömning beställs en transport till sjukhus i Värnamo, och akutambulansen kan sedan vara tillgänglig i samma område och återgå till Gislaved, en tidsbesparing på ca 2 timmar.

Sammantaget finns det ett stort patientunderlag som är aktuella för denna organisation.

KPS – kapacitets och produktionsstyrning

Ambulanssjukvården har sedan 2022 implementerat arbetssättet kapacitets- och produktionsstyrning och analyserat behovet av personal och resurser kopplat till ekonomiska ramar. I analysen framkommer att varje ambulansområde har olika utmaningar relaterat till geografi och befolkningsmängd. Område öster och söder har stora avstånd som gör att varje uppdrag som kan avlastas av en transportambulans är till stor nytta för tillgängligheten.

Område norr har kortare avstånd men betydligt fler uppdrag och högre beläggning eftermiddag/kväll. I tabell 4 nedan är de fordon med högst beläggning rödmarkerade, vilket visar på fordon i Jönköping samt Nässjö och Vaggeryd. Den enkla förklaringen här är att kringliggande stationer som Nässjö och Vaggeryd utför många uppdrag i Jönköpingsområdet.

En sammanställande analys av resonemanget är att Jönköpingsområdet behöver förstärkas framförallt kvällstid. Transportambulanser kan frigöra tid från akutambulanser dagtid och möjliggöra förskjutning av akuta resurser till kvällstid när beläggningen är som störst.

I ett övergripande perspektiv sett över länet så finns det en ort som klarar den målsättning på tillgänglighet på 80 procent inom 20 minuter som råder idag, och det är Tranås med omnejd. Om vi tittar på beläggingsstatistiken för Tranås så visar den i snitt 45 procent, vilket föranleder slutsatsen att Tranås är rätt dimensionerat med rätt redundans för att hålla en bra tillgänglighet. Samma resonemang ger att när beläggningen går över 50 procent så försämras tillgängligheten och redundansen minskar.

Analysen är grunden för slutsatsen att redundansen bör öka för att öka tillgängligheten, och detta görs troligen bäst genom att frigöra tid för de akutambulanser som finns idag.

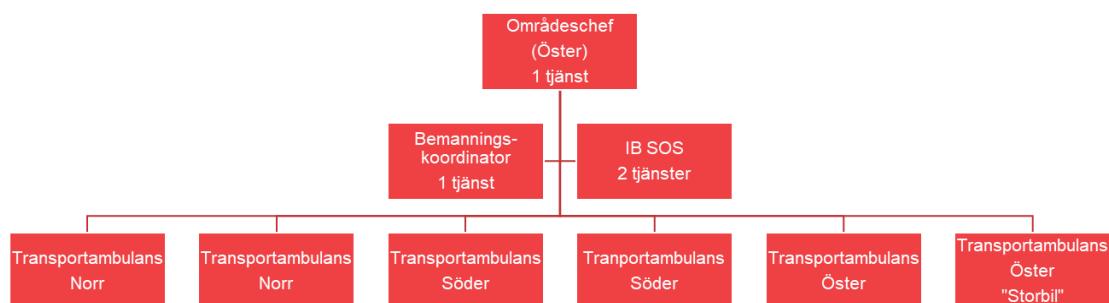
Tabell 4

Öster															
%				%				%				jan-okt			
2020	07-17	17-24	00-07	2021	07-17	17-24	00-07	2022	07-17	17-24	00-07	2022	07-17	17-24	00-07
Nässjö 9210	53,9	54,8	34,5	Nässjö 9210	54,7	60	39,1	Nässjö 9210	54,7	58	34,7	Nässjö 9210	54,7	58	34,7
9220	52,3	56,9	17,3	9220	52,8	59,3	18,4	9220	52,6	57,3	20,8	9220	52,6	57,3	20,8
Sävsjö 9250	43,9	44,5	19,4	Sävsjö 9250	46,8	49,2	22,7	Sävsjö 9250	48,5	48,9	25,3	Sävsjö 9250	48,5	48,9	25,3
Tranås 9310	40,8	36,9	24,5	Tranås 9310	43,4	46,4	31	Tranås 9310	43,5	45,5	27,8	Tranås 9310	43,5	45,5	27,8
9320	37,6	43,7	14,3	9320	41,4	46,4	13,5	9320	37	42,1	15	9320	37	42,1	15
Vetlanda 9410	47,7	48,2	28,6	Vetlanda 9410	52,8	53,3	33,9	Vetlanda 9410	52	52,9	32,7	Vetlanda 9410	52	52,9	32,7
9420	44,2	46,4	16,2	9420	46,3	50,2	16,1	9420	48,3	51,3	18,8	9420	48,3	51,3	18,8
Eksjö 9610	48	46,4	21,7	Eksjö 9610	47,7	48,7	22,9	Eksjö 9610	47,8	47,5	25,6	Eksjö 9610	47,8	47,5	25,6
9620				9620				9620				9620			
9630				9630				9630				9630			
Söder															
%				%				%				jan-okt			
2020	07-17	17-24	00-07	2021	07-17	17-24	00-07	2022	07-17	17-24	00-07	2022	07-17	17-24	00-07
Värnamo 9510	44,9	48,1	18,2	Värnamo 9510	49,3	54,8	17	Värnamo 9510	51,4	57,2	14,7	Värnamo 9510	51,4	57,2	14,7
9520	43,6	41,9	26,1	9520	50,4	42,4	31	9520	49,1	38,9	29,5	9520	49,1	38,9	29,5
9530				9530				9530				9530			
Gislaved 9710	44,3	49,2	21,2	Gislaved 9710	45,4	53,6	16,7	Gislaved 9710	45,9	52,6	15,3	Gislaved 9710	45,9	52,6	15,3
9720	41,8	41,5	28,4	9720	44,9	41,8	31,5	9720	42,4	37,8	27,2	9720	42,4	37,8	27,2
Vaggeryd 9850	45,6	49,8	18,7	Vaggeryd 9850	51,7	56,6	20,4	Vaggeryd 9850	47,8	52,5	19	Vaggeryd 9850	47,8	52,5	19
Norr															
%				%				%				jan-okt			
2020	07-17	17-24	00-07	2021	07-17	17-24	00-07	2022	07-17	17-24	00-07	2022	07-17	17-24	00-07
Jönköping 7110				Jönköping 7110				Jönköping 7110				Jönköping 7110			
9120				9120				9120				9120			
9130				9130				9130				9130			
9140	58,9	64,4	27,3	9140	60,1	75,7	27,4	9140	57,2	73,8	26,1	9140	57,2	73,8	26,1
9150	48,8	62,3	38,1	9150	56,9	56	48,2	9150	54,4	48,2	46,3	9150	54,4	48,2	46,3
9160	43,7	54,5	42,8	9160	44,9	58	38	9160	43,5	59,2	35	9160	43,5	59,2	35
Habo 9810	34,7	46,4	19	Habo 9810	41,2	48,2	18,7	Habo 9810	38,8	44,8	21,2	Habo 9810	38,8	44,8	21,2
Mullsjö 9830				Mullsjö 9830				Mullsjö 9830				Mullsjö 9830			

* De rödmarkerade siffrorna visar fordon med högst beläggning.

Organisationsförslag

Ledningsgruppen har tagit fram ett förslag på en organisationsstruktur baserat på statistikunderlag som redovisats i dokumentet. Nedan finns en schematisk bild över förslaget.



Område norr

Två stycken enkelbemannade mindre fordon inklusive den lättvårdsambulans som finns idag. Fordonen ska ta en liggande patient vardera. Arbetstider föreslås vara mellan kl. 7-17 samt 8-18 vardagar. Ett av fordonen arbetar helg enligt schema kl. 7-17.

Område söder

Två stycken enkelbemannade mindre fordon som tar en liggande patient vardera. Arbetstider föreslås likt område norr vara kl. 7-17 samt 8-18 vardagar. Ett av fordonen arbetar helg enligt schema kl. 7-17.

Område öster

Ett mindre enkelbemannat fordon som tar en liggande patient, vardagar kl. 7-17.

Ett större dubbelbemannat fordon som tar 1-2 liggande samt 1-2 sittande patienter. Detta fordon ska gå på linje vardagar mellan Eksjö- Ryhov- Linköpings universitetssjukhus, samt tillbaka samma väg på eftermiddagen. Av erfarenhet i ambulanssjukvården finns det stora vinster för länets avdelningar att ha fasta tider för transport av patienter mellan länets sjukhus, men även för avdelningar på sjukhuset i Linköping. Analys av patientunderlag ger att överlägset flest transporter beställs från Höglandssjukhuset tidig morgon, varför den fasta linjen bör utgå där från start.

Summering organisation fullt utbyggd

- 6 fordon totalt i länet inklusive dagens lättvård
- Vardagar 6 aktiva, helger 2
- 2 fordon per område (varav 1 storbil öster)
- 1 tjänst områdeschef med placering i öster
- 1 tjänst bemanningskoordinator/administrativt
- 2 tjänster IB (inre befäl, sjuksköterska) på SOS
- 2 tjänster sjuksköterska i fordon
- 11 tjänster undersköterska i fordon
- Totalt 17 tjänster (5+1 chef öster, 2 norr, 4 söder, 2 IB, 1 administrativt)

Administration

En utökning av ny organisation förutsätter tillsättandet av en områdeschef som ska fungera som närmsta chef och sköta sedvanliga uppgifter för de nya medarbetarna. Ledningsgruppen anser inte att en utökning av organisationen kan påföras ordinarie chefslinjer med risk för betydligt sämre arbetsmiljö. Kopplat till en områdeschef behövs även en

schemaläggare/bemanningskoordinator som kan sköta det administrativa kring organisationen tillsammans med övriga schemaläggare i kliniken.

Fordon

De enkelbemannade fordonen som föreslås kan vara av olika karaktär, men det finns betydande fördelar för både patient och vårdare/förare att kommunikationen underlättas genom en nära kontakt dem emellan. Lättvårdsambulansen som finns idag är ett bra exempel på en väl fungerande miljö för dessa typer av uppdrag.

Gällande upphandling och kostnadseffektivitet finns det fördelar med att ha samma typ av fordon och storlek för både de enkelbemannade samt det dubbelbemannade fordonet. Det ger även redundans vid service och andra relaterade problem.

Placeringsorter

Det mest önskvärda och logistiskt fördelaktiga är att fordonen kan placeras så nära som möjligt respektive sjukhus i länet, men inte nödvändigtvis på ambulansstationerna.

Det är av vikt att fordon finns i varje ambulansområde/sjukhusområde för att minimera transporttiden från uppställningsplats till sjukhus.

Utredningen visar på eventuella svårigheter att hitta uppställningsplatser och då framförallt garageplats till fordonen, men det bör finnas tid att undersöka detta under tiden mellan beslut och införandeprocess. Utredningen har fått förslag på möjliga garage i område norr och söder i närheten av sjukhusen. I öster är det i skrivande stund ett svårare läge, men projektledaren får undersöka detta vidare.

Sjuksköterska på SOS Alarm (IB) och logistik

En grundläggande förutsättning för en transportorganisation är att ambulanssjukvården har en egen sjuksköterska på SOS, en så kallad IB (inre befäl) funktion. Ett projekt med en sådan funktion prövas just nu under 2022-2023 och visar på stora vinster med att frigöra tid för akutambulanter. Under en 6 veckors period december-januari 2023 sparades motsvarande 153 timmars akutambulanstid, genom vårdnivåbedömning.

Ambulanssjukvårdens egen sjuksköterska kan bedöma patientens vårdbehov på helt andra grunder än en SOS operatör, vilket har visat sig under projektiden. Genom att ringa upp avsändande vårdavdelning kan patienter med lägre vårdbehov planeras med transportambulans och på det sättet frigöra tid för en akutambulans. Att bedöma vårdnivå kräver ambulanssjukvårdens kompetens och kan inte läggas på SOS Alarms operatörer, som endast prioriterar hur snabbt den vårdsökande behöver hjälp.

En ambulanssjuksköterska på SOS Alarm är också en förutsättning för vårdnivåstyrning i arbetet med god och nära vård, i en framtid med fler mobila team i sjukvården.

Utredningen lägger förslaget att transportambulanter även finns under helger, och därmed behövs även ambulanssjukvårdens sjuksköterska på SOS Alarm helgtid, vilket föranleder ett behov av två tjänster.

Vinster i tillgänglighet

Omvärldsanalys och intervjuer visar att regioner med flera vårdnivåer inom ambulansorganisationen är bättre rustade för länsinvånarnas vårdbehov och får en effektivare patientstyrning. I statistikunderlaget för Region Jönköpings län visas att de tänkta transportambulanserna med föreslagna tider, täcker upp mot 85 procent av sekundäruppdragen prioritet 3, vardag som helg. Det innebär att fordonen tillsammans tar mellan 8-12 uppdrag per dag.

Varje uppdrag inomläns har i snitt en uppdragstid på 2,5 timmar. Utomlänsuppdrag ligger på snittet 4,5 timmar. Transportambulanserna beräknas ha en snittbeläggning på mellan 80-90 procent. Denna beläggning och antal uppdrag skulle innebära att tid motsvarande 5 akutambulanser/250 timmar skulle sparas vardagar.

Tidsbesparingen på helg skulle med samma räknesätt spara tid för 1,5-2 akutambulanser. *Sammantaget kan tillgängligheten till akutambulans öka med minst 290 timmar varje vecka, vilket motsvarar samma sak som att regionen tillför 6 dagambulanser.*

Region Jönköpings län mäter tillgänglighet i andel länsinvånare som nås inom 20 minuter på prioritet 1 alarm. Snittet för 2022 blev cirka 68,5 procent. En grov uppskattning är att en alternativ transportorganisation, tillsammans med en utökad IB-funktion kan öka andelen med cirka 5 procentenheter.

Nationellt redovisas tillgänglighet via vården i siffror med data som tas från SOS Alarm. Tiden som redovisas är mediantid från besvarat samtal till första resurs på plats.

Med detta sätt att mäta når ambulanssjukvården alla kommuner i länet utom tre i dagsläget, inom 20 minuter i median. Med en alternativ transportorganisation i full drift och med detta mätesätt bör alla kommuner nås inom målsättningen.

Fordonsutrustning

Alla tänkta fordon ska vara utrustade med nödvändiga delar som behövs för de patienter som transporterats. En grunduppsättning är tänkt enligt följande:

- EKG-övervakning
- Defibrillator
- Syrgas,
- Eventuell luft för neonataltransporter
- Förbandsväska
- Pensi-bår med automatisk båruppdragare
- System för journaldokumentation, ärendehantering och navigering

Läkemedel kommer finnas tillgängligt om fordonet bemannas av sjuksköterska.

Personal och kompetens

Ingången i utredningsuppdraget är primärt att frigöra tid för de akutambulanser som finns idag, inte att tillföra mer akuta resurser.

För varje uppdrag som kan läggas på en transportambulans så ökar tillgängligheten av akutambulanser. Utredningen har i möten med framförallt hjärtvårdsavdelningen och PCI-enheten (Perkutan Coronar Intervention) som utnyttjar ambulanssjukvårdens resurser vanligtvis, efterfrågat vilken typ av övervakning och omvårdnadsbehov som de behöver för sina patienter. Denna kunskap tillsammans med analys av omvärldsbevakning har legat till grund för kompetensfrågan.

Region Östergötland har valt att avveckla sina lättvårdsambulanser med kompetens sjuksköterska till förmån för enkelbemannad liggande sjuktransport med undersköterska samt dubbelbemannade transportambulanser med kompetens undersköterska och sjuksköterska. De patienter som behöver mer avancerad vård transporteras med akutambulans.

Region Kalmar och Kronoberg har idag lättvårdsambulanser med sjuksköterska och tycker att detta koncept fungerar bra för dem, eftersom fordonen kan användas till fler typer av uppdrag. Dock saknar de en lägre vårdnivå för den stora delen av överflyttningsuppdrag.

Baserat på uppdragsbeskrivningen, analys av patientunderlag samt journalanalyser så anser ambulanssjukvårdens ledningsgrupp att det är mest resurs – och kostnadseffektivt att bemanna de mindre fordonen i första hand med lägst kompetens undersköterska. Den stora mängden av uppdrag kommer att kunna hanteras med bra omvårdnadskompetens av internutbildade undersköterskor eller ambulanssjukvårdare. Detta innebär att dagens lättvårdsambulans omvandlas till transportambulans.

I det större fordonet som är dubbelbemannat så ser dock utredningen att det kan finnas ett behov av sjuksköterska i kombination med undersköterska, för att kunna hantera patienter med mer omvårdnadsbehov framförallt till och från vårt regionsjukhus i Linköping.

Vilken kompetens fordonen bör bemannas med kan även vara en öppen fråga och kan förändras över tid beroende på samhällsutveckling och önskemål från avsändande kliniker.

Organisationen som beredskap

Händelser med många skadade är komplexa och innebär en rad utmaningar för hälso- och sjukvården. Det absoluta antalet skadade kan variera beroende på t.ex. geografi och händelsens art samt i vilken grad lokala eller regionala resurser inte räcker till för att möta vårdbehovet som uppstår. Hanteringen av masskadehändelser kräver ofta betydande mängder utrustning, personalresurser, sjuktransporter, vårdplatser, ledningsförmåga och rutiner.

”Vid händelser med många skadade eller sjuka samt vid katastrofer behöver sjukvården kunna mobilisera resurser för att möta de ökade vårdbehoven och samtidigt, så långt det är möjligt,

upprätthålla annan vård som inte kan anstå”. Så skriver utredningen om hälso- och sjukvårdens beredskap i sitt slutbetänkande (SOU 2022:6).

Vidare sammanfattar utredningen:

”Regionerna ansvarar enligt hälso- och sjukvårdslagen för att det inom regionen finns en ändamålsenlig organisation för sjuktransporter.

Regionerna behöver, var och en för sig eller gemensamt, säkerställa att hälso- och sjukvården har kapacitet att hantera sina behov av sjuktransporter. Vissa myndigheter som normalt inte utför sjuktransporter kan under vissa förutsättningar bistå hälso- och sjukvården, men det kan inte tas för givet eftersom myndigheterna i första hand är skyldiga att upprätthålla sin egen verksamhet. Deras möjligheter att stödja hälso- och sjukvården är beroende av vad som händer i samhället i övrigt.”

Jönköpings länstrafik är regionens trafikhuvudman i Jönköpings län och kan tillgodose transporter av oskadade patienter vid masskadesituationer. Det som Region Jönköpings län saknar idag är transportnivå/vårdnivå mellan busstransport och akutambulans.

En transportambulans med specialutbildad personal skulle vid en masskadesituation kunna användas som exempelvis:

- Transportör av patienter med lättare skador till sjukhus, vårdcentral eller annan offentlig anvisad plats.
- Fungera som sjukvårdsassistans och stöd vid skadeplats och uppsamlingsplats.
- Fungera som stöd till stab och ledning.
- Transportera patienter mellan sjukhus för att frigöra vårdutrymme.
- Transport av sjukvårdspersonal till skadeplats.
- Höjd förmåga vid ökad belastning i vardagen.

Utredningen som nämns ovan föreslår lagändringar i hälso- och sjukvårdslagen (2017:30):

- Regionen ska planera sin hälso- och sjukvård så att en katastrofmedicinsk beredskap upprätthålls.
- Regionen ska vid planeringen särskilt beakta behovet av beredskap för att hantera händelser som medför ett stort antal skadade eller sjuka, katastrofer samt andra händelser som allvarligt kan inverka på regionens förutsättningar att fullgöra sina skyldigheter enligt 8 kap. eller andra föreskrivna krav som gäller för hälso- och sjukvård.

Enligt Hälso- och sjukvårdslag (2017:30) ska hälso- och sjukvård erbjudas och utföras i alla lägen, utföras enligt alla rättsliga krav, och inkludera även ambulanssjukvård. Detta gäller även när det inträffar händelser eller uppkommer situationer som kan beskrivas som stor

olycka, kris, krig, extraordinära händelser i fredstid eller mycket omfattande och svåra extraordinära händelser som allvarligt kan påverka regioners verksamhet.

I Socialstyrelsens föreskrifter (SOSFS 2009:10) framgår att varje region ska upprätta en plan för ambulanssjukvården inom sitt geografiska område. Av planen ska det framgå vilka mål som har fastställts, vilka resurser som ska finnas, och hur ambulanssjukvården ska vara organiserad. Regionen ska samordna planen för ambulanssjukvården med den fredstida katastrofmedicinska beredskapsplanen och planeringen inför höjd beredskap.

Vid ett stort skadepanorama kommer ambulanssjukvården utsättas för ett massivt tryck. Det visar erfarenheten av de händelser som inträffat historiskt. Det kommer inte finnas möjlighet att använda den avancerade sjukvården som en akutambulans ger till massan av oskadade/lättare skadade patienter.

Utredningen tror att en alternativ transportorganisation kan komplettera behovet av förhöjd beredskap, både i handling och enligt regelverk i hälso- och sjukvårdslagen.

Implementering av organisation

Att starta en ny organisation kräver lång framförhållning och en noggrann planering. Fortlöpande utvärdering måste ske under resans gång, bland annat vilka effekter på tillgänglighet som införda resurser ger. Detta måste också balanseras mot behovet av beredskap enligt nationella lagkrav från Socialstyrelsen.

Organisationsförslaget kan införas fullt ut direkt, eller succesivt genom en 3-stegsmodell. Om 3-stegsmodell väljs så är det viktigt att sätta en tidsplan och arbeta proaktivt, eftersom upphandlingsfasen har mycket långa ledtider.

Steg 1

Baserat på utredningens organisationsförslag så är det mest naturliga och det som sannolikt ger effekt fortast, att som första åtgärd implementera en dubbelbemannad transportambulans på Högländet som kan ta flera patienter. Fordonet ska gå på fast linje mellan Högländssjukhuset, Ryhov och Linköpings universitetssjukhus måndag till fredag.

Steg 1 beräknas kunna införas utan att förstärka organisationen med områdeschef eller bemanningsplanering. Dock är IB på SOS Alarm en förutsättning för att kunna avgöra vårdbehov och fullt ut belägga transportambulansen med rätt patientgrupp.

Behov och kostnad för steg 1

- 1 fordon
- 2 tjänster sjuksköterska
- 2 tjänster undersköterska
- 1 tjänst IB SOS Alarm (måndag-fredag)
- Total kostnad/år **5 880 668 kr**

Steg 2

Som steg 2 i implementeringen för att möta upp behovet av sekundära överflyttningar enligt statistik och analys föreslår utredningen implementering av ytterligare 2 transportambulanser. I detta steg bör organisationen förstärkas med en ansvarig områdeschef som placeras på Högländet, som får ansvar för medarbetare i alla steg, samt bemanningsplanering. Steg 2 innebär också en förstärkning av transportambulans lördag-söndag, vilket också då kräver en utökad IB organisation.

Behov och kostnad för steg 2

- 2 fordon
- 1 tjänst områdeschef
- 5 tjänster undersköterska
- 1 tjänst IB SOS Alarm (lördag-söndag)
- 1 tjänst bemanningsplanering

Kostnad steg 2: **10 176 465 kr**

Total kostnad/år **16 024 466 kr**

Steg 3

Om utvärdering av tidigare steg visar att tillgänglighet och organisation fortfarande är i behov av förstärkning så föreslår utredningen ett sista steg till full implementation av organisationsförslaget.

Behov och kostnad för steg 3

- 2 fordon
- 4 tjänster undersköterska
- Total kostnad/år inkl. engångskostnad år 1:

Kostnad steg 3: **6 149 161 kr**

Total kostnad/år **22 140 960 kr**

En preliminär uppskattad tidsaxel efter beslut i budget är 1 år och 4 månader tills fordonen är upphandlade, levererade och startklara, vilket gäller för alla 3 steg.

Diskussion

I linje med Region Jönköpings läns ambitioner att styra patienter till rätt vårdnivå, inklusive transportnivå, så behöver ambulanssjukvården fler verktyg i verktygslådan. Nationellt har de allra flesta regioner olika vårdnivåer inom ambulanssjukvård, visar den omvärldsanalys som gjorts.

Statistiken visar att interna överflyttningar mellan länets sjukhus ökat kraftigt senaste femårsperioden, även om det var en reducering under 2022, och med ökad specialisering så lär trenden fortsätta. Avsändande läkare är av naturliga skäl restriktiva med att skicka

innetiggande patienter med sjukresa(taxi) och alternativet som då återstår är akutambulans eller den lättvårdsambulans som finns idag. En väl dimensionerad transportorganisation med utbildad sjukvårdspersonal och fordon med medicinsk utrustning skulle fylla luckan som ambulanssjukvården och övrig länssjukvård idag saknar.

Bilaga 1 Ekonomisk kalkyl

Kostnad per steg samt total kostnad/år

Steg 1	
Bemanning	4 216 556 kr
Fordon	1 631 445 kr
Utbildning	32 667 kr
Kostnad steg 1	5 880 668 kr
Total kostnad/år	
5 880 668 kr	
Steg 2	
Bemanning	6 845 008 kr
Fordon	3 298 790 kr
Utbildning	32 667 kr
Kostnad steg 2	10 176 465 kr
Kostnad från steg 1	5 848 001 kr
Total kostnad/år i steg 2	16 024 466 kr
Steg 3	
Bemanning	2 817 704 kr
Fordon	3 298 790 kr
Utbildning	32 667 kr
Kostnad steg 3	6 149 161 kr
Kostnad från steg 1 + 2	15 991 799 kr
Total kostnad/år i steg 3	22 140 960 kr

Kostnad alla steg

Bemanning

<i>Undersköterska</i>	6 300 420 kr
<i>Sjuksköterska</i>	1 434 720 kr
<i>Administratör</i>	538 020 kr
<i>IB SOS</i>	1 434 720 kr
<i>Områdeschef</i>	914 634 kr

Kostnad bemanning	10 622 514 kr

OH-kostnad	3 186 754 kr

Övrig kostnad för personal

<i>Kläder</i>	70 000 kr

Total övrig kostnad för personal	70 000 kr

Total kostnad inkl. OH-kostnad	13 879 268 kr

Fordon

<i>Småbil 1</i>	1 649 395 kr
<i>Småbil 2</i>	1 649 395 kr
<i>Småbil 3</i>	1 649 395 kr
<i>Småbil 4</i>	1 649 395 kr
<i>Storbil</i>	1 631 445 kr

Total kostnad fordon	8 229 025 kr

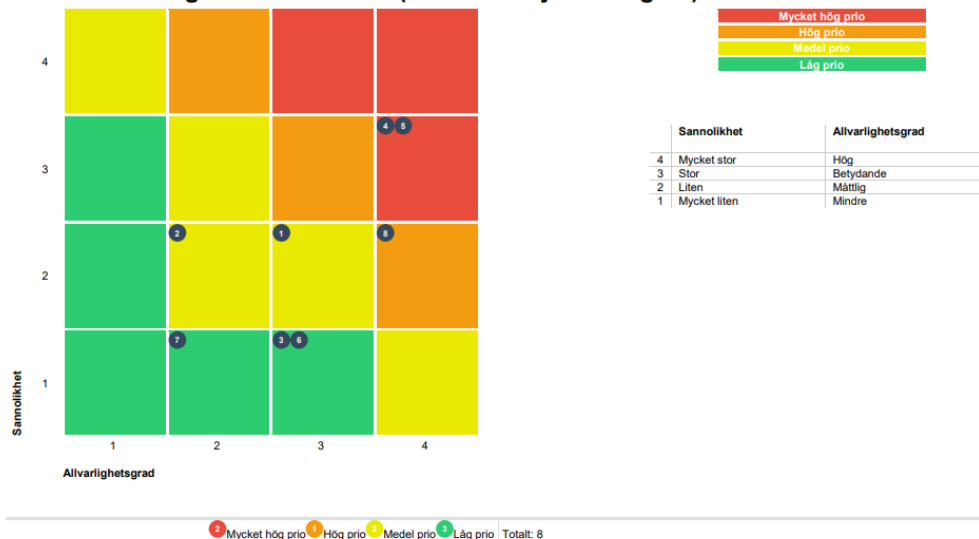
Total kostnad/år transportorganisation	22 108 293 kr

Engångskostnad utbildning första året	32 667 kr

Total kostnad/år inkl. engångskostnad första året	22 140 960 kr

Bilaga 2 Risk och konsekvensanalys

Inför förändring i verksamheten (Ambulanssjukvård gem)



Förändring i verksamheten	Beskrivning av förändring	ID	Risk	Beskrivning av risk	Riskbedömning	Risken	Friskfaktorer	Åtgärd	Beskrivning	Ansvaret för åtgärden	Skrivet klart	Tid för uppföljning	Status vid uppföljning
Alternativ transportorganisation i ambulanssjukvården	Uppdrag från sjukvårdsdirektör att undersöka förutsättningar för alternativ transportorganisation. Utredningen ger förslag på både enkelbemannade samt dubbelbemannade fordon. Fordon placeras i varje ambulansområde.	1	Ergonomi-lastning på bår	Risk för felaktiga lyft av patient vid ensamarbete	Liten	6		Vid lastning på vårdenheter eller sjukhus finns personal att tillgå för säker överflyttning. Transportambulans skall aldrig lasta patient ensam, exempelvis i bostad.			Slutdatum 2024-06-30		---
		2	Ergonomi- och urlastning i fordon	Risk för felaktiga lyft och snedbelastning	Liten	4		Automatisk uppdagare för Pensibär installeras i alla fordon som går att hantera för en personal.			Slutdatum 2024-06-30		---
		3	Hot och våld	Patient kan bli orolig under transport	Mycket liten	3		Rätt patienturval. larma ytterligare resurs vid akut händelse. Överfallsalarm i Rakel			Slutdatum 2024-06-30		---

Förändring i verksamheten	Beskrivning av förändring	ID	Risk	Beskrivning av risk	Riskbedömning	Riskvärde	Friskfaktorer	Åtgärd	Beskrivning	Ansv. ansvarig för åtgärden	Ska vara klart	Tid för uppföljning	Status vid uppföljning
		4	 Distraction vid bilkörning	Patient påkallar uppmärksamhet	Stor	12		Stanna fordonet vid närmsta tillfälle och ge patienten vård eller uppmärksamhet. Ett vanligt samtal ska kunna hållas även vid färd genom nära kontakt mellan patient och förare.			Slutdatum 2024-06-30		—
		5	 Distraction	Övervakningsutrustning larmar	Stor	12		Övervakningsutrustning placeras ej i primärt blickfång för bilkörning. Erfarenheter från lättvården tas i beaktning.			Slutdatum 2024-07-31		—
		6	 Patientsäkerhet	Patient blir sämre under färd	Mycket liten	3	Betydande	Ringklocka för patienten finns tillgänglig. Möjlighet finns att följa vitalparametrar under färd. Patienten kameraövervakas. Kontakta SOS Alarm för assistans om patienten blir sämre			Slutdatum 2024-06-30		—

Förändring i verksamheten	Beskrivning av förändring	ID	Risk	Beskrivning av risk	Riskbedömning	Riskvärde	Friskfaktorer	Åtgärd	Beskrivning	Ansv. ansvarig för åtgärden	Ska vara klart	Tid för uppföljning	Status vid uppföljning
		7	 Arbetsmiljö	Risk för långa arbetspass vilket kan medföra trötthet	Mycket liten	2		Schemaläggning med fokus på återhämtning mellan arbetspass			Slutdatum 2024-06-30		—
		8	 Arbetsmiljö	Risk för trötthet i samband med lång transportsträcka	Liten	8	Hög	Upprätta rutiner för maximala färdsträckor. Uppmana till pauser vid tillfälle			Slutdatum 2024-06-30		—

Ansvarig utredare

Rickard Joneman

Bitr. Verksamhetschef

Ambulanssjukvården Region Jönköpings län

2026-03-17

§ 40**Remiss: Europeiska kommissionens förslag på
förordning och direktiv om bioteknik - hälsa**

Diarienummer: RJL 2026/494

Beslut

Presidiet föreslår nämnden för folkhälsa och sjukvård att

- godkänna yttrandet som svar till Socialdepartementet.

Sammanfattning

Förvaltningen ser inga hinder för att reglerna för bioteknik baserad på genetiskt modifierade organismer skulle anpassas bättre till hantering av genetiskt modifierade mikroorganismer. Vad gäller förslaget gällande organtransplantation har förvaltningen inga synpunkter.

Beslutsunderlag

- Tjänsteskrivelse: Remiss – Europeiska kommissionens förslag på förordning och direktiv om bioteknik – hälsa
- Yttrande: Remiss – Europeiska kommissionens förslag på förordning och direktiv om bioteknik – hälsa
- Missiv: Europeiska kommissionens förslag på förordning och direktiv om bioteknik – hälsa
- Remiss: Europeiska kommissionens förslag på förordning och direktiv om bioteknik – hälsa
- Remiss: Europeiska kommissionens förslag på förordning och direktiv om bioteknik – hälsa

Beslutet skickas till

Nämnden för folkhälsa och sjukvård

Remiss - Europeiska kommissionens förslag på förordning och direktiv om bioteknik - hälsa

Förslag till beslut

Nämnd för folkhälsa och sjukvård

- godkänner yttrandet som svar till Socialdepartementet.

Sammanfattning

Förvaltningen ser inga hinder för att reglerna för bioteknik baserad på genetiskt modifierade organismer skulle anpassas bättre till hantering av genetiskt modifierade mikroorganismer. Vad gäller förslaget gällande organtransplantation har förvaltningen inga synpunkter.

Ärendebeskrivning

EU vill stärka sin konkurrenskraft inom bioteknik genom European Biotech Act. För att detta ska fungera föreslås ändringar i två EU-direktiv. Dels ska reglerna för genetiskt modifierade mikroorganismer anpassas och förenklas, med snabbare godkännande för lågriskprodukter, utan att tumma på säkerhet för hälsa och miljö. Dels ska reglerna för organtransplantation uppdateras så att modern bearbetning av organ regleras tydligare, med krav på tillstånd, risk–nytto-bedömning och samordning mellan myndigheter.

Sammantaget ska förslaget underlätta innovation, minska onödig administration och samtidigt behålla höga skyddsnivåer för människor och miljö.

Förvaltningen ser inte att vi som region skulle ha några invändningar mot att reglerna för bioteknik baserad på genetiskt modifierade organismer skulle anpassas bättre till hantering av genetiskt modifierade mikroorganismer. Det handlar om genetiskt modifierade mikroorganismer med låg risk.

Vad gäller organtransplantation har Region Jönköpings län inget ansvar för själva tekniken för donationen utan bara ansvar för själva patientförberedelserna för uttag. Resten hanteras av transplantationsteam från Sahlgrenska. Därför har förvaltningen inga synpunkter på reglerna för organtransplantation.

Beslutsunderlag

- Tjänsteskrivelse: Remiss – Europeiska kommissionens förslag på förordning och direktiv om bioteknik – hälsa
- Yttrande: Remiss – Europeiska kommissionens förslag på förordning och direktiv om bioteknik – hälsa
- Missiv: Europeiska kommissionens förslag på förordning och direktiv om bioteknik – hälsa
- Remiss: Europeiska kommissionens förslag på förordning och direktiv om bioteknik – hälsa
- Remiss: Europeiska kommissionens förslag på förordning och direktiv om bioteknik – hälsa

Beslutet skickas till

Socialdepartementet

Regionledningskontoret – Folkhälsa och sjukvård

Mats Bojestig
Hälso- och sjukvårdsdirektör

Anette Peterson
Bitr. hälso- och sjukvårdsdirektör

Socialdepartementet

Remiss - Europeiska kommissionens förslag på förordning och direktiv om bioteknik - hälsa

Sammanfattning

Region Jönköpings län har getts möjlighet att yttra sig över Europeiska kommissionens förslag på förordning och direktiv om bioteknik – hälsa.

Region Jönköpings län ställer sig positiv till att reglerna för bioteknik baserad på genetiskt modifierade organismer anpassas bättre till hantering av genetiskt modifierade mikroorganismer.

Region Jönköpings län lämnar inga synpunkter gällande organtransplantation.

Synpunkter på förslaget

Region Jönköpings län har inga invändningar mot att reglerna för bioteknik baserad på genetiskt modifierade organismer skulle anpassas bättre till hantering av genetiskt modifierade mikroorganismer. Det handlar om genetiskt modifierade mikroorganismer med låg risk.

Vad gäller organtransplantation har Region Jönköpings län inget ansvar för själva tekniken för donationen utan bara ansvar för patientförberedelserna för uttag. Resten hanteras av transplantationsteam från Sahlgrenska. Därför har Region Jönköpings län inga synpunkter på reglerna för organtransplantation.

Thomas Gustavsson
Ordförande i nämnden för folkhälsa
och sjukvård



Socialdepartementet

Enheten för sjukvård och läkemedelsfrågor,
Läkemedel, medicinteknik och apotek

Remiss Europeiska kommissionens förslag på förordning och direktiv om bioteknik - hälsa

Remissinstanser

1. Akademiska sjukhuset
2. Apotek Produktion & Laboratorier AB
3. Arbetsmiljöverket
4. AstraZeneca AB
5. ATMP Sweden
6. Barncancerfonden
7. Boverket
8. Bristol Myers Squibb
9. Cancerfonden
10. CCRM Nordic
11. Chalmers tekniska högskola AB
12. Cytiva
13. E-hälsomyndigheten
14. Etikprövningsmyndigheten
15. Finansinspektionen
16. Finspångs kommun
17. Folkhälsomyndigheten
18. Formas
19. Forte

20. Föreningen för Generiska läkemedel och Biosimilarer
21. Företagarna
22. Försäkringskassan
23. Försvarsmakten
24. Förvaltningsrätten i Stockholm
25. Farmaciförbundet
26. Funktionsrätt Sverige
27. Genomics Medicine Sweden
28. Gentekniknämnden
29. Göteborgs kommun
30. Göteborgs universitet
31. Handelshögskolan i Stockholm
32. Havs- och vattenmyndigheten
33. Hjärt-Lungfonden
34. Huddinge kommun
35. Härjedalens kommun
36. IKEM – Innovations- och kemiindustrierna i Sverige
37. Inspektionen för vård och omsorg
38. Integritetsskyddsmyndigheten
39. Karlstads universitet
40. Karolinska Institutet
41. Karolinska Universitetssjukhuset
42. Kemikalieinspektionen
43. Kommerskollegium
44. Konkurrensverket
45. Krka Sverige AB
46. Kungliga Tekniska högskolan
47. Linköpings kommun
48. Linköpings universitet
49. Linnéuniversitetet

50. Luleå kommun
51. Luleå tekniska universitet
52. Lunds kommun
53. Lunds universitet
54. Läkarförbundet
55. Läkemedelsdistributörsföreningen
56. Läkemedelshandlarna
57. Läkemedelsindustriföreningen
58. Läkemedelsverket
59. Malmö kommun
60. Malmö universitet
61. Medicon Valley
62. Merck Sharp & Dohme (MSD) Sverige
63. Mittuniversitetet
64. Myndigheten för civilt försvar
65. Mälardalens universitet
66. Mölndals kommun
67. Naturvårdsverket
68. Nordic X Biologics
69. Norrlands universitetssjukhus
70. Näringslivets Regelnämnd
71. Orifarm AB
72. Patent- och registreringsverket
73. Pfizer Sverige
74. Post- och telestyrelsen
75. Regelrådet
76. Region Blekinge
77. Region Dalarna
78. Region Gotland
79. Region Gävleborg

80. Region Halland
81. Region Jämtland Härjedalen
82. Region Jönköpings län
83. Region Kalmar län
84. Region Kronoberg
85. Region Norrbotten
86. Region Skåne
87. Region Stockholm
88. Region Sörmland
89. Region Uppsala
90. Region Värmland
91. Region Västerbotten
92. Region Västernorrland
93. Region Västmanland
94. Region Örebro län
95. Region Östergötland
96. Regionala Cancer Centra (RCC)
97. Regionernas Ömsesidiga Försäkringsbolag (Löf)
98. Reumatikerförbundet
99. RISE Research Institutes of Sweden AB
100. Roche AB
101. Sahlgrenska Universitetssjukhuset
102. Sanofi Sverige
103. SciLifeLab
104. Socialstyrelsen
105. Solna kommun
106. Skogsstyrelsen
107. Skånes universitetssjukhus
108. Statens Jordbruksverk
109. Statens medicinsk-etiska råd (SMER)

- 110.Stockholms kommun
- 111.Stockholms universitet
- 112.Strålsäkerhetsmyndigheten
- 113.Swedac
- 114.SwedenBIO
- 115.Swedish Medtech
- 116.Svenska Diabetesförbundet
- 117.Svenska Läkaresällskapet
- 118.Svenskt Näringsliv
- 119.Svenskt Vatten
- 120.Sveriges Apoteksförening
- 121.Sveriges Farmaceuter
- 122.Sveriges Kommuner och Regioner
- 123.Sveriges lantbruksuniversitet
- 124.Swedish Orphan Biovitrum
- 125.Södertälje kommun
- 126.Tamro AB
- 127.Tandvårds- och läkemedelsförmånsverket
- 128.Testa Center
- 129.Teva Sverige AB
- 130.Totalförsvarets Forskningsinstitut
- 131.Umeå kommun
- 132.Umeå universitet
- 133.Universitetssjukhuset i Linköping
- 134.Universitetssjukhuset i Örebro
- 135.Upphandlingsmyndigheten
- 136.Uppsala kommun
- 137.Uppsala universitet
- 138.Verket för innovationssystem
- 139.Vetenskapsrådet

140. Vårdförbundet

141. Västra Götalandsregionen

142. Örebro kommun

143. Örebro universitet

Remissvaren ska ha kommit in till Socialdepartementet **senast den 7 april 2026**. Svaren bör lämnas per e-post till s.remissvar@regeringskansliet.se och med kopia till s.sl@regeringskansliet.se. Ange diarienummer S2026/00180 och remissinstansens namn i ämnesraden på e-postmeddelandet.

Svaret bör lämnas i två versioner: den ena i ett bearbetningsbart format (t.ex. Word), den andra i ett format (t.ex. pdf) som följer tillgänglighetskraven enligt lagen (2018:1937) om tillgänglighet till digital offentlig service. Remissinstansens namn ska anges i namnet på respektive dokument.

Remissvaren kommer att publiceras på regeringens webbplats.

Cecilia Halle
Departementsråd



EUROPEAN
COMMISSION

Strasbourg, 16.12.2025
COM(2025) 1031 final

2025/0405 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**amending Directives 2001/18/EC and 2010/53/EU as regards the placing on the market
of genetically modified micro-organisms and the processing of organs**

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

This proposal accompanies the Regulation (EU) .../... [European Biotech Act], which establishes a legislative framework to strengthen the competitiveness of the health biotechnology sector. That Regulation creates and reinforces favourable conditions for health biotechnology, from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety, and biosecurity. For the purposes of that Regulation, health biotechnology means the application of biotechnology for the promotion, protection, or restoration of human health and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public-health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union. The overall context, rationale and objectives of that horizontal initiative are set out in detail in its accompanying Explanatory Memorandum. In order for the new framework to operate effectively within the existing acquis, targeted updates are required in two pieces of sectoral legislation.

Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms¹

Genetically modified micro-organisms (GMMs) play a decisive role in biotechnology, both as a tool for manufacturing but also as products themselves. Micro-organisms reproduce and grow rapidly and can be easily engineered. Their applications are broad and diverse and go well beyond the health sector. Products explored for agri-food use include novel biofertilisers and biopesticides, biological food preservatives, and biosensors registering the contamination of food products. In the industrial sector GMMs can be used to remove harmful chemicals and gases, including CO₂, from effluents and emissions or to recover valuable metals like gold or lithium from electronics and battery waste. Similar GMMs can also be used in environmental applications to restore soil health and water quality. Also, applications to modulate the gut microbiome of cattle to reduce methane emissions are explored. A number of these products are already commercialised or in later stages of development in third countries, notably the USA and China. Together, these products could have a substantial impact on the EU economy and competitiveness, and contribute to, for example, the reduction of greenhouse gas emissions, the use of more sustainable tools in agriculture, the reduction of food waste, the removal of residues of pesticide and medicines use from the environment or the combat of antimicrobial resistance.

The development time and costs for a GMM are much lower compared to other genetically modified (GM) organisms such as GM plants. Hence, the regulatory framework needs to ensure that GMMs and their derived products reach the Union market before becoming obsolete.

¹ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms, and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1, ELI: <http://data.europa.eu/eli/dir/2001/18/oj>).

To unlock the innovation potential of GMMs and to render the EU market more attractive for their development, production and marketing, it is necessary to make the applicable rules on GMMs fit for purpose. Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (GMOs) was primarily designed to regulate GM plants, making it less suitable for GMMs, which differ significantly from plants in terms of biological properties and capabilities as well as potential applications.

Directive 2010/53/EU on quality and safety of human organs intended for transplantation²

The area of solid organ transplantation, which forms part of the broader domain of Substances of Human Origin (SoHO), is subject to continuous innovation, in particular through technologies aimed at expanding the ex-vivo time window between procurement from the donor and transplantation into the recipient. The extension of this time window creates opportunities for applying different types of processing operations to maintain or improve the functional status of organs prior to transplantation. To achieve legal certainty, this Act introduces provisions clarifying how these processing activities can be organised under the oversight of the transplant authorities. Where such processing involves medicinal products, medical devices or SoHO preparations, transplant authorities shall collaborate closely with the corresponding competent authorities with the relevant expertise in those areas, ensuring coherent oversight and coordinated regulatory implementation.

- **Consistency with existing policy provisions in the policy area**

The targeted amendments to Directive 2001/18/EC are consistent with the overall objectives of that Directive, namely, to ensure a high level of protection of human health and the environment in the deliberate release and placing on the market of GMOs and to ensure the effective functioning of the internal market. The adjustments proposed here have the aim of creating a tailored, more efficient and streamlined regulatory framework for GMMs. They relate to the risk assessment, to the validity of the consent granted for their placing on the market, and to detection methods applicable to all GMMs, as well as to the introduction of the concept of low-risk GMMs, including scientific criteria confirming this status, and set a framework for a streamlined authorisation procedure for eligible low-risk GMMs. These measures to be introduced reflect recent scientific assessments and are in line with scientific and technical progress after the adoption of the Directive.

The amendments to Directive 2010/53/EU are likewise consistent with its objective of ensuring high standards of quality and safety of human organs intended for transplantation. Clarifying the regulatory treatment of organ processing activities and strengthening oversight mechanisms aligns the Directive with current clinical practice and supports coordinated implementation across Member States.

Together, these targeted amendments preserve the protection objectives of the existing legislation while contributing to the objectives of the Biotechnology Act.

² Directive [2010/53/EU](http://data.europa.eu/eli/dir/2010/53/oj) of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6.8.2010, p. 14, ELI: <http://data.europa.eu/eli/dir/2010/53/oj>).

- **Consistency with other Union policies**

The proposal supports the wider objectives of the European Biotechnology Act, which forms part of the Union's strategic efforts to strengthen competitiveness, innovation capacity and the safe development of biotechnology across sectors. The proposal contributes to a more consistent, inclusive and predictable regulatory environment for biotechnology applications in the Union.

The amendments to Directive 2001/18/EC are coherent with Union policies promoting science-based risk assessment and proportionate regulatory requirements, including the work of the European Food Safety Authority (EFSA) in the area of GMMs. They also complement Union initiatives aimed at supporting research, innovation and the safe use of biotechnology in industrial, environmental and health-related applications.

The amendments to Directive 2010/53/EU are consistent with broader Union policies on public health, quality and safety of medical treatments, and the effective functioning of cross-border healthcare systems. By clarifying the regulatory treatment of organ processing technologies, the proposal supports coordinated implementation across Member States and complements Union actions in adjacent areas, such as medicinal products, medical devices and substances of human origin.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

- Article 114 of the Treaty on the Functioning of the European Union ('TFEU') which provides the basis to take measures for the approximation of laws which have as their object the establishment and functioning of the internal market. In accordance with Article 114(3) TFEU, the proposal seeks to achieve the objective of a high level of health and safety protection;
- Article 168(4) TFEU, concerning the achievement of a high level of human health protection through the adoption, in order to meet common safety concerns, of measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; in the veterinary and phytosanitary fields which have as their direct objective the protection of public health; and measures setting high standards of quality and safety for medicinal products and devices for medical use.

- **Subsidiarity (for non-exclusive competence)**

In accordance with the principle of subsidiarity, in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States.

The requirements for the placing on the market of GMMs as or in products are already harmonised at Union level under the existing legal framework applicable to GMOs. For the reasons explained above, the regulatory framework needs to be adapted to the specificities of GMMs. To this end, action needs to be taken by the Union by amending Directive 2001/18/EC.

To achieve the goals outlined above, an amendment to Directive 2010/53/EU is necessary, which can only be done at Union level.

- **Proportionality**

The proposal does not go beyond what is necessary to ensure the main objectives of Regulation (EU) .../... [European Biotech Act] and the existing sectoral legislation are met, namely safeguarding high standards for the protection of human health, animal health, patients and consumers, and the environment, while strengthening the competitiveness of the biotechnology sector.

Moreover, as regards the amendment of Directive 2001/18/EC, the proposal ensures proportionality by providing for the adaptation of risk assessment and other requirements to reflect the specificity of GMMs and creating tailored provisions for low-risk GMMs. These adaptations are intended to ensure that the applicable requirements do not go beyond what is necessary to ensure the legislation's objectives, and in particular a high level of safety for human health and the environment.

- **Choice of the instrument**

Since the proposal amends existing directives, a Directive is the appropriate instrument. This ensures that the necessary adjustments are made directly to Directives 2001/18/EC and 2010/53/EU while preserving their legal structure and transposition mechanisms.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks**

The Commission published in 2021 a study on new genomic techniques ('NGTs') applied to plants, animals and micro-organisms³, which concluded that data was still too limited to take any policy actions in this area. The study identified limitations to the capacity of the GMO legislation to keep pace with scientific developments that cause implementation challenges and legal uncertainties. It concluded there were indications that the applicable legislation needed to be adapted to scientific and technological progress. As follow-up to the study, the Commission adopted a legal proposal on plants obtained by certain NGTs⁴. However, for other NGTs and for applications in other organisms, including micro-organisms, the study concluded that the necessary scientific knowledge was still limited or lacking, especially on safety aspects.

To address these knowledge gaps, the Commission requested EFSA and the European Union Reference Laboratory for genetically modified food and feed and the European Network of GMO laboratories (ENGL) to deliver reports on micro-organisms.

On 19 June 2024, EFSA adopted an opinion on the application of new developments in biotechnology to micro-organisms, in which it concluded that possible hazards relate to the changes introduced, regardless of the method used, and that the risk assessment should be based on the characteristics of the product containing or consisting of micro-organisms. It also

³ Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16, SWD(2021) 92 final.

⁴ COM(2023) 410 final.

concluded that for certain GMMs fewer requirements for risk assessment would be needed compared to those applicable to GMOs in general⁵ and provided some criteria to identify those GMMs⁶.

The EURL-ENGL delivered its report on the detection of micro-organisms obtained with NGTs⁷ in 2025, pointing to certain challenges due to technical difficulties and to the fact that in some instances similar modifications to those obtained with NGTs may also occur naturally.

This opinion and report provide relevant scientific evidence for this proposal. EFSA's wider work on micro-organisms has also been taken into account⁸.

For organ transplantation, implementation experience with Directive 2010/53/EU has shown the emergence of increasingly sophisticated organ preservation and processing technologies, which are not fully covered by the existing provisions but have clear implications for quality, safety and oversight.

In addition, the Commission has drawn on contacts with competent authorities, transplantation centres, industry and research organisations, which have stressed both the innovation potential of organ processing and the need for legal clarity and proportionate, science-based requirements.

• Stakeholder consultations

Concerning Directive 2001/18/EU, an external study commissioned by the European Commission is being carried out (**'Analysis of the Regulatory Framework for Biotechnology and Biomanufacturing in the EU'**)⁹. The study provides an extensive mapping of the main EU and national legislations that apply to biotechnology and biomanufacturing products and processes – whether they are horizontal or sector-specific – and identifies, through surveys, interviews and workshops, the challenges, their causes and consequences for stakeholders. The study also assesses the impacts of policy options related to the EU regulatory framework. Evidence on the impacts of options on **genetically modified micro-organisms** has been collected through **25 interviews** (by November 2025).

⁵ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins, E., Bresson, J.-L., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Moreno, F. J., Naegeli, H., Nogué, F., Rostoks, N., Sánchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Cocconcelli, P. S., Glandorf, D., Herman, L., Dalmay, T. (2024). New developments in biotechnology applied to microorganisms. EFSA Journal, 22(7), e8895; point 4: <https://doi.org/10.2903/j.efsa.192024.8895>

⁶ EFSA Scientific Committee, Bennekou, S. H., Allende, A., Bearth, A., Casacuberta, J., Castle, L., Coja, T., Crépet, A., Halldorsson, T. I., Hoogenboom, R., Jokelainen, P., Knutsen, H. K., Lambré, C., Nielsen, S. S., Turck, D., Civera, A. V., Villa, R. E., Zorn, H., Gómez, M. A., ... Glandorf, B. (2025). Guidance on the characterisation of microorganisms in support of the risk assessment of products used in the food chain. EFSA Journal, 23(11), e9705. <https://doi.org/10.2903/j.efsa.2025.9705>

⁷ Sowa, S., Broothaerts, W., Burns, M., De Loose, M., Debode, F. et al., Detection of microorganisms, obtained by new genomic techniques, in food and feed products, Publications Office of the European Union, Luxembourg, 2025, <https://data.europa.eu/doi/10.2760/1846532>, JRC143597

⁸ EFSA Scientific Committee, Bennekou, S. H., Allende, A., Bearth, A., Casacuberta, J., Castle, L., Coja, T., Crépet, A., Halldorsson, T. I., Hoogenboom, R., Jokelainen, P., Knutsen, H. K., Lambré, C., Nielsen, S. S., Turck, D., Civera, A. V., Villa, R. E., Zorn, H., Gómez, M. A., ... Glandorf, B. (2025). Guidance on the characterisation of microorganisms in support of the risk assessment of products used in the food chain. EFSA Journal, 23(11), e9705. <https://doi.org/10.2903/j.efsa.2025.9705>.

⁹ Impact assessment supporting study – Analysis of the regulatory framework for biotechnology and biomanufacturing in the EU; request for service No 1005/PP/GRO/IMA/24/2129/14500

Furthermore, stakeholders' views on GMMs expressed in the calls for evidence related to the Biotech Act¹⁰ and the Food and Feed Safety Simplification Omnibus¹¹ stressing the recent innovations regarding GMMs and underlining the necessity to adapt the GMO framework to these developments have been taken into account.

Finally, targeted consultation activities are also being conducted in the context of the **supporting study for the evaluation of the European Food Safety Agency**¹².

- **Impact assessment**

Considering the political urgent need to address the policy challenges identified in the European Biotech Act (Regulation (EU) .../...), an impact assessment could not have been delivered in the timeframe available before the proposal's adoption. Instead, an analytical Staff Working Document (SWD) will be prepared. The analytical SWD will explain the proposal and will present the underlying evidence and impact analysis, including a cost–benefit assessment.

The provisions of the proposal concern simplification measures which typically do not offer viable alternatives and do not modify the objectives of the amended legislation. Nevertheless, the underlying policy rationale, options considered and supporting evidence were developed through stakeholder consultations and analyses conducted during the preparation of the European Biotech Act.

- **Regulatory fitness and simplification**

The proposal is part of the European Biotechnology Act having the main policy objectives of, *inter alia*, modernising and simplifying the regulatory framework, removing duplications and unnecessary administrative steps. The proposal is therefore aiming at improving the regulatory landscape of the biotechnology sector and reducing unnecessary burdens and costs for businesses and authorities, without undermining the protection of human health and the environment.

- **Fundamental rights**

The proposal respects the rights and principles enshrined in the Charter of Fundamental Rights of the European Union and does not undermine the level of protection of human health, animal welfare or the environment guaranteed under the existing legislative framework.

4. BUDGETARY IMPLICATIONS

The proposal has no direct implications for the Union budget.

¹⁰ European Commission Have Your Say website: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14627-Biotech-Act_en.

¹¹ European Commission Have Your Say website: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14824-Food-and-feed-safety-simplification-omnibus_en

¹² [Performance Evaluation of European Food Safety Authority - Food Safety: https://food.ec.europa.eu/horizontal-topics/general-food-law/performance-evaluation-european-food-safety-authority_en](https://food.ec.europa.eu/horizontal-topics/general-food-law/performance-evaluation-european-food-safety-authority_en)

5. OTHER ELEMENTS

- **Detailed explanation of the specific provisions of the proposal**

Amendments to Directive 2001/18/EC (genetically modified micro-organisms)

This Directive introduces specific provisions in Part C of Directive 2001/18/EC on the placing on the market of GMMs as or in products other than food and feed with the aim of creating a tailored, more efficient and streamlined regulatory framework for GMMs while maintaining a high safety level for human health and the environment.

The provisions proposed relate to the risk assessment, to the validity of the consent granted for their placing on the market, and to detection methods applicable to all GMMs. In relation to a tailored risk assessment, provision is made for the information requirements in Annex III of Directive 2001/18/EC to be amended by delegated act in order to adapt them to the specificities of GMMs, respecting the general principles for the environmental risk assessment of Annex II of Directive 2001/18/EC. The validity of consent granted by the competent authorities would last for an unlimited period of time for GMMs. The modalities to comply with detection method requirements in cases where it is not feasible to provide a method that detects, identifies and quantifies are also adapted in the proposal.

Further, the proposal would also introduce the concept of low-risk GMMs, including scientific criteria confirming this status, and set a framework for a streamlined authorisation procedure for eligible low-risk GMMs. It is proposed that, by way of delegated acts, the Commission supplements the low-risk criteria and amends the Directive to adapt the risk assessment information requirements in Annex III and certain procedural elements. The requirement for post-market environmental monitoring of low-risk GMMs is equally adapted in the proposal, providing the possibility to a notifier, based on certain conditions, to propose to omit post-market environmental monitoring.

Amendments to Directive 2010/53/EU (organ processing)

Scope

The scope of Directive 2010/53/EU is amended to expressly include processing alongside donation, testing, characterisation, procurement, transport and transplantation, and to clarify that where organs are used for research purposes, the Directive applies only where they are intended for transplantation into the human body.

Definitions

The definition of “transplantation” is adjusted to reflect a process intended to restore certain functions of the human body by transferring an organ to a recipient.

A new definition of “processing” is added, covering operations involving the handling of organs, including but not limited to preservation, application of chemotherapy and surgery, performed to maintain or improve organ function prior to transplantation. The definition excludes:

- preparatory handling during the surgical transplantation intervention;
- the repurposing of organs into tissues or cells;

- the use of substances with a pharmacological, immunological or metabolic action where the primary aim is to treat or prevent a disease in the recipient and not to process the organ.

Organ processing regime (new Article 6a)

A new Article 6a:

- requires transplantation centres to obtain prior authorisation from the competent authority before applying a processed organ to a recipient, with an exception for clinical outcome monitoring plans forming part of a processed organ authorisation;
- obliges transplantation centres to perform a benefit–risk assessment of the processing, including the intended clinical indication;
- provides that where evidence is limited or risks are significant, the benefit–risk assessment and a clinical outcome monitoring plan must be submitted for approval by the competent authority;
- requires competent authorities, where processing involves a medicinal product, medical device or SoHO preparation, to verify that this product or preparation used is authorised or certified under the relevant Union framework (Directive 2001/83/EC of the European Parliament and of the Council¹³, Regulation (EC) No 726/2004 of the European Parliament and of the Council¹⁴, Regulation (EU) 2017/745 of the European Parliament and of the Council¹⁵ and Regulation (EU) 2024/1938 of the European Parliament and of the Council¹⁶, and to cooperate with the authorities designated under those frameworks, including on clinical outcome data;
- requires the Commission to publish a list of authorised organ processing operations, including where relevant associated products;
- empowers the Commission to adopt implementing acts specifying detailed rules for organ processing authorisation, in accordance with the comitology procedure referred to in Article 30(2) of Directive 2010/53/EU.

Annex Part B

Information required to characterise an organ and a donor is laid down in Annex to Directive 2010/53/EU including a Part A (minimum data) and Part B (complementary data). Part B is amended to add “Processing” as a step applied to the organ with the aim of improving its

¹³ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67, ELI: <http://data.europa.eu/eli/dir/2001/83/2025-01-01>

¹⁴ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, p. 1, ELI: <http://data.europa.eu/eli/reg/2004/726/oj>.

¹⁵ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>.

¹⁶ Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC, OJ L, 2024/1938, 17.7.2024, ELI: <http://data.europa.eu/eli/reg/2024/1938/oj>.

functional status and potentially affecting its quality and safety, with examples such as preservation, application of chemotherapy and surgery.

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directives 2001/18/EC and 2010/53/EU as regards the placing on the market of genetically modified micro-organisms and the processing of organs

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Regulation (EU) .../... [European Biotech Act] establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union, from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity. For the purposes of that Regulation, health biotechnology means the application of biotechnology for the promotion, protection, or restoration of human health and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public-health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union.
- (2) Given that the objectives of Directive 2001/18/EC of the European Parliament and of the Council³ and Directive 2010/53/EU of the European Parliament and of the Council⁴ are closely linked to those of Regulation (EU) .../... [European Biotech Act], and considering that, since the adoption of those Directives, significant progress in biotechnology has taken place, it is appropriate to adapt them in order to align with new technological realities and with the objectives and provisions laid down in

¹ OJ C , , p. .

² OJ C , , p. .

³ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms, and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1, ELI: <http://data.europa.eu/eli/dir/2001/18/oj>)

⁴ Directive [2010/53/EU](http://data.europa.eu/eli/dir/2010/53/oj) of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6.8.2010, p. 14, ELI: <http://data.europa.eu/eli/dir/2010/53/oj>)).

Regulation (EU) .../... [European Biotech Act]. Those adaptations are intended to improve consistency, legal clarity and the smooth functioning of the Union legislative framework for biotechnology, and eventually to ensure the availability of safe and high-quality therapies and other products for Union citizens.

- (3) Genetically modified micro-organisms (GMMs), such as bacteria, algae, fungi and viruses, as or in products for uses other than food and feed are subject to the requirements of Directive 2001/18/EC. Since the adoption of that Directive, significant progress in biotechnology has taken place, and GMMs can now be used for example as or in fertilisers, biocontrol, bioremediation, wastewater treatment, biomining and bioleaching, offering benefits in the wider agri-food, industrial and environmental sectors.
- (4) Following a Commission mandate, on 19 June 2024, the European Food Safety Authority ('the Authority') adopted an opinion on the application of new developments in biotechnology to micro-organisms⁵. It concluded that possible hazards relate to the changes introduced, regardless of the method used, and that the risk assessment should be based on the characteristics of the product containing or consisting of micro-organisms. It also concluded that for certain GMMs, fewer requirements for risk assessment would be needed compared to those applicable to GMOs in general. Finally, the Authority considered that, for certain GMMs, the need for post-market environmental monitoring (PMEM) may be waived based on the environmental risk assessment.
- (5) Considering that Directive 2001/18/EC was primarily designed to regulate genetically modified plants obtained by certain established genomic techniques, in particular techniques that introduce into an organism genetic material from non-crossable species (transgenesis) and taking into account the Authority's conclusions on GMMs, as well as the biological properties, capabilities and potential applications of GMMs, which differ significantly from those of plants, Directive 2001/18/EC should be adapted to the specificities of GMMs to enable innovative products to reach the market before they become obsolete and without disproportionate authorisation costs, while maintaining a high level of safety.
- (6) For that reason, Directive 2001/18/EC should be amended to introduce specific provisions applicable to the placing on the market of GMMs with the aim of creating a tailored, more efficient and streamlined legislative framework, while maintaining a high level of safety for human health and the environment. Considering that possible hazards relate to the changes introduced into the genome of a micro-organism regardless of the method used, and that micro-organisms are often modified through a combination of different techniques, including both established and new genomic techniques⁶, those provisions should cover GMMs in general without focus on specific techniques.

⁵ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins, E., Bresson, J.-L., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Moreno, F. J., Naegeli, H., Nogué, F., Rostoks, N., Sánchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Cocconcelli, P. S., Glandorf, D., Herman, L., Dalmay, T. (2024). New developments in biotechnology applied to microorganisms. EFSA Journal, 22(7), e8895; point 4: <https://doi.org/10.2903/j.efsa.192024.8895>

⁶ Parisi, C., Rodríguez-Cerezo, E., Current and future market applications of new genomic techniques, EUR 30589 EN, Publications Office of the European Union, Luxembourg, 2021, ISBN 978-92-76-30206-3, doi:10.2760/02472, JRC123830.

- (7) For the purpose of Directive 2001/18/EC, the definitions of ‘micro-organism’ and ‘GMM’ should be based on those of Directive 2009/41/EC of the European Parliament and of the Council⁷ with the exclusion of animal and plant cells in culture. In order to ensure that the overall applicable framework on GMOs remains consistent, animal and plant cells should be subject to the same rules, regardless of whether they are in culture, not in culture or embedded in the complete organisms. The specific provisions should therefore cover only micro-organisms in the biological sense, including the taxonomic groups Archaea and Bacteria, the unicellular species and life stages of Protozoa, Chromista and Fungi, as well as filamentous fungi and viruses, while excluding animal and plant cells in culture.
- (8) To reflect the specific properties of GMMs, the information requirements as set down in Annex III to Directive 2001/18/EC to be used in the risk assessment should be adapted based on the available information and evidence in relation to GMMs, while respecting the principles for the environmental risk assessment of GMOs laid down in Annex II to that Directive. In order to carry out those adaptations, the power to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending the information requirements laid down in Annex III to the Directive.
- (9) Considering that the product cycles of GMMs are very short and new generation GMMs are developed in short timeframes, with new products building on the experience gained with previous ones, including as regards the risk assessment, the limitation of the period of validity of the consent laid down in Directive 2001/18/EC implies a burden for operators and national competent authorities while bringing limited value to the safety of such products given the short life-time of those products. Directive 2001/18/EC already lays down measures to ensure that any new relevant information is provided by the notifier, as well as safeguard measures in case new risks are identified. Therefore, Directive 2001/18/EC should provide that consents granted for the placing on the market of GMMs should be valid for an unlimited period of time. Any measures necessary to protect human health and the environment should continue to be adopted anytime where such consents granted do no longer meet the safety conditions set out in that Directive, taking into account new information that has become available as well as scientific and technical progress.
- (10) On 2 October 2025, the European Network of GMO Laboratories (ENGL) Working Group on New Mutagenesis Techniques published a report on the analytical possibilities and challenges related to the detection of micro-organisms modified using new genomic techniques, concluding that analytical testing is not feasible for certain GMMs obtained through those techniques, especially in the context of routine laboratory control⁸. Therefore, in cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the notifier, the modalities to comply with analytical method performance requirements should be adapted by means of implementing acts.

⁷ Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms, OJ L 125, 21.5.2009, p. 75, ELI: <http://data.europa.eu/eli/dir/2009/41/oj>).

⁸ Sowa, S., Broothaerts, W., Burns, M., De Loose, M., Debode, F. et al., Detection of microorganisms, obtained by new genomic techniques, in food and feed products, Publications Office of the European Union, Luxembourg, 2025, <https://data.europa.eu/doi/10.2760/1846532>, JRC143597.

- (11) Furthermore, for certain GMMs, the Authority concluded that fewer data requirements for risk assessment would be needed⁹ and provided some criteria to identify those GMMs¹⁰. Thus, Directive 2001/18/EC should establish specific requirements for GMMs with an inherently low risk profile to ensure that the risk assessment and procedures are proportionate to the risks the GMMs raise. Such adaptation should lead to a reduction of time to market for low-risk GMMs, enabling innovation without lowering the safety standards.
- (12) Specifically, it is necessary to lay down the criteria defining low-risk GMMs on the basis of general safety standards as expressed in the Authority's concept of Qualified Presumption of Safety (hereinafter referred to as "QPS")¹¹ and an absence of genes of concern not naturally present in the parental organism as described in the glossary of the Authority's guidance on the characterisation of micro-organisms¹², including acquired antimicrobial resistance genes, virulence factors and genes known to contribute to the production of toxins or harmful metabolites.
- (13) While the basic criteria to be fulfilled for a GMM to be considered a low-risk GMM should be established in Directive 2001/18/EC, the Commission should be empowered, in accordance with Article 290 of the Treaty on the Functioning of the European Union, to supplement Directive 2001/18/EC by further specifying these criteria and adding further criteria if necessary. Moreover, the Commission should be empowered, in accordance with Article 290 of the Treaty on the Functioning of the European Union, to amend Directive 2001/18/EC by adapting the risk assessment requirements and the authorisation procedure to provide for the demonstration of low-risk status, to streamline certain procedural elements and to expedite the timelines to reflect the adapted risk assessment requirements.
- (14) In line with the recommendations of the Authority¹³, and in order to not impose disproportionate administrative burden, low-risk GMMs should not be subject to the obligation to establish a post-market environmental monitoring plan if the GMM does not give rise to concerns that warrant monitoring, such as indirect, delayed or unanticipated effects on human health or on the environment.

⁹ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins, E., Bresson, J.-L., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Moreno, F. J., Naegeli, H., Nogué, F., Rostoks, N., Sánchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Cocconcelli, P. S., Glandorf, D., Herman, L., Dalmay, T. (2024). New developments in biotechnology applied to microorganisms. EFSA Journal, 22(7), e8895; point 3.3.2.9.: <https://doi.org/10.2903/j.efsa.2024.8895>

¹⁰ EFSA Scientific Committee, Bennekou, S. H., Allende, A., Bearth, A., Casacuberta, J., Castle, L., Coja, T., Crépet, A., Halldorsson, T. I., Hoogenboom, R., Jokelainen, P., Knutsen, H. K., Lambré, C., Nielsen, S. S., Turck, D., Civera, A. V., Villa, R. E., Zorn, H., Gómez, M. A., ... Glandorf, B. (2025). Guidance on the characterisation of microorganisms in support of the risk assessment of products used in the food chain. EFSA Journal, 23(11), e9705. <https://doi.org/10.2903/j.efsa.2025.9705>

¹¹ <https://doi.org/10.5281/zenodo.1146566>

¹² EFSA Scientific Committee, Bennekou, S. H., Allende, A., Bearth, A., Casacuberta, J., Castle, L., Coja, T., Crépet, A., Halldorsson, T. I., Hoogenboom, R., Jokelainen, P., Knutsen, H. K., Lambré, C., Nielsen, S. S., Turck, D., Civera, A. V., Villa, R. E., Zorn, H., Gómez, M. A., ... Glandorf, B. (2025). Guidance on the characterisation of microorganisms in support of the risk assessment of products used in the food chain. EFSA Journal, 23(11), e9705; page 22: <https://doi.org/10.2903/j.efsa.2025.9705>.

¹³ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins, E., Bresson, J.-L., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Moreno, F. J., Naegeli, H., Nogué, F., Rostoks, N., Sánchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Cocconcelli, P. S., Glandorf, D., Herman, L., Dalmay, T. (2024). New developments in biotechnology applied to microorganisms. EFSA Journal, 22(7), e8895; point 3.3.2.9.: <https://doi.org/10.2903/j.efsa.2024.8895>

- (15) Processing, including preservation, of human organs is increasingly frequent and allows the ex-vivo time window between procurement from the donor and transplantation into the recipient to be extended.
- (16) The uptake of those preservation and processing technologies not only allows for more efficient organisational set-up, but also for improving human organs during the extended ex-vivo time window, increasing treatment options for patients on waiting lists. Such activities need to be subject to oversight by the competent authorities in order to ensure their quality, optimise the effectiveness of transplants and protect recipients' health.
- (17) To ensure a consistent and comprehensive legislative framework by providing clarity for all actors involved, Directive 2010/53/EU should cover processing of organs, beyond preservation of such organs. In order to ensure coherence and efficient coordination among authorities operating under different Union legislative frameworks in the health area, provisions should be laid down to clarify which of the technologies used fall under Union legislative frameworks other than Directive 2010/53/EU, in particular the frameworks established in Directive 2001/83/EC of the European Parliament and of the Council¹⁴, Regulation (EC) No 726/2004 of the European Parliament and of the Council¹⁵, Regulation (EU) 2017/745 of the European Parliament and of the Council¹⁶ and Regulation (EU) 2024/1938 of the European Parliament and of the Council¹⁷. Such provisions should aim to at ensuring coherence and efficient coordination among authorities operating under those frameworks. Directive 2010/53/EU should therefore be amended accordingly.
- (18) To ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission. Those powers should cover, in particular, the adapted modalities to comply with analytical method requirements and the supporting information to be submitted to demonstrate the fulfilment of the criteria for being considered a low-risk GMM concerning Directive 2001/18/EC, as well as the establishment of detailed rules for the authorisation of organ processing, concerning Directive 2010/53/EU. Those implementing acts should be adopted in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council¹⁸.

¹⁴ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67, ELI: <http://data.europa.eu/eli/dir/2001/83/oj>).

¹⁵ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1, ELI: <http://data.europa.eu/eli/reg/2004/726/oj>).

¹⁶ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>).

¹⁷ Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L, 2024/1938, 17.7.2024, ELI: <http://data.europa.eu/eli/reg/2024/1938/oj>).

¹⁸ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13, ELI: <http://data.europa.eu/eli/reg/2011/182/oj>).

- (19) Since the objectives of this Directive, including to ensure legal clarity across Member States cannot be sufficiently achieved by the Member States but can rather, by reason of their scale and effects, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendments to Directive 2001/18/EC

Directive 2001/18/EC is amended as follows:

- (1) in Article 2, the following points (9), (10) and (11) are added:
- ‘(9) ‘micro-organism’ means a micro-organism as defined in Article 2, point (a), of Directive 2009/41/EC of the European Parliament and of the Council*, with the exception of animal and plant cells in culture;
 - (10) ‘genetically modified micro-organism’ or ‘GMM’ means a genetically modified micro-organism as defined in Article 2, point (b), of Directive 2009/41/EC, with the exception of genetically modified animal and plant cells in culture;
 - (11) ‘Status of Qualified Presumption of Safety’ means the safety status assigned by the Authority to selected groups of micro-organisms on the basis of an assessment showing no safety concerns;’

* Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (OJ L 125, 21.5.2009, p. 75, ELI: <http://data.europa.eu/eli/dir/2009/41/oj>).’;

- (2) In Part C, after the heading ‘PLACING ON THE MARKET OF GMOs AS OR IN PRODUCTS’ the following title is inserted:

‘TITLE I

GENERAL PROVISIONS APPLICABLE TO GMOs AS OR IN PRODUCTS’

- (3) after Article 24, the following title and Articles 24a to 24g are inserted:

‘TITLE II

SPECIFIC PROVISIONS APPLICABLE TO GENETICALLY MODIFIED MICRO-ORGANISMS (GMMs) AS OR IN PRODUCTS

Article 24a

Subject matter and status of GMMs

1. This Title lays down specific rules for the placing on the market of genetically modified micro-organisms (GMMs) as or in products.
2. Articles 24e and 24f shall apply only to the placing on the market of GMMs with a low-risk profile as or in products.

3. Unless otherwise provided for in this Title, the rules of this Directive applicable to GMOs as or in products shall apply to GMMs as or in products.

Article 24b

Adaptation of information requirements

The Commission is empowered to adopt delegated acts in accordance with Article 29a to amend Annex III in order to provide for specific information requirements in notifications concerning the placing on the market of GMMs, so as to adapt them to scientific and technical progress.

Article 24c

Validity of the consent

Without prejudice to Article 20(2) and (3) and Article 23, the consent granted under Part C shall be valid for an unlimited period of time and Article 17 shall not apply.

Article 24d

Detection methods

1. In cases where it is not feasible to provide a method for detection, identification and quantification of the transformation event as detailed in point 7 of Section A of Annex IV, to which Article 13(2), point (a), refers, and where this is duly justified by the notifier, the modalities to comply with analytical method performance requirements shall be adapted as specified in the implementing act adopted in accordance with Article 24g(1), point (a).
2. The competent authority shall assess whether the information on the analytical method provided by the notifier justifies the application of adapted modalities to comply with detection method requirements in accordance with paragraph 1.

Article 24e

Low-risk GMMs

1. A GMM shall be considered a 'low-risk GMM' where it fulfils all of the following criteria:
 - (a) it is taxonomically and molecularly well characterised;
 - (b) it belongs to a taxonomic unit having the Status of Qualified Presumption of Safety;
 - (c) it does not contain genes of concern which are not naturally present in the parental organism, in particular acquired antimicrobial resistance genes.

The Commission may supplement those criteria by establishing further criteria, as provided for in paragraph 3, point (b), based on available scientific evidence concerning the safety of GMMs and on experience gained from the release of comparable micro-organisms.

2. The risk assessment of low-risk GMMs and the specific information requirements in notifications concerning their placing on the market shall be adapted to their characteristics.

The procedural requirements laid down in Title I shall be adapted as provided for in paragraph 3, point (d), to provide for the demonstration of low-risk status, to streamline certain procedural elements and to expedite the timelines. Such adaptations shall ensure a high level of protection of human health and the environment as well as the necessary consultations of competent authorities and the public.

3. The Commission is empowered to adopt delegated acts in accordance with Article 29a to:
 - (a) supplement this Directive by further specifying the low-risk criteria of GMMs as referred to in paragraph 1, first subparagraph, points (a), (b) and (c);
 - (b) supplement this Directive by establishing, where necessary, additional low-risk criteria of GMMs as referred to in paragraph 1;
 - (c) amend this Directive by providing for specific information requirements in Annex III in notifications concerning the placing on the market of low-risk GMMs;
 - (d) amend this Directive by setting out procedural requirements for the risk assessment of low-risk GMMs adapted to their characteristics.

Article 24f

Monitoring and reporting of low-risk GMMs

1. If, on the basis of the results of any release notified in accordance with Article 6, of the findings of the environmental risk assessment carried out in accordance with Article 13(2), point (b), of the characteristics of the GMM, of the characteristics and scale of its expected use, and of the characteristics of the receiving environment, the notifier considers that a monitoring plan referred to in Article 13(2), point (e), is not needed, the notifier may propose not to submit a monitoring plan.
2. The written consent referred to in Article 19 shall either specify the monitoring requirements, as provided in Article 19(3), point (f), or state that monitoring is not required.

Article 24g

Implementing acts

1. The Commission shall adopt implementing acts concerning:
 - (a) adapted modalities to comply with analytical method requirements referred to in Article 24d(1);
 - (b) the supporting information to be submitted in the notification referred to in Article 13(2) to demonstrate fulfilment of the criteria referred to in Article 24e(1) for being considered a low-risk GMM.
 2. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 30(2).';
- (4) Article 29a is replaced by the following:

Article 29a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
 2. The power to adopt delegated acts referred to in Article 16(2), Article 21(2) and (3), Article 24b, Article 24e(3), Article 26(2) and Article 27 shall be conferred on the Commission for a period of five years from *[the date of entry into force of this Directive]*. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
 3. The delegations of power referred to in Article 16(2), Article 21(2) and (3), Article 24b, Article 24e(3), Article 26(2) and Article 27 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
 4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making**.
 5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
 6. A delegated act adopted pursuant to Article 16(2), Article 21(2) and (3), Article 24b, Article 24e(3), Article 26(2) and Article 27 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.'
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** OJ L 123, 12.5.2016, p. 1.'

Article 2

Amendments to Directive 2010/53/EU

Directive 2010/53/EU is amended as follows:

- (1) in Article 2, paragraph 1 is replaced by the following:
‘1. This Directive applies to the donation, testing, characterisation, procurement, processing, transport and transplantation of organs intended for transplantation.’
- (2) Article 3 is amended as follows:
 - (a) point (q) is replaced by the following:

‘(q) “transplantation” means a process intended to restore certain functions of the human body by transferring an organ to a recipient;’

(b) the following point (ka) is inserted:

‘(ka) “processing” means any operation involving the handling of organs, including but not limited to preservation, application of chemotherapy and surgery, performed to maintain or improve the functional status of an organ prior to transplantation, with the exception of the preparatory handling of the organ during the surgical transplantation intervention, and excluding the following:

- (i) the repurposing of organs into tissues or cells;
- (ii) the use of a substance with a pharmacological, immunological or metabolic action with the aim to treat or prevent a disease in the patient to whom the organ will be transplanted, where such use does not constitute processing of the organ.’

(3) the following Article 6a is inserted:

Article 6a

Organ processing

1. Transplantation centres shall not apply a processed organ to a recipient without prior authorisation by the competent authority, other than in the context of an approved clinical-outcome monitoring plan referred to in paragraph 3 of this Article, as part of an organ processing authorisation.
2. The transplantation centre shall conduct a benefit-risk assessment of the processing of the organ, considering with the intended clinical indication for which the organ processing authorisation is requested.

The transplantation centre shall submit the benefit-risk assessment to the competent authority for revision.
3. In cases where the scientific evidence and clinical data available to perform the benefit-risk assessment are not sufficient, or where the assessment identifies a significant risk, the transplantation centre shall submit a proposal for a clinical-outcome monitoring plan for approval by the competent authority.
4. Where the processing of an organ entails the use of a medicinal product, the competent authority shall verify that the medicinal product has been authorised by a competent authority of a Member State or by the European Commission in accordance with Directive 2001/83/EC of the European Parliament and of the Council* or Regulation (EC) No 726/2004 of the European Parliament and of the Council**.
5. Competent authorities shall, after consulting the authorities designated under Directive 2001/83/EC, publish guidelines setting out the necessary requirements for the benefit-risk assessment and the management of the organ after the administration of the medicinal product.
6. Where the processing of an organ entails the use of a medical device, the competent authority shall verify that the medical device has been certified by a

notified body in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council***.

7. Where the processing of an organ entails the use of a SoHO preparation, the competent authority shall verify that the SoHO preparation has been authorised by the competent authority in accordance with Regulation (EU) 2024/1938 of the European Parliament and of the Council****.
8. Where applicable, competent authorities under this Directive and the competent authorities under Directive 2001/83/EC, Regulation (EC) No 726/2004, Regulation (EU) 2017/745 and Regulation (EU) 2024/1938 shall collaborate in order to exchange clinical outcome data under such Union legislative frameworks including the clinical outcome monitoring plan under this Directive.
9. Transplant centres shall not make any significant change regarding the steps of the processing applied, without prior written agreement of the competent authority.
10. Competent authorities may suspend the authorisation where there is reasonable ground to suspect that the performed processing activities are not in compliance with the authorisation.
11. The Commission shall publish a list of operations that have been authorised as organ processing or have received approval for a clinical outcome monitoring plan, including, where relevant, the use of medicinal products, medical devices or SoHO preparations.
12. The Commission shall adopt implementing acts laying down detailed rules for the application and authorisation of organ processing in accordance with the procedure referred to in Article 30(2).

* Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67, ELI: <http://data.europa.eu/eli/dir/2001/83/oj>).

** Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1, ELI: <http://data.europa.eu/eli/reg/2004/726/oj>).

*** Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>).

**** Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L, 2024/1938, 17.07.2024, ELI: <http://data.europa.eu/eli/reg/2024/1938/oj>).’;

(4) in Part B of the Annex, the following entry is added:

‘Processing

Processing steps applied to the organ with the aim of improving its functional status and with a potential impact on its quality and safety, including in particular, but not limited to, preservation, application of chemotherapy and surgery.’

Article 3

Transposition

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive by *[24 months from the date of entry into force]* at the latest. They shall forthwith communicate to the Commission the text of those provisions.
2. When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.
3. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 4

Entry into Force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 5

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg,

For the European Parliament
The President

For the Council
The President



EUROPEAN
COMMISSION

Strasbourg, 16.12.2025
COM(2025) 1022 final

2025/0406 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act)

{SWD(2025) 1055 final}

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Biotechnology and biomanufacturing are essential to the EU's competitiveness, strategic autonomy and economic security. They are a pillar of the Union's societal wellbeing in key areas such as health and food.

This strategic importance is underscored by the sector's rapid expansion. Over the last decade, **the EU biotechnology industry has grown more than twice as fast as the overall EU economy** and is one of the most economically productive industries. The spillover effect is also significant, each job in industrial biotechnology generates 3.4 additional jobs in the broader economy. In 2022, it accounted for EUR 38.1 billion of Union GDP and contributed to 913 160 jobs, with more than 75% of those jobs (685 000) coming from the health biotechnology sector ¹.

However, **the EU lags behind other global regions when it comes to translating its world-class science and innovation into commercially viable products**, and even more so in manufacturing such products at scale. Despite world-leading biotechnology science, reflected by a publication record comparable to that of the US and China (Figure 1), the EU faces structural barriers in clinical development, regulation and manufacturing. As a result, too often Union start-ups end up investing, growing, employing, creating value and placing their products on the market abroad rather than in the EU. This is especially true for health biotechnology, where it is at times challenging for the legislative frameworks to keep pace with the speed of scientific developments.

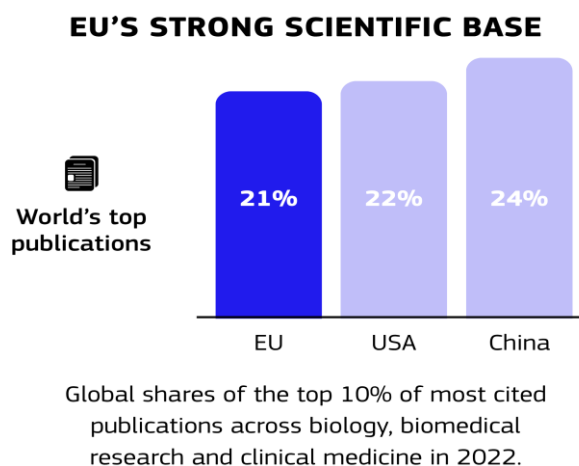


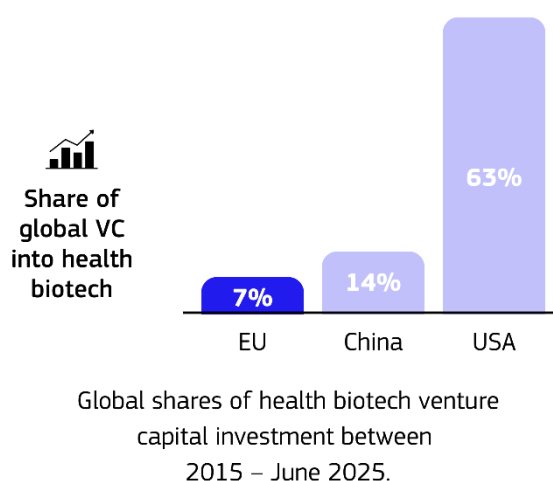
Figure 1: Top tier life science publications of the EU compared to the USA and China

¹ https://www.europabio.org/wp-content/uploads/2025/03/WifOR_EuropaBio2025.pdf

To remain a biotechnology powerhouse, the EU must make the most of its scale. Fragmented governance and suboptimal coordination across Member States weaken the EU's ability to deploy industrial facilities at scale, resulting in underused **biomanufacturing potential** - including in strategic areas such as **biosimilars**, where the EU has strong expertise but insufficiently exploited capacity. It should also ensure a strong alignment between the available labour supply and the specialised skills that the biotechnology and biomanufacturing sectors will require in the future. Current skill shortages across key areas including R&D, regulatory affairs, AI, and data analytics further hinder Europe's competitiveness. At the same time, the widening gender gap and the untapped potential of a diverse workforce represent missed opportunities for innovation and resilience.

Access to finance for scale-up funding in the EU remains limited compared to other regions. US biopharma start-ups received around nine times more late-stage funding than EU biopharma start-ups, with around EUR 219 billion of venture capital focused on health biotechnology invested in the US compared to EUR 25 billion in the EU between 2015 and June 2025 (Figure 2). EU public equity markets for biotechnology also remain comparatively underdeveloped, with stock exchanges still largely fragmented across EU Member States ². As a result, many EU scale-ups choose to list abroad: over the last six years, 66 out of 67 EU biotechnology companies that went public chose to list on non-EU stock exchanges, illustrating the persistent structural disadvantages faced by EU-based innovators ³.

EU LAGGING IN BIOTECH VC INVESTMENT



Source: Technopolis Group (2025) based on Crunchbase.

Figure 2: Health Biotechnology investment in the EU compared to the US and China

Aligned with the objectives of the AI Continent Action Plan and the Apply AI Strategy, the EU must also tap into the massive **potential of AI for biotechnologies**, addressing obstacles like limited testing environments, fragmented data, and exploiting the full potential of AI across the lifecycle of biotechnology products, in particular for medicines. Further,

² Joint Research Centre (2024), Exploring the global landscape of biotechnology Innovation: preliminary insights from patent analysis, <https://publications.jrc.ec.europa.eu/repository/handle/JRC137266>.

³ From discovery to economic impact: Biotechnology Competitiveness for Europe, Vlaams Instituut voor Biotechnologie, 2024

Regulation (EU) 2024/1689 (AI Act)⁴, which entered into force in August 2024, lays down a uniform legal framework in particular for the development, the placing on the market, the putting into service and the use of AI systems and models in the Union, in accordance with Union values, to promote the uptake of human centric and trustworthy AI. At the same time, biotechnology introduces new **biosecurity risks** as the wider accessibility of these technologies increases their potential for misuse, posing significant health threats. However, divergent or absent national rules on screening biotechnology products with significant potential for misuse, such as the synthetic DNA of dangerous pathogens, raise compliance costs, fail to offer a level playing field to competitors, and weaken prevention.

Fragmentation and the complexity of the EU regulatory framework are factors that make the EU less attractive for translating cutting-edge research and innovation into marketable products. For instance, the global share of commercially sponsored clinical trials in the European Economic Area has declined from 22% in 2013 to 12% in 2023, while China's share of commercial clinical trials rose from 5% to 18% in the same period, with the US share remaining considerably more stable⁵. Importantly, the overall reported decline in small molecule trials suggests a strategic shift toward the development of biological medicines at the expense of small molecule programs. The drop in the number of small molecule trials was the most significant in Phase II trials from 62% in 2015 to 47% in 2024 and in Phase III trials from 65% to 53% during the same period⁶. In particular, the EU is losing ground to other regions with increasingly agile regulatory and financial systems. Most of these regions issue decisions on validated clinical trial applications within 60 days, whereas in the EU it takes on average 113 days for multinational trials.

Highlight: the need to simplify and streamline the Clinical Trials Regulation (CTR)

Clinical trials in the EU are crucial to provide patients with early and equal access to innovative treatments, uphold scientific excellence, and support the EU's long-term competitiveness and prosperity. By attracting investment in research and development (R&D), creating jobs, and reducing healthcare costs, these trials deliver substantial economic and societal benefits. They also significantly benefit patients by providing earlier access to new therapies, including personalised therapies (e.g. for rare diseases and cancers), improving quality of life, and strengthening the evidence base for clinical guidelines, marketing authorisation and health technology assessments. The share of clinical trials with biological medicines seems to be increasing at the expense of low molecule trials. Biological medicines sales are key drivers of growth. In 2024, the European Union spent €228 Bn on medicines at list prices, including €95 Bn on biological medicines, which now comprise 41% of total pharmaceutical spending. Increased clinical trials in the Union for biological medicines could potentially contribute to more manufacturing in the Union, higher number and earlier regulatory submission of biological medicines for marketing authorisation applications and a higher percentage of EU clinical data in marketing authorisation applications. A conducive environment for clinical trials is essential to speed-up market access for novel medicines,

⁴ Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (Text with EEA relevance), OJ L, 2024/1689, 12.7.2024, ELI: <http://data.europa.eu/eli/reg/2024/1689/oj>

⁵ European Federation of Pharmaceutical Industries and Association, Assessing the clinical trial ecosystem in Europe (2024) [assessing-the-clinical-trial-ecosystem-in-europe.pdf](#)

⁶ [Global Trends in R&D 2025 - IQVIA](#)

especially against global competition. There are still significant regulatory fragmentations across Member States that limit the system's efficiency. Against this background, further regulatory streamlining and simplification of the authorisation and conduct of clinical trials are imperative. This is a key point of the Draghi report on the future of European Competitiveness⁷, which highlights the need to address these inefficiencies, stressing the importance of reducing regulatory delays and administrative burdens. It calls for harmonised templates, stronger coordination between national ethics committees, and a greater emphasis on using artificial intelligence (AI) and digital tools to streamline the process. At a time when global competitors – particularly the US, China, and Japan – are rapidly improving their R&D incentives and regulatory agility, Europe risks losing its competitive edge in clinical research. The EU's position in the global clinical trial landscape has already weakened, and immediate action is needed to close this gap.

This is why a European Biotech Act was announced by the President of the European Commission in the 2024 - 2029 Political Guidelines of the Commission⁸, with the aim of creating an enabling environment to make it easier to bring biotechnology products from the laboratory to the factory and then onto the market, while maintaining the highest safety standards for the protection of the population and the environment. As previously acknowledged in the Communication on Biotechnology and Biomanufacturing (March 2024) and the reports by Enrico Letta⁹ (April 2024) and Mario Draghi¹⁰ (September 2024), it is necessary to address the challenges faced by EU companies, users and consumers to boost the EU's technological advancement, competitiveness and economic growth. In its resolution 'Future of the EU biotechnology and biomanufacturing sector'¹¹, the European Parliament recommended 'facilitating a fast and efficient uptake of biotechnology and biomanufacturing through clear regulatory frameworks'. The European Parliament is now preparing an own-initiative report on 'Public health aspects of biotechnology and life sciences'¹². More recently, EU Member States urged the Commission to unlock the potential of biotechnologies, by reducing fragmentation and simplifying the EU regulatory framework across policy areas¹³.

Given the importance of health biotechnology amongst the other applications of biotechnology as, it is appropriate that the European Biotech Act focusses on, and sets out specific measures for, the health dimension of biotechnology. To ensure the effectiveness of this proposal, its scope of application extends to health biotechnology in a comprehensive manner and cover health within the wide meaning of Article 168 of the Treaty of the Functioning of the European Union (TFEU) on the protection of public health. In this regard, Article 168(1) TFEU emphasises that a high level of human health protection is to be ensured

⁷ Draghi, Mario. [The future of European competitiveness: A competitiveness strategy for Europe](#), European Commission, 9 September 2024.

⁸ European Commission (2024), Political Guidelines for the Next European Commission 2024-2029, [e6cd4328-673c-4e7a-8683-f63ffb2cf648_en](#)

⁹ Enrico Letta (2024), *Much more than a Market*. [Enrico Letta - Much more than a market \(April 2024\)](#)

¹⁰ Draghi, Mario. [The future of European competitiveness: A competitiveness strategy for Europe](#), European Commission, 9 September 2024.

¹¹ European Parliament (2025). Future of the EU biotechnology and biomanufacturing sector: leveraging research, boosting innovation and enhancing competitiveness. [Texts adopted - Future of the EU biotechnology and biomanufacturing sector: leveraging research, boosting innovation and enhancing competitiveness - Thursday, 10 July 2025](#)

¹² European Parliament: [2025/2087\(INI\)](#)

¹³ Council of the European Union, [A call for action on life sciences for the Union's competitiveness - Council conclusions](#) (approved on 30 September 2025) (13323/25).

when defining and implementing all Union policies and activities. Article 168(4) TFEU clarifies that this objective is, amongst others, to be pursued through measures setting high standards of quality and safety for medicinal products and devices for medical use and of organs and substances of human origin, blood and blood derivatives, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health. Accordingly, and in line with the One Health approach, this Regulation should apply to health biotechnology, understood as the application of biotechnology in the human medical, veterinary, pharmaceutical and phytosanitary areas for the development of biotechnology products and services. The Regulation should apply to their entire lifecycle, including the related research, access to funding, development, innovation, testing, validation, manufacturing, placing on the market and use activities.

The proposal for a European Biotech Act acknowledges the EU's potential to be a global leader. The region combines a highly skilled workforce, world-class scientific institutes, innovative startups and scaleups, advanced infrastructure and large private capital pools that could be used to support the domestic scale-up of promising companies. The proposal therefore seeks to address the barriers hindering the development of the EU's health biotechnology sector, starting from early-stage research through to later-stage deployment and scale-up. It introduces facilitation measures in the health biotechnology areas, including a framework for the recognition of, and support for, health biotechnology strategic projects and high impact health biotechnology strategic projects, aimed at reducing time-to-market, with particular attention paid to the needs of small and medium-sized enterprises (SMEs), and includes future-proofing provisions to anticipate the needs of health biotechnologies. Acting decisively now will allow the EU to fully harness its fast-moving biotechnology sector, reinforce strategic autonomy and economic security, and lay the foundations for a competitive and forward-looking EU biotechnology sector.

With a view to ensure the effectiveness of the substantive provisions put forward in this proposal, amendments to Union legislation in the areas of health and food and feed safety are also established for regulatory simplification, that have an impact on innovation and the time to market for biotechnology products and services, including where such legislation also applies to products other than biotechnology products. In this regard, without an efficient, accelerated and streamlined legislative framework for clinical trials in the Union, the other measures in this Regulation, and in particular the framework for the recognition and support of health biotechnology strategic projects and high impact biotechnology strategic projects would be deprived of their effectiveness, as all health biotechnology medicinal products require state of the art clinical research and a globally competitive regulatory framework for clinical trials authorisation. Similarly, a timelier risk assessment process for products subject to pre-market authorisation in accordance with Union food and feed legislation, including for biotechnology innovations where pre-submission advice of the European Food Safety Authority for aspects such as study design is paramount, as well as accelerated procedures are needed for the effectiveness of the substantive facilitation measures put forward in this proposal.

In a second stage, following this health-focused initiative, the Commission will address in 2026 the wider biotech ecosystem beyond health to ensure a competitive internal market for all areas of biotechnology.

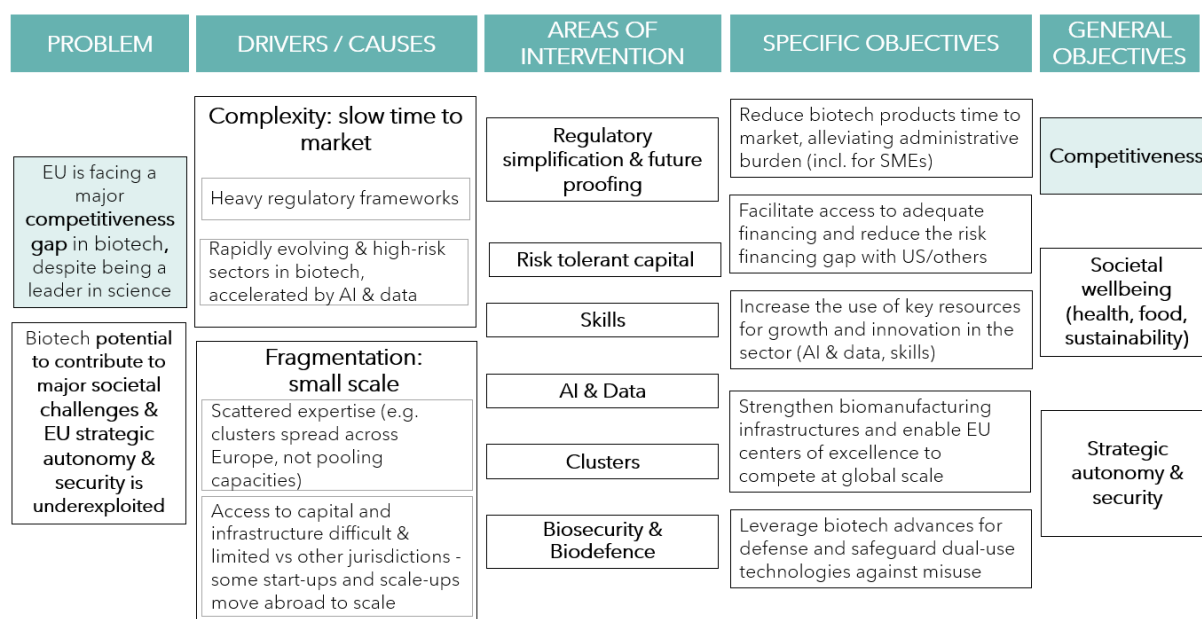


Figure 3: Biotechnology and biomanufacturing sector in Europe, problem tree

- **Consistency with existing provisions in the policy area**

The European Biotech Act will seek to streamline the relevant EU legislative frameworks to create an enabling environment for innovation and development in order to accelerate time to market. With its primary focus on health, the present proposal will amend the **Regulation on clinical trials (CTR)**¹⁴, the **Regulation on advanced therapy medicinal products (ATMPs)**¹⁵, the **Regulation on standards of quality and safety for substances of human origin intended for human application (SoHO)**¹⁶ and the **Regulation on veterinary medicinal products (VMPs)**¹⁷. In the field of food safety, the proposed measures are built on the **General Food Law**¹⁸. The proposal will also amend the **legislation on the deliberate release of genetically modified organisms (GMO)**¹⁹.

¹⁴ Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance, OJ L 158, 27.5.2014, pp. 1–76. ELI: <http://data.europa.eu/eli/reg/2014/536/oj>.

¹⁵ Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (Text with EEA relevance), OJ L 324, 10.12.2007, pp. 121–137. ELI: <http://data.europa.eu/eli/reg/2007/1394/oj>.

¹⁶ Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (Text with EEA relevance), OJ L, 2024/1938, 17.7.2024. ELI: <http://data.europa.eu/eli/reg/2024/1938/oj>.

¹⁷ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (Text with EEA relevance), OJ L 4, 7.1.2019, pp. 43–167. ELI: <http://data.europa.eu/eli/reg/2019/6/oj>.

¹⁸ Regulation (EC) No 178/2002, of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food

The proposal also considers other existing legislation that is being revised to ensure the coherence of the overall EU regulatory system, in particular the **Regulation on medical devices (MDR)** and the **Regulation on in vitro diagnostic medical devices (IVDR)**²⁰, as well as the **proposed simplification measures in food and feed safety legislation (food and feed simplification package)**.

The Biotech Act will also exploit synergies with other EU legislation. It will complement the **Critical Medicines Act (CMA)**²¹ to strengthen EU-based biotechnology research and manufacturing. The Act is also in line with the **pharmaceutical strategy for Europe**²² and complements the ongoing **revision of the EU pharmaceutical legislation**²³ to create the appropriate conditions for biotechnology from the innovation stage. Moreover, the proposed measures are complementary to the **proposed regulation on plants obtained by certain new genomic techniques** and their use in food and feed.

- **Consistency with other Union policies**

As one of the flagship initiatives of the **Competitiveness Compass**²⁴, the proposed Biotech Act aligns with the EU's broader innovation and competitiveness agenda, translating the priorities of the Compass into concrete actions within the strategic sector of biotechnology.

In particular, the Biotech Act is part of the **Commission's life sciences strategy**²⁵. It was presented as a central instrument to strengthen the Union's biotechnology ecosystem, streamline regulatory procedural pathways and boost Europe's competitiveness in life sciences, recognising biotechnology as a strategically critical and cross-sectoral technology.

Furthermore, the proposed Act is complementary to the other policy initiatives announced in the Compass. First, it aims to improve access to later-stage capital for biotechnology firms,

Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, pp. 1–24. ELI: <http://data.europa.eu/eli/reg/2002/178/oj>.

¹⁹ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration, OJ L 106, 17.4.2001, pp. 1–39. ELI: <http://data.europa.eu/eli/dir/2001/18/oj>.

²⁰ Regulations (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance), OJ L 117, 5.5.2017, pp. 1–175. ELI: <http://data.europa.eu/eli/reg/2017/745/oj> and (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance), OJ L 117, 5.5.2017, pp. 176–332. ELI: <http://data.europa.eu/eli/reg/2017/746/oj>.

²¹ [Critical medicines Act - Public Health - European Commission](#)

²² Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Pharmaceutical Strategy for Europe*, COM/2020/761 final.

²³ European Commission website, [Reform of the EU pharmaceutical legislation](#)

²⁴ European Commission, European Competitiveness Outlook (Competitiveness Compass): [Competitiveness compass - European Commission](#)

²⁵ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Choose Europe for life sciences A strategy to position the EU as the world's most attractive place for life sciences by 2030*, COM/2025/525 final.

aligning with the **start-up and scale-up strategy**²⁶ and complementing the Scaleup Europe Fund established under that strategy, as well as the **Savings and Investments Union**²⁷, which seeks to mobilise larger pools of private capital, support investment within the EU, and reduce financing costs for Union businesses.

Second, the provisions on biosecurity also reflect the Compass's emphasis on talent as a cornerstone of innovation and on the interdependence between economic strength and security. In this context, the Act is consistent with the objectives put forward in the **Union of Skills**²⁸ and contributes to EU security by reinforcing safeguards for dual-use biotechnologies. It also complements the **EU Regulation (EU) 2022/2371 on serious cross-border threats to health**²⁹, helping to ensure a coordinated Union-level response to health risks that may arise from the misuse of emerging biotechnologies and to the **strategic technologies for Europe platform (STEP)**³⁰ that also target biotechnologies.

Third, the emphasis on the use of AI in the proposed Act also aligns with the Competitiveness Compass, and echoes the recent **Apply AI strategy**³¹, the **AI continent action plan**³², the **European AI Act**³³ and the **Data Union strategy**³⁴, which stress the need to strengthen Europe's innovation capacity, technological competitiveness and secure, data-driven ecosystems while supporting the biotechnology landscape.

Overall, the Biotech Act is also consistent with the **vision for agriculture and food**³⁵, as it amends the General Food Law to broaden the scope of pre-submission advice provided by the European Food Safety Authority (EFSA) to study design, and reforms the EFSA Panel system to speed up risk assessment procedures.

²⁶ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *The EU Startup and Scaleup Strategy Choose Europe to start and scale*, COM/2025/270 final.

²⁷ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Savings and Investments Union A Strategy to Foster Citizens' Wealth and Economic Competitiveness in the EU*, COM/2025/124 final.

²⁸ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *The Union of Skills*, COM/2025/90 final.

²⁹ Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (Text with EEA relevance), OJ L 314, 6.12.2022, pp. 26–63. ELI: <http://data.europa.eu/eli/reg/2022/2371/oj>.

³⁰ [Strategic Technologies for Europe Platform](http://data.europa.eu/eli/reg/2022/2371/oj)

³¹ Communication from the Commission to the European Parliament and the Council, *Apply AI Strategy*, COM/2025/723 final.

³² <https://ec.europa.eu/newsroom/dae/redirection/document/114523>

³³ Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act), OJ L, 2024/1689, 12.7.2024, ELI: <http://data.europa.eu/eli/reg/2024/1689/oj>.

³⁴ Communication from the Commission to the European Parliament and the Council, *Data Union Strategy Unlocking Data for AI*, COM(2025) 835 final.

³⁵ Communication from the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *A Vision for Agriculture and Food Shaping together an attractive farming and agri-food sector for future generations*, COM/2025/75 final

Lastly, the proposed Act was informed by the preparation of upcoming and recent initiatives, such as the future **European Innovation Act**³⁶ and the recently adopted **bioeconomy strategy**³⁷, in order to ensure synergies.

Furthermore, climate change has shown the need to also prioritise the resilience of the Union, including, for instance to focus on sustainable food systems, stronger health prevention and innovative health solutions. In this context, biotechnology has been identified in the **Farm to Fork Strategy**³⁸, which is a key component of the **European Green Deal**³⁹, as a technique that is safe for consumers and the environment. The proposed Act is also consistent with the European Commission's objectives to achieve climate neutrality set out in the **EU Climate Law**⁴⁰ and the **Union's Strategy on Adaptation to Climate Change**⁴¹.

In this context, the proposed European Biotech Act, including through its measures supporting innovation, will accelerate the placing on the market of biotechnology products that are adaptable to climate change, that contribute to health and food security through sustainable biomanufacturing and to the protection of biodiversity. Such biotechnology products have also the potential to replace products potentially more harmful for the environment while providing great benefits for consumers and users. Biotechnology and biomanufacturing will also need to comply with Union legislation in these areas, such as, the Regulation concerning the **Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)**⁴² or applying without prejudice to the provisions of **Regulation (EU) 2024/1735 regarding sustainable biogas and biomethane technologies and biotechnology climate and energy solutions**⁴³.

This also shows that the proposed Act is in line with the '**do no significant harm**' principle. The positive environmental impact of biotechnology and biomanufacturing was also recognized by stakeholders in their responses to the Public Consultation.

³⁶ European Commission 'Have your say' website: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14593-European-Innovation-Act_en

³⁷ European Commission 'Have your say' website: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14555-Towards-a-circular-regenerative-and-competitive-bioeconomy_en

³⁸ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system*, COM/2020/381 final

³⁹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *The European Green Deal*, COM/2019/640 final.

⁴⁰ Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999 ('European Climate Law'), OJ L 243, 9.7.2021, pp. 1–17. ELI: <http://data.europa.eu/eli/reg/2021/1119/oj>.

⁴¹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Forging a climate-resilient Europe - the new EU Strategy on Adaptation to Climate Change*, COM/2021/82 final

⁴² Consolidated text: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance). ELI: <http://data.europa.eu/eli/reg/2006/1907/2025-09-01>

⁴³ Consolidated text: Regulation (EU) 2024/1735 of the European Parliament and of the Council of 13 June 2024 on establishing a framework of measures for strengthening Europe's net-zero technology manufacturing ecosystem and amending Regulation (EU) 2018/1724 (Text with EEA relevance). ELI: <http://data.europa.eu/eli/reg/2024/1735/2025-08-17>

Finally, the proposed Biotech Act will support **digital transformation** in line with the ‘**digital by default**’ principle. One of its specific objectives is to “facilitate the application of AI into the Union’s biotechnology and health technology manufacturing ecosystems and frameworks, in line with Regulation (EU) 2024/1689”. The Act is expected, among others, to support the use of data, digital platforms and analytical methodologies (e.g. reducing the need for clinical data), in the development of biotechnology and in biomanufacturing. Digitalisation will also be reinforced in networking cooperation of biotechnology clusters (e.g. through the promotion of the development of infrastructure and digital platforms, and AI-enabled technologies). Overall, accelerated digitalisation, in particular through greater data use and AI integration, aims at contributing to the Union’s technological sovereignty.

Moreover, the proposed European Biotech Act will ensure coherence with relevant digital policies, such as the **Artificial Intelligence Act**⁴⁴, on development and testing of AI enabled biotechnology solutions, as well as the **EU Cybersecurity framework**⁴⁵, on access principles and security safeguards.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

The general objective of this Regulation is threefold: (i) to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector, from research to production, (ii) to create the conditions for the development and timely placing on the EU market, of biotechnology innovations, products and services, (iii) while safeguarding high standards for the protection of human health, animal health, patients and consumers, the environment, ethics, quality, food and feed safety, and biosecurity.

This general objective translates into the establishment of measures to:

- (i) strengthen the biotechnology sector and reinforce the EU’s research, development and production capabilities, by establishing a framework for the recognition of, and support measures for, strategic health biotechnology projects and high impact strategic health biotechnology projects (pillar 1);
- (ii) support funding of, investments in, and access to capital for, biotechnology companies and projects, including through the setting up of an EU health biotechnology investment pilot to fill the gap in spending on biotechnology innovation (pillar 2);
- (iii) improve the EU manufacturing capacity of, and expertise in biosimilars, including through international cooperation (pillar 3);

⁴⁴ Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (Text with EEA relevance), *OJ L*, 2024/1689, 12.7.2024. ELI: <http://data.europa.eu/eli/reg/2024/1689/oj>

⁴⁵ Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (Text with EEA relevance), *OJ L* 151, 7.6.2019, pp. 15–69. ELI: <http://data.europa.eu/eli/reg/2019/881/oj>

- (iv) facilitate the application of AI into the Union's biotechnology and health technology manufacturing ecosystems and frameworks, in line with the Regulation (EU) 2024/1689 (pillar 4);
- (v) ensure a legislative framework that encourages innovation and takes account of technological and scientific developments and progress, by establishing provisions for health biotechnology products (pillar 5);
- (vi) prevent the misuse of biotechnologies and strengthen biodefence capabilities (pillar 6).
- (vii) enable the effectiveness of the measures under the pillars 1 to 6 through a legislative framework conducive to the use of biotechnology innovations, by amending Union legislation in particular on clinical trials, veterinary medicinal products, food and feed safety and related legislation (pillar 7).

The appropriate legal basis is therefore as follows:

- Article 114 of the Treaty on the Functioning of the European Union ('TFEU') which allows the EU to take measures that increase harmonisation and remove fragmentation to create a level playing field within, and fully exploit the scale of, the EU single market, so that the health biotechnology and biomanufacturing sectors can thrive. In accordance with Article 114(3) TFEU, the proposal seeks to achieve the objective of a high level of health and safety protection.
- Article 168(4) TFEU, which mandates the Union to contribute to the achievement of a high level of human health protection through the adoption - in order to meet common safety concerns - of (i) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; (ii) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health; and (iii) measures setting high standards of quality and safety for medicinal products and devices for medical use.
- Article 173(3) TFEU, which allows the Union to decide on specific measures in support of action taken in the Member States to ensure the conditions necessary for the competitiveness of the Union's industry, excluding any harmonisation of the laws and regulations of the Member States. This article provides a legal basis for the provisions in this Regulation regarding the EU health biotechnology investment pilot, establishing the basis for future Union financial support together with implementing partners, to support the financing of, and investments in, companies and projects falling within the scope of the European Biotech Act.

- **Subsidiarity (for non-exclusive competence)**

The objectives of the proposal cannot be achieved by Member States acting alone, as the issues tackled are of a cross-border nature and are not limited to single Member States or to several Member States. The proposed actions focus on areas where there is a demonstrable value added in acting at EU level due to the scale, speed, and scope of the efforts needed.

Furthermore, the market drivers identified are shared across the Member States, affecting the functioning of the single market and the global competitiveness of EU companies. Access to finance is scattered across the EU and EU companies lack the capacity to access private finance at a competitive scale, including at later stages of development. Similarly, European biotechnology clusters are scattered across the EU, without sufficient continental scale to compete globally. The development and deployment of AI solutions for biotechnology

remains limited, also due to the low level of storage, access and sharing of data relevant for biotechnology in the EU, including across borders. There is also a clear need across the EU to attract, reskill and upskill the workforce.

Moreover, while several Member States have taken action to boost innovation in biotechnology, the above-mentioned bottlenecks persist; improvements are expected to take considerably more time and without achieving the levels needed to compete at global level. For example, access to finance would remain scattered at EU level. The growth of clusters in the EU would also remain limited, without sufficient benefits from cross-border connections.

Lastly, important regulatory barriers faced by European biotechnology companies stem from EU legislation. Therefore, with a view to enable the effectiveness of the substantive measures put forward in this proposal, it is proposed to simplify EU legislation in the area of health and of food and feed safety to make it easier to innovate and place biotechnology products and services on the Union market and to enhance legal clarity.

- **Proportionality**

The selected measures under the industrial policy and substantive part of the proposal are targeted at the specific areas of interventions listed below.

- The provisions on strategic health biotechnology projects and high-impact strategic health biotechnology projects are proportionate to the aims pursued, including by recognising the first category of projects at Member State level, and the second category at EU level on the basis of an assessment at Member State level. Moreover, the recognition of such projects is based on clear criteria tailored to ensure that projects that contribute substantially to the Union's competitiveness, resilience, and security fall within the enhanced support regime. Moreover, the recognition of such projects does not restrict Member States' ability to support additional projects through other instruments. Member States benefit from flexibility as regards the authorities that they intend to designate to recognise strategic health biotechnology projects and assess applications for high-impact strategic health biotechnology projects. This flexibility also applies to the single points of contact and the provision of administrative, technical, and financial support, in line with Union law and the national systems. Accelerated permitting timelines apply only to recognised projects and are designed to streamline procedures without lowering any environmental, health or safety standards.

Similarly, measures aimed at supporting networking among health biotechnology clusters are limited to what is necessary to foster synergies in the internal market, while the EU Health Biotechnology Support Network is aiming to build on and complement existing national and EU structures, avoiding any duplication.

- On access to funding, the interventions focus on measures mobilising public funding and private capital; public funding needs to be in line with State aid rules.
- The proposed interaction modalities with Member States in the context of a European Health Biotechnology Steering Group allows for priorities to be adjusted, including by ensuring that the support measures for strategic health biotechnology project and high-impact strategic health biotechnology projects remain closely aligned with the Regulation's general objective.

The proposed amending provision aimed at reducing the time-to-market of biotechnology products and services focus on certain sectoral Union legislation where room for simplification of regulatory and administrative complexities has been identified. Simplification relates to changes that are necessary with a view to secure the effectiveness of the substantive provisions put forward in this proposal and will improve the legal clarity, certainty, and overall efficiency of the concerned EU legislative frameworks.

- **Choice of the instrument**

The proposal takes the form of a regulation of the European Parliament and of the Council.

A regulation is the most suitable legal instrument for Pillars 1 to 4, given the need for a uniform application of the new rules, in particular the conditions and procedure for recognising health biotechnology strategic projects and high impact health biotechnology strategic projects, and for their administrative, technical and financial support, and also more broadly for companies and non-profit organisations active in the relevant biotechnology sectors across the internal market. This is also the case for Pillar 5, regarding the provisions on biotechnology health products, given that they aim to ensure a dialogue and more flexibility across the Union legislative frameworks in the area of health. The choice of a regulation as a legal instrument is also appropriate for Pillar 6 because only a regulation, with its directly applicable legal provisions, can provide the necessary degree of uniformity needed to boost EU biodefence and biosecurity and prevent biotechnology misuse.

In all cases, the choice of the instrument is justified considering that the Pillar 7 establishes provisions amending several existing Union regulations in the area of health and food and feed safety.

Lastly, a regulation is appropriate for the provisions regarding on evaluating this Regulation which do not need to be transposed through national measures and are directly applicable.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

The proposed measures amend several pieces of EU legislation in a targeted manner, without modifying their objectives, the overall regulatory framework put in place or their functioning. When relevant, these measures were informed by several studies or ongoing evaluations, such as the ongoing evaluation of the EFSA. Regarding the Clinical Trials Regulation, an ongoing study will contribute to the Commission's report, which will be presented five years after the application date of the legislation (1 January 2022).

The extensive consultation process and a comprehensive supporting study identifying over 200 regulatory challenges stemming from EU legislation have gathered evidence on the challenges and problems, the relevant provisions of the legislation, and issues for which there is no legislation.

- **Stakeholder consultations**

Extensive stakeholder consultations were carried out to prepare for the proposal. A **call for evidence**⁴⁶, opened for feedback from 14 May to 11 June 2025, gathered 222 valid individual contributions⁴⁷ from a wide range of stakeholders: business associations⁴⁸ (63), companies (50), non-governmental organisations (NGOs) (44), academic and research institutions (20), public authorities in the EU (14), EU citizens (14) and other categories (17)⁴⁹.

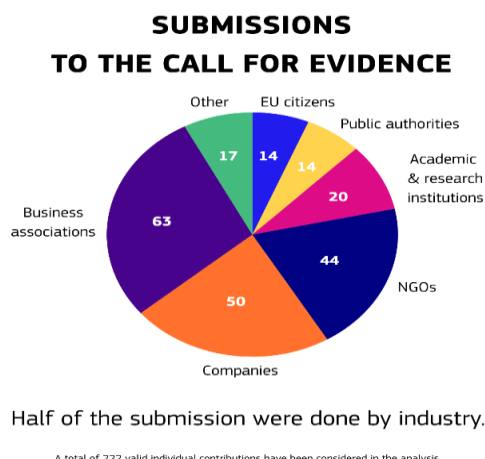


Figure 4: submissions to the call for evidence

The respondents were largely based in the EU (197 responses from 15 Member States). Among these, most of the contributions came from Belgium (74), followed by Germany, (29), France (20), the Netherlands (16), Denmark (12) and Spain (11). 25 contributions were received from 7 non-EU countries (the United States, Switzerland, the United Kingdom, Norway, Canada, Australia and Argentina).

With regard to current biotechnology related regulation, various stakeholder groups such as academic/research institutions, NGOs, representatives of companies (including SMEs), and public authorities underlined **slow and complex regulatory frameworks** that lead to long authorisation/approval processes, thereby hindering innovation and delaying market access. Representatives from businesses (both associations and large companies) referred to the **unpredictability of some authorisation procedures**. Representatives from academic/research institutions and business associations also expressed concerns regarding **outdated regulatory frameworks**, while business associations mentioned in particular the **limited flexibility** of the EU regulatory frameworks. In addition, NGOs/others, large companies and SMEs, business associations and trade unions agreed that **divergent national rules and interpretation/implementation of EU rules** create fragmented market entry

⁴⁶ European Commission ‘Have your say’ website: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14627-Biotech-Act_en

⁴⁷ Three submissions were received from a single respondent and have been counted as one response. Two submissions were received from another respondent and have been counted as one response.

⁴⁸ Three respondents that selected trade unions are analysed together with business associations as representing the industry.

⁴⁹ In the analysis, they are grouped together with feedback from NGOs.

conditions. Feedback from small companies indicated **high regulatory costs** as a result of the regulatory fragmentation, while public authorities also acknowledged high **compliance costs**. Lastly, some feedback pointed to **inconsistencies between EU legislative frameworks**, in particular the CTR, ATMPs Regulation, MDR/IVDR, REACH Regulation and the General Data Protection Regulation (GDPR).

Most stakeholders also indicated a **shortage of risk-tolerant capital**. Stakeholders highlight **fragmented funding schemes, limited early-stage financing, and low EU venture capital share** compared to the US and China. For instance, representatives from academic/research institutes indicated that the EU's venture capital accounted for only about 5% of global venture capital. Representatives of large companies particularly underlined **public R&D under-investment**, indicating poor alignment across policies and programmes. Some contributions from NGOs/others also indicated the risk of dependence on foreign capital, particularly in health and defense-related biotechnologies.

Stakeholders stressed the fundamental role of **education and skills** for the biotechnology and biomanufacturing workforce. Stakeholders expressed concerns about **talent drain and global competition**. This is exacerbated by existing **regulatory and mobility barriers** that hamper cross-border and cross-sector mobility, as indicated in feedback from academic/research institutions. In addition, stakeholders underlined the limited **entrepreneurial pathways** from academia to company building. Moreover, many stakeholders experienced **shortages in the specialised and interdisciplinary competences** needed for the biotechnology and biomanufacturing workforce. Other limitations mentioned were an insufficient number of STEM graduates, the lack of funding or low investment in life-long learning (e.g. digital, AI competencies), and unequal access to upskilling programmes.

Stakeholders across all groups (including academic/research institutions, business associations/trade unions, large companies, citizens, as well as NGOs/others and public authorities) stressed the limited **manufacturing capabilities** in the Union. Some of the underlying factors mentioned were, among others, the high costs, infrastructure and investment gaps, limited digitalisation, supply chain vulnerabilities, and the fragmented regulatory frameworks. SMEs underscored this statement, also pointing to the challenges related to lack of recognition for quality control technologies.

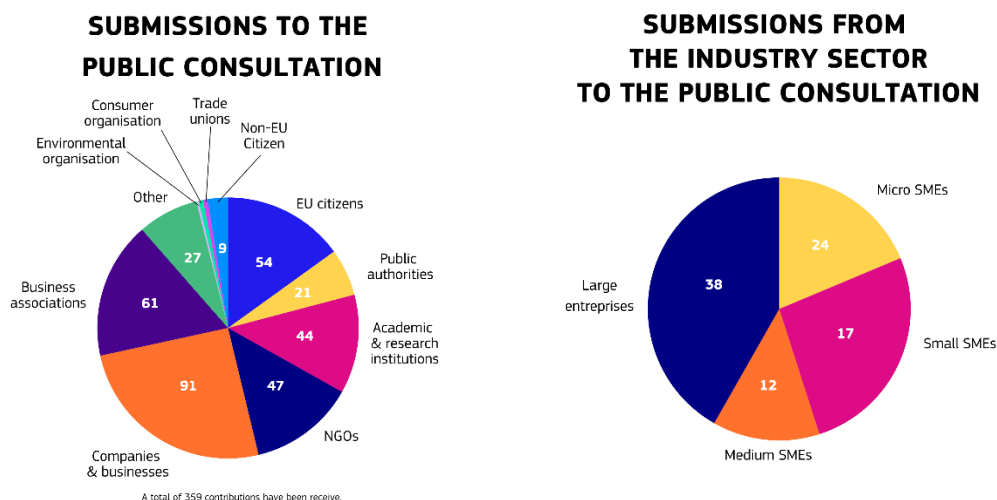
Furthermore, **incubation and acceleration limitations** in the EU were mentioned. Many stakeholder groups, such as academic/research institutions, large companies, NGOs/others and public authorities, highlighted the need to bridge the gap between research and industry in Europe's biotechnology ecosystem. They expressed concerns on the barriers faced in incubation and acceleration, such as funding gaps in early stages, a fragmented support landscape, regulatory burdens, hindrances in public-private collaboration and cultural/skill barriers. Business associations' and public authorities' feedback was in line with this statement, underlining that the EU lacks **cohesive pathways to commercialisation**. Large companies specifically pointed out the lack of financial and administrative capacity of SMEs and start-ups to **access EU-level funding** or to protect their intellectual property.

Stakeholders overall recognised the pivotal role of **AI and data** to advance biotechnology. As part of the challenges faced however, academic/research institutions and large companies indicated a **lack of access to data and secure data sharing**, fragmented data ecosystems including limited data interoperability, unclarity on data governance and insufficient coordination. Business associations and public authorities also mentioned **fragmented computing power and uneven access to testing infrastructures**. Furthermore, SMEs

referred to a lack of information and knowledge among companies about AI implementation and compliance. Feedback from NGOs/others overall echoed these statements, while also advocating to take into consideration the environmental impact of AI infrastructures. Most stakeholders additionally pointed out **regulatory fragmentation**, technical and legal barriers, innovation barriers, and governance gaps. AI skills shortages were also mentioned by several stakeholder groups, as well as ethical uncertainties.

Finally, on biosecurity, stakeholders mentioned that while biotechnology and biomanufacturing offer transformative opportunities across multiple application areas, these must be governed by policies that balance innovation with safety, equity, and environmental protection. Various challenges were pointed out by different stakeholder groups in relation to biosecurity. For instance, academic/research institutions, NGOs and public authorities mentioned a **fragmented biosecurity governance and regulatory complexity** as major issues. Specifically, disjointed EU and national regulations that hinder coherent biosecurity frameworks were highlighted. Public authorities furthermore indicated limited collaboration as a key challenge – for instance gaps in cooperation between national authorities and limited cross-border collaboration. Regarding nucleic acid screening, academic/research institutions, and NGOs mentioned inconsistent compliance in screening due to current voluntary systems as a threat to biosecurity. Finally, dual-use risks were mentioned by SMEs and NGOs.

A **public consultation**⁵⁰ was carried out from 4 August to 10 November 2025. A total of 359 contributions were received. No duplicates or campaigns were identified. The contributions considered for the analysis⁵¹ were submitted by 91 companies/businesses and 61 business associations, 47 NGOs, 44 academic/research institutions, 54 EU citizens and 9 non-EU citizens, and 21 public authorities. A further 2 contributions were submitted by 2 trade unions, 2 consumer associations, and 1 by an environmental organisation⁵², while 27 additional respondents identified themselves as ‘Other’.



⁵⁰ European Commission ‘Have your say’ website: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14627-Biotech-Act/public-consultation_en

⁵¹ Four trade unions were analysed under business associations.

⁵² In the statistics, the 2 trade unions, 2 consumer organisations and the environmental organisation are reflected with the respondents who identified themselves as ‘other’.

Figures 5 and 6: submissions to the public consultations and industry submissions per company size

Concerning the industry sector, **most of the contributions came from SMEs** (53 in total out of which 12 medium-, 17 small-, and 24 micro-sized SMEs) and 38 contributions came from large enterprises. Of the contributing **public authorities**, 8 had a national remit and 8 had a regional scope, 2 of them were local authorities and 3 were international organisations.

As part of all contributions received, **16 respondents identified as private investors**, including 13 from the EU and 3 from outside of the EU (Switzerland and the UK). Most of them identified as company/business. When asked about the type of investment they provided, 8 stated that they provided ‘Venture capital’, 5 chose ‘Business Angel’, 4 ‘Private equity’, 3 ‘Corporate Venture Capital (CVC)’, and 1 ‘Other’.

Lastly, **43 respondents** of all contributions received indicated **being part of a cluster or of a cluster organisation**. These represented 26 companies/businesses, 15 business associations, 1 NGO and 1 ‘Other’.

There is a strong overall interest from stakeholders to the biotechnology sector and acknowledgment of its great potential, in line with the EU’s economic, social and environmental policy goals. More precisely, a strong majority of respondents agreed that biotechnology and biomanufacturing products could positively impact the EU’s economy and the society, also recognizing its contribution to the environment⁵³. Respondents considered biotechnology and biomanufacturing products that reached the EU market to be safe and secure⁵⁴. However, they did not consider that information to users and consumers⁵⁵ on biotechnology and biomanufacturing products in the EU was sufficiently accessible and broadly communicated. Moreover, only a minority of respondents were willing to pay a price premium for such products⁵⁶.

Answers to the public consultation on the **EU regulatory framework** were in line with the **focus of the proposed Act**. The main regulatory barriers⁵⁷ identified by stakeholders concerned the **assessment and obtaining authorisation to market products**, followed by the **pre-commercial testing or clinical trials stage, in commercialising products** as well as in the **scaling-up production or manufacturing and product development**.

Another finding of the public consultation relates to the **perception of the EU regulatory environment compared to that of some countries outside the EU**. The EU regulatory environment is perceived by some stakeholders to have a **lower level of predictability**⁵⁸ and it is also seen as more **complex and unclear**⁵⁹, leading to **more compliance costs**⁶⁰ and

⁵³ Positive economic impact: 90.3% strongly agreed/agreed (324/359); Positive social impact: 89.7% strongly agreed/agreed (322/359); Positive environmental impact: 80.2% strongly agreed/agreed (288/359)

⁵⁴ 76.3%: 175 strongly agreed, 99 agreed (out of 359).

⁵⁵ 28.1%: 30 strongly agreed, 71 agreed (out of 359).

⁵⁶ 15.6%: 13 strongly agreed, 43 agreed (out of 359).

⁵⁷ Agreement/strong agreement on these barriers ranged from 63% to 76%.

⁵⁸ More predictable: 40.8%: 45 strongly disagreed/92 disagreed (out of 336).

⁵⁹ Less complex and clearer: 64.6%: 99 strongly disagreed/116 disagreed (out of 333).

slower access to the market⁶¹. Views on whether the EU regulatory environment ensures a higher **level of safety and security** were rather mixed⁶². Public authorities (57,9%, 11/19), NGOs (46,5%, 20/43), other stakeholders (48,5%, 15/31) and academic/research institutions (42,9%, 18/42) had a positive stance.

These findings underscore the urgent need to take action to simplify and streamline the regulatory environment, making it flexible and innovation-friendly so that biotechnology products and services can reach the EU market more quickly.

Furthermore, respondents reported **low level of access to private investments** in the EU, in particular in accessing to publicly listing, private equity, debt financing, venture capital (VC) across series B (expansion stage) and C (growth stage) and capital markets/shareholders⁶³. It should be noted that stakeholders also expressed **low level of accessibility to some public funding**, especially for support for capacity expansion, debt/equity instruments, and commercialisation support⁶⁴. Stakeholders indicated less difficulties in accessing strategic research or sales partnerships/collaborations, angels, venture capital at start-up/early-stage (series A) and corporate funding⁶⁵ and public grants and subsidies⁶⁶.

When asked about the **factors driving forward investments** in a biotechnology company, there were no major differences in the answers. Some factors scored highly, which are (i) groundbreaking technology; (ii) regulatory certainty; (iii) innovative science; (iv) scientific evidence; (v) experienced management team; and (vi) sufficient protection of intellectual property rights⁶⁷.

On **clusters**, the five main barriers faced by EU biotechnology clusters and/or cluster organisations preventing them from reaching their full potential were identified as: (i) insufficient financial support; (ii) insufficient public support; (iii) incapacity to reach a critical mass of stakeholders; (iv) insufficient start-up incubators or business support infrastructure; and (v) insufficient collaboration among existing clusters⁶⁸.

Stakeholders identified the main challenges impacting the EU biomanufacturing sector as: (i) **global competition**; (ii) length and/or complexity of **permitting processes for new facilities**; (iii) difficulty of **scaling up from pilot to industrial production**; (iv) high energy costs; and (v) the high cost of raw material and/or of the operations⁶⁹. A majority of respondents also agreed that major challenges are also posed by the inconsistent environmental and sustainability policies, vulnerabilities in the supply chains and other operational costs⁷⁰.

⁶⁰ Leads to lower costs for complying with the regulation: 62%: 98 strongly disagreed/109 disagreed (out of 334).

⁶¹ Enables biotechnology and biomanufacturing products to reach the market faster: 65.7%: 126 strongly disagreed/92 disagreed (out of 332)

⁶² Ensures a higher level of safety and security: 21.4% disagreed/strongly disagreed. (72/337) 36.8% agreed/strongly agreed (124/337). 41.8% were neutral or Not applicable/I don't know (141/337).

⁶³ Agreement/strong agreement that there is easy access to these options ranged from 3.9% to 6.7%.

⁶⁴ Agreement/strong agreement that there is easy access to these options ranged from 4.2% to 5.6%.

⁶⁵ Agreement/strong agreement that there is easy access to these options ranged from 11.4% to 21.2%.

⁶⁶ Agreement/strong agreement that there is easy access was 19.2% (69/359).

⁶⁷ Agreement/strong agreement on these factors ranged from 72.4% to 79.9%.

⁶⁸ Agreement/strong agreement on these barriers ranged from 46.2% to 58.5%.

⁶⁹ Agreement/strong agreement on these challenges ranged from 58.2% to 66.9%.

⁷⁰ Agreement/strong agreement on these challenges ranged from 50.1% to 51.5%.

The public consultation also confirmed the challenges faced by the **EU workforce**. Stakeholders' views were aligned on three main challenges: (i) the limited financial, entrepreneurial skills and mindsets; (ii) the insufficient regulatory and quality assurance expertise; and (iii) the shortage of vocational skills⁷¹.

Some stakeholders indicated having difficulties **accessing or using data** for the development of biotechnology or biomanufacturing products⁷². Stakeholders also emphasised that technological challenges and challenges in the implementation of regulatory frameworks were the main barriers to both the **use of AI in R&D**⁷³ and to the **deployment of AI-based biotechnology products**⁷⁴. When asked about the types of **support needed for biotechnology companies, in particular for SMEs**, stakeholders stressed (i) skills development and AI training; (ii) access to annotated datasets; (iii) partnerships with public research institutions or AI hubs/factories; (iv), dedicated funding instruments; and (v) regulatory sandboxes for testing biotech-related AI models⁷⁵.

When it comes to the application of biotechnology in defence and security, the main challenges identified by stakeholders were: (i) the **risks to strategic autonomy** in biomanufacturing (and availability of medical and non-medical countermeasures); (ii) **cybersecurity risks** to biotechnology infrastructure and AI tools used in biotechnology; (iii) vulnerabilities in the **resilience of biotechnology supply chains**; and (iv) threats related to biosecurity and biosafety including **misuse of biotechnology**⁷⁶. The four main **opportunities** that biotechnology for defence and security were creating were: (i) to develop **new innovative medical countermeasures**; (ii) to facilitate **detecting biological and chemical threats**, (iii) to increase **food security**; and (iv) to develop **materials with new functions and / or improved characteristics**⁷⁷.

In addition, **targeted consultation activities** were carried out, as detailed below, including in the context of an external study announced in the Commission Communication 'Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU' (Action 1)⁷⁸.

First, the following consultation activities took place on the analysis of regulatory problems and challenges faced by the biotechnology sector and on the mapping of applicable EU and national legislations to biotechnologies:

- **survey for public authorities;**
- **survey for other stakeholders**, including industry representatives and patient organisations;

⁷¹ Agreement/strong agreement on these challenges ranged from 51.8% to 58.5%.

⁷² 21.4% replied partially (77/359) and 18.4% replied Yes (66/359) totalling 39.8%. However 44% replied Not applicable/I don't know (158/359 answers) and 16.2% replied No (58/359).

⁷³ Technological challenges:61.3%: 65 strongly agreed/155 agreed (out of 359); challenges in the implementation of regulatory frameworks: 59.1%: 81 strongly agreed/ 131 agreed (out of 359).

⁷⁴ Technological challenges:51.5%: 63 strongly agreed/122 agreed (out of 359); challenges in the implementation of regulatory frameworks: 52.1%: 81 strongly agreed/106 agreed (out of 359).

⁷⁵ Agreement/strong agreement on the needed types of support ranged from 59.1% to 65.5%

⁷⁶ Agreement/strong agreement on the four main challenges ranged from 42.3% to 51.5%

⁷⁷ Agreement/strong agreement on the three main opportunities ranged from 43.7% 48.2%.

⁷⁸ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU*, COM(2024) 137 final.

- **interviews** with representatives of SMEs and large enterprises, and representatives of the spin-off, alliance/platform, scale-up and EU association sectors;
- **five thematic workshops** covering (i) health/pharma; (ii) agriculture/environment; (iii) food and feed; (iv) bio-based chemicals and plastics; and (v) bio-based materials.

Second, to analyse the impacts of identified policy provisions, evidence was collected on the impacts of these provisions.

On **clinical trials**, evidence has been collected (by November 2025) through:

- **three workshops organised by the European Commission** in June, September, and November 2025⁷⁹, with representatives of national competent authorities and ethics committee members from across the EU to exchange views with experts to inform how policy options would be defined;
- **targeted interviews**;
- **targeted survey** to various stakeholder groups:
 - **a survey targeted to sponsors and clinical research organisations** received 48 responses⁸⁰.
 - another **targeted survey collected views from 44 public authorities** representing 25 EU/EEA countries⁸¹.
 - **a survey tailored to patient representatives** received 1 response from a disease-specific patient representing an organisation at national level.

Evidence on the impacts of options on **genetically modified microorganisms** was collected through **25 interviews** (by November 2025).

Finally, targeted consultation activities were also conducted as part of the **supporting study for the evaluation of EFSA**.

• **Collection and use of expertise**

The major competitiveness gap in biotechnology and the market and regulatory barriers faced by European companies were identified in the Commission Communication ‘Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU’⁸² and in the Draghi⁸³ and Letta⁸⁴ reports.

⁷⁹ CTAG: Clinical Trials Advisory Group; MedEthics-EU, the Clinical Trials Coordination Group of the Heads of Medicines Agencies (HMA) was also invited to the workshop. The EMA is an observer to the CTAG.

⁸⁰ 32 from commercial sponsors, 6 from non-commercial sponsors, 3 from Clinical Research Organisations (CROs), and 7 from other stakeholders such as non-profits, hospital owners, advocacy groups, research infrastructures, trade associations and life sciences providers

⁸¹ 20 responses from ethics committees, 20 from national competent authorities, 3 from ministries or government bodies, and 1 from a respondent identified as both a ministry and an ethics committee

⁸² Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU*, COM(2024) 137 final.

⁸³ Draghi, Mario. [The future of European competitiveness: A competitiveness strategy for Europe](#), European Commission, 9 September 2024.

In addition, the above-mentioned external study commissioned by the European Commission (**‘Analysis of the Regulatory Framework for Biotechnology and Biomanufacturing in the EU’**) provides an extensive mapping of the main pieces of EU and national legislation that apply to biotechnology and biomanufacturing products and processes – whether they are horizontal or sector-specific – and identifies the challenges, their causes and the consequences for stakeholders. The study also assesses the impacts of policy options related to the EU regulatory framework.

- **Impact assessments**

Considering the politically urgent need to address the policy challenges identified, an impact assessment could not have been delivered in the timeframe available before the proposal’s adoption. Instead, an analytical staff working document (SWD) will be prepared. The analytical SWD will explain the proposal and will present the underlying evidence and impact analysis, including cost-benefit analysis. A large number of provisions of the proposal concern simplification measures which typically do not offer viable alternatives and do not modify the objectives of the amended legislation. Nevertheless, the proposed measures are based on extensive stakeholder consultations, complemented with an analysis of the current situation to ensure a transparent, proportionate, and evidence-based approach.

- **Regulatory fitness and simplification**

The proposal lays down measures to strengthen the EU biotechnology and biomanufacturing ecosystem and reduce time-to-market for biotechnology products in the EU.

The proposed Act aims to **simplify the existing regulatory framework and remove regulatory burdens hampering the innovation and competitiveness of EU operators**. In particular, the measures seek to clarify and reduce procedural timelines across the full development cycle (e.g. by alleviating complex and disproportionate requirements) and provide a flexible regulatory environment for a fast-growing innovative sector (e.g. through regulatory sandboxes and by enabling an increasing use of data and AI). As such, all actors, in particular **companies**, will benefit from a more predictable EU regulatory framework, i.e. increased legal certainty, reduced procedural timelines, and a flexible and collaborative regulatory environment. Overall, these measures are expected to enable companies to bring innovation to the market. SMEs in particular are expected to benefit from these measures through reduced entry barriers in the field of biotechnology. The supporting measures also target the needs of SMEs, start-ups and scale-ups.

National and regional authorities will benefit from streamlined, more coherent procedures and improved coordination, reducing duplication of work, and supporting more consistent regulatory decisions across the Union.

The proposed measures are targeted amendments that preserve the objectives of the existing regulations to maintain and safeguard a high level of **protection of health and the environment**. Similarly, measures to prevent the misuse of biotechnologies and strengthen EU biodefence capabilities, including monitoring AI-enabled biological risks, will ensure that innovation is accompanied by robust safeguards for public health and security.

⁸⁴ Enrico Letta (2024), *Much more than a Market*. [Enrico Letta - Much more than a market \(April 2024\)
https://www.consilium.europa.eu/media/ny3j24sm/much-more-than-a-market-report-by-enrico-letta.pdf](https://www.consilium.europa.eu/media/ny3j24sm/much-more-than-a-market-report-by-enrico-letta.pdf)

Furthermore, **EU biotechnology businesses**, and in particular those with the potential to be transformative for the biotechnology ecosystem are expected to have improved access to capital throughout the different stages of their development and better access to the infrastructure needed to assess the industrial potential of their innovation, thus contributing to a thriving biotechnology and biomanufacturing ecosystem in the EU. Strategic biotechnology projects, which the proposal aims to foster, may also include activities addressing the growing skills gap in biotechnology and biomanufacturing and are expected to contribute to a workforce capable of supporting innovation, industrial scale-up and long-term competitiveness. **Investors and financial** intermediaries will benefit from a more predictable pipeline of projects and clearer regulatory certainty, supporting greater availability of risk-tolerant capital in the EU.

The initiative will foster, in line with the Union policy and legislation on AI, the use of AI across the biotechnology ecosystem, giving **companies – and more particularly SMEs** – more guidance and opportunities to integrate trustworthy, high-quality AI solutions into research, testing and production processes.

End-users, including **patients and citizens** will benefit from biotechnology products that meet their needs. Faster time-to-market and, improved clinical-trial performance are expected to result in earlier access to safe, effective, high-quality and affordable biotechnology products, including advanced therapies, diagnostics, biosimilars and innovative biomanufactured products which will also benefit **healthcare systems**.

Overall, these targeted measures combined are expected to (i) facilitate the growth of the EU biotechnology and biomanufacturing industry in the EU; (ii) improve the global competitiveness and innovation capacity of the EU's biotechnology companies; and (iii) increase the EU's strategic autonomy in critical technological areas.

- **Fundamental rights**

The Act respects the fundamental rights and principles laid down in the Charter of Fundamental Rights of the European Union⁸⁵.

The proposed measures simplifying EU legislation and the new initiatives on EU industrial policy are expected to contribute to the smooth functioning of the internal market and, in particular, support the freedom to conduct a business (Article 16 of the Charter). The measures under this proposal seek to enable innovation, expand the EU's manufacturing capacity and clarify procedures for biotechnologies to reach the market. The proposed measures will also ensure a high level of human health protection and will enhance the right of access to preventive healthcare and the right to benefit from medical treatment under the conditions laid down by national laws and practices, as provided in Article 35 of the Charter. Similarly, the proposal will help ensure a high level of environmental protection and improve the quality of the environment, in line with Article 37 of the Charter.

4. BUDGETARY IMPLICATIONS

Without prejudice to the outcome of the negotiations on the next Multiannual financial framework (MFF) proposal, strategic health biotechnology projects and high-impact strategic

⁸⁵ Charter of Fundamental Rights of the European Union, ELI: http://data.europa.eu/eli/treaty/char_2012/oj

biotechnology projects may be supported by Union programmes, funds and instruments, in accordance with the objectives set out in the regulations establishing those funds and programmes. A contribution is expected to come from the “health, biotechnology, agriculture and bioeconomy” window under the European Competitiveness Fund which, according to the proposal of the Commission, would receive a total allocation of EUR 20.4 billion over the MFF 2028-2034. Two agencies, EMA and EFSA are proposed to be reinforced in staff and financially to conduct tasks related to these projects. The necessary financial resources will be compensated from applicable programmes under the agencies' headings in the 2028-2034 MFF and where possible by additional income to be generated from third parties. The Legislative Financial and Digital Statement (LFDS) also presents estimated budgetary impact under Heading 4 including related human and administrative resources.

5. OTHER ELEMENTS

• Implementation plans and monitoring, evaluation and reporting arrangements

In the short term, implementation will focus on completing the strategic mapping of the Union’s biotechnology ecosystem within six months of the Regulation’s entry into force, and on setting up the new governance and support structures, including the EU Health Biotechnology Support Network, the Foresight Panel for Emerging Health Innovation and the European Health Biotechnology Steering Group. To support Member States in implementing the Regulation, to promote a uniform application of the Regulation and to clarify technical or operational elements where needed, the Commission may issue guidance on specific matters, including the criteria and procedures for recognising strategic health biotechnology projects and high-impact health biotechnology strategic projects, and the coordination between the EU Health Biotechnology Support Network and other relevant networks. Member States will be required to designate national single points of contact and begin applying the streamlined regulatory procedures.

Monitoring will rely on the strategic mapping as a continuous evidence base, complemented by regularly updated information on the list of strategic health biotechnology projects and high-impact health biotechnology projects.

In the medium term, the strategic mapping of the biotechnology ecosystem will be updated periodically and used to inform project selection and guide the deployment of Union support. Five years after the Regulation’s entry into application, and every five years thereafter, the Commission will evaluate the Regulation’s effectiveness and impact, and report its findings to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

• Detailed explanation of the specific provisions of the proposal

Chapter I – Subject Matter, Scope and Definitions

This Chapter sets out the subject matter of this proposal, which consists of measures that articulate its overall objective (i) to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the biotechnology sector, from research to production, (ii) to create the conditions for the development and timely placing on the Union market, of biotechnology innovations, products and services, (iii) while safeguarding high standards for the protection of human health, animal health, patients and consumers, the environment, ethics, quality, food and feed safety, and biosecurity. This Chapter also specifies the scope of the proposal, which applies to health biotechnology

products and services during their entire lifecycle, including related activities on research, funding, development, innovation, testing, validation, manufacturing, placing on the market and use. Lastly, this Chapter establishes definitions for key terms used throughout the proposal, including ‘biotechnology’, ‘health biotechnology’, ‘biotechnology product’, ‘biotechnology service’ and ‘biomanufacturing’.

Chapter II – Union health biotechnology and biomanufacturing

This Chapter introduces the concepts of health biotechnology strategic projects and high impact health biotechnology strategic projects and establishes a framework for the recognition and the support of such projects aimed at strengthening the EU’s industrial biomanufacturing capacity and value chains. Strategic projects should mobilise and focus action at Union and Member State level, including on public and private investments and accelerated permitting and other support measures, to boost Europe's competitiveness and resilience in biotechnology. To build a strong EU biotechnology ecosystem, provisions are included to encourage pro-competitive collaboration between projects, networks and clusters. These measures are to be underpinned by a strategic mapping of the Union’s biotechnology ecosystem to identify capacities, gaps, dependencies and investment needs, thereby guiding the prioritisation of strategic and high-impact projects and informing Union policy and funding decisions. This Chapter also sets up an EU health biotechnology support network of national and regional antennas to support biotechnology projects and innovators in navigating regulatory procedural pathways relevant to health biotechnologies and identifying opportunities for funding, scaling up and networking, leveraging and complementing the activities of existing national and European networks that support SMEs, start-ups and scale-ups, and innovators.

Finally, this Chapter establishes the European Health Biotechnology Steering Group, composed of representatives of Member States and the Commission and its tasks, which include facilitating communication among Member States, the Commission, and various stakeholders to ensure biotechnology projects are recognised and implemented effectively.

Chapter III – Access to funding

This Chapter establishes an EU health biotechnology investment pilot in partnership with the European Investment Bank Group and other implementing partners, which brings together equity instruments and venture-style debt tailored to biotechnology-specific risk profiles, in order to mobilise private investment into the sector. Projects contributing to an EU late-stage Capital Booster Pilot will be recognised by the Commission as high-impact strategic health biotechnology projects. Companies, projects and initiatives falling within the scope of this Regulation may be considered for Union and Member State financial support, in line with applicable State aid rules.

Chapter IV – Extension of the supplementary protection certificate

This chapter introduces an extension of 12 months of the Supplementary Protection Certificate (SPC) for medicinal products developed by means of biotechnology processes and for Advanced Therapy Medicinal Products. This provision aims at incentivising the development of products developed with innovative biotechnology technologies which will bring a therapeutic advantage to patients. This incentive will also support the clinical

development and the manufacturing of these products in the Union, subject to compliance with applicable competition rules.

Chapter V - Enhancing competitiveness in biosimilars

This Chapter supports EU competitiveness in the field of biosimilars by encouraging the development of EMA guidelines on facilitating the authorisation of biosimilar medicinal products. This Chapter also includes measures supporting strategic health biotechnology projects focused on biosimilar research, development, manufacturing and marketing authorisation and promotes international cooperation between economic operators and biotechnology clusters in this area, subject to compliance with applicable competition rules. Any funding from Member States should be in line with applicable State aid rules.

Chapter VI – Artificial intelligence and data as biotechnology enablers

This Chapter aligns with the AI-first policy introduced in the Apply AI Strategy and encourages the adoption and integration of AI in actions supporting biotechnology, in order to foster innovation, efficiency and technological sovereignty in biotechnology and biomanufacturing. It also provides for guidance to be issued by the EMA on the use of AI across the medicinal-product lifecycle and creates trusted AI testing environments and data-quality accelerators as high-impact strategic health biotechnology projects to advance safe AI-enabled biotechnology.

Chapter VII – Regulatory tools for novel health biotechnology products

This Chapter sets out a flexible, collaborative and anticipatory approach to regulate novel health biotechnology products by reinforcing and complementing existing mechanisms in Union law, notably (i) those introduced in the revised Directive 2001/83/EC on the interaction and combinations between medicinal products and medical devices, and on regulatory sandboxes; and (ii) the mechanisms provided under the [revised] MDR, IVDR, the revised Pharmaceutical Regulation and the SoHO Regulation, which allow for the provision of opinions, recommendations or binding decisions on the regulatory status of products. This Chapter lays down a Union-wide, cross-framework regulatory status repository, which will compile relevant opinions, recommendations, decisions and guidance, thus fostering transparency, consistency and mutual learning across Union and national authorities. Recognising the need for anticipatory governance, this Chapter also sets up a foresight panel for emerging health innovation to advice the Commission and conduct structured horizon-scanning and cross-framework dialogue on forthcoming scientific and technological developments. Lastly, this Chapter provides for the establishment of a Union level regulatory sandbox for health biotechnology products at an early stage of development that fall outside existing health legal frameworks.

Chapter VIII – Biodefence and preventing biotechnology misuse

This Chapter establishes a framework for preventing the misuse of biotechnology products of concern. It includes provisions for screening, reporting, and tracking suspicious transactions of biotechnology products of concern, and enforcement mechanisms to ensure compliance. This Chapter sets out specific conditions for the Commission to recognise high-impact strategic health biotechnology projects in the form of EU biodefence capability projects, that may be given particular consideration for funding under Union basic acts, subject to compliance with applicable State aid rules. Ultimately, the Regulation seeks to promote a high level of protection against biotechnological threats, while fostering innovation and

competitiveness in the biotechnology sector.**Chapter IX – Amendments to Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938**

This Chapter introduces amendments to EU legislative frameworks in the areas of health and food and feed safety with the aim of simplifying procedures and accelerating time to market that are necessary to ensure the effectiveness of the substantive provisions established in this proposal by creating legislative frameworks conducive to innovation. Further, it establishes amendments to Regulation (EU) 2024/795 (STEP Regulation)⁸⁶ regarding the status of health biotechnology strategic projects and of high impact health biotechnology strategic projects under that Regulation.

Amendments to Regulation (EC) No 178/2002 (General Food Law)

This Regulation proposes amendments to Regulation (EC) No 178/2002⁸⁷ laying down the general principles and requirements of food law, in order to streamline risk assessment processes. Key changes include (i) broadening pre-submission advice to include scientific matters, such as study design and testing strategies, while merging it with the renewal-related advice into a single, unified procedure to simplify application procedures; (ii) shortening the procedural delay for non-compliance with the study notification requirements at pre-submission phase from six to three months to reduce time-to-market; (iii) requiring EFSA staff to chair panels and serve as vice-chairs of the Scientific Committee (without voting rights) to improve efficiency and coherence across Panels; and (iv) introducing provisions for regulatory sandboxes, allowing Member States to test innovative technologies under harmonised conditions that foster innovation while safeguarding consumer health and safety. Such amendments should contribute, amongst others, to accelerating the risk assessment process carried out by EFSA for products that are subject to pre-market authorisation in accordance with Union food and feed law and foster innovation in the sector. As such, those are necessary amendments with a view to ensure the effectiveness of the substantive measures put forward in this proposal towards the strengthening of an innovative biotechnology sector in food and feed safety.

Amendments to Regulation (EC) No 1394/2007 (Advanced Therapy Medicinal Products Regulation)

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⁸⁶ Regulation (EU) 2024/795 of the European Parliament and of the Council of 29 February 2024 establishing the Strategic Technologies for Europe Platform (STEP), and amending Directive 2003/87/EC and Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241, ELI: <http://data.europa.eu/eli/reg/2024/795/oj>

⁸⁷ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, pp. 1–24. ELI: <http://data.europa.eu/eli/reg/2002/178/oj>

on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act)

(Text with EEA relevance)

To speed up access to advanced investigational therapy medicinal products that consist or contain GMOs that are complex innovative products, this Regulation proposes special provisions for facilitating related clinical trials. In this regard, it is proposed to amend Regulation (EC) No 1394/2007 to provide that when controlling under Regulation (EU) No 536/2014 for risks from the deliberate release into the environment of GMOs, sponsors are to be exempted from the requirement to submit an environmental risk assessment in respect of certain clearly delineated categories of advanced investigational therapy medicinal products that consist or contain GMOs which present no or negligible risks to human health and the environment. Sponsors of clinical trials are, however, to submit a declaration as part of the clinical trial application that explains why the advanced investigational therapy medicinal products concerned fall into one or more of the specific categories of products presenting no or negligible risks to human health and the environment. The Committee for Medicinal Products for Human Use (CHMP) referred to in Article [148] of Regulation [...] [revised Regulation No (EC) 726/2004] is to verify this declaration. For the same considerations of a risk-proportionate approach, this Regulation also proposes that the above-mentioned categories of advanced investigational therapy medicinal products be exempted from the GMO related requirements of Regulation (EU) No 536/2014 regarding manufacturing and import.

Scientific and technological advances are driving forward the development of ATMPs. To future-proof the ATMP regulatory framework and ensure that it can encompass certain innovative products that could benefit from the ATMP framework, without them falling under other EU legal frameworks, the [revised Directive 2001/83/EC] empowers the Commission to adopt delegated acts to amend the definitions laid down in the ATMP Regulation of a gene therapy medicinal product and a somatic cell therapy medicinal product, without extending the scope of these definitions. It should be also possible to amend the definition of a tissue engineered product in the light of technical and scientific advancements.

Amendments to Regulation (EU) No 536/2014 (Clinical Trials Regulation)

This Chapter, critical to improving Europe's clinical-trial framework, aims to cut approval timelines, foster greater collaboration across borders, and improve regulatory efficiency, without compromising safety, quality, or ethical standards. Simplification and acceleration of procedures are necessary for ensuring the effectiveness of the enabling substantive measures put forward in this proposal. Authorisation timelines will be shortened for multinational clinical trials from 106 days to 75 days, including validation and ethical review. When there is no request for information to the sponsor, timelines for initial clinical trial authorisations will be reduced from 75 days to 47 days from submission to decision. Given the growing scientific and regulatory expertise in ATMPs, the additional 50 days for assessing these products will be eliminated. The assessment period for substantial modifications will be reduced from 96 days to 47 days, with options for parallel substantial modifications. If there is no request for information to sponsor, the timelines for the assessment of substantial modifications will be reduced from 64 days to 33 days from submission till decision. The reporting Member State's role will be strengthened so that it can lead the scientific, ethical, and regulatory assessment harnessing mutual trust between Member States and reliance on the assessment of the

reporting Member State. Communication between sponsors and Member States will be improved during assessments. A single, core dossier for investigational products will simplify clinical trials using the same investigational medicine and help the conduct of registration trials and the preparation of marketing authorisation applications in Europe. Simplifications for low-intervention clinical trials will be further supported by introducing a new category of 'minimal-intervention' clinical trials. Mandatory EU harmonised templates will enable harmonisation. A single assessment process will be defined for combined studies involving the investigation of a medicine together with a medical device or an in-vitro diagnostic. The legal basis for processing personal data in clinical trials in accordance with Regulation (EU) 2016/679 requirements will be harmonised. Accelerated and simplified procedures will enable multinational clinical trials to be carried out on in relation to public health emergencies. The uptake of the use of AI systems and digitalisation in clinical trials will be fostered. Clinical trial sandboxes will be created to test innovative approaches. Annex I to Regulation (EU) No 536/2014 is also amended to ensure consistency with the amendments to Regulation (EC) No 1394/2007 proposed in this Regulation, regarding certain categories of advanced investigational therapy medicinal products containing or consisting of GMOs.

Amendments to Regulation (EU) 2019/6 (Veterinary Medicine Products Regulation)

Biological veterinary medicinal products, derived from living sources, have more complex lifecycle and variation handling than chemically synthesised medicines. Regulation (EU) 2019/6⁸⁸ introduced variations not requiring assessment to reduce administrative burden, which will be further optimised in this section without affecting quality, safety, or efficacy. To cut administrative burden for innovations, this section foresees that the assessment of human health and environmental impacts of veterinary medicinal products containing genetically modified organisms should be made solely under the Environmental Risk Assessment (ERA) pursuant to Regulation (EU) 2019/6, removing the need for assessment under the Union GMO legislation, while reinforcing obligations under Regulation 2019/6. The section also clarifies that administering veterinary medicinal products does not place treated animals or their products under the Union GMO legislation. Also, the Commission is empowered to adapt technical requirements in Annex II to Regulation 2019/6 to scientific and technical progress. Veterinary medicinal products developed by means of biotechnology processes to diagnose, treat or prevent zoonotic diseases are entitled to an extra year of SPC. Finally, the introduction of regulatory sandboxes for animal health innovation will allow new technologies, methods, or products to be tested, marketed, or used under proportionate oversight where no specific EU legislation exists, fostering responsible innovation in veterinary medicine

Amendments to Regulation (EU) 2024/795 (STEP Regulation)

This provision introduce amendments to Regulation (EU) 2024/795 to establish that health biotechnology strategic projects, including high-impact health biotechnology strategic projects recognised in accordance with this Regulation are to be deemed to contribute to the STEP objectives referred to in Article 2 paragraph 1, point (a)(iii) or point (b) of the STEP Regulation, as appropriate.

⁸⁸ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (Text with EEA relevance), OJ L 4, 7.1.2019, pp. 43–167. ELI: <http://data.europa.eu/eli/reg/2019/6/oj>

Substances of human origin (SoHO) are a key pillar of biotechnology as they can become starting materials for innovative medicinal products. This section introduces a regulatory sandbox in the SoHO framework. It enables access to very innovative but regulatory challenging therapies and products while generating insights that can inform updates to regulatory frameworks, ensuring that they remain flexible, adaptive and fit for purpose in the face of evolving scientific and technological advancements.

Chapter X – Final provisions

This Chapter contains provisions on (i) monitoring; (ii) delegation of power; (iii) committee procedure, (iv) an obligation for the Commission to prepare regular reports to the European Parliament and to the Council for the evaluation of this Regulation; (v) handling of confidential information, and entry into force and application.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114, 168(4) and 173(3) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Biotechnology is a strategic technology central for the Union's competitiveness, strategic autonomy and innovation leadership. It has applications across several sectors, with prominence in the health area. In 2021, the Union was the second largest contributor to the global value of biotechnologies. Between 2008 and 2018, the biotechnology industry in the Union grew more than twice as fast as the overall economy, making it one of the fastest growing innovative industries in the Union. Health biotechnology specifically contributes over 80% to the value of the overall biotechnology market and it is a key driver of today's innovative medical industry. Biological medicines, including biosimilars count for 40% of overall pharmaceutical sales in the Union.
- (2) While recognised globally for its scientific excellence, the Union continues to face structural challenges in translating cutting-edge research and innovation into large-scale development, testing, manufacturing and deployment of biotechnology. As a result, the significant potential of biotechnology applications across several sectors to contribute to major societal challenges, modernise the Union economy and strengthen Union strategic autonomy and security remains largely underexploited.
- (3) This is due in particular to limited access to risk capital and other sources of funding, skills shortages within the internal market, slow permitting processes that hinder the timely deployment of projects and initiatives aiming to bring biotechnology innovations to the market, as well as fragmented and at times complex regulatory frameworks.

- (4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality, food and feed safety and biosecurity.
- (5) Given the importance of health biotechnology amongst the other applications of biotechnology as referred to in recital (1), it is appropriate that this Regulation focusses on, and sets out specific measures for, the health dimension of biotechnology. To ensure the effectiveness of this Regulation, its scope of application should extend to health biotechnology in a comprehensive manner and cover health within the wide meaning of Article 168 TFEU on the protection of public health.
- (6) Article 168(1) TFEU emphasises that a high level of human health protection is to be ensured when defining and implementing all Union policies and activities. Article 168(4) TFEU clarifies that this objective is, amongst others, to be pursued through measures setting high standards of quality and safety for medicinal products and devices for medical use and of organs and substances of human origin, blood and blood derivatives, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health.
- (7) Accordingly, and in line with the One Health approach, that aims to comprehensively and sustainably balance and optimise the health of people, animals, and ecosystems¹, this Regulation should apply to health biotechnology, understood as the application of biotechnology in the human medical, veterinary, pharmaceutical and phytosanitary areas for the development of biotechnology products and services. This Regulation should apply to their entire lifecycle, including the related research, access to funding, development, innovation, testing, validation, manufacturing, placing on the market and use activities.
- (8) With a view to ensuring the effectiveness, consistence and unity of some of the legal acts that this Regulation should amend to foster the Union's competitiveness in biotechnology, this Regulation should in certain cases also apply to products and activities other than biotechnology products and activities, so as to avoid the creation of different sets of rules for biotechnology and non-biotechnology products and activities. This is in particular the case in the area of health for Union legislation regarding clinical trials, and in the food and feed safety area, for Regulation (EC) No 178/2002 of the European Parliament and of the Council².
- (9) This Regulation should apply without prejudice to the harmonised legal framework for the development, the placing on the market, the putting into service and the use of

¹ European Commission: Group of Chief Scientific Advisors and Directorate-General for Research and Innovation, One Health governance in the European Union, Publications Office of the European Union, 2024, <https://data.europa.eu/doi/10.2777/8697309>.

² Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1. ELI: <http://data.europa.eu/eli/reg/2002/178/oj>.

artificial intelligence (AI), laid down by Regulation (EU) 2024/1689³ of the European Parliament and of the Council³.

- (10) This Regulation should not affect to the application of the Directive 2010/63/EU of the European Parliament and of the Council⁴ on the protection of animals used for scientific purposes and of Regulation (EC) 2006/1907 of the European Parliament and of the Council⁵.
- (11) The Union has adopted other initiatives to strengthen the competitiveness of particular sectors of the Union economy. In this regard, Regulation (EU) 2024/1735 of the European Parliament and of the Council⁶ focuses on clean and resource-efficient technologies which include, in particular, net-zero technologies. That Regulation establishes a framework to ensure the Union's access to a secure and sustainable supply of net-zero technologies listed in Article 4 thereof. Such technologies include sustainable biogas and biomethane technologies and biotechnology climate and energy solutions. However, as acknowledged by Regulation (EU) 2024/795 of the European Parliament and of the Council⁷, biotechnologies have applications beyond the clean and resource-efficient technologies. It is therefore appropriate that this Regulation applies without prejudice to the provisions of Regulation (EU) 2024/1735 regarding sustainable biogas and biomethane technologies and biotechnology climate and energy solutions.
- (12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such

³ Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: <http://data.europa.eu/eli/reg/2024/1689/oj>).

⁴ Consolidated text: Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (Text with EEA relevance). ELI: <http://data.europa.eu/eli/dir/2010/63/2019-06-26>

⁵ Consolidated text: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance). ELI: <http://data.europa.eu/eli/reg/2006/1907/2025-09-01>.

⁶ Regulation (EU) 2024/1735 of the European Parliament and of the Council of 13 June 2024 on establishing a framework of measures for strengthening Europe's net-zero technology manufacturing ecosystem and amending Regulation (EU) 2018/1724 (Text with EEA relevance), OJ L 1735 28.6.2024, p. 1. ELI: <http://data.europa.eu/eli/reg/2024/1735/oj>.

⁷ Regulation (EU) 2024/795 of the European Parliament and of the Council of 29 February 2024 establishing the Strategic Technologies for Europe Platform (STEP), and amending Directive 2003/87/EC and Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241 (OJ L, 2024/795, 29.2.2024. ELI: <http://data.europa.eu/eli/reg/2024/795/oj>).

recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support. It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.

- (13) NAMs applied in biological research, early discovery, preclinical development, and the regulatory and quality testing of medicinal products and medical technologies, have the potential to generate scientific and technological data that are comparable to, or in some cases more informative and generated more rapidly than, those obtained through current standard methods. The resulting advantage will contribute to strengthen the innovation ecosystem and enhanced European competitiveness in biotechnology.
- (14) Certain health biotechnology strategic projects have the potential to contribute to the Union's objectives in biotechnology in a manner that is systemic and can produce a multiplier effect. Such projects act as catalysts for cooperation between academia, industry and public authorities, and can serve as anchors for regional biotechnology clusters and innovation ecosystems across Member States. Experience in several Member States has shown that such projects can quickly raise industrial capability, attract investment and strengthen the Union's position in global value chains. Accordingly, such projects should be recognised as high impact health biotechnology strategic projects by the Commission and could be given particular consideration for Union funding, priority access to administrative support and fast-tracked procedures at Member State level. As regards national funding of such projects, Regulation (EU) 2024/795⁸ provides measures for the support of critical and emerging strategic technologies and their respective value chains within programmes implemented under shared management. That Regulation amends the basic acts of several shared-management funds, namely Regulations (EU) 2021/1056⁹, (EU) 2021/1057¹⁰ and (EU) 2021/1058 of the European Parliament and of the Council¹¹, in order to enable Member States to steer their national and regional programmes towards investments in critical technologies, including biotechnologies. Without prejudice to the applicable rules governing each such funding instrument, and in line with applicable State aid rules, this approach may therefore be applied to high-impact health biotechnology strategic projects, which are deemed in accordance with this Regulation as to contribute to the STEP objectives.

⁸ Regulation (EU) 2024/795 of the European Parliament and of the Council of 29 February 2024 establishing the Strategic Technologies for Europe Platform (STEP), and amending Directive 2003/87/EC and Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241, ELI: <https://eur-lex.europa.eu/eli/reg/2024/795/oj>.

⁹ Regulation (EU) 2021/1056 of the European Parliament and of the Council of 24 June 2021 establishing the Just Transition Fund (OJ L 231, 30.6.2021, p. 1, ELI: [http://data.europa.eu/eli/reg/2021/1056/oj](https://data.europa.eu/eli/reg/2021/1056/oj)).

¹⁰ Regulation (EU) 2021/1057 of the European Parliament and of the Council of 24 June 2021 establishing the European Social Fund Plus (ESF+) and repealing Regulation (EU) No 1296/2013 (OJ L 231, 30.6.2021, p. 21, ELI: [http://data.europa.eu/eli/reg/2021/1057/oj](https://data.europa.eu/eli/reg/2021/1057/oj)).

¹¹ Regulation (EU) 2021/1058 of the European Parliament and of the Council of 24 June 2021 on the European Regional Development Fund and on the Cohesion Fund (OJ L 231, 30.6.2021, p. 60, ELI: [http://data.europa.eu/eli/reg/2021/1058/oj](https://data.europa.eu/eli/reg/2021/1058/oj)).

- (15) The strategic importance of biotechnology for European competitiveness has already been established, including through the proposed a European Competitiveness Fund (ECF) for the Multiannual Financial Framework (MFF) period 2028-2034, which includes a dedicated ‘Health, Biotech, Agriculture and Bioeconomy’ window. The Draghi Report on the Future of European Competitiveness¹² recommends that the Union should focus resources on a limited number of world-class centres of excellence in life sciences and biotechnology. High impact biotechnology health strategic projects have the potential to contribute to this focus of efforts and be a tool for an impactful use of resources in the MFF period 2028-2034, to help position the Union among the leading regions for biotechnology. Examples of categories of such high impact projects and specific criteria should be established for their recognition by the Commission. Amongst those categories, high impact health biotechnology strategic projects in the form of biotechnology development accelerators providing, amongst others, trusted testing or demonstration facilities replicating real-world biomanufacturing processes, should play a key role in translating Europe’s scientific excellence into productive industrial capacity. By pooling advanced equipment and expertise and offering criteria-based access, including for small and medium-sized enterprises, start-ups and scale-ups, such projects should reduce duplication of efforts, lower entry barriers, and foster the specialised skills required for advanced biomanufacturing. Similarly, high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products, should combine research, regulatory science and manufacturing capabilities, enabling faster, safer and more efficient development of innovative therapies. When connected to digital and data infrastructures, they should have the potential to accelerate clinical translation, improve quality control and facilitate patient access across the Union.
- (16) To maximise the Union-wide benefits of investments made in projects or entities operating infrastructures, facilities and services supported and established or recognised in accordance with this Regulation, such projects or entities should provide open, non-discriminatory, transparent and criteria-based access to users from all Member States, including academic institutions, industrial undertakings, with particular attention to SMEs, start-ups and scale-ups, and public research bodies. Access conditions should be proportionate and ensure fair treatment among users, taking into account the objectives and capacity of each infrastructure, the need to guarantee equitable opportunities for SMEs, start-ups and scale-ups, and research actors, and appropriate safeguards to protect security, confidentiality, intellectual property and economic-security interests.
- (17) Effective implementation of objectives pursued in this Regulation relies on good governance and partnership between all actors at the relevant territorial levels and socio-economic actors. In particular, biotechnology strategic projects aimed at targeting talent and skills shortages vital to supporting biotechnology and biomanufacturing industries and to ensuring a workforce capable to supporting innovation, industrial scale-up and long-term competitiveness should be designed and developed with the full involvement of the relevant social partners. Such active engagement is essential to ensure that social implications are addressed from the outset and to foster responsible innovation.

¹² Draghi, Mario. [The future of European competitiveness: A competitiveness strategy for Europe](#), European Commission, 9 September 2024.

- (18) Directive (EU) 2022/2555 of the European Parliament and of the Council¹³ lays down obligations for essential and important entities to ensure a high common level of cybersecurity throughout the Union, including requirements on risk management, incident reporting and the protection of network and information systems. Therefore, entities established or supported under this Regulation and falling within the scope of the Directive (EU) 2022/2555 should comply with the requirements set out in that Directive.
- (19) In order to safeguard the Union's security, public order and strategic interests, access to biotechnology infrastructures and datasets of health biotechnology strategic projects and of high impact health biotechnology strategic projects recognised in accordance with this Regulation and that receive funding in accordance with Union programmes, in relation to such infrastructures or datasets, should be governed by the rules established in those programmes. This addresses risks linked to unlawful technology transfer, hostile interference or strategic dependency.
- (20) To provide an evidence base for future Union action to further strengthen the biotechnology and biomanufacturing sectors, the Commission should carry out a strategic mapping of the Union's biotechnology ecosystem. That mapping should analyse industrial capacities, infrastructures and facilities relevant to biotechnology research, development, testing and manufacturing, and assess factors affecting the Union's ability to attract and retain investment in biomanufacturing, including access to public and private risk-tolerant capital across all stages of the innovation cycle, the development and coordination of biotechnology clusters and biomanufacturing ecosystems across the Union, and assess challenges and needs in terms of the workforce.
- (21) Recognising the transformative role of data and AI in the area of biotechnology and biomanufacturing, that mapping should also assess access to data, computing capacity and digital infrastructure for the health biotechnology sector and identify measures to foster responsible AI-enabled biotechnology innovation and possible measures to mitigate related risks, building on analyses done in the context of existing Union initiatives such as the European Health Data Space¹⁴, the Apply AI Strategy¹⁵, the Data Union Strategy¹⁶, the AI Continent Action Plan¹⁷ and the European Strategy for AI in Science¹⁸. With a view to ensuring appropriate cooperation with the Member States and optimising the use of relevant knowledge and expertise available at Union

¹³ Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 (NIS 2 Directive), OJ L 333, 27.12.2022, pp. 80. ELI: <http://data.europa.eu/eli/dir/2022/2555/oj>.

¹⁴ Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (OJ L, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj>).

¹⁵ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: *Apply AI Strategy*, COM(2025)723 final of 8 October 2025.

¹⁶ Communication from the Commission to the European Parliament and the Council, Data Union Strategy, Unlocking Data For AI, COM(2025) 835 final, 19 November 2025.

¹⁷ <https://ec.europa.eu/newsroom/dae/redirection/document/114523>

¹⁸ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: *European Strategy for Artificial Intelligence in Science – Harnessing AI for research, innovation and excellence in the Union*, COM(2025)724 final of, 8 October 2025.

level, such mapping should be conducted by the Commission in cooperation with relevant Union agencies and bodies, including, where relevant, the AI Board established under the Regulation (EU) 2024/1689, and with the European Health Biotechnology Steering Group ('the Steering Group') established in accordance with this Regulation, to facilitate its implementation, provide advice to the Commission and to the Member States, and ensure coordinated action in particular with regard to health biotechnology strategic projects and high impact health biotechnology strategic projects.

- (22) In order to ensure a transparent, coherent and efficient process for the identification of health biotechnology strategic projects, each Member State should designate a competent authority responsible for assessing and verifying whether a project fulfils the conditions set out in this Regulation for its recognition as a health biotechnology strategic project. The designated authority should carry out the assessment through a fair, transparent and time-bound process. Where a project is found to fulfil the conditions for recognition as a biotechnology strategic project, the designated authority should issue a formal recognition decision.
- (23) Considering their systemic and cross-border relevance and the benefits associated with their status as high impact health biotechnology strategic project, the recognition of such projects should take place through a two-tier process, involving authorities designated by the Member States for that purpose and the Commission. Such authorities should assess and transmit the applications and their assessment to the Commission in view of the adoption of a Commission decision. This two-tier process should ensure that such projects are subject to an additional Union-level verification and benefit from consistent recognition standards across the Union. With a view to ensure peer review, cooperation with the Member States and coherent implementation across the Union, in adopting its decision the Commission should take into account the views of the European Health Biotechnology Steering Group established by this Regulation.
- (24) With a view to enabling the efficient alignment between the Union funding procedures and the objectives of this Regulation regarding the support to high impact strategic health biotechnology projects, and to ensure that projects with the highest Union added value can rapidly benefit from priority support, in addition to the recognition of such projects through a Commission decision, the Commission could have the possibility to recognise such projects also in the context of calls for proposals launched under the relevant Union funding programmes.
- (25) To achieve critical mass and ensure that strategic investments deliver wider benefits, creating positive spill-over effects that reinforce the Union's competitiveness, networking and cooperation among health biotechnology strategic projects, high impact health biotechnology strategic projects, research organisations, industrial clusters and other relevant actors across borders, should be promoted and facilitated by the Commission and the Member States, with a view to help pooling national and Union resources and facilities, promote the development of interoperable infrastructures and digital platforms and facilitate knowledge transfer. This cooperation should be in compliance with Union competition law.
- (26) Such networking and cooperation should integrate, collaborate with, or build upon, existing networks emerging from other Union initiatives relevant for biotechnology, including those operating under the European Cluster Collaboration Platform, the European Cluster Alliance, networks supported under Horizon Europe, the Smart

Specialisation Partnerships, and the European Network of Centres of Excellence for Advanced Therapy Medicinal Products (ATMPs) announced by the Commission in the European Strategy for Life Sciences¹⁹, the European Reference Networks as defined in Directive 2011/24/EU of the European Parliament and of the Council²⁰ and the EU Network of Comprehensive Cancer Centres announced by Europe's Beating Cancer Plan²¹. Such cooperation should aim to reinforce synergies, facilitate access to regional and Union level funding, and enhance the coordination of biotechnology-related innovation ecosystems across the Union.

- (27) In order to reduce complexity and increase efficiency, transparency and consistency in the permit-granting process for health biotechnology strategic projects and high impact health biotechnology strategic projects, there should be a single point of contact at national level that is responsible for facilitating and coordinating the entire permit-granting process. The single point of contact should be the interface between the promoters of health biotechnology strategic projects or of high impact health biotechnology strategic projects and the relevant permitting authorities. To that end, Member States should establish or designate one or more authorities as single points of contact. With a view to ensure streamlined processes, that single point of contact should be the same as the single point of contact referred to in Regulation (EU) ... [Regulation on speeding-up environmental impact assessments - permitting regulation], responsible for facilitating and coordinating all aspects of the environmental assessments. It should be for Member States to decide whether a single point of contact is also an authority that makes permitting decisions. To ensure the effective implementation of their responsibilities, Member States should provide their single points of contact, as well as any authority involved in the permit-granting process with sufficient personnel and resources.
- (28) The Union has progressively recognised health biotechnology as a strategic sector contributing to Union's overall resilience. Regulation (EU) 2024/795 identifies biotechnology among the strategic technologies essential for reducing the Union's strategic dependencies and strengthening its economic and industrial resilience. The Commission Communication Commission Communication 'Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU' further identifies biotechnology and biomanufacturing as strategic technologies for Europe's competitiveness, resilience and autonomy, and furthermore explicitly recognises that health biotechnology is essential for health-system resilience. In view of this consistent Union framework confirming biotechnology's systemic contribution to resilience, health biotechnology strategic projects and high impact health biotechnology strategic projects should therefore be deemed to contribute to the objectives referred to in Article 14 of Regulation [...] [Regulation on speeding-up environmental assessments – permitting regulation].

¹⁹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *A strategy for European life sciences: Choose Europe for life sciences – A strategy to position the EU as the world's most attractive place for life sciences by 2030*, COM(2025) 525 final of 2 July 2025.

²⁰ Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 4.4.2011, pp. 45–65. ELI: <http://data.europa.eu/eli/dir/2011/24/oj>.

²¹ Communication from the Commission to the European Parliament and the Council, *Europe's Beating Cancer Plan*, COM/2021/44 final of 3 February 2021.

- (29) In light of their contribution to the Union's competitiveness, resilience and preparedness, health biotechnology strategic projects recognised by the Member States in accordance with this Regulation should be considered to be in the public interest. Similarly, Member States should grant such projects the highest national significance available under their national law, meaning the strongest designation applicable to major strategic projects, and should apply the corresponding procedural advantages, including priority treatment and coordinated and accelerated permit-granting, and adopt facilitation measures in compliance with Union law.
- (30) In view of the potential for cross-border and systemic benefits of high impact health biotechnology strategic projects, on the basis of its case-by-case assessment, a permitting authority can conclude that the public interest served by the project overrides the public interests related to nature and environmental protection and that consequently the project can be authorised, provided that all relevant conditions set out in Directives 2000/60/EC²², 2009/147/EC²³ or 92/43/EEC²⁴ of the European Parliament and of the Council, or in Union legislative acts on nature restoration, are met.
- (31) To ensure predictability and administrative efficiency, the overall duration of the permit-granting process should be limited to ten months from the acknowledgement of a complete application, for biotechnology health strategic projects, and to eight months, for high impact health biotechnology strategic projects, given the need to prioritise the speed of their implementation over any other type of biotechnology project. In exceptional and duly justified circumstances an extension of up to three months should be permitted.
- (32) Member States whose territories are concerned by health biotechnology strategic projects or high impact health biotechnology strategic projects should take all appropriate measures to facilitate their timely and effective development and deployment. Such measures should include the provision of administrative support, upon the request of project promoters, as well as, without prejudice to Union competition law, of public financial and technical support, with a particular attention paid to SMEs, start-ups and scale-ups.
- (33) The Commission should complement the action of the Member States in support of health biotechnology strategic projects, closely cooperating with them, including through the European Health Biotechnology Steering Group established by this Regulation, to ensure synergy and optimal outcomes. In particular, the Commission should assist project promoters in identifying relevant funding opportunities available under existing Union funding programmes, including through actions of the EU Health Biotechnology Support Network established in this Regulation with the purpose of assisting biotechnology actors in navigating regulatory health biotechnology procedural pathways and identifying funding, scaling up and networking opportunities across the Union. Further, to strengthen the Union's biotechnology innovation ecosystem, the Commission should also promote measures that enhance access of

²² Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, OJ L 327, 22.12.2000, p. 1. ELI: <http://data.europa.eu/eli/dir/2000/60/oj>.

²³ Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds, OJ L 20, 26.1.2010, pp. 7-25. ELI: <http://data.europa.eu/eli/dir/2009/147/oj>.

²⁴ Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora, OJ L 206, 22.7.1992, p. 7. ELI: <http://data.europa.eu/eli/dir/1992/43/oj>

small and medium-sized enterprises, start-ups and scale-ups to research and technological infrastructures, including those funded through Union programmes.

- (34) High impact health biotechnology strategic projects should benefit from financial, technical and administrative support measures. In addition, in order to ensure that Union resources for biotechnology are channelled towards the actions that have the potential to deliver the most benefits at Union level, high impact health biotechnology strategic projects could be given particular consideration for financial support, in the context of the preparation, adoption and implementation by the Commission of work programmes for the relevant Union programmes, funds and instruments.
- (35) The scale and nature of the Union support for high impact health biotechnology strategic projects might require long-term coordination and large-scale public and private investment. In this context, public-private partnerships play a key role in pooling expertise, sharing risks and accelerating the uptake of innovation. Consequently, the Commission could envisage to propose in the future the establishment of appropriate legal entities to mobilise investments, coordinate research and innovation activities and support for the industrial deployment of biotechnology and biomanufacturing capacities across Member States, while ensuring close alignment with Union policy objectives. Those legal arrangements could take the form of European Partnerships where the Union together with private and/or public partners, acting in full compliance with competition rules, commit to jointly supporting the development and implementation of a programme of activities, including those related to market, regulatory or policy uptake.
- (36) With a view to ensuring that the most favourable provisions apply cross-frameworks, the provisions of this Regulation regarding the permit granting process, the priority status of health biotechnology strategic projects and of high impact health biotechnology strategic projects and the administrative, technical or financial support for such projects should apply without prejudice to more favourable provisions laid down in other Union legislation.
- (37) Biotechnology undertakings, especially SMEs, start-ups and scale-ups, and non-profits face challenges in navigating the regulatory processes, financing, scaling up and networking opportunities in the Union. To address those challenges, the Commission should manage, coordinate and support an EU Health Biotechnology Support Network, composed of national and regional antennas, leveraging and complementing existing structures such as the European Enterprise Network. The Network should assist developers and project promoters, in particular SMEs, start-ups, and scale-ups, in navigating more efficiently the legislative framework, health biotechnologies regulatory pathways and funding opportunities at Union and national level. Moreover, the EU Health Biotechnology Support Network should provide support for health biotechnology strategic projects and enhanced assistance for high impact health biotechnology strategic projects. The Commission should make available to the Network an AI powered interactive tool to assist developers and project promoters, in particular SMEs, start-ups, and scale-ups, in navigating more efficiently the regulatory framework and pathways and funding opportunities at EU and national level.
- (38) The European Health Biotechnology Steering Group ('the Steering Group') should be established to provide advice to the Commission and to the Member States with a view to facilitate the implementation of this Regulation, foster cooperation with the Commission and among the Member States, and the exchange of best practice. The

Steering Group should be composed of representatives from all Member States and the Commission.

- (39) Member States should provide to the Steering Group, on an annual basis, an overview of the health biotechnology strategic projects and of the high impact health biotechnology strategic projects that they recognise, as well as of the existing and emerging cooperation initiatives and networks among such projects. Such overview is aimed at informing monitoring of progress in the implementation of this Regulation, supporting coordination and proposals of measures to enhance the Union's biotechnology and biomanufacturing ecosystem and facilitate exchange of best practices. In such overview, Member States should identify progress, obstacles and best practices.
- (40) To ensure effective governance and learning across the Union, the Steering Group should periodically review systemic challenges in the financing and deployment in particular for high impact health biotechnology strategic projects and recommend corrective measures to the Commission and to Member States.
- (41) Given the capital-intensive nature of biotechnology and the high probability of non-commercialisation of individual projects, access to finance is a structural bottleneck for the sector. To boost the potential of biotechnology to contribute to the Union's competitiveness, resilience and the creation and maintenance of quality jobs, sufficient funding tailored to the sector's risk profile needs to be mobilised across the financing life cycle.
- (42) To address key challenges in the functioning of Union capital markets, the Commission is implementing the Savings and Investment Union (SIU) Strategy. The SIU will reduce market fragmentation, create better investment opportunities for citizens and help to expand funding options for businesses. In particular, it will seek to improve access to equity and debt financing for all companies, including startups and scaleups, strengthen the role of venture capital and institutional investors and better align Union public funding instruments with SIU objectives. Recent Commission guidance on legislative programmes²⁵ also clarifies that the biotechnology sector can be the target of Union, national and regional legislative programmes via reference to the Competitiveness Compass, supporting favourable prudential treatment of investments made under such programmes.
- (43) The Union's biotechnology sector faces a persistent financing gap compared with other leading regions, particularly for the scale-up and industrial deployment stages. The Union has been acting to address this, including through the flagship InvestEU programme established by Regulation (EU) 2021/523 of the European Parliament and of the Council²⁶. InvestEU supports biotechnology investments in a transversal manner, enabling investment in biotechnology projects and enterprises targeting all stages of development, including start-up to scale-up stages as well as deployment. The recent agreement between the Council and the European Parliament on enhancing the InvestEU programme increases the Union guarantee by EUR 2.9 billion unlocking nearly EUR 55 billion in additional public and private investments, including investment into biotechnology. Overall, InvestEU has already mobilized EUR 7.5

²⁵ C(2025) 7231 final

²⁶ Regulation (EU) 2021/523 of the European Parliament and of the Council of 24 March 2021 establishing the InvestEU Programme and amending Regulation (EU) 2015/1017, OJ L 107, 26.3.2021, pp. 30–89. ELI: <http://data.europa.eu/eli/reg/2021/523/oj>.

billion of biotechnology investments. During the 2026-2027 period, mobilization of at least EUR 4 billion of additional biotechnology investments is expected. InvestEU implementing partners play a key role in helping to stimulate investment in biotechnology projects and enterprises. Both the EIB as well as EIF support biotechnology – including health biotechnology – via several InvestEU financial products. HERA Invest further boosts investments in health biotechnology. The project pipeline is strengthened through InvestEU advisory, supporting initiatives such as the European Tech Championship Initiative of the European Investment Bank.

- (44) Complementing the European Innovation Council support for deep tech and disruptive innovators in the area of biotechnology, an EU Health Biotechnology Investment Pilot to mobilise public and private investment and strengthen the Union's competitiveness and resilience should be created in partnership with the European Investment Bank Group (EIBG) or other implementing partners, for implementation in indirect management, linking equity and guarantee instruments with venture debt tailored to biotech-specific risk profiles.
- (45) The Health Biotechnology Investment Pilot would aim to mobilise a substantial amount of capital, from the EIBG, Union budget, public national schemes and private sector investors (including institutional investors), to narrow the sector investment gap, currently estimated at EUR 40 billion annually, amounting to EUR 400 billion for the next 10 years, and ensure the sector's long term competitiveness and strategic autonomy.
- (46) The Health Biotechnology Investment Pilot should be tailored to biotechnology risk profiles and lifecycle needs on the Union market. It should be possible to include newly created and established instruments, encompassing advisory services, direct and indirect individual investments, direct and indirect intermediated financing or portfolio financing. The detailed instruments, eligibility and risk parameters, and indicative allocations should be specified in the operational design of the Pilot.
- (47) The Pilot may receive Union financial support through Union programmes. Pending the establishment of the Pilot, a scheme, also covering ongoing investment activities, launched with the support of the EIBG under the current Multiannual Financial Framework 2021-2027 and supported under the InvestEU programme, will mobilise up to 10 billion in investments in the biotechnology sector in 2026 and 2027 .
- (48) Union public equity markets for biotechnology remain shallow relative to global peers, which constrains late-stage financing and exit options for European start-ups and scale-ups. Stock exchanges are still largely fragmented across Member States, with limited specialised research coverage and dedicated market-making, prompting European scale-ups to list abroad. To address this bottleneck for a competitive Union biotechnology sector and complement the SIU strategy, which seeks to promote integration and increase the depth of Union capital markets, projects contributing to a Union late-stage capital booster pilot should be recognised by the Commission as high-impact health biotechnology strategic projects in accordance with the conditions laid down in this Regulation.
- (49) Biotechnology is central for the Union's sovereignty, strategic autonomy and innovation leadership. In this regard, the Union is taking action to pursue its policy objectives in biotechnology, including through the Framework Programme for Research and Innovation established by Regulation (EU) 2021/695 of the European

Parliament and of the Council²⁷ which is supporting the implementation of the Life Sciences Strategy, and other relevant ‘Choose Europe’ initiatives.

- (50) The Commission has proposed a European Competitiveness Fund (ECF)²⁸ for the MFF period 2028-2034, aiming to increase European competitiveness, notably in strategic sectors and technologies along the investment journey. It is proposed to be structured along four policy windows reflecting strategic priorities crucial to Union competitiveness and resilience. It proposes funding to support the biotechnology sector through a ‘Health, Biotech, Agriculture and Bioeconomy’ window.
- (51) Companies, projects and initiatives falling within the scope of this Regulation could be given particular consideration for financial support from Union led initiatives, including those that aim to leverage private capital, and from Union funding programmes and instruments, as projects in a strategic technology and, where appropriate, in a strategic deep tech area. Such initiatives, programmes and instruments include the cohesion policy programmes, the InvestEU programme, the EIBG’s TechEU programme and the European Tech Champions Initiative, supported by InvestEU, and launched by the EIBG with several Member States, and the European Innovation Council established under the Horizon Europe Programme, as well instruments for the duration of the MFF 2028-2034.
- (52) Further, high-impact health biotechnology strategic projects are projects with a high European added value, including cross-border projects, expected to bring structural economic transformation, productivity, long-term growth and quality jobs in the biotechnology sector, and benefiting the Single Market. Considering the necessity to align Union, public and private spending with Union competitiveness priorities²⁹, such projects could be given particular consideration for Union financial support including in the form of blended financing, under Union programmes, funds and financial instruments.
- (53) Regulation (EU) 2024/795 establishes that the development and manufacturing in the Union of biotechnologies, together with digital technologies and deep tech innovation, clean and resource-efficient technologies are essential for the purpose of reducing the Union’s strategic dependencies, and for the green and digital transitions, thus ensuring the sovereignty and strategic autonomy of the Union and promoting the competitiveness and sustainability of the Union’s industry. Accordingly, that Regulation establishes a Strategic Technologies for Europe Platform (STEP) to better channel and mobilise resources within the existing Union programmes towards critical investment, including in Union-wide and cross-border projects, that have the aim of supporting the development or manufacturing of critical and emerging technologies and their respective value chains, in strategic sectors, including in biotechnology.

²⁷ Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013, OJ L 170, 12.5.2021, pp. 1. ELI: <http://data.europa.eu/eli/reg/2021/695/oj>.

²⁸ As per Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing the European Competitiveness Fund (‘ECF’), including the specific programme for defence research and innovation activities, repealing Regulations (EU) 2021/522, (EU) 2021/694, (EU) 2021/697, (EU) 2021/783, repealing provisions of Regulations (EU) 2021/696, (EU) 2023/588, and amending Regulation (EU) [EDIP].

²⁹ Commission Staff Working Document, Impact Assessment Report on the European Competitiveness Fund, SWD(2025) 555 final.

- (54) Union-level funding may be leveraged to facilitate investments in health biotechnology strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation. Such projects may benefit from access to existing Union funding instruments, where they fulfil the criteria established in those instruments. Authorities in charge of the Union programmes covered by Regulation (EU) 2024/795 should consider supporting biotechnology health strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation. Therefore, Regulation (EU) 2024/795 should be amended to provide that health biotechnology strategic projects and high-impact health biotechnology strategic projects recognised in accordance with this Regulation should be deemed to contribute to the STEP objectives of supporting the development or manufacturing of critical technologies in biotechnologies throughout the Union, or safeguarding and strengthening their respective value chains and also in addressing shortages of labour and skills critical to all kinds of quality jobs in support of that objective, as appropriate.
- (55) Member States may provide financial support to biotechnology as a strategic technology for the Union's innovation capacity, sovereignty, resilience and leadership, including in the implementation of the relevant Union programmes. In this regard, Member States should act in compliance with Union competition law and make use as appropriate of the relevant frameworks. This includes the criteria for the analysis of the compatibility with the internal market of State aid to promote the execution of important projects of common European interest³⁰ (IPCEIs), the guidance on the basis of a compatibility assessment conducted by the Commission regarding aid to promote research, development and innovation³¹, the Commission Regulation (EU) No 651/2014³² and the Clean Industrial Deal State Aid Framework³³.
- (56) Strategic projects in health biotechnology may require blended financing from private, national and Union sources. National funding should be in full compliance with State Aid rules. The Commission, including through the European Biotechnology Support Network, should support project promoters in liaising with potential investors. Similarly, the European Health Biotechnology Steering Group established by this Regulation should coordinate financing for biotechnology health strategic projects and high-impact health biotechnology strategic projects.
- (57) Medicinal products developed with innovative biotechnology technologies which will bring a therapeutic advantage to patients should be incentivised with an extension of the Supplementary Protection Certificate.
- (58) The significant advances in analytical methodologies and biocompatibility assessment tools enable more precise demonstration of comparability between biosimilar medicines ('biosimilars') and their reference biological medicinal products. Building

³⁰ Communication from the Commission Criteria for the analysis of the compatibility with the internal market of State aid to promote the execution of important projects of common European interest 2021/C 528/02, C/2021/8481, OJ C 528, 30.12.2021, pp. 10.

³¹ Communication from the Commission Framework for State aid for research and development and innovation 2022/C 414/01, C/2022/7388, OJ C 414, 28.10.2022, pp. 1.

³² Commission Regulation (EU) No 651/2014 of 17 June 2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty Text with EEA relevance, OJ L 187, 26.6.2014, pp. 1. ELI: <http://data.europa.eu/eli/reg/2014/651/2023-07-01>.

³³ COMMUNICATION FROM THE COMMISSION – Framework for State Aid measures to support the Clean Industrial Deal (Clean Industrial Deal State Aid Framework), C/2025/7600, OJ C, C/2025/3602, 4.7.2025.

on its ongoing work on a Reflection paper on a tailored clinical approach in biosimilar development³⁴, the European Medicines Agency³⁵ ('the Agency') should develop non-binding guidance giving consideration to a potential reduction of the clinical data required for the development and marketing authorisation procedures for biosimilars, based on robust analytical and other non-clinical evidence.

- (59) The manufacturing capacity and expertise for biosimilars in the Union can greatly contribute to ensure Union competitiveness, strategic autonomy and resilience, both from a health and sustainability perspective. Therefore, Member States should recognise, and support projects that fulfil the conditions laid down in this Regulation for strategic projects for biosimilars manufacturing.
- (60) Biosimilars can play an important role in diversifying and strengthening supply chains, promoting competition and fostering economic growth in the Union and for its global partners. Accordingly, the promoters of strategic projects for biosimilars and the companies active in this area should be encouraged to establish or strengthen cooperation with international biotechnology clusters.
- (61) AI can enhance the development, safety, efficiency and scale-up of biotechnology and biomanufacturing, provided that its use is responsible and aligned with Union legislation. To pursue this, the Commission and the Member States should promote an AI-first policy approach as introduced in the Apply AI Strategy when implementing this Regulation and the exchange of knowledge, standards and best practices relevant to the responsible application of the AI-First Policy Approach³⁶. The responsible and effective integration of AI can enhance research, development and regulatory processes and thereby support the competitiveness of Union innovators in biotechnology. The Commission and the Member States should therefore encourage the uptake of such approaches and facilitate the exchange of knowledge, standards and best practices relevant to their application. That cooperation should remain fully compliant with Union competition rules.
- (62) The rapid expansion and increasing complexity of AI applications throughout the medicinal-product lifecycle requires structured and coherent guidance to ensure their safe, effective and trustworthy use. The Agency is developing expertise in this area through initiatives such as the Good Manufacturing Practice (GMP) Annex 22 – Artificial Intelligence, Q&A in AI in Pharmacovigilance, the GCP Annex to the Guideline on computerised systems and electronic data in clinical trials and AI in Clinical Development. It is therefore appropriate for the Agency to develop non-binding guidance on the deployment and use of systems based on advanced technologies, including of AI systems and of general-purpose AI models across development, manufacturing, clinical trials, and post-authorisation activities for compliance with applicable Union legislation in the health area. To ensure consistency

³⁴ EMA [Reflection paper on a tailored clinical approach in biosimilar development](https://www.ema.europa.eu/en/documents/other/reflection-paper-tailored-clinical-approach-biosimilar-development_en.pdf), 17 March 2025, draft accessible at: https://www.ema.europa.eu/en/documents/other/reflection-paper-tailored-clinical-approach-biosimilar-development_en.pdf

³⁵ [Revised REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006]

³⁶ Communication from the Commission to the European Parliament and the Council, *Apply AI Strategy*, COM/2025/723 final.

across the health and digital domains, when developing or updating such guidance, the Agency should cooperate with the Commission, including the AI office and should consult relevant national competent authorities and stakeholders, and relevant expert coordination groups established under Union legislation in the health and digital areas, as appropriate.

- (63) Moreover, the Agency should develop non-binding guidance on the deployment and use of AI systems and of general-purpose AI models also in the procedures for the authorisation of medicinal products, with a view to optimising processes and increasing efficiency of regulatory activities. Such guidance should be developed and published in agreement with the Commission, the AI Board and the competent authorities.
- (64) In order to accelerate the development and scale-up of biotechnology innovations that are enabled, enhanced or significantly supported by AI and advanced computational methods, the Union requires dedicated testing environments that combine experimental, computational and data-driven capabilities. Given their essential role for supporting AI-enabled biotechnology innovations, it is appropriate to establish requirements in this Regulation for the recognition by the Commission and the support for high-impact health biotechnology strategic projects in the form of biotechnology testing environments, under certain conditions.
- (65) Such environments could provide the wet-lab, bioprocess, pilot-line and translational validation capacities necessary for AI-enabled biotechnology development, and should complement, without duplicating, the functions of regulatory sandboxes established under Union or national law as well as the testing and experimentation facilities established in accordance with Regulation (EU) 2024/1689. Where relevant, they should also leverage health data and the European Health Data Space in accordance with Union legislation. These infrastructures should support the development of biotechnology applications where the use of AI has the potential to accelerate progress, in particular in health-related areas such as advanced therapies, where AI can improve efficacy and safety — for example through optimised CRISPR site prediction, tumour antigen identification, sequence engineering, delivery-vehicle design, or the matching of diverse patient cancer-cell variants with CAR-T cell types.
- (66) Having high-quality, interoperable, provenance-verified and well-annotated datasets is essential for the development, testing and validation of trustworthy and competitive AI systems and models used in biotechnology applications. For example, datasets generated in the course of provision of healthcare are usually recorded in a way that supports their initial purpose, such as diagnosis or treatment. Often, they are technically not easily usable and fit for training, testing and validation of AI systems, for example due to the use of different data standards or lacking annotations. Given the potential of AI systems and models to support research and innovation in biotechnology applications, it is important to ensure that high-quality data are available for training, testing and validating AI systems and models used in health biotechnology applications. To make such data more easily usable for those purposes, it is appropriate to facilitate the enhancement of the quality of that data. Therefore, this Regulation should lay down provisions for the recognition by the Commission of high impact health biotechnology strategic projects in the form of biotechnology data quality accelerators, to provide assistance to entities that lawfully hold relevant data to improve data quality, standardize such data and make further improvements.

- (67) Such biotechnology data quality accelerator projects should complement Union initiatives such as data labs³⁷ and by addressing the specific data-quality requirements of biotechnology, ensuring that biological and health datasets are reliable, interoperable and usable for the development of advanced AI models.
- (68) The processing of personal data by the entities that lawfully hold the relevant data and by the biotechnology data quality accelerators, in the context of biotechnology data quality accelerators projects, takes place in the public interest. The Commission should specify in the decision recognising the project as a high impact health biotechnology strategic project, the specific provisions concerning the processing of personal data necessary in order to achieve the objectives of the project. Such provision may in particular include the categories of data, the specific roles of the parties engaged in the processing, and the entities to which the personal data may be disclosed. Where biotechnology data quality accelerators are recognised by the Commission through calls for proposals, the Commission should be empowered to adopt, by means of an implementing act, specific provisions concerning the processing of personal data, through a decision prior to the launch of the call and the beneficiaries of the call should be subject to the obligations laid down in that decision.
- (69) Electronic health data referred to in Article 51 of Regulation (EU) 2025/327 of the European Parliament and of the Council³⁸, enhanced by biotechnology data quality accelerators should be made available in accordance with that Regulation. The biotechnology data quality accelerators support the objectives of the European Health Data Space by contributing to improving the quality of data that is to be made available under that space.
- (70) To enable innovation and competitiveness in biotechnology, it is necessary to ensure that SMEs, start-ups and scale-ups, and research organisations can access the high computing capacity and AI resources required for advanced research, development and biomanufacturing. Those actions may be supported through Union funding programmes, funds and financial instruments, in accordance with the regulations governing them. The Commission should ensure effective coordination with other Union initiatives offering computing capacities to maximise efficiency and avoid duplication. The Commission, including through the European Biotechnology Support Network, should provide information and support, in particular to SMEs, start-ups and scale-ups, for accessing high computing capacity and AI resources relevant to biotechnology and biomanufacturing activities.
- (71) Very innovative health biotechnology products or services vary significantly in the degree to which they align or can align with existing Union legislative frameworks and procedures. These products, despite their complexity, should however be efficiently and adequately assessed within a single regulatory pathway, possibly through a combination pathway. This is notwithstanding the fact that such health biotechnology products or services, in the form of preparations, devices, diagnostics, or other, for human use, exhibit characteristics that challenge the Union legislative

³⁷ Proposed in the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *A European Strategy for Artificial Intelligence in Science – Paving the way for the Resource for AI Science in Europe (RAISE)*, COM(2025) 724 final of 8 October 2025.

³⁸ Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847, OJ L, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj> .

frameworks in the area of health ('health biotechnology products'), for example because they are under development and could potentially fall under the scope of an Union legislative framework but there are questions related to the relevance of other Union legislative frameworks; and/or because they combine different products, technologies, processes, or components regulated under different Union legislative frameworks; and/or because they require targeted adaptations of certain requirements of the applicable Union legislative frameworks, ideally at an early stage of development. These characteristics are not mutually exclusive and may overlap.

- (72) Developers of such health biotechnology products can consequently face regulatory uncertainty, potentially delaying or preventing patient access to beneficial technologies and creating barriers to innovation and access to finance, hampering competitiveness. To offer developers efficient and predictable regulatory procedural pathways, the Union legislative frameworks in the health area should be equipped with the right tools and should integrate consultative and collaborative approaches, to be able to assess these health biotechnology products efficiently and timely. In addition, developers of health biotechnology products should be supported in navigating regulatory procedural pathways for their products in the best possible way. This Regulation should therefore provide for measures and facilitators to ensure efficient pathways to developers with reduced time-to-market, while safeguarding all existing provisions to protect public health.
- (73) At the same time, the Union has the strong experience and expertise to handle regulatory complexity, and important measures to deal with health biotechnology products have already been proposed. Directive 2001/83/EC of the European Parliament and of the Council³⁹ clarifies which legislative frameworks apply to combinations of medicinal products and other products and establishes a single authorisation pathway for them. In addition, existing Union legislative frameworks in the area of health such as [revised Regulation (EU) 2017/745 of the European Parliament and of the Council, [revised Regulation (EU) 2017/746], [revised Regulation No (EC) 726/2004], Regulation (EU) 2024/1938 of the European Parliament and of the Council⁴⁰ contain specific mechanisms to manage the determination of the regulatory status of products that do not fall clearly within a Union legislative framework in the area of health. These mechanisms include the possibility of requesting a recommendation or opinion from the respective advisory bodies or the Agency, as applicable, at Union level, and eventually the possibility for binding decisions of the Commission on the regulatory status. These mechanisms should ensure predictability and conclusive opinions for products of which the status is being debated, avoiding cases where it remains unclear which framework applies, and the assessment of the product is consequently halted or delayed.
- (74) Developers of health biotechnology products, in particular SMEs, start-ups and scale-ups, often lack the regulatory expertise and capacity needed to identify, anticipate and plan their entry into the appropriate regulatory procedural pathways. In order to

³⁹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67, ELI: <http://data.europa.eu/eli/dir/2001/83/oj>.

⁴⁰ Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L, 2024/1938, 17.07.2024, ELI: <http://data.europa.eu/eli/reg/2024/1938/oj>).

address this challenge, the EU Health Biotechnology Support Network, acting as a service provider, should provide preliminary support to such developers by facilitating information on, and access to, applicable legislative frameworks, and should point to relevant opinions, recommendations, guidance and decisions.

- (75) To allow developers to anticipate and navigate procedures to determine the regulatory status, a Union-wide and cross-framework Regulatory Status Repository should be established. That Repository should compile relevant opinions, recommendations, decisions and guidance developed under the mechanisms established in the Union legislative frameworks in the area of health with a view to determine the regulatory status of a product. That Repository should also include the recommendations on the classifications of products as advanced therapy medicinal products (ATMPs) issued by the Committee for Advanced Therapies, established in accordance with Regulation (EC) No 1394/2007 of the European Parliament and of the Council⁴¹ prior to the date of application of Regulation (EC) No 726/2004. Such repository should be accessible for developers and authorities to enable them to understand how similar health biotechnology products are evaluated in terms of status, and what considerations are put forward. This will guide developers and authorities, to improve efficiency, foster transparency, and ensure consistency and mutual learning across Union and national authorities. This Regulatory Status Repository should not include opinions, recommendations, decisions and guidance on the regulatory status of AI systems and models within the scope of the Regulation (EU) 2024/1689.
- (76) Existing mechanisms for addressing health biotechnology products, including those for determining their regulatory status as described above, provide for consultation among various advisory bodies and the Agency. However, such procedures are typically focused on individual products on a case-by-case basis. There is, therefore, a need for more systematic coordination across Union legislative frameworks to better identify and prepare for emerging innovations driving the development of health biotechnology products that may challenge existing Union legislative frameworks in the area of health. With an expected increase in health biotechnology products entering the regulatory system, there is a growing need for horizontal foresight anticipating technological developments through structured horizon-scanning activities which will enable the regulators to adopt regulatory approaches proactively, rather than reactively addressing each new difficult case.
- (77) To that end, this Regulation should establish a Foresight Panel for Emerging Health Innovation to complement existing mechanisms by providing a platform for horizontal coordination and forward-looking analysis. The Panel should conduct horizon scanning to identify emerging technologies at an early stage and discuss cross-cutting regulatory issues, thereby informing and anticipating discussions on health biotechnology products that may subsequently arise within individual frameworks. It should provide expertise on emerging science and technology in the field of health underpinning the development of health biotechnology products to the Commission, the Agency and to relevant Union-level advisory bodies and competent authorities and other entities in the Member States in the area of health.

⁴¹ Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004, OJ L 324, 10.12.2007, p. 121. ELI: <http://data.europa.eu/eli/reg/2007/1394/oj>.

- (78) This Panel should complement, without replacing, existing classification mechanisms established under the respective Union legislative frameworks, which remain exclusively competent to provide opinions, recommendations or binding determinations on the regulatory status of specific products. Member States, as authorities primarily responsible for decisions on regulatory status, should be closely involved in the Panel's work, sharing practical expertise and experience to inform cross-framework dialogue, support harmonisation efforts, and designate experts that bring the Member State perspective.
- (79) Health biotechnology products increasingly challenge Union legislation in the area of health and necessitate further flexibility of that legislation, in particular regarding health biotechnology products that could be candidates for regulatory sandboxes under such frameworks. The development and implementation of those sandboxes can clearly benefit from effective consultation across the authorities responsible for regulatory sandboxes falling within the scope of Union legislative acts other than this Regulation. By facilitating the exchange of information and experiences between sandboxes, including on regulatory approaches, technological challenges, and emerging scientific understanding, the Union can develop more coherent and responsive regulatory responses to health biotechnology products. The activities of sandboxes should be carried out in full compliance of antitrust information exchanges provisions under Union competition law. The Foresight Panel for Emerging Health Innovation could play a role in promoting such coherence and knowledge sharing.
- (80) The Commission should be able to establish regulatory sandboxes for health biotechnology products which are at a very early stage of development and do not fall within the scope of existing Union legislative acts in the area of health, thus not being in a position to benefit from the regulatory sandboxes established in accordance with those other acts. Those sandboxes should provide a controlled environment in which to explore and assess innovative technologies. The sandboxes should operate according to a specific sandbox plan that specifies the duration of the sandbox, risk mitigation measures and supervision arrangements. For the development and implementation of the sandbox plan for such products, the Commission may consult advisory bodies and Agencies established under the Union legislative acts in the area of health for example to determine which requirements or rules laid down in those acts could, or could not, be applied to the products concerned. The outcome of the sandbox would be a recommendation by the Commission on an existing appropriate regulatory procedural pathway for authorising the product in question. The lessons learned from those sandboxes should lead to reflections on possible regulatory actions to be taken at Union level for the products or categories of products concerned. Accordingly, this approach would provide a flexible Union response to emerging innovations while building an evidence base for potential future legislative developments.
- (81) Biotechnologies are critical for the Union's defence and security. Closer coordination between civil and defence research, development and manufacturing can accelerate safe innovation and reduce fragmentation. Therefore, this Regulation should make provisions for the recognition by the Commission and support of projects contributing to an EU Biothreat Radar as high impact health biotechnology strategic projects, subject to conditions established in this Regulation.
- (82) Furthermore, this Regulation should make provisions for the recognition by the Commission and support of high impact biodefence capability projects, as part of the category of high impact health biotechnology strategic projects, subject to conditions

laid down in this Regulation. Such projects should make a significant contribution to objectives such as the prevention or mitigation of the misuse of biotechnologies. As such, those projects should benefit from priority status in administrative procedures in accordance with this Regulation and could be given particular consideration for support under national and Union funding programmes and instruments, including from those budgets allocated to defence.

- (83) Without prejudice to Member States' competences and in accordance with the Union funding programmes and instruments, biotechnology activities relevant to defence, security, safety, preparedness, and resilience, including dual-use technologies could be given particular consideration, where appropriate, for support under the European Defence Fund, the Union Research Framework Programmes and other Union funding instruments.
- (84) Moreover, where national authorities so decide, expenditure on such dual-use infrastructures and related biodefence activities may be counted toward relevant defence spending targets.
- (85) The biotechnology landscape is evolving at an unprecedented speed, driven by advances in synthetic biology and genome editing, which, coupled with AI, make biotechnology stand at the forefront of innovation, offering unprecedented opportunities for advancing health and protecting against biological threats. These advances also make biotechnological misuse faster, cheaper, and more accessible. Biotechnologies can pose serious and distinctive risks that call for continuous assessment and anticipatory safeguards. Therefore, a limited set of biotechnology products with significant potential for misuse ('biotechnology products of concern') require a specific framework to prevent and protect against their misuse.
- (86) Union and international rules address certain aspects related to biological threats, biological incidents or biological risks, in particular in relation to serious cross-border threats to health⁴², the control of exports, brokering, technical assistance, transit and transfer of dual-use items⁴³, resilience in biosafety and biosecurity through the Biological and Toxin Weapons Convention (BTWC)⁴⁴, the Chemical Weapons Convention (CWC), the contained use of genetically modified micro-organisms⁴⁵, workers' protection from risks related to exposure to biological agents at work⁴⁶, in relation to AI systems and models through Regulation (EU) 2024/1689. However, the

⁴² Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/, p. 26. ELI: <http://data.europa.eu/eli/reg/2022/2371/oj>.

⁴³ Regulation (EU) 2021/821 of the European Parliament and of the Council of 20 May 2021 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items, OJ L 206, 11.6.2021, pp. 1. ELI: <http://data.europa.eu/eli/reg/2021/821/oj>.

⁴⁴ Council Decision (CFSP) 2023/2636 of 20 November 2023 amending Decision (CFSP) 2021/2072 in support of building resilience in biosafety and biosecurity through the Biological and Toxin Weapons Convention, no longer in force. OJ L, 2023/2636, 22.11.2023, ELI: <http://data.europa.eu/eli/dec/2023/2636/oj>

⁴⁵ Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (Recast) (Text with EEA relevance), OJ L 125, 21.5.2009, p. 75. ELI: <http://data.europa.eu/eli/dir/2009/41/oj>.

⁴⁶ Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC), OJ L 262, 17.10.2000, p. 21. ELI: <http://data.europa.eu/eli/dir/2000/54/oj>.

approach remains fragmented and does not sufficiently address all aspects related to the misuse related to biotechnologies. A consistent and high level of protection throughout the Union should therefore be ensured in order to guarantee biotechnology remains trustworthy and provides legal certainty for economic operators in the biotechnology sector.

- (87) There are divergent requirements in Member States for screening, verification, reporting and tracking of suspicious transactions for biotechnology products of concern, which includes benchtop equipment and sequences of concern. This lack of harmonisation creates additional costs for economic operators, especially for those with strong security systems in place, and might distort competition within the internal market as well as potentially create barriers to trade and innovation.
- (88) A Union framework for strengthening monitoring of the potential misuse of biotechnology products of concern is therefore needed and requested by industry actors, including SMEs, to safeguard the free movement of goods and ensure a level playing field in the internal market. This framework needs to take into account recent international developments and good practices in other jurisdictions and relevant industry consortia and standard-setting fora, including to promote interoperability for Union operators active globally and providing for a level playing field in the internal market.
- (89) To ensure that oversight remains proportionate and appropriately calibrated to the risks, and in line with existing Union harmonisation legislation, the complementary harmonisation measures established in this Regulation to prevent misuse should only apply to a limited subset of biotechnology products of concern which pose the highest risk of misuse, and whose misuse has the highest consequences, such as certain sequences of concern or benchtop nucleic synthesis equipment able to create such sequences of concern. For the purposes of legal clarity and certainty, such products should be listed in Annex I to this Regulation. As biotechnology will continue to rapidly evolve, the Union framework should remain flexible and capable of responding to emerging biotechnology products, materials, and scientific evidence regarding potential risks. Therefore, the Commission should be empowered to adopt delegated acts to amend Annex I to respond swiftly to scientific and security developments and in consultation with relevant experts including the Advisory Group on Biosecurity established under this Regulation, while following the existing international and other relevant regulatory frameworks
- (90) The Union framework should be comprehensive to apply to the making available to, introduction, or use of, biotechnology products of concern, by any natural or legal person in the Union as well as to the making available to any natural or legal person outside the Union.
- (91) To reduce risks at the point of sale within the Union, economic operators should verify the legitimate need and peaceful purposes of prospective customers before making available the biotechnology products of concern included in Annex I to this Regulation.
- (92) Apart from economic operators, other natural and legal persons that are not economic operators, including researchers, laboratories, universities, or research institutes, may also make available and use biotechnology products of concern. Such persons should be subject to the same screening obligations as economic operators, while preserving freedom of research and academic freedom in accordance with Article 13 of the Charter of Fundamental Rights of the European Union and Article 179 of the Treaty

on the Functioning of the European Union, except where knowledge and material are shared with persons employed within the same legal entity. Biotechnology products of concern should not be made available to members of the general public.

- (93) Benchtop nucleic acid synthesis equipment poses a particular challenge to the verification of legitimate need and the tracking and monitoring of sequences of concern. Such equipment should therefore contain an automatic mechanism to screen for sequences of concern.
- (94) This Regulation should lay down provisions requiring economic operators to report suspicious transactions throughout the supply chain, regardless of whether the prospective customer is a member of the general public or an economic operator, private or public, and should apply in relation to biotechnology products that are considered of concern provided the risk or threat they may pose, which includes certain sequences of concern and biotechnology products. Reporting and recording for three years the suspicious transactions would allow other operators to be aware of the risks of the concerned product, while avoiding duplicate reporting, and allowing authorities to monitor and assess the risks and verify compliance with the obligations laid down in this Regulation.
- (95) Suspicious transactions should be detected and reported rapidly through harmonised procedures, with Member States designating national contact points that provide clear reporting channels, as well as record data and ensure compliance, with a view to contributing to safeguarding national and Union's safety.
- (96) Where a biotechnology product of concern falls also under categories regulated under other Union legislation, to avoid duplication of reporting, where a suspicious transaction of that biotechnology product of concern has already been reported under one legal framework, it should not be reported again.
- (97) Licensed biotechnology products containing nucleic acid sequences, including authorised medicinal products for human and veterinary use, should not be subject to verification of legitimate need, as they have undergone regulatory assessment and do not constitute independent biological threats. However, the stand-alone nucleic acid sequences in synthetic form should fall within the scope of legitimate-need screening, as they may be misused and be relevant to biosecurity oversight.
- (98) Certain tools with a potential to be misused without further modification and to cause serious harm to public health and safety, agricultural crops and other plants, to animals, the environment, material or government security (dual-use research of concern - 'DURC') are increasingly affordable and accessible, also through progress in AI capabilities, which elevates the risk of misuse by actors lacking appropriate competence, oversight, legitimate or peaceful intent. A proportionate and risk-based framework is therefore necessary to minimise opportunities for misuse of DURC, including on AI models in biological applications, while preserving legitimate research and innovation.
- (99) Supervision by the public authorities is needed to ensure that research, innovation and commercial operations are conducted responsibly and securely. This in turn can build public trust in biotechnology. Effective supervision requires adequately resourced and trained national inspection authorities with adequate investigative powers, complemented by risk-based audits to verify the effectiveness of the screening obligations laid down in this Regulation, as well as training and awareness-raising for the staff of the designated inspection authorities and stakeholders, and regular

exchanges among inspection authorities and economic operators, including operators involved in online marketplaces. Moreover, Member States should lay down rules on penalties applicable to infringements of the provisions laid down in this Regulation regarding the prevention of biotechnology misuse. Such penalties should be effective, proportionate and dissuasive.

- (100) The Commission should monitor Member States in the enforcement of this legislation, including by requesting information and records to check the screening and suspicious transaction reporting frameworks of economic operators.
- (101) Considering the evolving biosecurity landscape and the misuse risks of biotechnology products of concern, this Regulation should establish an Advisory Group on Biosecurity ('the Advisory Group') to monitor the landscape of biological risks and alert the Commission when it identifies new biotechnology products of concern. The Advisory Group should complement the work of existing expert groups in health security. It should be composed of globally leading independent scientists. Its members should be selected and operate in accordance with the Commission Decision of 30 May 2016 establishing horizontal rules on the creation and operation of Commission expert groups. The members of the Advisory Group should be appointed by the Commission based on up-to-date scientific or technical expertise in the area of biosecurity, biodefence and AI.
- (102) AI offers significant potential to enhance the Union's competitiveness and innovation capacity, including in the area of biotechnology. This potential should be realised in a safe and responsible manner. In this regard, Regulation (EU) 2024/1689 lays down harmonised rules for placing on the market putting into service and use of AI systems and models in the Union, prohibitions of certain AI practices, harmonised transparency rules for certain AI systems, rules on market monitoring, market surveillance, governance and enforcement as well as measures to support innovation. AI systems and general-purpose AI models can lower the barrier for actors to misuse biotechnology. The provisions of Regulation (EU) 2024/1689 governing AI systems and general-purpose AI models aim to mitigate this. Further, AI models, as described in Regulation (EU) 2024/1689, used in biological applications, that are not covered by Regulation (EU) 2024/1689 ('AI models in biological applications') can also pose risks, including different types of systemic biological risks.
- (103) AI models in biological applications encompass both specialised tools and more general models trained on large datasets of biological sequences that can be adapted for a variety of downstream tasks. Such models in biological applications can aid in the development of novel, more dangerous biological threats, increasing the ceiling of harm of biotechnology misuse. Capabilities of such AI models in biological applications therefore need to be monitored, investigating and assessing risks to identify any models posing biological systemic risks and ensuring necessary risk mitigation measures are taken. In addition, systemic resilience would need to improve to prevent, detect and respond to any misuse incidents.
- (104) The Advisory Group should therefore monitor the capabilities of AI models in biological applications, working closely with scientists and companies developing such models and should be tasked to issue a qualified alert to the Commission if it identifies that an AI model in biological applications not covered by Regulation (EU) 2024/1689 poses biological systemic risk. The Advisory Group should inform the Scientific Panel of independent experts established under Article 68 of Regulation (EU) 2024/1689, if it has reasonable grounds to suspect that an AI model covered by

that Regulation poses biological systemic risks. That panel could in turn issue a qualified alert to the AI Office in accordance with Regulation (EU) 2024/1689. Considering that the AI Office established by Commission Decision C(2024) 390⁴⁷ has as its mission to develop Union expertise and capabilities in the field of AI and to contribute to the implementation of Union law on AI, that office should participate in the establishment of the Advisory Group.

- (105) The European Health Biotechnology Steering Group established by this Regulation should also ensure proper coordination and information exchanges among Member States on the enforcement of the biosecurity provisions in this Regulation, consulting the Advisory Group, other relevant existing bodies and external experts where appropriate.
- (106) This Regulation should establish a framework of measures, in particular for health biotechnology strategic projects and high impact health biotechnology strategic projects, to ensure the growth of the health biotechnology sector. This Regulation and, in particular, the measures in Chapters II to VIII, should serve the aim of creating and reinforcing favourable conditions for health biotechnology, from research and development to the timely placing on the Union market and production of biotechnology innovations and products. The pathway to placing on the the market of health biotechnology innovations and products are governed by important and comprehensive sets of regulatory rules and procedures. Reviewing and streamlining these rules and procedures is an inherent part to achieve the aim of facilitating and accelerating the development, placing on the market and production of health biotechnology innovations and products. The practical effectiveness of the measures of this Regulation, in particular those in Chapters II to VIII, depends to a large extent on a review and streamlining of certain rules and procedures applicable to health biotechnology innovations and products so as to facilitate timely access to the market. As set out in recitals [5 to 7], health biotechnology must be understood broadly and encompasses also the veterinary and phytosanitary fields which have as their direct objective the protection of public health.
- (107) For instance, a timelier and facilitated risk assessment process for products subject to pre-market authorisation in accordance with Union food law, accelerated procedures and measures facilitating innovation, such as measures on regulatory sandboxes are needed for the efficiency of the facilitation measures laid down in this Regulation.
- (108) Regulation (EC) No 178/2002 lays down the general principles and requirements of food law, so as to form a common basis for measures governing food law at both Union and national level. For the purposes of risk assessment at Union level, it establishes the European Food Safety Authority ('the Authority'), as the responsible Union risk assessment body in matters primarily relating to food and feed safety.
- (109) Considering the increasing prevalence of diet-related health issues, it is essential to expand the Authority's mandate to encompass all aspects of nutrition and to enable it to provide advice concerning the nutritional properties of food products and practices, including those derived from advanced biotechnological processes.
- (110) It has been observed that a significant number of application and notification dossiers submitted to the Authority are either incomplete or do not meet the applicable

⁴⁷ Commission Decision of 24.1.2024 establishing the European Artificial Intelligence Office C(2024) 390.

regulatory and scientific specifications requirements to enable the best quality scientific assessment by the Authority, resulting in the need for requests for additional information during the risk assessment process and, consequently, leading to sometimes significant delays. This is also the case where biotechnology innovations and products are concerned, as such products would benefit strongly from pre-submission scientific advice on study design and testing strategies. Applicants or notifiers of such products, in particular small and medium-sized enterprises do not always have a clear understanding of the applicable regulatory and scientific requirements when compiling application dossiers, in particular as regards the types and details of studies to conduct. It is thus appropriate to enlarge the scope of the general pre-submission advice provided by the Authority at the request of a potential applicant or notifier to encompass non-committal advice on regulatory aspects including applicable rules and guidance documents, as well as scientific advice on study design and testing strategies. This advice should be provided by the staff and experts of the Authority to ensure the most updated scientific advice. Given the broadening of the scope of the general pre-submission advice which is already available for both new and renewals of approvals/authorisations, it is no longer necessary to provide for a specific pre-submission advice for renewals.

- (111) Practice has shown that the existing procedural consequences in the event of non-compliance with the notification requirement of commissioned studies at pre-submission phase appear to be too severe, particularly for small and medium-sized enterprises, and could impede competitiveness and innovation in the food chain. It is therefore necessary to shorten the existing procedural consequence in the event of non-compliance from six months to three months following the re-submission of the relevant application or notification.
- (112) In order to strengthen the coherence of risk assessments carried out by different Scientific Panels within the Authority, foster stronger synergies and promote greater harmonisation across guidance documents and scientific opinions, for the benefit of applicants while enhancing the effectiveness and efficiency of the Authority's risk assessment processes, it is appropriate that the staff of the Authority chairs the Scientific Committee and the Scientific Panels, without voting rights. The Scientific Committee should continue to be composed by experts.
- (113) The food and feed sector is experiencing rapid technological advancements, including biotechnology, AI, smart farming techniques, development of new approach methodologies, that could contribute to reduction of animal testing and circular economy practices promoting resource efficiency and waste reduction. It is therefore appropriate to provide Member States with the possibility of setting up regulatory sandboxes that can provide an environment for the testing of those innovations in a controlled manner, incentivising research and development, whilst allowing for adaptive regulatory practices that can be modified based on feedback and results from live trials. Regulation (EC) No 178/2002 should therefore be amended accordingly.
- (114) Given the diversity of sectors covered by Union food law, and the fact that Member States have diverse food systems, cultural preferences, local market conditions, and research and risk assessment bodies, regulatory sandboxes should be established a national level in order to ensure the necessary flexibility to allow for experimentation specifically tailored to address local needs, preferences, and consumer behaviours. For the same reasons, and in order to support innovation along the whole food chain, regulatory sandboxes should be allowed also at retail level and, thus, making available products under the regulatory sandboxes to food business operators or consumers

should not be considered as placing on the market. However, in order to ensure that the establishment of regulatory sandboxes does not jeopardise food safety or consumers' information and that they are established and function in such a way as to enable the collection of sound and useful information to inform future regulatory changes, rules should be laid down concerning the objectives pursued within regulatory sandboxes, the modalities for their adoption, amendment and revocation, the control of the activities carried out under the regulatory sandbox, monitoring and reporting as well as rules ensuring the protection of human and animal health and of the environment.

- (115) Regulatory sandboxes should not be allowed for some products. Experience has shown that certain types of novel foods trigger ethical or cultural concerns among various consumer segments regarding their acceptability. Since those aspects are best addressed within the applicable rigorous regulatory framework established by Regulation (EU) 2015/2283 of the European Parliament and of the Council⁴⁸, it is appropriate to exclude novel foods from the scope of regulatory sandboxes. For GMOs legal pathways exist to allow testing of innovations, such as under Part B of Directive 2001/18/EC on the deliberate release of genetically modified organisms (GMOs) for purposes other than placing on the market, and there should not be a duplication of paths in order to maintain legal certainty. For this reason, regulatory sandboxes should be restricted to products containing or consisting of GMOs subject to authorisation under Part C of Directive 2001/18/EC. As regards innovations concerning novel plastic recycling technologies for plastics intended to come into contact with food, chapter IV of Commission Regulation (EU) 2022/1616⁴⁹ already establishes a framework that is meant to encourage the development of such novel technologies without prior authorisation. To ensure uniform rules on the development of novel recycling technologies that safeguard the health of the consumers, it is appropriate to exclude the development of recycling technologies from the possible use of regulatory sandboxes and rely instead on the procedure established in chapter IV of Regulation (EU) 2022/1616.
- (116) To ensure uniform conditions and principles for the setting up, operation and supervision of Regulatory sandboxes, implementing powers should be conferred on the Commission in the context of Regulation (EC) No 178/2002. Those implementing powers should be exercised in accordance with Regulation (EU) 182/2011 of the European Parliament and of the Council⁵⁰. In case of emergencies, the Commission may provisionally adopt an measures in accordance with an urgency procedure requesting the suspension of the regulatory sandbox concerned.

⁴⁸ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1, ELI: <http://data.europa.eu/eli/reg/2015/2283/oj>).

⁴⁹ Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008 (OJ L 243, 20.9.2022, p. 3, ELI: <http://data.europa.eu/eli/reg/2022/1616/oj>).

⁵⁰ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13, ELI: <http://data.europa.eu/eli/reg/2011/182/oj>).

- (117) Considering the additional financial burden established on the Authority with the expansion of its mandate following the amendments set out in this Regulation, the possibility of establishing fees in order to fully or partially fund EFSA's new tasks could be considered.
- (118) Clinical trials with advanced investigational therapy medicinal products (ATMPs), including those consisting or containing genetically modified organisms (GMOs) within the meaning of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council⁵¹, can provide early access to transformative treatments for patients with rare or otherwise untreatable conditions and are important to prepare for the marketing authorisation of the medicinal products for such treatments. The nature and design of certain advanced investigational therapy medicinal products is such that the risks to human health and the environment resulting from a deliberate release of a GMO into the environment are, in practice, either excluded or negligible. For example, in viral vectors, which are genetically modified viruses used to deliver genetic material into cells, the wild-type virus genome is largely removed resulting in replication-defective recombined particles. As these particles cannot reproduce themselves, they present at most a negligible risk to human health and the environment.
- (119) Consequently, when controlling under Regulation (EU) No 536/2014 for risks from the deliberate release into the environment of GMOs, a risk-proportionate approach should be applied and Regulation (EC) No 1394/2007 should be amended with respect to certain, clearly delineated categories of advanced investigational therapy medicinal products that consist or contain GMOs, which present no or negligible risks to human health and the environment. Whilst it is appropriate to exempt such clearly delineated categories of advanced investigational therapy medicinal products from the requirement to submit an environmental risk assessment, sponsors of clinical trials should, however, submit a declaration as part of the clinical trial application that explains why the advanced investigational therapy medicinal products concerned falls into one or more of the specific categories of products presenting no or negligible risks to human health and the environment. The Committee for Medicinal Products for Human Use (CHMP) referred to in Article [148] of Regulation [...] [revised Regulation No (EC) 726/2004] should verify this declaration. For the same considerations of a risk-proportionate approach, the above-mentioned categories of advanced investigational therapy medicinal products should also be exempted from the requirements of Regulation (EU) No 536/2014 regarding manufacturing and import. Annex I to the Regulation (EU) No 536/2014 should also be amended to ensure consistency with the aforementioned amendments to the Regulation (EC) No 1394/2007.
- (120) Scientific and technological advances are driving the development of advance therapy medicinal products (ATMPs). To future proof the ATMPs legislative framework, the power to adopt delegated acts should be delegated to the Commission to amend Regulation (EC) No 1394/2007, by clarifying the definition, without extending its scope, of what constitutes a tissue engineered product, in light of technical and scientific advancements in the field of ATMPs. To that effect, the Commission should carry out appropriate consultations of the Agency and of the Substances of Human Origin Coordination Board ('the SCB').

⁵¹ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106, 17.4.2001, p. 1, ELI: <http://data.europa.eu/eli/dir/2001/18/oj>.

- (121) The measures established in this Regulation, including regarding health biotechnology strategic projects and high impact health biotechnology strategic projects, access to funding, biosimilars and the application of artificial intelligence in the health biotechnology sector aim to strengthen the health biotechnology sector. Those measures aim to foster research, development, testing, and preparing for market entry of health biotechnology products and services. This is the case for the centres of excellence for advanced therapies, the overall aim of which is to accelerate the placing on the market of advanced therapies, accelerate clinical translation, improve quality control and facilitate patient access across the Union. Similarly, the biotechnology development accelerators aim to provide trusted testing or demonstration facilities for process testing, validation, and small batch manufacturing, including for the initial phases of clinical trials. Similarly, time to market for biotechnology products is one key factor that impacts investments in the sector and accordingly access to funding for developers and start-ups in the biotechnology sector. Many of the products subject to those measures are expected to be biological medicinal products ('biologicals'), for which clinical research and trials are an essential step on their way to the market. Therefore, the measures established in this Regulation, in particular on biotechnology health strategic projects and high impact health biotechnology strategic projects, are intrinsically intertwined with, and depend on, the strengthening of clinical research in Europe. This is because all biotechnology products expected to be developed or supported through the health biotechnology strategic projects and high impact health biotechnology strategic projects are depending to a very large extent on an efficient and vibrant ecosystem of clinical research in the Union.
- (122) Amending Regulation (EU) No 536/2014 of the European Parliament and of the Council⁵² to bring simplification and shorten the time for biotechnology innovations to reach the Union market is crucial to streamline and accelerate clinical trials processes in the Union and to make the legislative framework competitive globally so as to attract more clinical research to the Union. Without an efficient, accelerated and streamlined legislative framework for clinical trials authorisation in the Union, the other measures in this Regulation, and in particular the framework for the recognition and support of health biotechnology strategic projects and high impact health biotechnology strategic projects would be deprived of their effectiveness, as all health biotechnology medicinal products require state of the art clinical research and a globally competitive regulatory framework for clinical trials authorisation.
- (123) The clinical trials offer early access to the most innovative therapies, contribute to a sustainable healthcare system, maintain scientific excellence and specialised skills and they also support prosperity in the Union. Enabling the development of innovative biological medicines through clinical trials is particularly important, since those medicines often provide life-saving therapeutic options, including in cancer care or against rare genetic conditions, and, due to their complexity, they are often more difficult and expensive to develop. Increased clinical trials in the Union for biological medicines could potentially contribute to more manufacturing in the Union, higher number and earlier regulatory submission of biological medicines for marketing authorisation applications and higher percentage of EU clinical data in marketing authorisation applications. In relation to this, biological medicines sales are key

⁵² Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1, ELI: <http://data.europa.eu/eli/reg/2014/536/oj>).

drivers of growth. In 2024, the European Union spent €228 billion on medicines at list prices, including €95 billion on biological medicines, which now comprise 41% of total pharmaceutical spending. Spending on biological medicines continues to outpace that of small molecules (~5%) by 3x and the total prescription market, at a rate of 14.7% in the most recent period⁵³. In this context, simplifying Regulation (EU) No 536/2014 and accelerating multinational clinical trials appears necessary with a view to accelerate time to market of health biotechnology innovations and thus secure the effectiveness of the substantive provisions laid down in this Regulation.

- (124) At the same time, Regulation (EU) No 536/2014 applies to all clinical trials irrespective of the type of investigational medicinal product, whether it be biological or chemical molecules. However, the amendments to Regulation (EU) No 536/2014 through this Regulation, for streamlining and simplifying that Regulation, are particularly relevant for biologicals. This is because the development of biologicals relies heavily on multinational clinical trials to be able to recruit the necessary number of patients.
- (125) Moreover, the limitation of the scope of the envisaged amendments to biologicals would be against the core principle of Regulation (EU) No 536/2014 to create a harmonised EU-level system for clinical trials authorisations. It would create two authorisation pathways for chemical medicines and biologicals and it would not be appropriate to distinguish these procedurally, considering the coordinated assessment procedure established in Regulation (EU) No 536/2014 and the single EU Portal and database as IT system provided for in that Regulation for the electronic submissions and assessment of all applications. In addition, providing for different timelines for biological and chemical medicines could create uncertainty for developers and could be perceived as creating double standards for clinical research on medicines, where the biotechnology products, often more complex, would benefit from shorter and more streamlined timelines. Such fragmented approach could potentially also increase the burden on regulators and could lead to different national interpretations regarding the implementation of the respective authorisation procedures. This in turn would risk putting multinational clinical trials at disadvantage with more associated negative effects for biological development. Further, such an approach could have a particularly negative impact on combination trials testing combination medicinal products, where biological and chemical active substances are combined within a single pharmaceutical form, to treat debilitating medical conditions for example but not limited to breast, lung, colorectal cancers or autoimmune diseases, as well as on trials comparing a biological and a chemical medicinal products or on trials using a chemical medicine as a standard of care treatment in the control arm . Consequently, the amendments to Regulation (EU) No 536/2014 should apply to both biologicals and chemicals.
- (126) The Union has unique advantages as a place for multinational clinical trials due to its large population, rich genetic diversity, scientific excellence and robust research infrastructures, and high ethical, quality and safety standards. To fully leverage these strengths and considering the key and increasing role of research and clinical trials for a thriving health biotechnology sector, it is necessary to amend the Regulation (EU) No 536/2014 to further streamline and speed up the authorisation processes especially for multinational clinical trials.

⁵³ See figure 2, EU spending growth at list price levels by segment and leading therapy area, in Annex to this document.

- (127) To accelerate and streamline the approval processes in multinational clinical trials it is necessary to give a stronger leading role to the reporting Member State and further strengthen the principles of mutual trust and reliance. The assessment by the reporting Member State, including of the ethical aspects of the trial, should serve as a reference for the other Member States concerned. Member States concerned should complement the assessment by the reporting Member State only when necessary, and be entitled to raise considerations from ethical, relevant national law or national standard of care perspectives. Strengthening reliance on the reporting Member State's assessment would reduce duplication of work and allow Member States and sponsors to allocate resources more effectively, while ensuring high level of protection of subjects and the robustness of data.
- (128) Defined timelines in the context of clinical trials approval are necessary to guarantee speed and enhance predictability of the authorisation process, especially for multinational clinical trials. Defined maximum timelines should allow the Member State authorities with efficient planning to reduce periods of inactivity and thus regulatory delays between the assessment phases and enable short procedure for clinical trial approval overall. Stronger reliance on the reporting Member State would also result in efficiency gains, improve resource allocation and would enable the shortening of the consecutive assessment steps without compromising the quality of the assessments. It would benefit the sponsors as well, as it will result in a quicker start of a clinical trial, as well as in increased transparency and predictability for more effective planning. To reduce regulatory bottlenecks by allowing coordinated interaction between Part I and Part II assessments in multinational clinical trials, their respective assessment timelines should be aligned.
- (129) Recognising the importance of advanced therapeutic medicinal products (ATMPs) as drivers of innovation in biotechnology and regenerative medicine, it is appropriate to introduce a series of regulatory provisions to simplify and shorten the timelines for authorisation of clinical trials in the Union. In particular, to accelerate the conduct of clinical trials investigating the ATMPs, the authorisation procedure should be shortened by removing the additional 50 days of assessment period which is currently applicable
- (130) Furthermore, to leverage the mutual trust and foster the high ethical standards, the ethics committees should be involved in the assessment of ethical aspects of Part I of the application dossier. This ethical perspective should be integrated in the assessment report by the reporting Member State. Member States concerned should be able to raise, where relevant, consolidated considerations integrating inputs from their responsible ethics committees. The mandatory integration of ethical review in Part I assessment by the reporting Member State would ensure that the ethical review is conducted in a more harmonised and transparent manner. Such integration should also result in fewer and more consistent considerations and therefore support overall robustness of the evaluation with decreased burden for sponsors and national regulatory bodies.
- (131) It is appropriate that an enhanced EU portal provides technical means for a clear and timely communication between the involved Member States and the sponsor during the assessment, when requests for information are issued.
- (132) To increase further the efficiency and speed of Part I assessments in multinational clinical trials, when translations of Part I documents are required by national law, these should be assessed with the Part II. Considerations regarding the accuracy of

these translations will be raised by the Member States concerned with the sponsor in the Part II assessment process. Moving the assessment of translation quality into Part II of the application will allow the reporting Member State to focus on the technical and scientific assessment of the trial, while Member States concerned would retain their ability to verify the linguistic accuracy and suitability for their territories.

- (133) To ensure that the sponsor of clinical trials can adapt them dynamically through their life cycle to changed circumstances or to consider the scientific developments and ensure smooth conduct of the clinical trial, a submission of parallel substantial modification should be allowed. Such submissions should be allowed when the substantial modification, despite an ongoing approval of another one, concerns distinct and independent aspects of the dossier. Allowing parallel substantial modifications would support increased flexibility and responsiveness of the regulatory system. It would facilitate updates related to subjects' safety and enable timely response to emerging scientific knowledge or allow operational adaptations to improve patients access and trial efficiency.
- (134) To further support the efficiency and consistency of clinical trial submissions across the Member States, it is appropriate to develop and oblige the use of harmonised templates for the submission of Part II documents of clinical trial applications. The use of harmonised templates is expected to simplify the application and assessment processes reducing administrative burden both for sponsors and Member States. Harmonised templates may be updated in the light of technical and scientific evolution. Member States concerned may choose to rely also on the assessment of the reporting Member State of common aspects and elements in Part II application further streamlining initial authorisation and for additional efficiency gains.
- (135) Innovative and personalised therapies often combine the use of medicinal products with medical devices, including in vitro diagnostic medical devices. During the development of such therapies, clinical trials of one or more medicinal products may need to be combined with clinical investigation of one or more medical devices or performance studies of one or more in-vitro diagnostic medical devices. The authorisation and conduct of such combined studies are complex due to the application of requirements of two or three Union legislative frameworks in the area of health and the fact that these are typically conducted across several Member States. In order to support innovation and make efficient use of sponsors' and Member States' resources, it is necessary to put in place a dedicated pathway for the authorisation and conduct of such combined studies, involving coordinated assessment across Member States.
- (136) The experience gained during the Covid-19 pandemic has shown the need for the Union to swiftly take up measures to strengthen the development and access to crisis-relevant medicines, including to accelerate, simplify, and streamline the authorisation of multinational clinical trials relevant to prevent, treat or diagnose the disease caused by an emerging serious cross-border threat to health. Regulatory flexibility, including an accelerated authorisation procedure for clinical trials, is necessary to address and possibly contain an emerging health threat in a timely, efficient and coordinated manner. Therefore, it is appropriate to allow for an accelerated procedure for the authorisation of multinational clinical trials in situations where a public health emergency at Union level has been recognised in accordance with Article 23(1) of

Regulation (EU) 2022/2371 of the European Parliament and of the Council⁵⁴, or in situations of an emerging serious cross-border threat to health that is likely to lead to the recognition of a public health emergency at Union level. This should also complement measures from the Regulation (EU) 2022/2372 of the Council⁵⁵ on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

- (137) Based on the experiences gained from the application of Regulation (EU) No 536/2014, it is appropriate to further tailor the requirements for the authorisation and oversight of clinical trials according to the risks they pose to the subjects. In this context, the risk categorisation scheme should be further refined by differentiating between minimal-intervention clinical trials that present post-marketing authorisation trials and low-intervention clinical trials that use authorised medicinal products with proven scientific evidence on the efficacy and safety but are used outside their initial marketing authorisation.
- (138) Clinical trials that meet the criteria for minimal-intervention clinical trials should only require an ethical review before the clinical trial can begin. An enhanced application of a risk-proportionate approach will contribute to fostering a regulatory framework that is conducive to research and innovation. Sponsors, particularly non-commercial ones who conduct the majority of minimal-intervention and low-intervention clinical trials in the Union, will greatly benefit from simplified and risk-proportionate regulatory requirements through a reduced administrative burden, while not compromising subjects' safety, well-being, and rights. A reinforced application of a risk-proportionate regulatory framework further allows Member States to concentrate on their assessment on clinical trials associated with greater risk to the subjects.
- (139) To ensure that clinical trials accurately represent the target population in all its diversity, and to enhance the treatments available for vulnerable populations, medicinal products which are likely to offer significant clinical benefit should be fully and appropriately studied for their effects in these specific groups, including as regards requirements related to their specific characteristics and the protection of the health and well-being of subjects belonging to these groups. The protection of vulnerable populations, in this context, such as incapacitated subjects, minors and pregnant or breastfeeding women, requires a proper consideration of the risks of exclusion against risks of inclusion in clinical trials. This is in accordance with the 2024 version of the World Medical Association's Declaration of Helsinki.
- (140) Electronic health data accessed under Chapter IV of Regulation (EU) 2025/327 can offer valuable insights for clinical trials, particularly regarding the protocol or the investigational medicinal products dossier design. Therefore, sponsors should be able to utilize this data when applying for clinical trial authorisation or modifications. Additionally, competent authorities should consider this data during the assessment of such applications.

⁵⁴ Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (*OJ L 314*, 6.12.2022, ELI: <http://data.europa.eu/eli/reg/2022/2371/oj>)

⁵⁵ Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

- (141) The development of a medicinal product may require various clinical trials until robust data regarding its safety and efficacy are available to support the submission of a marketing authorisation application. The knowledge of the products is built gradually during this development. Using the same dossier for an investigational medicinal product in different clinical trials helps to ensure the collection of consistent and complete information, streamlines product development, supports efficient assessment, management and oversight, and can speed up the time to the market. For this reason, a sponsor should be able to request the establishment of an investigational medicinal product core dossier and rely on this dossier by referencing it in all clinical trials related to the investigational product concerned. In order to keep the core dossier updated, sponsors should be able to request its modification. One of the Member States concerned by the trials with investigational medicinal product should assume the role of core dossier depositary Member State and take responsibility for verifying completeness and suitability of the core dossier and managing the requests for its updates. Member States concerned in the core dossier should rely on the assessment by the depositary Member State. The depositary Member State may consult the Member States concerned as appropriate.
- (142) In the development of biosimilar medicinal products, the rapid evolution of analytical and functional characterisation methods for complex biological and biotechnological active substances calls for tailored clinical approach in biosimilar development with reduced need for confirmatory comparative clinical efficacy trials. Submission of a simplified investigational medicinal product dossier (IMPD) for biosimilar medicines to replace, as appropriate quality and quality control data, with a reference to the relevant additional quality substance master file or corresponding certificates would complement the shift in more risk proportionate clinical data requirements. This dual simplification and streamlining should focus on the regulatory scrutiny of key comparability data rather than require duplicative submission and assessment of the full IMPD quality dossier. Combining streamlined and robust quality data assessment with targeted clinical data generation should support an integrated and efficient development pathway for biosimilars with reduced administrative burden and development costs for biosimilar manufacturers, in particular in the Union. Accelerated access to biosimilar medicines to the market should support patients' access to more affordable biological therapies.
- (143) To further optimise the use of resources for both the sponsors and Member States, the possibility to refer, in a clinical trial application, to an active substance master file or a corresponding certificate, or a certificate confirming that the quality of the substance is suitably controlled by the relevant monograph of the European Pharmacopeia, or a certified platform technology master file should be available as appropriate for any investigational medicinal product, including for ATMPs. In these cases, the simplified IMPD must contain all relevant data to the active substance or its manufacturing, which is not covered in the referenced master file or certificate.
- (144) To address the increased significance of delivery of investigational medicinal products and auxiliary medicinal products to subjects, Regulation (EU) No 536/2014 should be amended to provide a framework for the controlled transport within a Member State, where the clinical trials have been authorised, of such products directly to subjects' residences or through a dispensing pharmacy or by an authorised person, under the investigator's oversight. This ensures responsible and transparent delivery practices and adapts to the real world necessities, as demonstrated during the COVID 19

pandemic. Distribution through a dispensing pharmacy or by an authorised person could be considered in particular in cluster trials.

- (145) To enhance regulatory efficiency, to ensure consistency in the implementation of Regulation (EU) No 536/2014 across the Union, and to facilitate predictability of requirements for the developers of medicinal products, it is necessary to provide a framework for the harmonisation of national requirements regarding the distribution of investigational and auxiliary medicinal products, notably for decentralised and multinational clinical trials. To achieve such harmonisation, the inspection working groups, which provide input and recommendations on all matters relating, directly or indirectly, to good clinical practice, good manufacturing practice, and good distribution practice should draw up guidelines, in collaboration with the Commission, and revise them as necessary to reflect technical and scientific progress in the field of clinical trials. In consideration of the specialised knowledge and experience of its members, who represent the Member States, the inspection working groups are particularly well-suited to facilitate the coordination of national requirements, eliminate unnecessary administrative obstacles, and promote a more efficient and harmonised approach to the conduct of clinical trials within the Union.
- (146) To facilitate the implementation of Regulation (EU) No 536/2014, while at the same time preserving the protection of quality of investigational medicinal products and ensuring greater predictability for sponsors, it is also appropriate to provide the general principles on how to ensure quality in the processes not subject to a manufacturing and import authorisation, such as re-packaging and re-labelling.
- (147) Verification of compliance with the legal requirements of manufacturing of investigational medicinal products by relevant entities through a system of supervision, is of fundamental importance to ensure that the objectives of this Regulation are effectively achieved. The provisions of Directive (EU) .../... [*reference to be added after adoption cf. COM(2023) 192 final*] regarding the supervision system and the cooperation on inspections, and provisions of [Regulation (EU) .../... of the European Parliament and the Council [*reference to be added after adoption cf. COM(2023) 193 final*] regarding the cooperation between national competent authorities and the Agency for inspections in third countries should apply to the supervisions of manufacturing of investigational medicinal products.
- (148) Verification of compliance with the provisions of Regulation (EU) No 536/2014, including for verification of compliance with good clinical practices, through a system of supervision, is of fundamental importance to ensure that the objectives of this Regulation are effectively achieved. Therefore, the competent authorities of the Member States should have the power to perform on site or remote inspections, including unannounced inspections, where necessary. Where needed, the competent authority of a Member State should also be able to request support from another Member State or the Agency to carry out a joint inspection, or to request a Member State or the Agency to carry out the inspection on their behalf.
- (149) The disruptive and innovative approaches to clinical trials may require adaptations to the rules governing clinical trial approvals and conduct. To harness the benefits of this innovation while providing necessary safeguards, it is essential to create a safe space for testing new regulatory approaches and technologies. This includes, where appropriate, the use of AI in trial design, data collection, analysis, and participant interaction. For that reason, it is necessary to provide for a possibility of setting up a controlled experimental environment in the form of a regulatory sandbox, allowing

regulators to test new methods for authorising and conducting clinical trials, for example, when some requirements of the dossier cannot be fully complied with, while ensuring strong safeguards for participant protection and data robustness. Insights gained from sandbox activities should inform future guidance and, where appropriate, legislative amendments.

- (150) The processing of personal data under Regulation (EU) No 536/2014 should comply with the requirements for the protection of personal data, including genetic data and data concerning health, laid down in Regulations (EU) 2016/679⁵⁶ and (EU) 2018/1725⁵⁷ of the European Parliament and of the Council. It is appropriate to clarify that the basis for the processing of personal data in the context of clinical trials is laid down in Regulation (EU) No 536/2014, pursuant to Article 6(1), point (c), of Regulation (EU) 2016/679. The Agency should have access to personal data necessary to perform its tasks in the public interest or complying with legal obligations in accordance with Articles 40, 80 and 81 of Regulation (EU) No 536/2014. The Commission should have access to personal data necessary for it to perform its task in accordance with Articles 78, 79, 80, 81, of Regulation (EU) No 536/2014.
- (151) In particular, Regulation (EU) No 536/2014 should be amended to require the processing of personal data by the sponsors and investigators where this is necessary to comply with the legal obligations imposed on them to ensure the safety and efficacy of medicinal products, when they request authorisation for and conduct clinical trials. This includes obligations to perform research activities in accordance with an authorised protocol, to perform safety reporting, and to perform archiving in accordance with Regulation (EU) No 536/2014. The relevant information to be collected according to the authorised protocol will contain personal data of the subjects, including genetic data or data concerning health. The processing of such special categories of personal data in the context of clinical trials takes place for reasons of public interest in the area of public health, in particular for ensuring high standards of medicinal products in compliance with Article 9(2), point (i), of Regulation (EU) 2016/679. Additionally, personal data may encompass identification details, such as sex and age, social insurance numbers and contact information. Moreover, sponsors may collect and process other data necessary for implementing the authorised protocol, such as the personal data of investigators. The categories of personal data to be collected and processed in the context of a specific clinical trial should be specified in the authorised protocol. Regulation (EU) No 536/2014 should be amended to establish specific safeguards for the processing of personal data, including genetic data or data concerning health, in compliance with Article 9(2), points (i) and (j), of Regulation (EU) 2016/679. For instance, it should require informed consent to participate in the clinical trial, as well as to maintain confidentiality of records and personal data of participants. The protocol should specify further appropriate safeguards such as specific technical and organisational

⁵⁶ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1, ELI: <http://data.europa.eu/eli/reg/2016/679/oj>).

⁵⁷ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39, ELI: <http://data.europa.eu/eli/reg/2018/1725/oj>).

measures that should be employed, including pseudonymisation, integrity and confidentiality controls, encryption and access restrictions. In addition, any clinical trial should be subject to ethical review.

- (152) Since this Regulation amends Regulation (EU) No 536/2014 to establish a harmonised framework for the processing of personal data in the context of clinical trials, Member States should not be able to maintain or introduce under Article 9(4) of Regulation (EU) 2016/679 further conditions, including limitations and specific provisions such as requesting the consent of natural persons in the sense of that Regulation, with regard to the processing of personal data, including genetic data or data concerning health under Regulation (EU) No 536/2014 as amended by this Regulation.
- (153) Personal data which is collected and processed under each authorised protocol in accordance with Regulation (EU) No 536/2014 as amended by this Regulation may be further processed by the same controller for the purposes of other clinical trials, conducted in accordance with Regulation (EU) No 536/2014. Such data may include names, contact details, health and genetic data of subjects. It should also be possible to further process such personal data by the same controller for scientific research purposes.
- (154) To further address the issue of fragmentation within and across Member States on the application of the measures applicable to the conduct of clinical trials and, as regards certain aspect that remain national, and drive further harmonisation, it is necessary to enable closer cooperation between and across Member States' competent authorities and ethics committees. For that purpose, the role and tasks of the Clinical Trials Coordination and Advisory Group (CTAG) should be extended. The CTAG should in particular be empowered to issue or endorse guidance documents related to clinical trials conduct and supervision, to ensure uniform interpretation and harmonised implementation of Regulation (EU) No 536/2014 across the Member States.
- (155) Ethics committees involved in the assessment of clinical trials application should collaborate in a dedicated forum with the objective to strengthen cooperation in the area of ethical aspects of clinical trials which are of national competence.
- (156) Regulation (EU) No 536/2014 outlines the responsibilities of Member States in designating competent authorities and ethics committees for regulatory activities, including oversight. To perform their roles as required by the provisions of this Regulation amending Regulation (EU) No 536/2014, these competent authorities and responsible ethics committees should be vested in the necessary powers, have at their disposal qualified personnel and sufficient resources to perform their duties effectively. Regulation (EU) 536/2014 emphasizes the importance of communication and coordination to ensure consistent and efficient regulatory actions within Member States. It is also essential to define how the Commission will verify the correct implementation of the law by the competent authorities. Regulation (EU) No 536/2014 should be amended accordingly.
- (157) The integration of AI in clinical trials presents opportunities to enhance the clinical trials' design, execution, and oversight. This technological advancement offers substantial benefits to clinical trial sponsors, regulators, and ultimately patients. Among the possible enhancements are improved endpoint determination, advanced statistical analysis, optimized patient selection, enhanced data handling and analysis. While AI tools aim to accelerate the development of medicinal products, it is imperative that their use in clinical trials adheres to applicable legislation. This

includes, when applicable, compliance with Regulation (EU) 2024/1689, Regulation (EU) 2017/746, Regulation (EU) 2017/745 and Regulation (EU) 2016/679.

- (158) Sponsors hold the responsibility to evaluate the potential impact and risk of AI tools on patient safety based on guidelines. Untested systems may introduce gender and other biases and errors, risking unreliable outcomes or failures in interpreting medical data accurately. Such risks could lead to misdiagnosis, incorrect treatment, or inaccurate patient selection, especially hazardous in extensive clinical trials with numerous participants. The guidelines on the developments and deployment of AI tools developed by the Agency, in cooperation with the Clinical Trials Coordination and Advisory Group, and as appropriate, with other expert groups established under Union law, should assist the sponsors, national competent authorities and ethics committees in assessment of AI tools benefits and risks in the context of the lifecycle of clinical trials.
- (159) To further strengthen the competitiveness of the European Union in clinical research and ensure timely access of patients to innovative medicines, it is necessary to monitor the effectiveness of the provisions in this Regulation amending Regulation (EU) No 536/2014 to streamline and simplify the authorisation and conduct of multinational clinical trials. Such monitoring should be based on key performance indicators such as the increase in the number of clinical trials in the Union over the period of five years, as this indicator reflects both the attractiveness of the Union and the capacity of the European regulatory system to support clinical research with maintained high data quality and patients' safety standards. Regulation (EU) No 536/2014 should be amended accordingly.
- (160) The management of changes through the lifecycle of veterinary medicinal products is subject to regulatory approvals. The handling of variations for biological products is particularly critical because of the impact that changes in the source materials or the manufacturing process can have on the safety and efficacy attributes of the finished product. It is necessary to continue ensuring that changes introduced during the lifecycle of a veterinary medicinal do not alter the positive benefit-risk balance while avoiding unnecessary administrative burden. To this end, the process for implementation of variations not requiring assessment laid down in Article 61 of Regulation (EU) 2019/6 of the European Parliament and of the Council⁵⁸ should be further optimised.
- (161) Advances in biotechnology bring new opportunities for the development of veterinary medicinal products, including the possibility to develop vaccines with improved safety and efficacy profiles in a much shorter timeframe. The possibility to deploy and use vaccines quickly is essential to react to outbreaks of certain animal diseases thereby reducing the risks for human health, contributing to animal welfare and reducing economic losses for farmers.
- (162) Safety for veterinary medicinal products is assessed during marketing authorisation procedures in accordance with Regulation (EU) 2019/6. The competent authorities responsible for the granting of marketing authorisations are required to verify the safety for the target species, for the user, for consumers and for the environment. Likewise, the conduct of clinical trials is subject to the approval and supervision by

⁵⁸ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 2, ELI: <http://data.europa.eu/eli/reg/2019/6/oj>).

competent authorities responsible for veterinary medicinal products. Regulation (EU) 2019/6 further requires that such trials are conducted in accordance with Good Clinical Practice, which includes the obligation for sponsors to ensure that there are no environmental grounds precluding the conduct of the trial.

- (163) Regulation (EU) 2019/6 and the Union GMO legislation (Directives 2001/18/EC⁵⁹ and 2009/41/EC⁶⁰, Regulations (EC) 1829/2003⁶¹, 1830/2003⁶² and 1946/2003⁶³ of the European Parliament and of the Council share the same protection goals as regards the protection of human and animal health and the environment from genetically modified organisms. Since parallel assessments and documentation and increased administrative burden is not conducive to increased protection of human health or the environment and has negative effects on the use of biotechnology in veterinary medicine, the risks for human and animal health and to the environment from veterinary medicinal products containing or consisting of genetically modified organisms should be solely assessed in accordance with Regulation (EU) 2019/6. This simplification should be coupled with a reinforcement of existing obligations as regards the conduct of clinical trials with veterinary medicinal products that contain or consists of GMOs.
- (164) To remove any legal uncertainty for developers, marketing authorisation holders and users, it should also be clarified that given the purpose of veterinary medicinal products to treat animals, their administration does not bring the treated animals or their products under the scope of the Union GMO legislation.
- (165) The Commission should be empowered to adopt delegated acts to amend Annex II to Regulation (EU) 2019/6 in order to adapt it to scientific and technical progress.
- (166) Veterinary medicinal products developed by means of biotechnology processes to diagnose, treat or prevent zoonotic diseases should be entitled to an extra year of supplementary protection certificate ('SPC') in order to support their development.
- (167) Scientific and technical progress in biotechnology enables the development of new technologies, methods or products that may not fit into existing Union legislation. The lack of harmonised requirements is an impediment to the development, marketing and use of new concepts that may, however, bring benefit to animal healthcare. Regulatory sandboxes may be established to facilitate the development, placing on the market or use of innovative technologies, methods or products related to animal health which are directly or indirectly related to the development, manufacturing or use of veterinary medicinal products under conditions that ensure protection of animal and public health as well as the environment. A regulatory sandbox should only be established if there is no Union legislation governing the marketing and use of the relevant technology, method or product.

⁵⁹ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

⁶⁰ Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (OJ L 125, 21.5.2009, p. 75.).

⁶¹ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

⁶² [Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

⁶³ Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p.1).

- (168) A regulatory sandbox may be established by the Commission, by way of an implementing act following a recommendation of the Agency which should analyse expected potential benefits and risks as well as existing regulatory challenges. Technical and scientific requirements for the technologies, methods or products under the regulatory sandbox and procedures should be developed and published by the Agency. The Agency should ensure that the requirements and procedures it develops are proportionate and are adapted to the specific risks. A regulatory sandbox may be terminated at any time where, following the identification of negative impacts on animal or public health or the environment, the benefit-risk balance becomes negative and there are no satisfactory risk mitigation measures that could be implemented.
- (169) Technologies, methods or products developed under a regulatory sandbox should only be placed on the market or used on the basis of an authorisation granted by the Commission. Depending on the specific characteristics of the products concerned, a class authorisation to market or use technologies, methods or products may be possible. Member States should be empowered to take interim measures where serious risks to animal or public health or the environment are identified. In such cases, Member States should swiftly inform the Agency.
- (170) To ensure legal certainty, the termination of a regulatory sandbox should not affect the validity of the authorisations to place on the market or use technologies, methods or products already granted, unless the regulatory sandbox has been terminated on grounds related to the protection of public or animal health or the environment.
- (171) To provide legal certainty to developers and competent authorities alike, time limits should be established also in the Regulation (EU) 2024/1938 and for all actors involved in the consultation process, at national and Union level, including the SoHO competent authorities, the Substances of Human Origin Coordination Board ('the SCB'), established in that Regulation and advisory bodies established under other relevant Union legislation. Consequently, Regulation (EU) 2024/1938 should be amended to provide the power for the Commission to adopt implementing acts to establish such time limits, that should be ambitious and determined based on experience gathered with the consultation process as of the entry into application of that Regulation.
- (172) The field of substances of human origin is characterised by rapid scientific and technological innovation, giving rise to health biotechnology approaches that may present scientific or regulatory challenges under existing legal requirements. To support the development of such innovations at early stages while maintaining public health protection, Member States should be able to establish regulatory sandboxes for substances of human origin that cannot yet be developed in full compliance with the requirements of Regulation (EU) 2024/1938, provided that the innovative characteristics or methods are expected to contribute distinctively to quality, safety, effectiveness, or patient access to treatment. The sandbox activities should enable a discussion on the development of common approaches and the potential adaptation of legislative frameworks based on accumulated experience. Any substances of human origin developed through regulatory sandboxes should only be distributed for human application when properly authorised, with initial authorisations limited to the regulatory sandbox duration. This framework should enable controlled experimentation with innovative regulatory approaches while preserving the essential safeguards for public health and safety. Regulation (EU) 2024/1938 should be amended accordingly.

- (173) The regulatory sandboxes in the field of substances of human origin should be conducted under the supervision of the concerned SoHO competent authorities, and, where relevant, competent authorities under other Union and Member State legislation concerned. The latter authorities should be in particular involved where the preparation of the SoHO requires steps using products regulated under another Union legislative framework, or where SoHO is presented as a therapy together with products regulated under another such Union framework.
- (174) In order to ensure uniform conditions for the implementation of this Regulation regarding the recognition by the Commission of high impact biotechnology strategic projects, the modalities for the processing of personal data necessary to achieve the purpose of such projects in the form of biotechnology data quality accelerators and the rules for the selection, composition, number of members, and functioning of the Foresight Panel for Emerging Health Innovation, implementing powers should be conferred on the Commission.
- (175) In order to ensure uniform conditions for the implementation of this Regulation, implementing power should be conferred on the Commission to detail the criteria to clarify in what cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem and accelerate innovation, detail the criteria for the recognition of centres of excellence for advanced therapies, including advanced therapy medicinal product, establish procedural rules for the recognition of high impact health biotechnology strategic projects and the format of the assessment report to be submitted by the designated authorities in relation to applications for recognition of high impact health biotechnology strategic projects, establish regulatory sandboxes for health biotechnology products and common principles, criteria and practical arrangements for the assessment of applications received from developers and for the establishment and supervision of the regulatory sandboxes and related sandbox plans. Those powers should be exercised in accordance with Regulation (EU) No 182/2011.
- (176) The power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of modifying Annex I to this Regulation listing the biotechnology products of concern. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.
- (177) The European Data Protection Supervisor and the European Data Protection Board were consulted in accordance with Article 42 of Regulation (EU) 2018/1725⁶⁴ and delivered an opinion [date].

⁶⁴ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295, 21.11.2018, pp. 39–98, ELI: <http://data.europa.eu/eli/reg/2018/1725/oj>

- (178) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States but can rather, by reason of the scale or effects of the action, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.
2. This Regulation lays down measures regarding:
 - (a) the establishment of a framework for the recognition of, and support measures for, health biotechnology strategic projects and high impact health biotechnology strategic projects;
 - (b) novel health biotechnology products and regulatory sandboxes to support innovation and take into account technological and scientific developments and progress;
 - (c) the support to promoters of biotechnology projects, SMEs, start-ups and scale-ups and non-profit developers of biotechnology products, by establishing an EU Health Biotechnology Support Network;
 - (d) the support for funding of, investments in, and access to capital for biotechnology companies and projects;
 - (e) the enhancement of the manufacturing capacity of, and expertise for biosimilars in the Union, including through international cooperation;
 - (f) the application in a facilitated manner of advanced technologies, including AI in biological applications, into the Union's health biotechnology ecosystems, while monitoring and mitigating, in line with the Union harmonisation legislation on AI, biological risks arising from the use of such technologies;
 - (g) the placing on the market in particular of health biotechnology products and biotechnology services in accelerated and streamlined procedures;
 - (h) the prevention of the misuse of biotechnologies and the strengthening of biodefence capabilities, without prejudice to, and in complementarity with, activities financed under any defence related Union funding programmes and instruments.

3. This Regulation applies to health biotechnology innovations and products and their ecosystem during their entire lifecycle, including related research, funding, development, innovation, testing, validation, manufacturing, placing on the market, and use activities.
4. The amendments to the Union legislation laid down in Articles 56 to 61 are not limited to health biotechnology products and activities, but also relate to the other products, services and activities that fall in the scope of that legislation.
5. This Regulation does not affect the application of Directive 2010/63/EU on the protection of animals used for scientific purposes and of Regulation (EU) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
6. This Regulation shall apply without prejudice to Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence.
7. This Regulation shall apply without prejudice to Regulation [...] [Regulation on speeding-up environmental impact assessments -permitting regulation].

Article 2

Definitions

1. For the purposes of this Regulation, the following definitions apply:
 - (1) ‘biotechnology’ means the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, products and services;
 - (2) ‘health biotechnology’ means the application of biotechnology for the promotion, protection, or restoration of human health and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union’s public health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union;
 - (3) ‘biotechnology product’ means any good, technology or activity resulting from the application of biotechnology, including any process, action, technique, tool or knowledge involving biotechnology;
 - (4) ‘advanced biotechnology innovation’ means a biotechnology product, process, service or enabling technology that demonstrates, on the basis of preliminary scientific or technical evidence, the potential to achieve a substantial improvement over existing solutions in terms of efficacy, safety, sustainability, accessibility, and/or cost-effectiveness, and that, by reason of its novelty, technical complexity and/or market-creating potential, entails a high level of technological or commercial risk and it is likely to create new markets or significantly disrupt existing ones;
 - (5) ‘biomanufacturing’ means the production of biotechnology products at a commercial scale;
 - (6) ‘biotechnology cluster’ means a geographic concentration of interconnected companies, research institutions and organisations focused on biotechnology and life sciences, fostering collaboration and innovation;

- (7) ‘project promoter’ means any undertaking or consortium of undertakings developing a health biotechnology strategic project referred to in Article 3 or a high impact health biotechnology strategic project referred to in Article 4;
- (8) ‘permit-granting process’ means a process that covers all relevant permits to build, expand, convert and operate health biotechnology strategic projects and high impact health biotechnology strategic projects, including building permits and environmental assessments and authorisations where required, and encompassing all applications and procedures from the acknowledgement that the application for such permits is complete to the notification of the decision on the outcome of the procedure by the single point of contact concerned;
- (9) ‘deep tech’ means an innovation with the potential to deliver transformative solutions and that is based on cutting-edge advances in science, technology and engineering;
- (10) ‘SME’ means a micro, small or medium-sized enterprise within the meaning of the Annex to Commission Recommendation 2003/361/EC⁶⁵;
- (11) ‘European Investment Bank Group (EIBG)’ means the European Investment Bank, the European Investment Fund or any subsidiary of the European Investment Bank;
- (12) ‘national promotion bank or institution’ means a legal entity as defined in Article 2, point (21), of Regulation (EU) 2021/523 of the European Parliament and of the Council⁶⁶;
- (13) ‘implementing partner’ means an entity implementing, in indirect management, support under the EU health biotechnology investment pilot;
- (14) ‘AI system’ means an AI system as defined in Article 3(1) of Regulation (EU) 2024/1689;
- (15) ‘general-purpose AI model’ means an AI model as defined in Article 3point (63) of Regulation (EU) 2024/1689;
- (16) ‘general-purpose AI system’ means a general-purpose AI system as defined in Article 3point (66) of Regulation (EU) 2024/1689;
- (17) ‘clinical trial’ means a clinical trial as defined in Article 2(2), point (2) of Regulation (EU) No 536/2014;
- (18) ‘advanced therapy medicinal product’ means an advanced therapy medicinal product as defined in Article 2(1) of Regulation (EC) No 1394/2007;
- (19) ‘New Approach Methodologies (NAMs)’ means innovative methods that do not involve live animals, such as in vitro (cell or tissue-based), in chemico (chemical-based), or in silico (computer-based) approaches, as well as combinations of these;
- (20) ‘biological threats’ means risks posed by harmful biological agents such as pathogens or toxins that can cause disease or significant societal consequences, whether arising naturally, through accidental release, or via deliberate misuse;

65 Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (Text with EEA relevance) (notified under document number C(2003) 1422), OJ L 124, 20.5.2003, pp. 36–41. ELI: <http://data.europa.eu/eli/reco/2003/361/oj>.

66 Regulation (EU) 2021/523 of the European Parliament and of the Council of 24 March 2021 establishing the InvestEU Programme and amending Regulation (EU) 2015/1017, OJ L 107, 26.3.2021, pp. 30–89. ELI: <http://data.europa.eu/eli/reg/2021/523/oj>.

- (21) 'biodefence' means actions, policies, and measures that are designed, in particular by state actors, for preventive, protective or peaceful purposes, to counter biological threats, reduce risks, and prepare for, detect, assess, respond to, and recover from biological threats;
 - (22) 'biosecurity' means the protection, control and accountability of high-consequence biological agents, technologies, materials and toxins of concern, as well as of critical relevant information against unauthorised access, loss, theft, misuse, diversion or intentional release by those who intend to misuse them;
 - (23) 'biotechnology product of concern' means any good, service or technology, including software resulting from the application of science and technology to living organisms, their parts, products or models with significant potential for biological misuse that are listed in Annex I, including any thresholds or exclusions;
 - (24) 'benchtop nucleic acid synthesis equipment' means any equipment that allows a user to synthesise nucleic acids individually or in a core research facility.
2. For the purpose of the provisions regarding biosecurity and the prevention of biotechnology misuse laid down in Chapter VIII, Section 2, the following definitions apply:
- (a) 'making available' means any supply, whether in return for payment or free of charge;
 - (b) "legitimate" means in good faith, in the ordinary course of recognised professional, research or commercial activities, and in accordance with applicable Union and national law;
 - (c) 'legitimate need' in a biotechnology product of concern means the need for such biotechnology for legitimate and peaceful purposes, including handling, production, cultivation, experimentation, preservation, destruction, internal transport, by a legitimate member of the scientific community or a legitimate enterprise, consistent with applicable international treaties, laws, standards and oversight;
 - (d) 'suspicious transaction' means any transaction concerning biotechnology products of concern for which there are reasonable grounds, taking into account all relevant factors, to doubt the legitimacy of the prospective customer's intentions.

CHAPTER II

UNION HEALTH BIOTECHNOLOGY AND BIOMANUFACTURING

SECTION 1

RECOGNITION OF HEALTH BIOTECHNOLOGY STRATEGIC PROJECTS IN THE UNION

Article 3

Health biotechnology strategic projects

1. To enable access to the support measures laid down in Section 2 of Chapter II, Member States shall recognise projects located in the Union, by means of a reasoned decision, as health biotechnology strategic projects if they make a substantial contribution to at least one of the following specific objectives:
 - (a) strengthening the industrial capacity and value chains in the health biotechnology sector, through one or more of the following activities:
 - (i) pooling resources and expertise among research organisations, biotechnology industry actors and/or public authorities within the Union;
 - (ii) creating new, or significantly expanding, production facilities for biotechnology products, in particular in biotechnology sectors where such facilities do not exist or where they are limited, including for biosimilars;
 - (iii) creating or upgrading industrial scale biomanufacturing sites with innovative, sustainable, safe and digitally enabled processes and technologies;
 - (iv) reducing dependencies on third-country suppliers for key biotechnology inputs and intermediates;
 - (v) integrating advanced digital and AI-driven manufacturing and supply-chain management systems to enhance productivity, traceability and sustainability across biotechnology value chains;
 - (b) scaling-up or upgrading critical research and technology infrastructures underpinning the development, testing and validation of health biotechnology products, including but not limited to pilot or testing infrastructures for biomanufacturing, data and digital platforms, through one or more of the following activities:
 - (i) establishing, expanding or upgrading pilot, testing and demonstration infrastructures linking research, development, validation and industrial deployment capacities for biotechnology products and processes; or
 - (ii) integrating advanced digital, data and AI capabilities to enhance modelling, simulation and process optimisation; or
 - (iii) establishing interoperable infrastructures connecting research organisations, industry and public authorities across the Union; or

- (iv) promoting and integrating the use of NAMs in areas such as biological research, discovery and preclinical development, regulatory and quality testing and production of medicinal products and medical technologies.
 - (c) accelerating innovation and technology deployment in health biotechnology through one or more of the following activities:
 - (i) introducing or scaling up breakthrough innovations in biotechnology that have the potential to strengthen the Union's industrial competitiveness, including AI-enabled technologies and tools;
 - (ii) supporting SMEs, start-ups and scale-ups, universities and research centres in accessing advanced biomanufacturing and laboratory capacities;
 - (iii) promoting technology transfer and collaboration with corresponding facilities in third countries, where Union-led partnerships are established under Union law.
 - (d) addressing talent and skills needs or preventing shortages of talent and skills critical to all kinds of jobs in support of the strengthening of the health biotechnology and biomanufacturing sectors, and supporting the creation and maintenance of quality jobs in the EU through one or more of the following activities:
 - (i) attracting and retaining talent in the Union and aiming to provide adequate upskilling or reskilling opportunities covering the broad range of skills required for biotechnology and biomanufacturing, including technical skills, data science, AI, intellectual property and project management, and entrepreneurial skills, through activities including apprenticeships, traineeships, continuing education and training, in close cooperation with regional and local authorities, education and training institutions, businesses and social partners;
 - (ii) establishing public-private partnerships between universities, vocational education and training providers, businesses, in particular SMEs, start-ups and scale-ups, social partners and applied research institutes;
 - (iii) establishing university alliances, also in cooperation with employers, to improve their delivery on innovation and the development of skills and talent.
 - (e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures.
2. The projects referred to in paragraph 1 may be located on the territory of two or more Member States.

Article 4

High impact health biotechnology strategic projects

1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's

biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:

- (a) the project is a biotechnology development accelerator that fulfils the conditions laid down in Article 5;
 - (b) the project is a centre of excellence for advanced therapies, including for advanced therapy medicinal products that fulfils the conditions laid down in Article 6;
 - (c) the project contributes to an EU biotechnology late-stage capital booster pilot, fulfilling the conditions laid down in Article 23;
 - (d) the project contributes to the development of trusted testing environments for advanced biotechnology innovations, fulfilling the conditions laid down in Article 32(1) or is a health biotechnology data quality accelerator, fulfilling the conditions laid down in Article 33.
 - (e) the project contributes to the EU Biothreat Radar fulfilling the conditions laid down in Article 41(1) or it is a biodefence capability high impact strategic project fulfilling the conditions laid down in Article 42(1).
2. The Commission may adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

Article 5

Biotechnology development accelerators

1. To enable access to the support measures laid down in Section 2 of Chapter II, the Commission shall recognise projects located in the Union as high impact health biotechnology strategic projects in the form of biotechnology development accelerators, only where they comply with the conditions laid down in Article 4(1), and they fulfil at least three of the following conditions:
- (a) provide trusted testing or demonstration facilities replicating real-world biomanufacturing processes, including good manufacturing practices (GMPs) compliant processes, or their enabling technologies, for process testing, validation, and small batch manufacturing, including for the investigational medicinal products for early stages of clinical trials; such enabling technologies may include digital technologies, with specific applicability in biotechnology and biomanufacturing;
 - (b) aim to operate state-of-the-art equipment, laboratories and technical expertise to support biotechnology and biomanufacturing processes and provide access thereof;
 - (c) aim to support hands-on and work-based training programmes aligned with the Union's skills and workforce development objectives in the biotechnology and biomanufacturing sectors or in relation to enabling technologies, such as digital

technologies, with specific applicability in biotechnology and biomanufacturing;

- (d) conduct applied research in biotechnology or biomanufacturing, or in relation to enabling technologies, with specific applicability in biotechnology and biomanufacturing;
- (e) seek to engage in partnerships among industry, academia, and public authorities to ensure the integration of research, innovation, and training in biotechnology and biomanufacturing or their enabling technologies.

Article 6

Centres of excellence for advanced therapies

1. To enable access to the support measures laid down in Section 2 of Chapter II, the Commission shall recognise projects located in the Union as high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products (ATMPs), only where they comply with the conditions laid down in Article 4(1) and reinforce the Union's capability in the area of advanced therapies, by fulfilling all of the conditions set out in paragraph 2 of this Article.
2. The centres referred to in paragraph 1 shall fulfil all of the following conditions:
 - (a) specialise in at least one advanced therapy, such as cell and gene therapies;
 - (b) provide or coordinate advanced infrastructures including downstream processing, delivery models and the manufacturing of therapies referred to in point (a);
 - (c) integrate quality, regulatory science, and safety testing functions supporting Union-wide development of advanced therapies;
 - (d) establish structured cooperation among clinical centres, research organisations, industrial developers of biotechnology products, investors and regulators;
 - (e) provide multiple services enabling the transition of advanced therapies from laboratory research to commercial manufacturing, including:
 - (i) provide acceleration programmes to transform innovative ideas into viable business propositions;
 - (ii) provide incubation programmes assisting early-stage companies requiring GMP infrastructure, technical and regulatory expertise;
 - (iii) carry out networking and partnership facilitation to foster alliances;
 - (iv) ensure access to clinical and hospital settings, including for paediatric patients, for testing, clinical validation, and feedback;
 - (v) provide education and training for researchers, clinicians, and developers; and
 - (vi) ensure the possibility of cross-border access to users from any Member State.
3. The Commission may adopt implementing acts to detail the conditions listed in paragraph 2 of this Article, with a view to ensure a consistent approach in their

implementation across the Member States. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

Article 7

Designation of the competent authority responsible for assessing applications for recognition of health biotechnology strategic projects and high-impact health biotechnology strategic projects

1. Member States shall designate an authority ('the designated authority') responsible for assessing applications for recognition of health biotechnology strategic projects and high impact health biotechnology strategic projects.
2. Member States shall inform the Commission within six months from the entry into force of this Regulation of the authority designated pursuant to paragraph 1.

Article 8

Application for recognition of a health biotechnology strategic projects or a high impact health biotechnology strategic project

1. An application for the recognition of a project as a health biotechnology strategic project or as a high impact health biotechnology strategic project shall be submitted by the project promoter to the designated authority referred to in Article 7 of a Member State on whose territory the project is located.
2. The application referred to in paragraph 1 of this Article shall contain the relevant evidence related to the fulfilment of the conditions laid down in Article 3 as regards health biotechnology strategic projects or in Article 4, as regards high impact health biotechnology strategic projects.

Article 9

Recognition by Member States of health biotechnology strategic projects

1. The designated authority shall assess the application for the recognition of a project as a health biotechnology strategic project within one month of the receipt of the complete application and communicate a reasoned decision to the project promoter. The assessment process shall be fair and transparent.
2. Where the designated authority concludes that the project fulfils the conditions of Article 3, it shall recognise the project as a health biotechnology strategic project.
3. Member States shall ensure that applicants have easy access to information on procedures for the settlement of disputes concerning the recognition process, including, where applicable, alternative dispute resolution mechanisms provided for by national law.
4. Where a project is located on the territory of two or more Member States, the decision recognising the project as a biotechnology strategic project issued by the designated authority of a Member State shall be recognised by the designated authorities of other Member States.

Article 10

Recognition by the Commission of high impact health biotechnology strategic projects

1. The designated authority shall assess the application for the recognition of a project as a high impact health biotechnology strategic project within one month of the receipt of the complete application and shall communicate its assessment report to the Commission. The assessment process shall be fair and transparent.
2. Where the designated authority concludes that the project fulfils the conditions of Article 4, the Commission shall, by means of implementing acts, adopt a decision approving or rejecting the application for recognition referred to in paragraph 1 of this Article, based on the assessment referred to in that paragraph and taking into account the views of the Steering Group referred to in Article 20.
3. By way of derogation from Article 8 and to paragraphs 1 and 2 of this Article, a project may also be recognised as a high impact health biotechnology strategic project in the framework of calls for proposals launched under Union programmes for the purpose of identifying, selecting and funding such projects, in line with the basic acts setting up those programmes.

The Commission shall recognise a project as a high impact health biotechnology strategic project in the context of a call for proposals where it fulfils the conditions set out in Article 4(1) and the specific criteria set out in those calls, based on the evidence submitted by the applicant.

4. The Commission shall adopt implementing acts laying down the format of the assessment report referred to in paragraph 1 of this Article and the procedural rules for the recognition of high impact health biotechnology strategic projects. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

SECTION [2]

SUPPORT OF HEALTH BIOTECHNOLOGY STRATEGIC PROJECTS AND HIGH IMPACT HEALTH BIOTECHNOLOGY STRATEGIC PROJECTS

Article 11

Single points of contact

1. Each Member State shall designate one or more authorities as single points of contact at the relevant administrative level to facilitate and coordinate the permit-granting process for health biotechnology strategic projects and high impact health biotechnology strategic projects and shall provide information on the general administrative support and the technical and financial support set out in this [Section] through a dedicated webpage.
2. This single point of contact shall be the same as the single point of contact referred to in Article 3(2) of the Regulation (EU) ../.. [Regulation on speeding-up environmental impact assessments -permitting regulation], responsible for facilitating and coordinating all aspects of the environmental assessments, pursuant to applicable Union and Member States rules.

3. The single point of contact shall be the sole point of contact for the project promoter during the permit-granting process and shall assist the project promoter in handling any administrative matter relevant to the permit-granting process.
4. It shall coordinate the exchange of documents and information between the project promoters and the competent authorities and shall notify the promoter of the outcome of the decision-making process related to permit-granting, in accordance with national administrative arrangements. The authorities involved in the permit-granting process and other authorities concerned shall specify and make available to the single point of contact concerned the requirements and the scope of information requested of a project promoter.
5. The single point of contact shall direct project promoters to the relevant national and regional antennas of the EU Health Biotechnology Support Network referred to in Article 19.
6. Project promoters shall be allowed to submit to the single points of contact any documents relevant to the permit-granting process in electronic form.
7. Member States shall promote the reuse of existing data, studies and authorisations in order to avoid duplication of procedures, reduce administrative burden and ensure consistency of decision-making. For that purpose, they shall ensure that, when assessing an application, competent authorities duly take into account all relevant studies, assessments and valid permits or authorisations already carried out or issued for the same project or its components, provided that they remain applicable and up to date.
8. Member States shall ensure that the single points of contact and all authorities involved in the permit-granting process have a sufficient number of qualified staff and adequate resources.
9. Member States shall ensure that applicants have easy access to information on procedures for the settlement of disputes concerning the permit-granting process, including, where applicable, alternative dispute resolution mechanisms provided for by national law.

Article 12

Priority status of health biotechnology strategic projects

1. Health biotechnology strategic projects shall be considered as contributing to the strengthening of the biomanufacturing capacity and to the supply resilience of biotechnology products in the Union and, therefore, shall be considered to be of public interest.

Health biotechnology strategic projects shall be deemed to contribute to the resilience objectives referred to in Article 14 of Regulation [Regulation on speeding-up environmental impact assessments – permitting regulation].
2. For the purposes of this Article, health biotechnology strategic projects shall be understood to cover also high impact health biotechnology strategic projects.
3. High impact health biotechnology strategic projects shall be considered to be of public interest and may be considered to have an overriding public interest with specific consideration given to the high impact strategic nature of such projects in accordance with Article 14 of Regulation [Regulation on speeding-up environmental

impact assessments – permitting regulation] and point I of the Annex to that Regulation.

4. Where a project is recognised as a health biotechnology strategic project, Member States shall grant that project the status of project with the highest national significance possible, where such a status exists in national law and shall ensure that the relevant process for permit-granting and the licensing procedures, including environmental assessments and spatial planning, are treated in the most rapid way possible in accordance with Union and national law and shall benefit from any accelerated procedures provided for in applicable Union and national law.
5. Health biotechnology strategic projects shall also benefit, where applicable, from the tacit-approval in accordance with Article 14 and point II of the Annex to [COM Proposal 2025(984) for a Regulation on speeding-up environmental impact assessments – permitting regulation].
6. The permit-granting process shall not exceed ten months for health biotechnology strategic projects, and eight months for high impact health biotechnology strategic projects, from the date of acknowledgement of the completeness of the permit application. In duly justified cases requiring complex procedures under Union or national legislation, such as in the case of multi-site or multi-purpose projects, the competent authority may extend the period by up to three additional months, provided that the reasons for such extension are communicated in writing to the project promoter.
7. Where an environmental impact assessment is required pursuant to Directive 2011/92/EU, the step of the preparation of the environmental impact assessment report referred to in Article 1(2), point (g)(i), of that Directive shall not be included in the maximum duration of the permit-granting process referred to in paragraph [5] of this Article.
8. No later than 45 days from the receipt of the permit-granting application, the single point of contact shall acknowledge that the application is complete or, if the project promoter has not sent all the information required to process the application, request the project promoter to submit a complete application without undue delay, specifying which information is missing. In the event that the submitted application is deemed to be incomplete for a second time, the single point of contact may, within 30 days of the second submission, make a second request for information. The single point of contact shall not request information in areas not covered in the first request for additional information and shall be entitled only to request further evidence to complete the identified missing information. The date of the acknowledgement of the completeness of the application from the single point of contact shall serve as the start of the permit-granting process for that particular application.
9. All dispute resolution procedures, litigation, appeals and judicial remedies relating to health biotechnology strategic projects before any national court, tribunal or panel — including mediation or arbitration — shall be treated as urgent, to the extent that national law allows such urgency, and without prejudice to the normal rights of defence of individuals or local communities. Project promoters of health biotechnology strategic projects shall be able to avail themselves of such urgency procedures, where applicable. This shall include the dispute-settlement provision in accordance with Article 14 and point III of the Annex to the Regulation [...][Regulation on speeding-up environmental impact assessments].

Article [13]

Administrative support

1. Upon request of a project promoter, Member States shall provide administrative support to biotechnology projects located on their territory, including health biotechnology strategic projects and high impact health biotechnology strategic projects and shall take all appropriate measures to facilitate their timely and effective implementation, including:
 - (a) assistance to project promoters to ensure compliance with applicable administrative, regulatory, and reporting obligations;
 - (b) support and facilitation of permitting and authorisation procedures; and
 - (c) assistance to inform the public and those in the vicinity of the project with the aim of increasing public acceptance of the project;
2. High impact health biotechnology strategic projects shall benefit from priority access to the administrative support measures referred to in paragraph 1,
3. The administrative support referred to in paragraphs 1 and 2 shall be provided including through the single points of contact and the national and regional antennas of the EU Health Biotechnology Support Network referred to in Article 19.
4. Member States shall provide online and in a centralised and easily accessible manner, information relevant to promoters of biotechnology projects, including health biotechnology strategic projects and high impact health biotechnology strategic projects covering at least the following elements:
 - (a) the designated authority referred to in Article 7(1);
 - (b) the single points of contact referred to in Article 11;
 - (c) the national and regional antennas of the EU Health Biotechnology Support Network referred to in Article 19;
 - (d) the permit-granting process, including information on dispute settlement;
 - (e) advice on financing and investment services;
 - (f) business support services, including corporate tax declaration, local tax rules and labour law.
5. When providing the administrative support referred to in paragraph 1 of this Article, Member States shall pay particular attention to SMEs, start-ups and scale-ups. Where appropriate, Member States shall ensure that a dedicated channel for communication with SMEs, start-ups and scale-ups is available within the single points of contact to provide guidance and respond to queries related to the implementation of this Regulation.

Article 14

Financial and technical support

1. Without prejudice to Articles 107 and 108 TFEU, Member States may make use, where applicable, of the relevant frameworks for providing public support to health biotechnology strategic projects and high impact health biotechnology strategic projects, including national promotional banks and other relevant public support instruments, as provided for in Article 24, paragraphs (4), (5) and (6). Where public

support is granted, Member States shall ensure that such support is coordinated with other support measures at Union or national level and is in line with applicable State aid rules.

2. Projects recognised as high impact health biotechnology strategic projects:
 - (a) may be given particular consideration for Union financial support including in the form of blended financing, under Union programmes, funds and financial instruments and for national support as provided for in Article 25, if the basic regulations setting up such Union programmes allow it;
 - (b) shall benefit from priority status in administrative procedures, including in the permit-granting process, as provided for in Article 12]and of priority access to administrative support referred to in Article 13.
3. The Commission, in cooperation with the Member States and, where appropriate, with the Steering Group referred to in Article 20, shall take the following measures to support the implementation of health biotechnology strategic projects and of high impact health biotechnology strategic projects, including through the EU Health Biotechnology Support Network referred to in Article 19:
 - (a) support project promoters in identifying funding opportunities at Union level, and facilitate the liaison between project promoters and investors;
 - (b) promote actions that strengthen the biotechnology innovation ecosystem;
 - (c) facilitating access, in particular for SMEs, to relevant research and technological infrastructures, including where such infrastructures are funded through Union funding programmes, funds and financial instruments.

Article 15

Networks of health biotechnology clusters

1. The Commission and the Member States shall promote and facilitate the cooperation and the establishment of networks among promoters of health biotechnology strategic projects, of high impact health biotechnology strategic projects and other relevant actors. A particular focus shall be placed on fostering cross-border synergies between regional and national health biotechnology clusters, and on supporting the networks constituted under the EU Competitiveness Coordination Tool pilot, in full compliance with EU competition law.
2. Such networks shall fulfil one or more of the following activities:
 - (a) facilitate synergies between innovation ecosystems at local, regional and Union levels;
 - (b) support the establishing of EU-wide interregional biotechnology value chains;
 - (c) pool national and Union resources and facilities across several Member States, bridging and upscaling research, pilot and industrial-scale biomanufacturing, including through cooperation between regional biotechnology clusters;
 - (d) provide transparent, open, and non-discriminatory cross-border access at market prices to research organisations, SMEs, start-ups and scale-ups, healthcare providers, and industrial actors from across the Union;

- (e) facilitate knowledge transfer, standardisation and inter-cluster collaboration, in line with competition rules, and the dissemination of best practices;
 - (f) promote the development of infrastructure and digital platforms, and AI-enabled technologies supporting biotechnology and biomanufacturing.
3. The networks referred to in this Article may establish governance arrangements appropriate to their objectives and may, where necessary, constitute themselves as legal entities under Union law, as appropriate for the implementation of specific actions and investments.
 4. The Steering Group referred to in Article 20 shall provide advice for the support of the federation and networking of biotechnology clusters.

SECTION 3

ACCESS PRINCIPLES AND STRATEGIC MAPPING

Article 16

Access principles and security safeguards

1. Health biotechnology strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation that receive financial support in accordance with Union programmes shall offer open, non-discriminatory, transparent, and criteria-based access at market prices to their facilities, equipment, services and training programmes for users, including SMEs, start-ups and scale-ups and other industrial actors, research organisations or training institutions.

The projects referred to in the first subparagraph shall ensure that access to, and the operation of their infrastructures, facilities and services comply, where applicable, with the requirements of Directive (EU) 2022/2555 of the European Parliament and of the Council⁶⁷, including with the relevant cybersecurity risk-management and reporting obligations.
2. The access criteria referred to in paragraph 1 of this Article shall ensure proportionality and fair treatment among users, while taking into account all of the following:
 - (a) the objectives and capacity of the infrastructure concerned;
 - (b) the need to ensure equitable opportunities in particular for SMEs, start-ups and scale-ups and research actors;
 - (c) any safeguards necessary for the protection of security, confidentiality or economic-security interests, in particular those referred to in paragraph [3].
3. In order to safeguard the Union's security, public order and strategic interests, access to biotechnology infrastructures and biotechnology datasets of projects referred to in

⁶⁷ Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 (NIS 2 Directive) (Text with EEA relevance), OJ L 333, 27.12.2022, pp. 80–152. ELI: <http://data.europa.eu/eli/dir/2022/2555/oj>

paragraph 1 of this Article shall be governed by the rules laid down in the relevant Union funding programmes under which those projects are funded.

Article 17

Strategic mapping of the Union's biotechnology ecosystem

1. The Commission, in close cooperation with the Steering Group referred to in Article 20 and where appropriate the AI Board established under the Regulation (EU) 2024/1689, shall conduct, no later than six months after the entry into force of this Regulation, and maintain thereafter a strategic mapping of the biotechnology ecosystem in the Union.
2. The strategic mapping shall provide a comprehensive overview of the Union's biotechnology and biomanufacturing landscape, to assess existing capacities and infrastructures, detect gaps, unused capacities, dependencies, and systemic challenges across the value chains. It shall cover in particular the following areas:
 - (a) industrial capacity and infrastructures, including on critical intermediates and key input, relevant to biotechnology research, development, testing, and manufacturing, and assessment of their distribution, interconnections and potential gaps;
 - (b) access to risk-tolerant capital, by analysing public and private funding sources supporting biotechnology across all stages of development and identifying gaps in risk-tolerant financing and market incentives;
 - (c) biotechnology clusters and biomanufacturing ecosystems, by mapping existing and planned clusters across the Union and assessing opportunities for coordination, investment, and both cross-border and interregional collaboration;
 - (d) skills, upskilling and reskilling, by analysing current and projected workforce needs, identifying gaps in education and training, and assessing measures to attract, retain, and upskill talent;
 - (e) use of data and AI, by assessing access to data, computing and digital infrastructures for biotechnology and identifying opportunities to foster responsible AI-enabled innovation and mitigate related risks.
3. The strategic mapping shall be based on information from relevant Union bodies and agencies, and, where appropriate, industry stakeholders and research organisations. The Commission may request Member States to submit data necessary for this purpose, while ensuring the protection of confidential and commercially sensitive information. The Member States shall submit such data within 30 days from the request of the Commission.
4. The Commission shall present the findings of the strategic mapping to the Steering Group.
5. The results of the strategic mapping shall be used for the following purposes:
 - (a) supporting the identification and prioritisation by the Member States and the Commission, as appropriate, of potential health biotechnology strategic projects and high impact health biotechnology strategic projects;

- (b) informing Union policy and funding priorities in biotechnology and biomanufacturing, including actions in accordance with this Regulation, as well as initiatives under Union programmes supporting research, innovation, skills development and industrial competitiveness;
- (c) informing the advice of the Steering Group on health biotechnology strategic projects and high-impact health biotechnology strategic projects and on initiatives supporting research, innovation, skills and industrial competitiveness in the biotechnology sector.

Article 18

More favourable treatment

The provisions of this Regulation regarding the permit granting process, the priority status of health biotechnology strategic projects and of high impact health biotechnology strategic projects and support for such projects shall apply without prejudice to more favourable provisions laid down in other Union rules.

SECTION 4

EU HEALTH BIOTECHNOLOGY SUPPORT NETWORK

Article 19

EU Health Biotechnology Support Network

1. The Commission shall set up, coordinate and support an EU Health Biotechnology Support Network ('the Network'), consisting of national and regional antennas in the Member States ('the antennas').
2. The Network shall assist and support the developers of health biotechnology products, in particular SMEs, start-ups and scale-ups, the promoters of biotechnology projects, including health biotechnology strategic projects and high impact health biotechnology strategic projects ('project promoters') in identifying the relevant applicable rules and funding, scaling-up and networking opportunities.
3. The Network shall fulfil in particular the following missions:
 - (a) provide information on the national and Union rules applicable to the development and placing on the market of health biotechnology products, including on the applicable authorisation procedures for health biotechnology products;
 - (b) information for the identification and use of the applicable regulatory frameworks and regulatory support mechanisms with regard to innovative health biotechnology products, as provided for in Article 34;
 - (c) facilitate the interactions of project promoters with potential public and private investors including venture-capital funds, corporate partners and national promotional banks and relevant funding structures and existing networks of investors, including with the European Innovation Council Trusted Investors

Network⁶⁸ through matchmaking initiatives, including host pitch sessions, demo days and investor forums, in cooperation with the Steering Group referred to in Article 20, the European Innovation Council and other relevant Union initiatives;

- (d) provide information and support to project promoters for intellectual property procedures and technology transfer and promote investors' awareness of Union regulatory frameworks and responsible-innovation principles;
 - (e) support project promoters in the identification of scaling up resources, including business support networks providing advice on commercial readiness of health biotechnology projects and testing and training facilities, state-of-the-art pilot plant facilities that simulate a real production environment, and relevant research and technology infrastructures across the Union, including technology centres, cutting-edge facilities, and data-sharing platforms to support the development and testing of health biotechnologies;
 - (f) support biotechnology actors in the responsible and effective integration of AI, by providing sector-specific guidance and promoting best practices and standards for trustworthy AI, in coordination with the bodies established under Regulation (EU) 2024/1689, and by providing information and support, in particular to SMEs, start-ups and scale-ups;
 - (g) facilitate liaison and exchanges among project promoters with a view to fostering networking and cooperation, including to support networks of health biotechnology clusters referred to in Article 15;
 - (h) provide incubation, acceleration and mentorship programmes for biotechnology start-ups and scale-ups and connect project promoters with projects and initiatives that address skills and expertise needs in health biotechnology and biomanufacturing, including with testing, training and technical support facilities, and regional skills partnerships;
 - (i) support Member States and the single points of contact in facilitating projects promoters' access to administrative support provided in accordance with Article 13.
4. The Network shall complement and, to the extent possible, rely on existing relevant organisations and networks at Union and Member State and regional level, including the European Enterprise Network.
5. The Commission shall select the members of the Network based on criteria made public pertaining to the expertise and capabilities required to fulfil the missions referred to in paragraph 3 of this Article, including to the ability to leverage, complement and strengthen existing national and European networks that support SMEs, start-ups and scale-ups, and innovators.

The Commission shall organise the management, coordination and support of the Network.

⁶⁸ The European Innovation Council (EIC) Trusted Investor Network brings together investors from across Europe, including venture capital funds, public investment banks, foundations, and corporate venture arms with experience and commitment to co-invest in promising deep tech start-ups in Europe, alongside the European Innovation Council Fund. List of members accessible at: https://eic.ec.europa.eu/eic-fund/trusted-investor-network_en

6. The Commission may support the Network through Union funds, programmes, and instruments, in accordance with the objectives established in their respective basic acts.
7. Member States shall take all necessary measures to facilitate the fulfilment of the tasks of the Network.

SECTION 5

EUROPEAN HEALTH BIOTECHNOLOGY STEERING GROUP

Article 20

European Health Biotechnology Steering Group

1. The European Health Biotechnology Steering Group (the “Steering Group”) is hereby established.
2. The Steering Group shall provide advice to the Commission and to the Member States to facilitate the implementation of this Regulation and shall carry out the tasks provided for in this Regulation.

Article 21

Composition and functioning of the Steering Group

1. The Steering Group shall be composed of representatives from all Member States and the Commission. It shall be chaired by a representative of the Commission (the ‘Chair’).
2. Each Member State shall nominate a member and an alternate member as its representatives to the Steering Group. Where relevant as regards function and expertise, a Member State may nominate different representatives in relation to the different subgroups of the Steering Group, while not exceeding a representative per subgroup. Nominated permanent representatives shall ensure the necessary coordination within their respective Member State. The Commission and the Member States shall have voting rights.
3. The Steering Group shall, upon a proposal by the Commission, adopt its rules of procedure by a simple majority of its members. Where appropriate, the Chair may invite external experts to attend meetings of the Steering Group.
4. The Steering Group shall meet as needed in order to allow the effective performance of its tasks provided for in this Regulation. Where necessary, the Steering Group shall meet on the basis of a reasoned request by the Commission or by a Member State. The Commission shall coordinate the work of the Steering Group by means of a secretariat that provides technical and logistical support.
5. The Steering Group shall carry out the following tasks:
 - (a) facilitate the exchange of information and best practices among Member States, the Commission, and relevant stakeholders in relation to the recognition and the implementation of health biotechnology strategic projects and high impact health biotechnology strategic projects;

- (b) discuss, at least once a year, the progress in the recognition of health biotechnology strategic projects and high impact health biotechnology strategic projects and provide advice including to overcome systemic challenges faced by such projects;
 - (c) provide advice for supporting the federation and networking of biotechnology clusters, as provided for in Article [15](4);
 - (d) discuss and coordinate funding for health biotechnology strategic projects, including high-impact health biotechnology strategic projects, without prejudice to the basic acts of the relevant Union programmes; this may include facilitating the liaison between project promoters and potential private and public investors, such as the European Investment Bank Group, national promotional banks and institutions and export credit agencies, to mobilise additional financing, including from private or venture capital sources;
 - (e) provide its views regarding the recognition of a project as a high impact health biotechnology strategic project, in accordance with Article [10](2);
 - (f) facilitate the coordination and information exchange among the Member States on enforcement of the biosecurity provisions in this Regulation and other emerging biosecurity topics.
6. The Steering Group may establish subgroups for the purpose of this Regulation.
 7. The Steering Group shall take the necessary measures to ensure the safe handling and processing of confidential and commercially sensitive information.
 8. The Steering Group shall use its best endeavours to reach consensus, where possible. Members with diverging positions may request that their positions and the grounds on which they are based be recorded in the Steering Group's position.

CHAPTER III

ACCESS TO FUNDING

Article 22

EU health biotechnology investment pilot

1. To support the financing of, and investments in, companies and projects falling within the scope of this Regulation, the Commission, together with the European Investment Bank Group (EIBG) or other implementing partners, shall develop an EU Health Biotechnology investment pilot ('the pilot'). The pilot is established for an initial period of two years, after which it shall be reviewed.
2. The pilot shall support the full lifecycle of companies and projects in the area of health biotechnology, including SMEs, start-ups and scale-ups through direct and indirect financing, other than direct equity operations, without prejudice to the basic acts to be agreed under the next Multiannual Financial Frameworks. It shall complement and be developed in a coordinated manner with other EU financing instruments.
3. The pilot shall be designed as a mechanism that may use and leverage different funding streams and instruments to accelerate and catalyse investments into the health

biotechnology sector. It may be used to provide Union support through Union programmes.

4. The pilot shall pursue the following objectives:

- (a) support early-stage applied research and innovation, technology transfer and spin-offs, with appropriate financing mechanisms, including equity;
- (b) provide support to projects, SMEs, including start-ups and scale-ups, and mid-caps across the Union, which are providing solutions and developments that contribute to the objectives of this Regulation;
- (c) finance late-stage development initiatives, industrial scale-up and production capacity build-up for companies that contribute to the objectives of this Regulation, through venture loans and other suitable debt or quasi-equity instruments;
- (d) anchor growth and manufacturing activities in the Union in order to gain or maintain strategic autonomy and resilience, as well as boost competitiveness of the sector;
- (e) mobilise private investments, including from institutional investors such as pension funds, and strengthen the availability of long-term risk finance for biotechnology companies established in the Union. Financial actors, including private institutional investors, shall be targeted by leveraging expertise in catalysing private capital and use appropriate risk-sharing mechanisms to achieve this objective;
- (f) assist early and growth-stage companies through blended and concessional finance, encompassing equity or debt operations, complementing the direct equity support provided by the European Innovation Council Fund and the Scale-Up Europe Fund under the Horizon Europe, including via the development of new products;
- (g) provide advisory support throughout the investment cycle, encompassing concrete capacity-building measures. These interventions shall be aimed at reinforcing the competencies and institutional preparedness of developers and promoters of projects and financial intermediaries to successfully develop and implement their initiatives.

Article 23

EU biotechnology late-stage capital booster pilot

1. To enable access to the support measures laid down in Section 2 of Chapter II, the Commission shall recognise projects located in the Union contributing to an EU biotechnology late-stage capital booster as high-impact health biotechnology strategic projects, only where in addition to the conditions laid down in Article [4][(1)], the projects facilitate access to capital markets in accordance with applicable law, and are led by private-sector operators or consortia, with the potential participation of market-infrastructure providers and investors.

2. The projects referred in paragraph 1 of this Article shall pursue at least one of the following objectives or activities:
 - (a) facilitating cross-border investment in accordance with Union law;
 - (b) mobilising long-term capital and attracting private investment, including institutional investors, and through private markets, with credible commitments or structures that support liquidity and follow-on financing;
 - (c) improving cross-border investors' access and issuers' visibility through practical steps and deliverables and demonstrating a credible issuance and investor pipeline with target numbers and timelines;
 - (d) enhancing biotechnology sector-specific investment expertise through exchange of best practices on these topics ;
 - (e) mobilising private capital through biotechnology accelerators and venture builders, including potential use of risk-sharing mechanisms.
3. The projects referred in paragraph 1 shall:
 - (a) ensure non-discriminatory, transparent and criteria-based access for eligible issuers;
 - (b) ensure the possibility of cross-border participation from any Member State;
 - (c) include proportionate risk-management, governance and reporting arrangements and operate without prejudice to applicable Union financial services legislation and the mandates of competent authorities.
4. The provisions of this Regulation regarding the application for, and the recognition of, high-impact health biotechnology strategic projects laid down in Articles 8 and [10], respectively, apply to projects referred to in this Article.

Article 24

Biotechnology as a strategic technology eligible for Union and national financial support

1. Union programmes may support biotechnology as a strategic technology for the Union's innovation capacity, sovereignty, resilience and leadership in line with the objectives set out in the Regulations establishing those Union programmes.
2. The Commission may adopt calls, windows or compartments for biotechnology and may establish instruments in the implementation of those programmes, funds and instruments, that support biotechnology companies, projects and initiatives falling within the scope of this Regulation, in line with the objectives and rules set out in the regulations establishing those programmes, funds and instruments.
3. Companies, projects and initiatives falling within the scope of this Regulation may be targeted for financial support from Union-led funding initiatives and from Union funding programmes and instruments, as projects in a strategic technology and, as appropriate, in a strategic deep tech area.
4. Member States may, in line with applicable State aid rules, provide financial support to biotechnology as a strategic technology for the Union's innovation capacity, sovereignty, resilience and leadership.

5. Member States shall pursue the support as referred to in paragraph 4, including for health biotechnology strategic projects and high impact health biotechnology strategic projects, in the implementation at national level of the relevant Union programmes that are shared-management basic acts.
6. Where State aid instruments, designed in compliance with Union competition law and making use of related EU guidance, are used by Member States for the purpose of supporting the health biotechnology sector or parts thereof, Member States shall give particular consideration to high-impact health biotechnology strategic projects for support under such instruments.

Article 25

Funding for high impact health biotechnology strategic projects

1. High impact health biotechnology strategic projects may be given particular consideration for financial support under Union funds, programmes and instruments in accordance with the objectives set out in the regulations establishing those funds, programmes and instruments.
2. Where high impact health biotechnology strategic projects benefit from financial support under Union funds, programmes and instruments, in accordance with the respective legal bases and eligibility criteria of those funds, programmes and instruments, such support may be used in combination with financing from the European Investment Bank Group, from national promotional banks and institutions or from other development or public financial institutions, as well as in combination with financing from private-sector finance institutions and from public-sector or private-sector investors, including through public–public or public–private partnerships.
3. When preparing and implementing the annual and multiannual work programmes of the relevant Union funds, programmes and instruments referred to in paragraph 1, the Commission may give particular consideration to actions supporting high-impact health biotechnology strategic projects.
4. The Commission shall ensure the coordination and the complementarity among the relevant Union funds, programmes and instruments that support actions under this Regulation, and shall provide strategic guidance for the implementation of such funds, programmes and instruments with regard in particular to the high impact health biotechnology strategic projects, including in cooperation with the Steering Group, referred to in Article 20, where appropriate.

Article 26

Coordination of financing for health biotechnology strategic projects

The Steering Group referred to in Article 20 may coordinate investments into health biotechnology strategic projects, including high impact health biotechnology strategic projects, with the project promoters and other relevant interested parties, in compliance with Union competition law.

CHAPTER IV

EXTENSION OF THE SUPPLEMENTARY PROTECTION CERTIFICATE

Article 27

Extension of the supplementary protection certificate concerning best-in-class biotechnology medicines developed in the Union

1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) .../... [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council⁶⁹, or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:
 - (a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union;
 - (b) the medicinal product has a mechanism of action distinctly different and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same disease;
 - (c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than two Member States;
 - (d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.
2. The European Medicines Agency ('the Agency') shall assess compliance with the conditions referred to in paragraph 1 as part of the marketing authorisation procedure concerned.
3. Where compliance is confirmed, the Agency shall issue a statement to that effect.
4. A copy of the statement referred to in paragraph 3 of this Article shall be included in the application for a certificate lodged under article 7 of Regulation (EC) No 469/2009.

⁶⁹ Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

CHAPTER V

ENHANCING COMPETITIVENESS IN BIOSIMILARS

Article 28

Guidance by the Agency on biosimilars

The Agency, in consultation with the Commission, shall develop and update non-binding guidance on a tailored regulatory approach for the development of biosimilars, reflecting advances in manufacturing and analytical testing. The guidance shall consider a potential reduction of the clinical data required for the development and approval of biosimilars, without affecting their quality, safety and efficacy.

Article 29

Biotechnology health strategic projects for biosimilars

To enable access to the support measures laid down in Section II of Chapter II, Member States shall recognise projects located in the Union as biotechnology health strategic projects in the form of biotechnology health strategic projects for biosimilars only where they make a substantial contribution to at least one the specific objectives referred to in Article [3][(1)] and fulfil either of the following conditions:

- (a) they contribute to the setting up and extension of innovative biomanufacturing capacity, and infrastructures for analytical testing procedures;
- (b) they contribute to the research, development and marketing authorisation of biosimilars, and where appropriate to strengthening the use of platform technologies; this includes analytical methodologies that would reduce the need for clinical data for biosimilars, without affecting their quality, safety and efficacy.

Article 30

International partnerships

Where appropriate, promoters of projects related to biosimilars and other companies working in this area, shall explore opportunities to establish or strengthen cooperation with international biotechnology clusters, including with a view to fulfilling the conditions referred to in Article [29] for the recognition of biotechnology health strategic projects for biosimilars.

CHAPTER VI

ARTIFICIAL INTELLIGENCE AND DATA AS BIOTECHNOLOGY ENABLERS

Article 31

Guidance on the deployment and use of systems based on advanced technologies, including AI, in the lifecycle of medicinal products

1. The Agency shall publish and regularly update, as appropriate, non-binding guidance on the deployment and use of systems based on advanced technologies, including AI, in the lifecycle of medicinal products development, including during pre-clinical research, clinical development and trials, manufacturing and post-authorisation monitoring.

Such guidance shall be developed, updated and published in agreement with the Commission, including with the AI Office.

Such guidance shall ensure full coherence with the requirements laid down in Regulation (EU) 2024/1689 and with any guidance issued under that Regulation regarding general-purpose AI models or AI systems.

2. In developing and updating the guidance referred to in paragraph 1, the Agency shall consult the relevant authorities, at national and European level, and stakeholders as appropriate.

To the extent that the guidance concerns the deployment and use of systems based on advanced technologies, including AI, across the clinical trials lifecycle, the Agency shall further cooperate with the Clinical Trials Coordination [and Advisory] Group ('CTAG') referred to in Article [85] of Regulation (EU) No 536/2014, with the Medical Device Coordination Group ('MDCG') referred to in Article 103 of Regulation (EU) 2017/745 and with the Artificial Intelligence Board referred to in Article 65 of Regulation (EU) 2024/1689, as appropriate and shall publish that guidance in agreement with the consulted entities referred to in this subparagraph.

3. The Agency shall develop and publish in agreement with the Commission, including the AI Office where appropriate, and in cooperation with the national competent authorities, non-binding guidance on the deployment and use of advanced technologies, including AI, in the procedures for the authorisation of medicinal products.

Article 32

Biotechnology testing environments for advanced biotechnology innovations

1. To enable access to the support measures laid down in Section 2 of Chapter II, the Commission shall recognise projects located in the Union as high impact health biotechnology strategic projects in the form of trusted testing environments for advanced health biotechnology innovations, where such innovations are enabled, enhanced or significantly supported by AI or advanced computational methods, only where they comply with the criteria laid down in Article 4(1) and substantially strengthens the Union's capacity for responsible experimentation, development, testing and validation of such innovations and they fulfil all of the following conditions:

- (a) operate under trusted conditions ensuring compliance and alignment with relevant Union and national legislation and complements where appropriate testing and experimentation facilities and AI regulatory sandboxes established in accordance with Regulation (EU) 2024/1689, while ensuring consistency and synergies in their implementation;
 - (b) seek, where appropriate, to leverage AI systems or other advanced computational tools, alongside advanced technologies and analytics, to optimise workflows and increase efficiency;
 - (c) aim to enable innovation in biotechnology areas where the use of AI-enabled or computationally enhanced methods can be particularly impactful, such as enhancing efficacy and safety of immunology treatments and of ATMP gene therapies, or developing NAMs that combine advanced experimental and computational approaches;
 - (d) make available, under fair and transparent conditions, evidence, results and lessons learned generated within such testing environments, to inform Union guidance, standardisation and best-practice frameworks, and, where appropriate, the design or implementation of regulatory sandboxes in accordance with Union or national law.
2. The Commission, in cooperation with the Member States, shall promote and facilitate, including through existing networks such as the European Digital Innovation Hubs and testing and experimentation facilities and relevant expert groups established under Union legislations, networking, knowledge-sharing and capacity-building among projects and initiatives providing such testing environments.
 3. The provisions of this Regulation regarding the application for, and the recognition of, high-impact health biotechnology strategic projects laid down in Articles 8 and 10, respectively, apply to projects referred to in this Article.

Article 33

Biotechnology data quality accelerator

1. To enable access to the support measures laid down in Section 2 of Chapter II, the Commission shall recognise projects located in the Union as high impact health biotechnology strategic projects in the form of biotechnology data quality accelerators, only where they comply with the criteria laid down in Article 4(1) and fulfil the conditions laid down in paragraph 2 of this Article and they make a significant contribution to the curation, maintenance and responsible use of high-quality, appropriately annotated and provenance-verified datasets that are essential for the training, validation and testing of AI systems and models used in health biotechnology applications.
2. The projects referred to in paragraph 1 shall:
 - (a) aim to foster the development and deployment of trustworthy and competitive AI systems in health biotechnologies, including large-scale and general-purpose models relevant for biological, biomedical or biomanufacturing use cases;
 - (b) assist entities that lawfully hold relevant data and, as regards health data, holders as defined in Article 2(2), point (t), of Regulation (EU) 2025/327

(‘health data holders’) to improve data quality, standardize and make other improvements to such data as referred to in paragraph 1 of this Article;

- (c) contribute to the development of Union standards and quality frameworks for data representativeness, provenance, interoperability and annotation in biotechnology;
 - (c) give due consideration to the interoperability with platforms deployed pursuant to the European Health Data Space (EHDS) and other relevant data spaces;
 - (d) be aligned with and complement Union initiatives such as the Data Union Strategy, including data labs and AI factories, while addressing the specific requirements of biotechnology datasets, including biological metadata, scientific taxonomies, experimental traceability and regulatory-grade data quality.
3. The provisions of this Regulation regarding the application for, and the recognition of, high-impact health biotechnology strategic projects laid down in Articles 8 and 10, respectively, apply to projects referred to in this Article.
 4. The processing of personal data by the entities that lawfully hold the relevant datasets enhanced as provided for in paragraph 2, point (b) of this Article, and by the biotechnology data quality accelerator projects takes place in the public interest.
 5. Entities that lawfully hold relevant datasets enhanced as provided for in paragraph 2, point (b) of this Article, shall make available such datasets under fair, reasonable and non-discriminatory conditions, ensuring equitable access for users including research organisations, SMEs and public institutions, under the conditions referred to in Article 16 of this Regulation.

Electronic health data referred to in Article 51 of Regulation (EU) 2025/327 shall be made available in accordance with that Regulation.

6. Entities that lawfully hold relevant datasets enhanced as provided for in paragraph 2, point (b) of the Article, shall support, where appropriate, the integration of such datasets into Union infrastructures, including the European Research Area data spaces, data labs, AI factories and the infrastructures operated by high impact health biotechnology strategic projects.
7. The decision of the Commission regarding the recognition of a high impact health biotechnology strategic project in the form of a biotechnology data quality accelerators, referred to in Article 10(2), shall specify the modalities of processing of personal data necessary to achieve the purpose of the project. In particular the Commission shall specify the categories of data to be processed, the roles of the entities participating in the project, the categories of the entities which may use the curated data and the safeguards.
8. With regard to biotechnology data quality accelerators recognised in the context of a call for proposals as provided for in Article 10(3), the Commission shall, by means of implementing acts, adopt, before the launch of the related call, a decision establishing the modalities of processing of personal data necessary to achieve the purpose of the project. That decision shall specify the categories of data to be processed, the roles of the entities participating in the project, the categories of the entities which may use the curated data and the safeguards. The selected beneficiaries shall comply with the conditions laid down in that decision.

CHAPTER VII

REGULATORY TOOLS FOR NOVEL HEALTH BIOTECHNOLOGY PRODUCTS

SECTION 1

SUPPORT IN DETERMINING THE REGULATORY STATUS OF NOVEL HEALTH BIOTECHNOLOGY PRODUCTS

Article 34

Assistance on regulatory procedural pathways

1. The EU Health Biotechnology Support Network referred to in Article 19 shall, upon request, assist developers, in particular SMEs, start-ups and scale-ups, with identifying and using the appropriate regulatory procedural pathway and regulatory support mechanisms with regard to innovative health biotechnology products or biotechnology services for human use that exhibit characteristics that raise questions on the application or applicability of the Regulation (EU) 2017/745, Regulation (EU) 2017/746, Regulation (EU) 2024/1938, Regulation (EU) .../... [reference to be added after adoption cf. COM(2023) 193 final] and Regulation (EU) .../... [reference to be added after adoption cf. COM(2023) 192 final] Regulation (EC) 1394/2007 and Directive 2010/45/EU.
2. The support provided pursuant to this Article shall not duplicate procedures pertaining to recommendations or opinions on regulatory status set out in with Regulation (EU) 2017/745, Regulation (EU) 2017/746, Regulation (EU) 2024/1938, Regulation (EU) .../... [reference to be added after adoption cf. COM(2023) 193 final] and Regulation (EU) .../... [reference to be added after adoption cf. COM(2023) 192 final] .
3. The support referred to in paragraph 1 shall be provided in particular on the following:
 - (a) procedures for seeking guidance on the regulatory status and on the nature and scope of such guidance;
 - (b) applicable rules for the authorisation of health biotechnology products that combine different products, technologies, processes, or components regulated under different regulatory frameworks;
 - (c) regulatory sandboxes established in Article 40 and under [revised Regulation (EU) 2017/745], [revised Regulation (EU) 2017/746], Regulation (EU) 2024/1938 and in Regulation (EU) .../... [reference to be added after adoption cf. COM(2023) 193 final].
4. In providing the support referred to in this Article, the EU Health Biotechnology Support Network referred to in Article 19 may request the assistance of the Foresight Panel for Emerging Health Innovation.

Article 35

Union regulatory status repository

1. The Commission shall compile, maintain, develop and make publicly available a regulatory status repository ('regulatory status repository').
2. The regulatory status repository shall contain:
 - (a) decisions, opinions, scientific recommendations regarding the regulatory status of a health innovations, issued pursuant to the mechanisms laid down in Article 4 of Regulation (EU) 2017/745, Articles 61 and 62 of Regulation (EU) .../... [reference to be added after adoption cf. COM(2023) 193 final], Article 13 of Regulation (EU) 2024/1938, and, where relevant, pursuant to similar mechanisms laid down in other legislative acts;
 - (b) the summaries of the scientific recommendations delivered by the Agency, prior to the application of Regulation (EU) .../... [reference to be added after adoption cf. COM(2023) 193 final], in accordance with Article 17 of Regulation (EC) No 1394/2007 on whether a product falls within the definition of an advanced therapy medicinal product or not;
 - (c) the discussion papers delivered by the Foresight Panel for Emerging Health Innovation.
3. Member States shall make publicly available, through the relevant national platforms or registries, decisions, opinions, scientific recommendations, and other outputs issued at national level concerning the regulatory status of health biotechnology products. Member States shall inform the Commission where such information is made available.

Article 36

Time limits in the regulatory status process

With a view to ensuring the timely assessment of the regulatory status of health biotechnology products, the advisory bodies and other relevant entities mandated under [revised Regulation (EU) 2017/745, [revised Regulation (EU) 2017/746], Regulation (EU) 2024/1938 Regulation], Regulation (EU) .../... [reference to be added after adoption cf. COM(2023) 193 final] and Regulation (EU) .../... [reference to be added after adoption cf. COM(2023) 192 final] to provide a recommendation or opinion, including preparatory consultations, on the regulatory status of a product, shall act swiftly, without prejudice to the time limits for the forming of such recommendations or opinions established in the above legal acts.

SECTION 2

FORESIGHT ON EMERGING HEALTH INNOVATION

Article 37

Foresight Panel for Emerging Health Innovation

1. A Foresight Panel for Emerging Health Innovation is hereby established ('the Foresight Panel').

2. The Foresight Panel shall provide regulatory, scientific and technical expertise on emerging science and technology in the field of health underpinning the development of health biotechnology products to the Commission, the Agency and to relevant Union-level advisory bodies and competent authorities and other entities in the Member States in the area of health. The Foresight Panel shall operate in accordance with the Commission's framework for expert groups.
3. The Foresight Panel shall carry out the following tasks:
 - (a) conduct horizon scanning by analysing, identifying and discussing emerging science and technology with the potential to drive the development of health biotechnology products, including upon request from the Commission, the Agency, Union-level advisory bodies or competent authorities in the Member States in the area of health, and develop and publish related considerations in the form of discussion papers
 - (b) engage with the Agency and relevant Union-level advisory bodies and competent authorities and other entities in the Member States in the area of health, to facilitate cross-framework dialogue and consistency;
 - (c) engage with existing relevant networks to contribute to enhancing regulatory expertise regarding health biotechnology products.
 - (d) accommodate exchanges among the authorities responsible for the setting up and the operation of regulatory sandboxes in accordance with article 39(5).
4. For the purpose of performing the tasks referred to in paragraph 2, point (a), of this Article, the Foresight Panel may engage in preliminary discussions with the Agency or relevant Union level advisory bodies in the area of health, networks and informal task forces, national competent authorities, developers, and other relevant actors and shall implement a collaborative approach with a view to ensuring an effective uptake of its discussion papers.
5. The Foresight Panel shall consist of scientific and regulatory experts from the SoHO Coordination Board ('the SCB'), the Medical Devices Coordination Group ('the MDCG'), the Coordination group on Health Technology Assessment ('the HTACG'), the Agency and the competent authorities of the Member States, appointed by the Commission in view of their regulatory, scientific or technical expertise in the relevant identified fields and frameworks. The panel may invite external experts selected to assist with specific tasks when such relevant external expertise is needed.
6. The Commission shall adopt an implementing act laying down detailed rules on the selection, composition, number of members, and functioning of the Foresight panel. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 65(2).

Article 38

Support to the Foresight Panel for Emerging Health Innovation

1. The Commission shall chair and provide the secretariat for the Foresight Panel and shall provide the support necessary to ensure it can efficiently perform its tasks.
2. The Commission shall in particular have the following tasks:
 - (a) to provide administrative and technical support to the Foresight Panel;

- (b) to facilitate and manage remote and physical meetings of the Foresight Panel;
 - (c) to ensure that the work of the Foresight Panel is carried out in an independent manner;
 - (d) to facilitate the dissemination of the discussion papers produced by the Foresight Panel with relevant competent authorities and advisory bodies;
 - (e) to ensure that remuneration and expenses are provided to the experts composing the Foresight Panel;
 - (f) to monitor compliance with the rules of procedure of the Foresight Panel;
 - (g) to issue annual reports on the work of the Foresight Panel, including on the number of discussion papers delivered by the Panel.
3. The Foresight panel shall establish its own rules of procedure.

SECTION 3

REGULATORY SANDBOXES AS TOOLS FOR NOVEL HEALTH BIOTECHNOLOGY PRODUCTS

Article 39

Regulatory sandboxes provided for in the applicable frameworks and cross-framework communication

1. Where a regulatory sandbox is established at Member State level for a health biotechnology product in accordance with [revised Regulation (EU) 2017/745], [revised Regulation (EU) 2017/746], Regulation (EU) 2024/1938, the authorities responsible for the operation of that sandbox shall, where appropriate and in accordance with the relevant legislative act referred to in this paragraph, conduct consultations with the competent authorities and the Commission, responsible for the operation of sandboxes under the other relevant Union legislative acts referred to in this paragraph and in paragraph 2 of this Article, and with the Foresight Panel referred to in Article 37, regarding the design and the implementation of the regulatory sandbox.
2. Where a regulatory sandbox is established at Union level for a health biotechnology product in accordance with Regulation (EU) .../... [reference to be added after adoption cf. COM(2023) 193 final] or with Article [40] of this Regulation, the Commission or the Agency shall consult, where appropriate and in accordance with the legislative acts referred to in this paragraph, the Agency, the SCB, the MDCG, and the Foresight Panel referred to in Article 37, regarding the design and the implementation of the regulatory sandbox.
3. The authorities responsible, pursuant to the applicable legislative act, for setting up a regulatory sandbox referred to in paragraphs 1 and 2 of this Article, shall ensure that due consideration is given to the regulatory challenges posed by combination products, and to consultations with the relevant authorities with expertise regarding the associated parts of such products.
4. For the purposes of the consultations referred to in paragraphs 1 and 2 of this Article, all authorities shall endeavour to provide their contribution swiftly, without prejudice

to time limits set out in the provisions of the Union legislative acts in the area of health governing the regulatory sandbox referred to in those paragraphs.

5. The Commission, the Agency, the MDCG and the SCB shall, through the Foresight Panel, facilitate the exchange of views and experiences among the authorities responsible for the setting up and the operation of regulatory sandboxes for health biotechnology products. Those exchanges shall include the following:
 - (a) promoting knowledge sharing, by facilitating the exchange of information, experiences and best practices, including on regulatory approaches, technological challenges, and emerging scientific insights and the appropriate regulatory responses (cross-framework knowledge sharing);
 - (b) identifying potential implications for the evolution or adaptation of the relevant Union legislative acts in the area of health (cross-framework regulatory learning).

Article 40

Regulatory sandboxes for novel health biotechnology products not falling under other regulatory sandboxes in Union legislation in the area of health

1. Upon a substantiated request from developers, the Commission may set up a regulatory sandbox that provides a controlled regulatory environment for the testing and development of a health biotechnology product, that:
 - (a) cannot be appropriately accommodated in any of the regulatory sandboxes available under the Union legislation in the area of health referred to in Article 39, paragraphs (1) and (2); and
 - (b) whose development is hindered by the challenge to identify a suitable regulatory procedure in the area of health.

A regulatory sandbox shall not be set up for health biotechnology products which are likely to fall under the scope of the Union legislation in the area of health referred to in Article 39, paragraphs (1) and (2).

The sandbox shall be set up in accordance with this Article.

2. Such regulatory sandbox shall set out a time limited framework to allow for the generation of evidence and data, in a real-world environment and under supervision of one or more competent authorities.
3. Developers wishing to participate in a regulatory sandbox referred to in paragraph 1 shall submit a substantiated application to the Commission. That application shall include the following:
 - (a) a justification for the establishment of a regulatory sandbox, including a description of the product in question, its level of development, and a justification with regard to the impossibility of appropriately accommodating the proposed sandbox in any of the regulatory sandboxes available under the Union legislation in the area of health referred to in Article 39, paragraphs (1) and (2).
 - (b) the identification of existing regulatory challenges;
 - (c) the assessment of potential benefits and potential risks of the health biotechnology product to be tested or developed.

4. Where the Commission concludes, on the basis of its assessment, that the application shall be accepted, it shall take a decision regarding the establishment of a regulatory sandbox, by means of an implementing act, in accordance with the examination procedure referred to in Article 65(2). That implementing act shall set out the duration of the regulatory sandbox and the principles for operating the regulatory sandbox.
5. The testing and development activities within the regulatory sandbox shall take place in accordance with a sandbox plan developed and updated as appropriate by the Commission based on the principles referred in paragraph 4 of this Article. The regulatory sandbox plan shall:
 - (a) set out the objectives, the specific innovations to be tested in the regulatory sandbox, the relevant activities to be carried out within the regulatory sandbox, the geographical and temporal scope of those activities, as well as the relevant conditions and requirements thereof;
 - (b) be informed by data provided by, and consultations with, the developer of the health biotechnology product concerned;
 - (c) identify the participants in the regulatory sandbox and their respective roles;
 - (d) include appropriate measures to mitigate potential risks, in particular to health and to the environment;
 - (e) include conditions regarding the suspension or the termination of the regulatory sandbox;
 - (f) set out the supervision measures and the related responsibilities.
6. When assessing the applications received in accordance with paragraph 3 of this Article and when developing and implementing the sandbox plan, the Commission may consult the Agency, the SCB, the MDCG, or the Foresight Panel, as appropriate.
7. Participants in the regulatory sandbox, in particular the developer, shall remain liable under applicable national legislation for any harm inflicted on third parties as a result of the testing taking place in the sandbox. They shall inform the Commission without undue delay of any information which might entail the amendment of the regulatory sandbox or concerns the quality, safety or efficacy of products developed as part of a regulatory sandbox.
8. The regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. In case of identification of risks to public health or safety concerns associated with the use of products covered by a sandbox, competent authorities shall take immediate and adequate temporary measures in order to suspend or restrict their use and inform the Commission. Where such mitigation is not possible or proves to be ineffective, the development and testing process shall be suspended without delay until an effective mitigation takes place.
9. When concluding the regulatory sandbox, the Commission shall, at the request of a developer and after having consulted the bodies referred to in paragraph [6] of this Article, deliver a recommendation on an existing appropriate regulatory procedural pathway for authorising the placing on the market and post-marketing surveillance and vigilance of the products concerned.
10. When a product is submitted for authorisation following a recommendation delivered in accordance with paragraph 9 of this Article, due consideration by the authorities

responsible for the assessment of the application for authorisation shall be given to data and evidence collected in the regulatory sandbox.

11. The Commission, after consulting competent authorities of the Member States, and after seeking the opinion of the bodies consulted in accordance with paragraph [6] of this Article, may publish a report on the lessons learned from the regulatory sandbox and, where appropriate, conclusions regarding possible measures at Union level for the regulation of the health biotechnology product or similar innovation categories concerned by the regulatory sandbox.
12. The Commission may, by means of implementing acts, lay down common principles, criteria and practical arrangements for the assessment of applications received from developers and for the establishment and supervision of the regulatory sandboxes and for sandbox plans referred to in this article. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

CHAPTER VIII

BIODEFENCE AND PREVENTING BIOTECHNOLOGY MISUSE

SECTION 1

UNION BIODEFENCE AND BIOSECURITY

Article 41

EU biothreat radar high impact health biotechnology strategic projects

1. To enable access to the support measures laid down in Section 2 of Chapter II, the Commission shall recognise projects located in the Union as high-impact health biotechnology strategic projects contributing to the EU Biothreat Radar for the detection, characterisation, identification, analysis and assessment of biological threats, including novel, unknown and engineered pathogens to ensure pathogen-agnostic cross-border surveillance and early threat detection, as well as the generation and sharing of data required for this, only where they comply with the conditions laid down in Article 4[(1)] and make a substantial contribution to at least one of the following:
 - (a) detection, characterisation, identification, analysis and assessment of biological threats, including novel, unknown and engineered pathogens;
 - (b) interoperable and pathogen-agnostic cross-border surveillance, as well as the generation and sharing of data required for such surveillance;
 - (c) building sampling and detection infrastructure for early detection of novel pathogens and situational awareness across environmental and clinical sources, including basic logistics for collection and transport, and support for the deployment of advanced detection methods, such as metagenomic sequencing;
 - (d) ensuring the appropriate use of internationally recognised pathogen data standards;

- (e) ensuring that sequencing data generated through early detection activities is shared in a timely manner through the European Nucleotide Archive (ENA)⁷⁰, to enable access and use by actors across the Union for the development, validation and deployment of advanced pathogen detection and characterisation methods, by engaging in partnerships among industry, academia, public authorities and defence actors to ensure data sharing and integration of warning systems.
- 2. The provisions of this Regulation regarding the application for, and the recognition of, high-impact health biotechnology strategic projects laid down in Articles 8 and 10, respectively, apply to projects referred to in this Article.

Article 42

Biodefence capability high impact strategic project

- 1. To enable access to the support measures laid down in Section 2 of Chapter II, the Commission shall recognise projects located in the Union as high impact health biotechnology strategic projects for biodefence capability only where they comply with the conditions laid down in Article 4(1) and make a substantial contribution to at least one of the following:
 - (a) preventing or mitigating misuse of biotechnologies;
 - (b) rapid surge capacity for safe sampling, testing sequencing and swift manufacturing of rapid diagnostics;
 - (c) analysis and assessment capacity of testing and sequencing data that can be mobilised across Member States;
 - (d) robust pathogen-agnostic pharmaceutical and non-pharmaceutical defences against biological threats;
 - (e) development, validation and benchmarking of methods for the detection and attribution of genetic engineering, including the creation of open genetic engineering detection tools;
 - (f) civilian and defence research, testing or demonstration infrastructures for biotechnology activities relevant to defence, security and resilience, provided that governance ensures clear separation of mandates and access regimes, with appropriate confidentiality and security safeguards, in line with relevant requirements arising from the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction ('BTWC'), Union and national law.
- 2. The provisions of this Regulation regarding the application for, and the recognition of, high-impact health biotechnology strategic projects laid down in Articles 8 and 10, respectively, apply to projects referred to in this Article.

⁷⁰ ENA, <https://www.ebi.ac.uk/ena>.

SECTION 2

PREVENTION OF BIOTECHNOLOGY MISUSE

Article 43

Biotechnology products of concern

1. Biotechnology products of concern in Annex I shall only be made available to, introduced, or used by any natural or legal person in the Union, as well as made available to any natural or legal person outside the Union, that has a legitimate need for those products, in accordance with this Section.
2. The Commission is empowered to adopt delegated acts in accordance with Article 64 (2) to amend Annex I by adding, removing or modifying categories of biotechnology products of concern, setting or adjusting thresholds or exclusions, and specifying technical parameters, in order to reflect developments in scientific evidence, biosecurity and biosafety risks or patterns of misuse, also considering the latest developments under relevant international fora and instruments.

Article 44

Verification of legitimate need

1. An economic operator that makes available on the Union market, including through online marketplaces, biotechnology products of concern, shall, for each transaction, verify proof of identity of the prospective customer, record the transaction, including the quantities ordered, and assess whether the customer has a legitimate need.
2. For the purposes of conducting the verification referred to in paragraph 1, the economic operator shall request the following information from the prospective customer prior to facilitating the exchange:
 - (a) proof of identity of the person;
 - (b) institutional or corporate affiliation;
 - (c) documentation establishing the legitimacy of the institution or corporation, such as address, any official registration number, evidence of legal personality and of a purpose, and, where applicable, evidence of authorisations, certifications or biosafety approvals appropriate to the intended use;
 - (d) information on the intended use of the product.

The first subparagraph, with the exception of transaction recording, shall not apply where the economic operator has conducted an equivalent verification for the same customer within the preceding five years and the new transaction does not significantly deviate in nature or scale from previous transactions.
3. When assessing legitimate need, the economic operator shall take into account all relevant circumstances, in particular, as applicable:
 - (a) the demonstrable need for the biotechnology product of concern and the legitimacy of its intended use;
 - (b) the background of the applicant;

- (c) the applicant's compliance history with the economic operator and, where available, with other operators, including past incidents or refused orders;
 - (d) credentials that demonstrate evidence of the legitimate need, including relevant academic publications, history or track record in a related domain;
 - (e) documentation establishing the existence of suitable facilities, competencies and biosafety arrangements appropriate to the intended use.
4. The economic operator shall refuse to make the biotechnology products of concern available in the case of a suspicious transaction.
 5. The economic operator shall report to the national contact point referred to in Article 46(3) any suspicious transaction, or attempted suspicious transaction, in accordance with Article 46(5).
 6. Economic operators shall keep and retain records of the transactions referred to in this Article for three years and shall make them available without undue delay to the competent authorities upon request.
 7. Paragraphs 1 to 7 shall also apply by analogy to persons that are not economic operators, except in the case where the biotechnology product of concern is supplied to a person that is employed by the same legal entity.

Article 45

Benchtop equipment

Benchtop nucleic acid synthesis devices made available in the Union shall contain a mechanism to screen for sequences of concern as defined in Annex I, provided that databases of sequences of concern are not stored on the equipment itself, in an unencrypted manner or a manner that could allow users to extract the database.

Article 46

Prevention and reporting of biotechnology misuse

1. For the purpose of preventing and detecting biotechnology misuse, economic operators and online marketplaces shall report suspicious transactions, having regard to all circumstances and in particular where the prospective customer:
 - (a) is not clear about their identity or affiliations, or provides information that cannot be confirmed or verified, including inconsistent addresses or unverifiable company details;
 - (b) would not be expected, in the normal course of business, to place such an order, including where there is no link to life science research or biotechnology, or no plausible requirement for biotechnology products of concern;
 - (c) proposes an intended use that does not match their reported job role or institutional affiliation;
 - (d) requests unusual labelling or shipping procedures, including misidentification of goods on packaging or changes to the recipient's name after the order has been placed but before shipment;

- (e) proposes unusual methods of payment, including cash for high-value items, personal credit cards for institutional purchases, or payment through non-bank third parties, or offers unusually favourable terms including above market prices;
 - (f) requests unusual confidentiality conditions regarding the order, including with respect to their identity, the final destination or the destruction of transaction records;
 - (g) requests delivery to an address without a legitimate biotechnology business or research justification, including a residential address.
2. Economic operators and online marketplaces shall have appropriate, reasonable and proportionate procedures in place to detect suspicious transactions, adapted to the specific environment in which biotechnology products of concern are made available.
 3. Each Member State shall set up at least one national contact point with clearly identified contact details, web form or other effective tool for the reporting of suspicious transactions of biotechnology products of concern. The contact point shall be part of or have direct links to law enforcement and national inspection authorities.
 4. Economic operators and online marketplaces shall refuse a suspicious transaction. They shall report any suspicious transaction or attempted suspicious transaction within 24 hours of determining that it is suspicious. Reports shall include, where possible, the identity of the prospective customer and the facts that led to the suspicion and shall be addressed to the national contact point of the Member State where the transaction was concluded or attempted.
 5. Where a biotechnology product of concern falls also under categories regulated under other EU legislation, to avoid duplication of reporting, where the transaction for that biotechnology product of concern has already been reported as a suspicious transaction under one legal framework, it shall not be reported again. Where in doubt, its intended use should be prioritised for reporting obligations, pursuant to Regulation (EU) 2021/821^[71] and Regulation (EU) 2019/1148^[72].

Article 47

Training and awareness-raising

1. Member States shall ensure adequate resources for, and the provision of, training for law enforcement authorities, first responders and customs authorities to recognise biotechnology products of concern and to react in a timely and appropriate manner to suspicious activity.

⁷¹ Regulation (EU) 2021/821 of the European Parliament and of the Council of 20 May 2021 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items, OJ L 206, 11.6.2021, pp. 1–461. ELI: <http://data.europa.eu/eli/reg/2021/821/oj>.

⁷² Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors, amending Regulation (EC) No 1907/2006 and repealing Regulation (EU) No 98/2013 (Text with EEA relevance), OJ L 186, 11.7.2019, pp. 1–20. ELI: <http://data.europa.eu/eli/reg/2019/1148/oj>.

2. Member States shall organise awareness-raising actions, including on the issue of insider threats, adapted to the specificities of each sector that uses biotechnology products of concern.
3. To facilitate cooperation and effective implementation, and avoid duplicate reporting, Member States shall organise regular exchanges between law enforcement authorities, national supervisory authorities, economic operators, online marketplaces and representatives of sectors that use biotechnology products of concern.
4. Economic operators shall inform their personnel about the conditions under which biotechnology products of concern may be made available and shall raise personnel's awareness accordingly.

Article 48

National inspection authorities

1. Each Member State shall designate a competent authority responsible for the inspection and control of compliance with the obligations laid down in this Section.
2. Member States shall ensure that the national inspection authority has the resources and investigative powers necessary to perform their tasks, including the power to request information and records, to carry out on-site inspections and, where appropriate, to conduct test purchases, including online.
3. Member States shall ensure that the national inspection authorities regularly run simulation exercises to test the procedures in place and to ensure appropriate response to incidents.
4. Member States shall ensure the participation of national inspection authorities, as appropriate, in the relevant activities of the Steering Group, in particular for the exchange of information on implementation practices, inspection findings and emerging risks. Member States shall ensure risk-based audits of economic operators, verifying, in particular, the existence and effectiveness of screening mechanisms for legitimate need, record-keeping as provided for in Article [44] [(6)] and detection of suspicious transactions and incidents, and response procedures.

Article 49

Commission enforcement support and monitoring

The Commission may support and monitor national competent authorities in the enforcement of this section, by taking actions such as requesting information and records and running training exercises.

Article 50

Audits

Member States shall ensure risk-based audits of economic operators, verifying, in particular, the existence and effectiveness of screening mechanisms for legitimate need, record-keeping as provided for in Article 44 [(6)] and detection of suspicious transactions and incidents, and response procedures.

Article 51

Penalties

1. Member States shall lay down the rules on penalties applicable to infringements of this Section and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive.
2. Member States may impose fines on economic operators not exceeding 5% of their annual total worldwide turnover in the preceding financial year when Member States finds that the provider intentionally or negligently infringed the relevant provisions of this Section.
3. In fixing the amount of the fine or periodic penalty payment, regard shall be had to the nature, gravity and duration of the infringement, taking due account of the principles of proportionality and appropriateness.

Article 52

Advisory group on biosecurity

1. An Advisory Group on Biosecurity ('the Advisory Group') is hereby established.
2. The Advisory Group shall provide independent scientific advice to the Commission on biosecurity risks arising from the rapid development of biotechnology, including from AI models as described in Regulation (EU) 2024/1689 in biological applications ('AI models in biological applications'). It shall be selected and operate in accordance with the Commission's framework for expert groups⁷³.
3. The tasks of the Advisory Group shall include:
 - (a) monitoring advances in biotechnology to advise the Commission on emerging biosecurity challenges, including on any potentially necessary updates to the list of biotechnology products of concern laid down in Annex I and on risk-based audits of economic operators;
 - (b) monitoring the capabilities and risk profile of AI models in biological applications throughout their life cycle;
 - (c) contributing to the preparation of Union guidance and best practices for responsible innovation on AI models in biological applications;
 - (d) facilitate dialogue and coordination among scientific, industry, and security stakeholders and support, where appropriate, international cooperation on biosecurity.
4. Where the Advisory Group has reasonable grounds to suspect that an AI model in a biological application not covered by Regulation (EU) 2024/1689, poses biological systemic risk, it shall issue a qualified alert to the Commission and to the Member States. A qualified alert may be issued following a decision of the Advisory Group or at the initiative of at least 50% of its members. The alert shall be concise and duly

⁷³ Commission Decision establishing horizontal rules on the creation and operation of Commission expert groups, C(2016)3301.

reasoned and shall indicate at least the point of contact of the developer of the model concerned and the factual basis for the alert.

5. Where the Advisory Group has reasonable grounds to suspect that an AI model covered by Regulation (EU) 2024/1689 poses biological systemic risk, it shall inform the scientific panel of independent experts referred to in Article 68 Regulation (EU) 2024/1689. That panel may issue a qualified alert to the AI Office in accordance with Regulation (EU) 2019/1689.
6. The Advisory Group shall be composed of up to 25 globally leading independent experts appointed by the Commission based on their recognized expertise in the areas of biotechnology, biosecurity, biodefence and AI.
7. The members of the Advisory Group shall perform their tasks with impartiality and objectivity. The Advisory Group shall liaise, where appropriate, with other Union and international expert structures addressing biotechnology, AI, or biosecurity to ensure coherence and efficiency, including the scientific panel referred to in Article 68 of Regulation (EU) 2024/1689.
8. The Advisory Group may adopt opinions, recommendations, or principles on matters within its mandate.

Article 53

Biological systemic risk

1. The Commission shall monitor biological systemic risk from AI models in biological applications and propose mitigating actions, based on advice provided by the Advisory Group and in line with the Union harmonisation legislation on AI, including boosting biodefence capabilities or regulation, including on assessment and mitigation of systemic risk from those AI models, as appropriate.
2. Where a qualified alert is issued by the Advisory Group as referred to in Article 52(3), point (d), the Commission and the Member States shall take appropriate measures to ensure a proper control of risks.

Article 54

Monitoring and guidance

The Commission, based on advice by the Advisory Group on Biosecurity, and where appropriate, in cooperation with the Steering Group, may issue and regularly update guidance, to assist actors in the supply chain and the competent authorities. The guidance may provide:

- (a) clarifications regarding the biotechnology products of concern listed in the Annex I;
- (b) clarification on the criteria for determining the sequences of concern referred to in Annex I;
- (c) information and methodologies for the assessment of legitimate need for the purposes of this Section;
- (d) information on how to exchange relevant information between competent authorities, national contact points and among Member States;
- (e) information on how to recognise, refuse, and report suspicious transactions;

- (f) obligations for natural or legal persons that are not economic operators that make available biotechnology products of concern;
- (g) requirements regarding benchtop nucleic acid synthesis equipment referred to in Article 45;
- (h) information on risk-based audits of economic operators referred to in Article 50;
- (i) any other information deemed useful for effective implementation, including on the investigative powers of national inspection authorities, test purchases, information requests from, and resources of, such authorities, or requested by relevant economic operators.

Article 55

Coordination on biosecurity and biosafety

The Steering Group referred to in Article 20 shall facilitate the coordination of and information exchange on the enforcement of the provisions in this section among Member States.

CHAPTER IX

AMENDMENTS TO REGULATIONS (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938

Article 56

Amendments to Regulation (EC) No 178/2002

Regulation (EC) No 178/2002 is amended as follows:

- (1) in Article 3, the following points 19, 20 and 21 are added:
 - ‘19. ‘regulatory sandbox’ means a controlled environment where participants can test innovative products or substances and related processes as well as data and other regulatory requirements at a pre-market stage under a set of defined rules and monitoring and for a limited period of time;
 - 20. ‘regulatory sandbox plan’ means a plan setting out the scope, the requirements and the conditions governing the operation of a specific regulatory sandbox;
 - 21. ‘participants’ means any natural or legal person participating in a regulatory sandbox to whom specific tasks are assigned in the regulatory sandbox plan, such as business operators, Union and national agencies, final consumers, academia and research institutions.’;
- (2) in Article 22(5), point (a) is replaced by the following:
 - ‘(a) scientific advice and scientific and technical support on human nutrition;’
- (3) Article 28 is amended as follows:
 - (a) paragraph 3 is replaced by the following:

- ‘3. The Scientific Committee shall be composed of the first Vice-Chairs of the Scientific Panels and six independent scientific experts who do not belong to any of the Scientific Panels.’
- (b) paragraph 6 is replaced by the following:
 - ‘6. The Scientific Committee and the Scientific Panels shall be chaired by the staff of the Authority without the right to vote. The Scientific Committee and the Scientific Panels shall each choose two Vice-Chairs from among their members.’
- (c) in paragraph 9, the following point (h) is added:
 - ‘(h) the role of the Authority when chairing the Scientific Committee and the Scientific Panels.’
- (4) in Article 32a, paragraph 1 is replaced by the following:
 - ‘1. Where Union law contains provisions for the Authority to provide a scientific output, including a scientific opinion, the Authority shall, at the request of a potential applicant or notifier, provide advice on the content of the application or notification, prior to its submission, including the rules applicable to and the required content thereof as well as on the design of the studies and testing strategies to support such an application or notification. Such advice provided by the Authority shall be without prejudice and non-committal as to any subsequent assessment of applications or notifications by the Scientific Panels.’
- (5) Article 32b is amended as follows:
 - (a) in paragraph 4, the third subparagraph is replaced by the following:
 - ‘The assessment of the validity or the admissibility of such re-submitted application or notification shall commence three months after the date of re-submission of the application and provided that a notification of the studies pursuant to the second subparagraph has taken place.’
 - (b) in paragraph 5, the third subparagraph is replaced by the following:
 - ‘The assessment of the validity or admissibility of such re-submitted application or notification shall commence three months after the date of re-submission of the application and provided that all studies that had previously been notified in accordance with paragraph 2 or 3 are included in the resubmitted application or notification.’;
 - (c) paragraph 6 is replaced by the following:
 - ‘6. Where the Authority detects, during its risk assessment, that studies notified in accordance with paragraph 2 or 3 are not included in the corresponding application or notification in full, and in the absence of a valid justification of the applicant or notifier to that effect, the applicable time limits within which the Authority is required to deliver its scientific output shall be suspended. That suspension shall end three months after the submission of all data of those studies.’
- (6) in Article 32c, paragraph 1 is deleted.
- (7) the following Chapter IIIA is inserted:

REGULATORY SANDBOXES

Article 49a

General provisions on regulatory sandboxes

1. A Member State or several Member States jointly may establish regulatory sandboxes in accordance with this Article and the procedure set out in Article 49b.
2. Regulatory sandboxes may be established in relation to the following:
 - (a) all stages of the production, processing and distribution of food with the exception of novel foods, and also of the feed produced for, or fed to food-producing animals;
 - (b) food contact materials, with the exception of plastic recycled materials;
 - (c) products, other than food and feed, containing or consisting of genetically modified organisms as defined in Article 2, point (2), of Directive 2001/18/EC.

The making available of products within a regulatory sandbox shall not be regarded as placing on the market.

3. Regulatory sandboxes shall pursue one or more of the following objectives:
 - (a) facilitating the development, testing and validation of technologies, products and substances before they obtain authorisation or approval for placing on the market, where so required by Union law;
 - (b) testing data requirements, including the type and design of studies required for conducting a safety and/or efficacy assessment;
 - (c) testing alternative regulatory requirements and appraising their performance as regards the attainment of the objectives of the applicable Union sectoral law in comparison to the existing requirements; in the areas where Union law provides for an approval or authorisation, as well as in the area of food information to consumers.
4. Member States shall monitor and supervise the operation of regulatory sandboxes that they establish and ensure compliance with the regulatory sandbox plan.
5. A participant to an established regulatory sandbox shall immediately inform the competent authorities of the Member State(s) concerned if it considers or has reason to believe that the conditions of the regulatory sandbox plan have not been complied with and/or there are potential risks to public health, animal health or welfare, plant health or to the environment, which may require the revocation of the regulatory sandbox or the amendment of the regulatory sandbox plan to provide for mitigating measures. Participants shall also immediately inform the competent authorities of any other information that concerns the quality, safety or efficacy of the subject matter of the relevant regulatory sandbox.

6. Member States shall immediately notify to the Commission and, where relevant, to the Authority any violation of the conditions set out in the regulatory sandbox plan and/or the identification of any potential risks to public health, animal health or welfare, plant health or to the environment.
7. Member States shall suspend or revoke a regulatory sandbox at any time on their own motion, or at the request of the Commission in accordance with paragraph 9, in either of the following cases:
 - (a) the requirements and conditions governing the regulatory sandbox plan are not met;
 - (b) where necessary to protect public health, animal health or welfare, plant health or the environment and there is no possibility for effective mitigation measures.

Member States shall inform the Commission, the Authority and the other Member States without delay of the suspension or revocation of a regulatory sandbox and of the reasons.

8. Where after the setting up of a regulatory sandbox in their territory, a Member State identifies risks to public health, animal health and welfare, plant health and to the environment which can be fully mitigated by amendments to the regulatory sandbox plan, it shall communicate to the Commission, the Authority and the other Member States the draft amendments in accordance with the procedure laid down in Article 49b.
9. Where the Commission considers that one of the cases referred to in paragraph 7 is fulfilled, it shall immediately adopt implementing acts in accordance with the procedure referred to in Article 58(2) requesting the suspension or the revocation of the regulatory sandbox concerned.

However, in emergencies, the Commission may provisionally adopt an implementing act requesting the suspension of the regulatory sandbox concerned after consulting the Member State(s) concerned and informing the other Member States. As soon as possible, and at most within 10 working days, the measure taken shall be confirmed, amended or revoked in accordance with the procedure referred to in Article 58(2) and the reasons for the Commission's decision shall be made public without delay.

10. A Member State may prolong the duration once of a regulatory sandbox for a limited time where this is justified by the need to attain the objective of the specific regulatory sandbox at hand and shall inform the Commission, the Authority and the other Member States thereof.
11. The Commission may, by means of implementing acts, specify common principles or practical arrangements for the establishment and supervision of regulatory sandboxes, including the establishment of sandboxes involving several Member States pursuant to this Article, Article 49b and 49c. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 58(2).

Article 49b

Establishment of regulatory sandboxes

1. Where a Member State deems it appropriate to establish a regulatory sandbox, it shall communicate to the Commission, the Authority and the other Member States a draft regulatory sandbox plan, which shall contain the following elements:
 - (a) the objectives of the regulatory sandbox;
 - (b) a description of the specific areas that the sandbox will cover, including the products or substances, processes, technologies and practices;
 - (c) a clearly defined geographical scope;
 - (d) a clearly defined and limited temporal scope;
 - (e) the regulatory or scientific justifications for setting up the regulatory sandbox;
 - (f) an identification of the relevant provisions of Union law that apply for the purposes of the regulatory sandbox and those that do not apply or are adapted;
 - (g) the procedure for the application and selection for participants, including clearly defined eligibility criteria, the modalities governing the provision of the explicit and prior consent from participating final consumers as well as the modalities by which the participants may end their participation;
 - (h) the possible involvement of the Authority, other Union agencies and national agencies, where relevant, provided that they have expressed interest to join the regulatory sandbox;
 - (i) the activities allowed to be carried out and the conditions and requirements that apply;
 - (j) an assessment that identifies how potential risks to public health, animal health or welfare, plant health or the environment are mitigated;
 - (k) details on how activities will be monitored, including responsibilities of the competent authorities entrusted with the supervision of the implementation of the sandbox plan.
2. Where several Member States deem it appropriate to jointly establish regulatory sandboxes, they shall collectively communicate a draft regulatory sandbox plan to the Commission, the Authority and the other Member States. The regulatory sandbox plan shall specify the activities to take place in each of the participating Member States in addition to the elements listed in paragraph 1.
3. Member States shall engage with relevant stakeholders during the preparation of a draft regulatory sandbox plan to gather diverse perspectives and foster collaboration.
4. The Member State(s) which deem it appropriate to set up a regulatory sandbox alone or jointly, shall communicate the draft regulatory sandbox plan to the Commission, the Authority and other Member States at least 60 days prior to the intended commencement of the sandbox activities. Member State(s) shall consider any feedback or recommendations from the Commission, the other

Member States and the Authority before deciding whether to establish the regulatory sandbox.

5. Member State(s) shall communicate to the Commission, the Authority and the other Member States any subsequent draft amendment to regulatory sandbox plans and the reasons thereof. Paragraphs 1 to 4 shall apply *mutatis mutandis*.

Article 49c

Other responsibilities, monitoring and reporting obligations regarding regulatory sandboxes

1. Regulatory sandboxes shall not affect the enforcement and monitoring responsibilities of the competent authorities set out in Article 17 and in other sectoral legislation.
2. Participants, with the exception of final consumers, in particular the operator that is the developer of the product or substance concerned, shall remain liable under applicable national legislation for any harm inflicted on third parties as a result from the testing taking place in the sandbox.
3. Member States shall submit annual reports to the Commission on the results from the implementation of regulatory sandboxes, including good practices developed, lessons learnt and recommendations on their setup and, where relevant, on the application of the relevant sectorial Union legislation. Those reports shall be made publicly available by the Commission.
4. The Authority shall also ensure the necessary revisions of its guidance where relevant and appropriate on the basis of those annual reports.

Article 57

Amendments to Regulation (EC) No 1394/2007

Regulation (EC) No 1394/2007 is amended as follows:

(1) Article 2 is amended as follows:

(i) in paragraph 1, the following point (e) is added:

‘(e) ‘viral vector’ means a genetically modified virus that is used to deliver genetic material into cells.’

(ii) the following paragraph 6 is added:

‘6. The Commission is empowered to adopt delegated acts in accordance with Article 25a to amend this Regulation in order to amend the definitions referred to in paragraph 1, regarding what constitutes a tissue engineered product, in light of technical and scientific advancements in the field of advance therapy medical products and taking into account definitions agreed at Union and international level without extending the scope of this definition. The delegated acts shall be adopted after consultations with the European Medicines Agency and the SoHO Coordination Board.’;

(2) The following Article 4a is inserted:

‘Article 4a

**Advanced therapy investigational medicinal products containing or consisting of
genetically modified organisms presenting no or negligible risks**

1. By way of exemption from Article 5a of Regulation (EU) No 536/2014 [*as added by the revised Regulation No (EC) 726/2004*], sponsors of clinical trials that concern advanced therapy investigational medicinal products as defined in Article 2(7) of that Regulation, consisting or containing GMOs, are not required to submit an environmental risk assessment, if those products belong to at least one of the following categories:
 - (a) non-viable or replication deficient viral vector that is used to deliver a genetic sequence of human origin, and the vector does not carry an antimicrobial resistance gene;
 - (b) genetically modified somatic cells, that cannot secrete or produce infectious agents due to the genetic modification;
 - (c) genetically modified bacteria that do not carry an antimicrobial resistance gene;
 - (d) genetic material altered using genome editing techniques (ex vivo or in vivo), provided that it has generally negligible adverse effects on human health and the environment.
2. The exemption provided for in paragraph 1 of this Article is subject to the sponsor submitting, through the EU Portal and as part of the clinical trial application dossier, a reasoned-declaration confirming that the advanced investigational therapy medicinal product concerned falls into one or more of the categories referred to in points (a) to (d) of paragraph 1, of this Article. The Committee for Medicinal Products for Human Use (CHMP) referred to in Article [148] of Regulation [...] [*revised Regulation No (EC) 726/2004*] shall verify this declaration and the reasons provided, and the CHMP may, to this end, access the information on the clinical trial application in the EU portal. The CHMP shall communicate its opinion on the declaration to the sponsor and to the reporting Member State within 21 days after the submission date referred to in Article 5(1) of Regulation (EU) No 536/2014 [*as revised by European Biotech Act*].
3. The reporting Member State, giving due consideration to the opinion of the CHMP, shall assess if the conditions of paragraph 1 of this Article apply or if the sponsor is to be requested to submit an environmental risk assessment pursuant to Article 5a of Regulation (EU) No 536/2014 [*as introduced by the revised Regulation No (EC) 726/2004*].

4. Sponsors of clinical trials concerning advanced investigational therapy medicinal products that fall under paragraph 1 of this Article are also exempted from complying with the GMO related requirements of Article 61(2), point (a), of Regulation (EU) No 536/2014 [as introduced by the revised Regulation No (EC) 726/2004] regarding the authorisation of manufacturing and import of advanced investigational therapy medicinal products.
5. The exemptions provided for in this Article shall apply only for the duration of the clinical trial, limited to the activities within the clinical trial.’;

(3) Article 25a is replaced by the following:

‘Article 25a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated referred to in Article 2, paragraph 6, and in Article 24 shall be conferred on the Commission for a period of five years from [insert date xx, from the entry into force of this Regulation].

The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 2, paragraph 6, and in Article 24 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 2, paragraph 6, and Article 24 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Amendments to Regulation (EU) No 536/2014

Regulation (EU) 536/2014 is amended as follows:

- (1) Article 2 is amended as follows:
 - (a) point (3) is replaced by the following:

‘(3) ‘Low-intervention clinical trial’ means a clinical trial which fulfils all of the following conditions:

 - (a) the investigational medicinal products, excluding placebos, are authorised;
 - (b) according to the protocol of the clinical trial, the use of the investigational medicinal product is evidence-based and supported by published scientific evidence on the safety and efficacy of those investigational medicinal products concerned; and
 - (c) the additional diagnostic or monitoring procedures do not pose more than minimal additional risk or burden to the safety of the subjects compared to normal clinical practice in any Member State concerned;’
 - (b) the following point (3a) is inserted:

‘(3a) ‘Minimal-intervention clinical trial’ means a clinical trial which fulfils all of the following conditions:

 - (a) the investigational medicinal products are authorised;
 - (b) according to the protocol of the clinical trial, the investigational medicinal products are used in accordance with the terms of marketing authorisation; and
 - (c) the additional diagnostic or monitoring procedures do not pose more than minimal additional risk or burden to the safety of the subjects compared to normal clinical practice in any Member State concerned;’
 - (c) points 12 and 13 are replaced by the following:

‘(12) ‘Member State concerned’ means the Member State where an application for authorisation of a clinical trial or a combined study of a substantial modification has been submitted under Chapters II, IIa or III of this Regulation respectively;’

‘(13) ‘Substantial modification’ means any change to any aspect of the clinical trial which is made after the notification of a decision referred to in Article 8 in at least one Member State concerned and which is likely to have a substantial impact on the safety or rights of the subject or on the reliability and robustness of data generated in the clinical trial;’
 - (d) the following point (13a) is inserted:

‘(13a) ‘Parallel substantial modification’ means a substantial modification for which an application is submitted to a Member State concerned before a

decision on a previous application for a substantial modification to the same clinical trial is notified by that Member State to the sponsor;'

(e) point (21) is replaced by the following:

'(21) 'Informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the clinical trial that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in a clinical trial, including consent given through the use of electronic systems, methods and processes, and signed electronically in accordance with Union law or equivalent standards;'

(f) the following points (36), to 47 are inserted:

(36) 'Consideration' means a justified concern or divergent view raised by a Member State concerned in the process of an assessment of an application for an authorisation of a clinical trial or for a substantial modification on the aspects that, if unresolved, will result in a negative decision on the clinical trial or substantial modification application;

(37) 'Reporting Member State' means the Member State concerned that:

- (a) is responsible for the assessment and authorisation of the clinical trial application in mono-national clinical trials, or
- (b) is leading the assessment for the authorisation of a multinational clinical trial or of a substantial modification regarding aspects covered by Part I of the application dossier, or
- (c) is leading the assessment for the authorisation of a multinational combined study;

(38) 'Investigational medicinal product core dossier' means a dossier, containing documents referred to in point (Ga), Part II of Annex I concerning the investigational medicinal product, established at the request of the sponsor in view of supporting the development of the investigational medicinal product.

(39) 'Core dossier depository Member State' means a Member State responsible for assessing suitability and completeness of the investigational medicinal product core dossier to be established and for the regulatory oversight of an already established dossier;

(40) 'Core dossier competent Member States' means the Member States concerned for all corresponding clinical trials and the Member States indicated by a sponsor at the time of the initial request for the establishment of the investigational medicinal product core dossier;

(41) 'Corresponding clinical trial' means a clinical trial tested to the investigational medicinal product for which an establishment of an investigational medicinal product core dossier has been requested and any subsequent clinical trial tested to that investigational medicinal product;

- (42) ‘Distribution’ means all activities, consisting of procuring, holding, supplying, shipping across Member States or exporting investigational medicinal product or auxiliary medicinal products, , including delivery of investigational and auxiliary medicinal products to the clinical trial participants;
- (43) ‘Direct delivery to the subject’ means controlled and documented direct delivery of an investigational medicinal product or an auxiliary medicinal product to the subject’s place of residence in a Member State, where the clinical trial has been authorised;
- (44) ‘Combined study’ means a clinical trial concerning one or more medicinal products combined with a performance study of one or more in vitro diagnostic medical devices, as defined in Article 2 point (42) of Regulation (EU) 2017/746 of the European Parliament and of the Council *and/or clinical investigation of one or more medical devices as defined in Article 2 point (45) of Regulation (EU) 2017/745 of the European Parliament and of the Council **;
- (45) ‘Regulatory sandbox’ means a regulatory framework that allows for the development and testing of innovative or adapted regulatory approaches in a controlled environment pursuant to a specific plan, for a limited time and under regulatory supervision, that enables innovation driven approaches to an authorisation and conduct of clinical trials that otherwise would not be possible or appropriate given current legal framework;’
- (46) ‘AI system’ means AI system as defined in Article 3(1) of Regulation (EU) 2024/1689 of the European Parliament and of the Council***;
- (47) ‘serious cross-border threat to health’ means serious cross-border threat to health as defined in Article 3(1) of Regulation (EU) 2022/2371 of the European Parliament and of the Council****‘

* Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (JO 5.5.2017, L117/176., ELI: <http://data.europa.eu/eli/reg/2017/746/oj>).

** Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (JO 5.5.2017, L 117/1., ELI: <http://data.europa.eu/eli/reg/2017/745/oj>).

*** Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (OJ L, 2024/1689, 12.7.2024, ELI: <http://data.europa.eu/eli/reg/2024/1689/oj>)

***** Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26, <http://data.europa.eu/eli/reg/2022/2371/oj>).

(2) Article 3 is replaced by the following:

'Article 3

General principles

1. A clinical trial may be conducted only if:
 - (a) the rights, safety, dignity and well-being of subjects are protected and prevail over all other interests; and
 - (b) it is designed to generate reliable and robust data.
2. Member States concerned shall cooperate closely and efficiently to ensure the effective and timely application of the provisions of this Regulation.
3. Member States shall take into account whether a clinical trial is a minimal-intervention or low-intervention clinical trial and, where this is the case, adapt the regulatory requirements throughout the lifecycle of such clinical trial, in particular with regard to the application dossier, the authorisation procedures, the safety reporting and oversight.'

(3) Articles 4 and 5 are replaced by the following:

'Article 4

Prior authorisation

A clinical trial shall be conducted only if it has been authorised by the Member State concerned in accordance with this Regulation. Applications for an authorisation shall be subject to scientific and ethical review.

In clinical trials concerning more than one Member States (multinational clinical trials) all the Member States concerned including the reporting Member State shall cooperate in good faith and in spirit of mutual trust and reliance. The reporting Member State shall have a leading role in the assessments.

The ethical review shall be performed by an ethics committee in accordance with the law of the Member State concerned. The reporting Member State shall involve its ethics committee in the assessment of ethical aspects of Part I of the application dossier referred to in Article 6.

Each Member State shall ensure that the organisation, timelines and procedures for the review by an ethics committee are compatible with the timelines and procedures set out in this Regulation for the assessment of the application for authorisation of a clinical trial and substantial modifications thereof.

Article 5

Submission of an application

1. In order to obtain an authorisation, the sponsor shall submit an application dossier to the intended Member States concerned throughout the Portal referred to in Article 80 ('the EU portal') referred to in Article 25. The date on which the sponsor submits the application for an authorisation of a clinical trial is referred to within this Chapter as the submission date.
2. The authorisation procedure of a clinical trial consists of three steps:
 - (a) a validation of the application dossier, as set out in Article 5b;
 - (b) an assessment, that consists of:
 - an assessment of Part I, as set out in Article 6, of the elements of the application dossier listed in Part I of Annex I, that constitute Part I of the assessment dossier, and
 - an assessment of Part II, as set out Article 7 of the application dossier, of the elements listed in Part II of Annex I, that constitute Part II of the application dossier.
 - (c) a decision resulting either an authorisation, conditional authorisation or refusal of an authorisation, as set out in Article 8.'

(4) the following Articles 5a and Article 5b are inserted:

"Article 5a

Appointment of the reporting Member State

1. In clinical trials concerning only one Member State, this Member State is the reporting Member State.
2. In clinical trials concerning more than one Member States, the sponsor shall propose one of the Member States concerned as the reporting Member State. All Member States concerned willing to become the reporting Member State shall declare their willingness through the EU portal.
The sponsor shall, when applying for a low-intervention clinical trial propose one of the Member States concerned where the use of the investigational medicinal product is evidence-based as a reporting Member State.
3. If the proposed Member State accepts the proposal by expressing willingness to become the reporting Member State, it shall be the reporting Member State.
4. If the proposed Member State does not accept the proposal, the following rules shall apply, and their application shall be supported by the EU Portal:
 - (a) where there is only one other Member State concerned willing to become the reporting Member State, that Member State shall become the reporting Member State;
 - (b) where there is more than one Member State concerned willing to become the reporting Member State or none of the Member States concerned is willing to become the reporting Member State, the reporting Member State shall be designated automatically by the EU Portal in application of the recommendation referred to in article 85(2)(c).

5. Within three days from the submission date, all Member States concerned, the sponsor and the reporting Member State shall be notified by the EU Portal of the appointment of the reporting Member State.

Article 5b

Validation of Part I of the application dossier

1. Within seven days from the submission date, the reporting Member State shall validate Part I of application dossier referred to in Article 6 and notify the sponsor, through the EU portal, of the following:
 - (a) whether the clinical trial applied for falls within the scope of this Regulation;
 - (b) whether the application dossier is complete in accordance with Part I of Annex I;
 - (c) whether it confirms that the clinical trial is a minimal-intervention or a low-intervention clinical trial, respectively, if such a claim was made by the sponsor.
2. Where the reporting Member State has not notified the sponsor within the period referred to in paragraph 1, the clinical trial applied for shall be deemed to fall within the scope of this Regulation and the application dossier shall be considered complete and, if applicable, the clinical trial shall be considered a minimal-intervention or low-intervention clinical trial.
3. Where the reporting Member State finds that the application dossier is not complete, or that the clinical trial applied for does not fall within the scope of this Regulation, or, if applicable, has doubts whether the clinical trial is a minimal-intervention or low-intervention clinical trial, the reporting Member State shall:
 - (a) inform the sponsor thereof through the EU portal and shall set a deadline of maximum seven days for the sponsor to comment on the application or to complete the application dossier through the EU portal;
 - (b) within seven days from the submission of the comments or the completed application dossier referred to in point (a) notify the sponsor as to whether or not the application complies with the requirements set out in paragraph 1 points (a), (b) and (c).

In case the reporting Member State requests the sponsor to comment on the application pursuant to this paragraph, the period referred to in paragraph 1 may be extended by a maximum of 14 days.

4. Where the reporting Member State has not notified the sponsor within the period referred to in paragraph 3, point (b), the clinical trial applied for shall be deemed to fall within the scope of this Regulation, the application dossier shall be considered complete in accordance with Part I of Annex I and the clinical trials is deemed to be a minimal-intervention or a low-intervention clinical trial, if claimed by the sponsor.
5. Where the sponsor has not provided comments or completed the application dossier within the period referred to in paragraph 3, point (a), the application shall be deemed to have lapsed in all Member States concerned.

6. For the purpose of this Chapter, the date on which the sponsor is notified in accordance with paragraph 1 or paragraph 3, point (b) shall be the validation date of the application. Where the sponsor is not notified within these time periods, the validation date shall be the last day of respective periods referred to in paragraph 1 or paragraph 3, point (b).”

(5) Article 6 is replaced by the following:

Article 6

Assessment report – Aspects covered by Part I of the assessment report

1. The reporting Member State shall assess the application relying on the information and the documents listed in Part I of Annex I, with regard to the following aspects:
 - (a) compliance with Chapter V as with respect to the following:
 - (i) the anticipated therapeutic and public health benefits taking account of all of the following:
 - characteristic of and knowledge about the investigational medicinal products;
 - relevance of the clinical trial, including whether the groups of subjects participating in the clinical trial represent the population to be treated, or if not, the explanation and justification provided in accordance with point 17(y) of Part I of Annex I; the current state of scientific knowledge; whether the clinical trial has been recommended or imposed by regulatory authorities in charge of the assessment and authorisation of the placing on the market of medicinal products; where applicable, taking into account any opinion formulated by the Paediatric Committee on paediatric investigational plan in accordance with Chapter VII of Regulation (EU) .../...[reference to be added after adoption cf. COM(2023)196final];
 - reliability and robustness of the data generated in clinical trial, taking into account of statistical approaches, design of the clinical trial and methodology, including sample size and randomisation, comparator and endpoints;
 - (ii) risk and inconveniences for the subjects, taking into account all of the following:
 - characteristic of and knowledge about the investigational medicinal product and the auxiliary medicinal product;
 - characteristic of the investigational medicinal product;
 - safety measures, including provisions for risk minimisation measures, monitoring, safety reporting, and the safety plan;

- risk to subjects' health posed by the medical condition for which the investigational medicinal product is being investigated;
 - aspects related to the protection of the subjects' safety, well-being and fundamental rights as a clinical trial participant.
- (b) compliance with the requirements concerning the manufacturing and import of investigational medicinal product set out in Chapter IX;
 - (c) compliance with the labelling requirements set out in Chapter X;
 - (d) completeness and adequacy of the investigator's brochure.

The adequacy of the translations of the documents, when translations are required pursuant to Article 26 and Article 69, submitted in Part I shall be assessed in Part II.

2. The reporting Member State shall draw up an assessment report. The assessment of the aspects referred to in paragraph 1 shall constitute Part I of the assessment report.

The ethics committee of the reporting Member State shall review, from the ethical perspective, aspects covered by Part I of the assessment report. That ethical review shall complement the scientific and regulatory assessment and shall cover Part I of the application dossier in order to evaluate whether the subjects' rights, safety and well-being are being ensured in the clinical trial."

- 2a. Notwithstanding paragraph 2, where the clinical trial is a minimal-intervention clinical trial, the assessment of the reporting Member State shall be limited to an ethical review by its ethics committee of the aspects referred to points (a) and (d) of paragraph 1.
3. The assessment report shall contain one of the following conclusions concerning the aspects addressed in Part I of the assessment report:
 - (a) the conduct of the clinical trial is acceptable in view of the requirements set out in this Regulation;
 - (b) the conduct of the clinical trial is acceptable in view of the requirements set out in this Regulation, but subject to compliance with specific conditions which shall be specifically listed in that conclusion; or
 - (c) the conduct of the clinical trial is not acceptable in view of the requirements set out in this Regulation.
4. The reporting Member state shall submit, through EU portal, the final Part I of the assessment report, including its conclusions, to the sponsors and to the other Member States concerned within 42 days from the submission date.
5. For clinical trials involving more than one Member State concerned, the assessment process shall include three phases:
 - (a) an initial assessment phase within 28 days from the submission date;
 - (b) a review phase within seven days from the end of the initial assessment;
 - (c) a consolidation phase within seven days from the end date of the review phase.

During the initial assessment phase, the reporting Member State shall assess Part I of the application dossier and draw up a draft Part I of the assessment report and circulate it to all other Member States concerned within 28 days from the submission date.

During the review phase, within seven days from the circulation of the draft assessment report all Member States concerned shall review the application based on the draft Part I of the assessment report and shall share considerations for their Member States relevant to the application. The consideration may be raised only on one of the following grounds:

- (a) one of the grounds referred to in Article 8(2);
- (b) issues that would lead to a negative opinion of the ethics committee of the Member State concerned.

During the consolidation phase, the reporting Member State shall take due account of the considerations of the other Member States concerned and finalise Part I of the assessment report and shall record how all considerations have been dealt with. The reporting Member State shall submit the final Part I of the assessment report to the sponsor and all other Member States concerned within seven days from the end of the review phase.”

- 5a. Where the clinical trial is a minimal-intervention clinical trial, other Member States concerned may only raise during the review phase considerations referred to in paragraph 5 related to ethical aspects of the draft assessment report.”
- 6. For the purpose of this Chapter, the date on which the final Part I of the assessment report is submitted by the reporting Member State to the sponsor and to the other Member States concerned through the EU portal shall be the reporting date.”
- 7. Between the validation date and the reporting date, only the reporting Member State may request additional information from the sponsor, taking into account the considerations referred to in paragraph 5.

For the purpose of obtaining and reviewing this additional information from the sponsor, the reporting Member State may extend the period referred to in paragraph 4 by maximum of 28 days.

The sponsor shall submit the requested information within the period set by the reporting Member State which shall not exceed 14 days from the receipt of the request.

Upon receipt of the requested additional information, the Member State concerned shall review additional information provided by the sponsor and shall identify and share with the reporting Member State any unaddressed considerations, relevant for the application. The coordinated review shall be performed within maximum 7 days of the receipt of the additional information and the further consolidation shall be performed within maximum seven days of the end of the coordinated review. When finalising Part I of the assessment report, the reporting Member State shall take due account of the considerations of the other Member States concerned and shall record how the considerations have been dealt with.

Where the sponsor does not provide additional information within the period set by the reporting Member State in accordance with the third subparagraph, the application shall be deemed to have lapsed in all Member States concerned.

The request for additional information and additional information shall be submitted through the EU Portal.’

- (6) Article 7 is replaced by the following:

‘Article 7

Assessment report – Aspects covered by Part II of the application dossier

1. Each Member State concerned shall assess, for its own territory, the application with respect to the following aspects. Such assessment shall constitute Part II of the assessment report:
 - (a) compliance with the requirements for informed consent set out in Chapter V;
 - (b) compliance of the arrangements for rewarding or compensating subjects with the requirements set out in Chapter V;
 - (c) compliance of the arrangements for recruitment of subjects with the requirements set out in Chapter V;
 - (d) compliance with Regulation (EU) 2016/679 of the European Parliament and of the Council*;
 - (e) compliance with Article 49;
 - (f) compliance with Article 50;
 - (g) compliance with Article 76;
 - (h) compliance with applicable rules for the collection, storage and future use of biological samples of the subject;
 - (i) accuracy of the translations of the documents and information submitted in Part I of the application dossier, when such documents are required to be submitted in the national language in accordance with Article 26 and 69.
2. Each Member State concerned shall complete the assessment within 42 days from the submission date and submit, through the EU portal, Part II of the assessment report, including its conclusions, to the sponsor.

Each Member State concerned may within the period referred to in this paragraph, and through EU portal, request on duly justified grounds additional information , from the sponsor regarding the aspects covered in paragraph 1 or to request to complement the documentation, required pursuant to Part II of Annex I, if such documentation is missing or documentation provided is not adequate or is incomplete.

The Member State concerned may decide within 28 days of the submission date to rely on the ethical review of the ethics committee of the reporting Member State of the common elements of the application dossier of Part II and inform the sponsor accordingly.

3. Each Member State concerned may extend the assessment period referred to in paragraph 2 by a maximum of 28 days:
 - (a) to requests additional documentation or information, as referred in paragraph 2, from the sponsor regarding Part II of the assessment for its territory;
 - (b) to align with the timeline for the assessment referred to in Article 6, when it has been extended to allow for a request for information by the reporting Member State related to Part I assessment and its review.

The sponsor shall submit the requested additional information and documentation within the period set by the Member State concerned which shall not exceed 14 days from the receipt of the request.

Upon receipt of the additional information and documentation, the Member State concerned shall complete its assessment within maximum of 14 days from the submission of the requested information by the sponsor.

Where the sponsor does not provide additional information and documentation within the period set by the Member State concerned in accordance with this paragraph, the application shall be deemed to have lapsed in that Member State concerned.

* Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 4.5.2016., ELI: <http://data.europa.eu/eli/reg/2016/679/oj>.’

(7) in Article 8, paragraphs 1 and 2 are replaced by the following:

- ‘1. Each Member State concerned shall notify the sponsor through the EU portal and by way of one single decision as to whether the clinical trial is authorised, authorised subject to conditions, or whether authorisation is refused.

The notification shall be made within five days from the reporting date or from the last day of the assessment referred to in Article 7, whichever is later.

2. Where the conclusion of the reporting Member State as regards Part I of the assessment report is that the conduct of the clinical trial is acceptable or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of the Member States concerned.

A clinical trial subject to conditions may start, unless the Member State concerned specified that the condition is suspensive. Unless otherwise specified, a fulfilment of the condition shall not require a submission of a request for a substantial modification.

Notwithstanding the first subparagraph of this paragraph, a Member State concerned may disagree with the conclusion of the reporting Member State as regards Part I of the assessment report only on the following grounds, provided that the corresponding consideration was raised during the process pursuant to Article 6(5) point (b) and the Member State concerned considers that it was not sufficiently addressed:

- (a) participation in the clinical trial would lead to a subject receiving an inferior treatment than in normal clinical practice in the Member State concerned; or
- (b) infringement of its national law as referred to in Article 90.

Where a Member State concerned disagrees with the conclusion, it shall communicate its disagreement, together with a detailed justification, through the EU portal, to the Commission, to all Member States, and to the sponsor.’

- (8) Article 9 is replaced by the following:

‘Article 9

Persons assessing the application

1. Member States shall ensure, including through the institutional safeguards, that persons validating and assessing the application do not have conflicts of interest, are independent of the sponsors, or the clinical trial site and the investigators involved and of persons financing the clinical trial, as well as free of any other undue influence and ensure their sufficient independence in performance of their tasks.

In order to guarantee independency and transparency, the Member States shall ensure that persons validating and assessing the application as regards the aspects covered in Parts I and II of the assessment report have no financial or personal interests which could affect their impartiality. These persons shall make an annual declaration of their financial interest.

2. Member States shall ensure that the assessment is done by persons who collectively have the necessary qualifications and experience.

These persons shall be sufficiently equipped and empowered to perform their tasks.

3. At least one layperson shall participate in the assessment.’

- (9) in Article 10, the following paragraph 6 is added:

- ’6. Where potential subjects of a clinical trial belong to vulnerable populations, Member States concerned and sponsors shall consider and weigh the harms and benefits of their inclusion as opposed to their exclusion from a clinical trial. The Member States concerned and sponsors shall assess in particular whether the exclusion of those subjects from a clinical trial could inadvertently perpetuate or exacerbate their vulnerabilities, particularly in relation to their specific health needs.’

- (10) Article 11 is replaced by the following:

‘Article 11

Submission and assessment of applications limited to aspects covered by Part I of the assessment report

1. Where the sponsor so requests, the application for authorisation of a clinical trial, its assessment and the conclusion shall be limited to the aspects covered by Part I of the assessment report.

After the notification of the conclusion on the aspects covered by Part I of the assessment report, the sponsor may, within two years, apply for an authorisation limited to aspects covered by Part II of the assessment report.

Where the sponsor submits only Part I of the application dossier to all of the Member States concerned, the sponsor shall declare at the time of the first submission of Part II of the application dossier to any of the Member States concerned that the sponsor is not aware of any new substantial scientific information that would change the validity of any item submitted in the application on the aspects covered by Part I of the assessment report. If an update of Part I of the application dossier is necessary, the sponsor shall submit a substantial modification of Part I of the application dossier, at the latest, at the same time as the submission of Part II of the application dossier to at least one of the Member States concerned.

The Part II of the application dossier shall be assessed in accordance with Article 7 and the Member State concerned shall notify the decision on clinical trial in accordance with Article 8.

In those Member States concerned where the sponsor does not apply for an authorisation limited to aspects covered by Part II of the assessment report within two years, the application on the aspects covered by Part I of the assessment report shall be deemed to have lapsed.

2. When the sponsor submits a substantial modification of Part I of the application dossier with regard to clinical trial that is subject to a request referred to in paragraph 1 and has been authorised or authorised subject to conditions by at least one Member State concerned, all Member States concerned that received the initial application shall participate in the assessment of that substantial modification in accordance with Article 18 or 22 as appropriate.'

(11) Article 14 is amended as follows:

- (a) paragraph 1 is replaced by the following:

'1. Where the sponsor wishes to extend an authorised clinical trial to another Member State (additional Member State concerned), the sponsor shall submit an application dossier to that Member State through the EU portal.

The application dossier may be submitted only after the notification date of the first initial authorisation decision by at least one Member State concerned.'

- (b) paragraph 3 is replaced by the following:

'3. The additional Member State concerned shall notify the sponsor, through the EU portal, within 47 days from the date of submission of the application dossier referred to in paragraph 1 of this Article, by way of one single decision as to whether the clinical trial is authorised, whether

it is authorised subject to conditions, or whether the authorisation is refused. Article 8(2), (3), (4) and (5) apply to the decision of the additional Member State concerned.'

(c) paragraph 4 is deleted;

(d) paragraph 5 to 8 are replaced by the following:

'5. Within 42 days following the submission date referred to in paragraph 1, the additional Member State concerned may communicate to the reporting Member State and the other Member States concerned any considerations through the EU portal.'

(e) paragraphs 6, 7 and 8 are replaced by the following:

'6. Between the submission date referred to in paragraph 1 and the expiry of the period referred to in paragraph 3, only the reporting Member State may request additional information from the sponsor concerning the aspects covered in Part I of the assessment report, taking into account the considerations referred to in paragraph 5.

For the purpose of obtaining and reviewing this additional information from the sponsor in accordance with the third and fourth subparagraphs, the reporting Member State may extend the period referred to in the first subparagraph of paragraph 3 by a maximum of 28 days.

The sponsor shall submit the requested additional information within the period set by the reporting Member State, which shall not exceed 14 days from receipt of the request.

Upon receipt of the additional information the reporting Member State, the additional Member State concerned and all other Member States concerned shall review any additional information provided by the sponsor together with the original application and shall share any unaddressed considerations relevant to the application. The coordinated review shall be performed within a maximum of seven days from the receipt of the additional information and the further consolidation shall be performed within a maximum of seven days from the end of the coordinated review. The reporting Member State shall take due account of the considerations of the Member States concerned and shall record how the considerations have been dealt with.

Where the sponsor does not provide additional information within the period set by the reporting Member State in accordance with the third subparagraph, the application shall be deemed to have lapsed in the additional Member State concerned.

The request for additional information and the additional information shall be submitted through the EU portal

7. The additional Member State concerned shall assess, for its territory, the aspects covered in Part II of the assessment report and submit Part II assessment report, including its conclusions, through the EU portal, to the sponsor.

Within period referred to in paragraph 3, additional Member State may request, through the EU portal, with justified reasons, additional

information from the sponsor regarding aspects covered in Part II of the assessment report as far as its territory is concerned.’

8. For the purpose of obtaining and reviewing the additional information referred to in paragraph 6 or 7 the additional Member State concerned may extend the period referred to in paragraph 5 by maximum of 28 days.

The sponsor shall submit the requested additional information within the period set by the additional Member State concerned, which shall not exceed 14 days from the receipt of the request.

Upon receipt of the additional information, the Member State concerned shall complete its assessment within a maximum of 14 days.

Where the sponsor does not provide additional information within the period set by the additional Member State concerned in accordance with second subparagraph, the application shall be deemed to have lapsed in the additional Member State concerned.’

(f) paragraphs 9 and 10 are deleted;

(g) paragraphs 11 and 12 are replaced by the following:

‘11. Where the additional Member State concerned has not notified the sponsor of its decision within the period referred to in paragraph 3, or in case that period has been extended in accordance with paragraph 6 or 8 and where that additional Member State concerned has not notified the sponsor of its decision within the extended period, the conclusion on Part I of the assessment report shall be deemed to be the decision of that additional Member State concerned on the application for authorisation of the clinical trial.’

12. A sponsor shall not submit an application dossier in accordance with this Article where a procedure for a substantial modification of Part I of the assessment report, set out in Chapter III, is pending as regards that clinical trial.’

(12) the following Article 14a is inserted:

‘Article 14a

Appointment of a new reporting Member State

1. The reporting Member State may initiate the procedure for an appointment of a new reporting Member State if:
 - (a) the reporting Member State has notified its decision refusing the authorisation of the clinical trial; or
 - (b) the clinical trial is no longer taking place in the reporting Member State.
2. The procedure can only be launched after the clinical trial has been authorised in at least one Member State concerned.
3. The reporting Member State shall notify the sponsor and other Member States concerned of its intention to cease to be a reporting Member State.

4. The Member States concerned shall declare their willingness to become new reporting Member State. The selection of new reporting Member State shall follow the rules established Article 5a (4) and (5).
5. Following the initiation of the procedure for the appointment of a new reporting Member State, the initial reporting Member State shall continue to carry out its tasks until all of the ongoing assessments and records are completed and the respective final assessment reports are submitted to the EU portal.
6. The new reporting Member State shall become responsible for the assessment of any application related to Part I of the assessment report, including an application based on Article 14, that has been submitted after it has been notified as the reporting Member State to the sponsor and all Member States concerned by the EU portal.'

(13) the following Chapter IIa is inserted:

‘Chapter IIa

SPECIAL AUTHORISATION PROCEDURES

Article 14b

Accelerated procedure for the authorisation of multinational clinical trials in the context of public health emergencies

1. During a recognised public health emergency at Union level pursuant to Article 23 of Regulation (EU) 2022/2371 of the European Parliament and of the Council, Member States shall apply an accelerated procedure for the authorisation of multinational clinical trials for medicinal products intended for the treatment, prevention or medical diagnosis of the disease or condition which are directly related to the public health emergency.
2. To address an emergence or development of a serious cross-border threat to health as defined in Article 3(1) of Regulation 2022/2371 that is likely to lead to the recognition of a public health emergency at Union level in accordance with Article 23(1) of Regulation (EU) 2022/2371, Member States shall apply an accelerated procedure for the authorisation of multinational clinical trials when this procedure is declared applicable in accordance with the criteria in paragraph 3 of this Article. The application of the accelerated procedure shall ensure the availability of medicinal products in order to prevent or swiftly contain the emerging serious cross-border health threat, to provide timely treatment options grounded in scientifically robust evidence or to facilitate medical diagnosis of the disease or condition directly related to the specific serious cross-border health threat.
3. The Commission shall, by means of implementing acts, lay down the detailed criteria and the processes for declaring applicability of the accelerated authorisation procedure to address an emergence or development of serious cross-border threat to health that is likely to lead to the recognition of a public health emergency at Union level in accordance with Article 23 (1) of Regulation (EU) 2022/2371, .

The criteria for declaring applicability of an accelerated authorisation procedure shall at least include the epidemiological situation and its dynamics

as well as the availability of treatment, prevention and diagnostics options addressing the emerging serious cross-border threat to health. The process of declaring applicability of the accelerated authorisation procedure shall involve consultations with relevant Union agencies, expert groups and advisory bodies in the field of public health and clinical trials.

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 88.

4. When submitting the application for the clinical trial authorisation during a public health emergency as referred to in paragraph 1 or when the accelerated procedure referred to in paragraph 2 is declared applicable to address an emerging serious cross-border health threat, pursuant to the procedure referred to in paragraph 3, the sponsor shall indicate whether the investigational medicinal products are intended for the treatment, prevention or medical diagnosis of a disease or a condition directly related to the specific serious cross-border threat to health. The reporting Member State shall confirm whether the accelerated procedure is applicable to the clinical trial application.
5. The Commission shall adopt delegated acts in accordance with Article 89 to supplement this Regulation by setting out the procedures for an accelerated authorisation of multinational clinical trials, including timelines, criteria for evaluating whether a clinical trial qualifies for an accelerated procedure and an integrated ethical review, and by laying down simplified requirements for the application dossier.

Article 14c

Combined studies

1. This Article applies to combined studies in which a clinical trial is combined with a performance study of an *in vitro* diagnostic medical device that is subject to authorisation pursuant to Article 58(1) of Regulation (EU) 2017/746, or is combined with a clinical investigation of a medical device that is subject to authorisation according to Article 62 of Regulation (EU) 2017/745.
2. By way of derogation from Article 5, the sponsor of a combined study referred to in paragraph 1, which is to be conducted in one or more Member States, may submit a single application for authorisation.
3. The single application referred to in paragraph 2 shall be submitted electronically through the EU Portal to all Member States in which the combined study is to be conducted ('Member States concerned'). Where a combined study has more than one sponsor, the sponsors shall designate one coordinating sponsor.
4. The Member States concerned shall assess the single application by means of a coordinated assessment procedure under the direction of a reporting Member State chosen from among the Member States concerned. If a combined study involves only one Member State, that Member State shall be the reporting Member State.
5. The coordinated assessment procedure shall include the assessment by the competent authorities and review by ethics committees. During the assessment

procedure, the Member States concerned may only raise considerations related to the following:

- (a) the grounds referred to in Article 14a(5) of this Regulation, Article 78(8) of Regulation (EU) 2017/746 or Article 74(8) of Regulation (EU) 2017/745; or
 - (b) issues that would lead to ethics committee of the Member State concerned issuing a negative opinion.
6. Where the conclusion of the reporting Member State as regards the area of coordinated assessment is that the conduct of the combined study is acceptable, or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of all Member States concerned.

Notwithstanding the first subparagraph of this paragraph, a Member State concerned may disagree with the conclusion of the reporting Member State concerning the area of coordinated assessment but only on one of the following grounds, provided that the corresponding consideration was raised during the assessment process and the Member State concerned has substantiated comments that were not sufficiently addressed:

- (a) participation in the combined study would lead to a subject receiving an inferior treatment than in normal clinical practice in the Member State concerned;
 - (b) infringement of its national law;
 - (c) with regard to the assessment of the medical device or in vitro medical device, grounds referred to in Article 78(8) of Regulation 2017/746 or Article 74(8) of Regulation (EU) 2017/745, respectively
7. Where a Member State concerned disagrees with the conclusion on the basis of paragraph 5, it shall communicate its disagreement, together with a detailed justification, through the EU Portal, to the Commission, to all other Member States concerned, and to the coordinating sponsor referred to in paragraph 2.
8. Each Member State concerned shall issue a single decision as to whether the combined study is authorised, whether it is authorised subject to conditions, or whether authorisation is refused and shall notify the coordinating sponsor referred to in paragraph 2.
9. The Commission shall, by means of a delegated act in accordance with Article 89, amend or supplement, as necessary, the provisions of Chapters II to V, VII, XIII, XIV and XVI and Articles 71 and 72 of this Regulation in order to:
- (a) enable a streamlined procedure for an authorisation of combined studies, including the coordinated assessment of initial applications, coordinated assessment of the request for substantial modifications and additions of Member State concerned;
 - (b) set the requirements applicable during the conduct of the combined studies, including as regards to the specific safety reporting requirements;
 - (a) clarify the responsibilities of the combined studies' sponsors and investigators;
 - (b) ensure supervision;

- (c) determine the functionalities of the EU portal and EU database necessary to support application of this Article.
- 10. When doing so, the Commission shall take into consideration, where relevant, provisions of Chapter VI and Annex XV of Regulation (EU) 2017/745 or Chapter VI and Annexes XIII and XIV of Regulation (EU) 2017/746 concerning the investigational device(s) or device(s) for performance study which are covered by the combined study, as applicable.

Article 14d

Persons assessing the applications

Article 9 applies to assessments made under this Chapter.’

- (14) Article 16 is replaced by the following:

‘Article 16

Submission of application

In order to obtain an authorisation, the sponsor shall submit an application dossier to the Member States concerned through the EU portal. The date on which the sponsor submitted the application for an authorisation of a substantial modification is referred to within this Chapter as the submission date.’;

- (15) the following Article 16a is inserted:

‘Article 16a

Parallel substantial modification

1. The sponsor may submit to the reporting Member State, through the EU portal, an application for a parallel substantial modification regarding aspects covered by Part I of the assessment report, prior to the notification of a decision on an ongoing assessment of a substantial modification in accordance with Article 19(1) or Article 23(1).
2. The sponsor may submit to the same Member State concerned, through the EU portal, an application for a parallel substantial modification of an aspect covered by Part II of the assessment report prior to the notification of a decision on an ongoing assessment of a substantial modification in accordance with Article 20(5) or Article 23(1) by the same Member State concerned.
3. The reporting Member State or Member state concerned, as applicable, shall accept the application for a parallel substantial modification if the parallel substantial modification concerns distinct and independent aspects of the application dossier and may be assessed concurrently by the same Member State concerned or reporting Member State.
4. When scope of the application for the parallel substantial modification covers both Part I and Part II of the assessment report, the sponsor shall seek the agreement of both, the reporting Member State and the relevant Member States concerned. The relevant Member State concerned may oppose the agreement if the substantial modification concerns aspects of Part II covered by an ongoing assessment.’

(16) Article 17 is amended as follows:

(a) paragraphs 1 and 2 are replaced by the following:

- ‘1. The reporting Member State for the authorisation of the substantial modification shall be the reporting Member State for the initial authorisation procedure.
2. Within four days from the submission date, the reporting Member State shall validate the application and notify the sponsor through the EU portal as to whether:
 - (a) the substantial modification concerns an aspect covered by Part I of the assessment report;
 - (b) the application dossier is complete in accordance with Annex II; and
 - (c) in case of parallel substantial modification to Part I, whether such a parallel substantial modification is acceptable taking into account the requirements of Article 16a.

When applicable, in the context of a substantial modification of Part I, the Member State concerned shall verify whether the translation or translations in the national language or languages in accordance with the requirements of Articles 26 and 69 has or have been submitted as a substantial modification of Part II. Article 21 applies to the assessment of the accuracy of translations.’

(b) paragraph 4 is replaced by the following:

- ‘4. Where the reporting Member State finds that the application does not concern an aspect covered by Part I of the assessment report or that the application dossier is not complete or, where applicable, that the parallel substantial modification is not acceptable, it shall inform the sponsor thereof through the EU portal and shall set a maximum of four days for the sponsor to comment on the application of to complete the application dossier through the EU portal.

The reporting Member State shall notify the sponsor within 14 days from the submission date, as to whether or not the application complies with the requirements set out in paragraph 2, points (a), (b), and when applicable point (c).

Where the reporting Member State has not notified the sponsor within the period referred to in the second subparagraph, the substantial modification applied for shall be deemed to concern an aspect covered by Part I of the assessment report, the application dossier shall be deemed to be complete and, when applicable, the parallel substantial modification shall be deemed to be acceptable taking into account the requirements of Article 16a.

Where the sponsor has not provided comments or completed the application dossier within the period referred to in the first subparagraph, the application shall be deemed to have lapsed in all the Member States concerned.’

(17) Article 18 is amended as follows:

(a) paragraphs 3 and 4 are replaced by the following:

‘3. The reporting Member State shall submit, through the EU portal, the final assessment report including its conclusions, to the sponsor and to the other Member States concerned within 28 days from the submission date.

For the purpose of this Article and of Articles 19 and 23, the reporting date shall be the date on which the final assessment report is submitted to the sponsor and the other Member States concerned.

4. For clinical trials involving more than one Member State the assessment process of substantial modification shall include three phases:

- (a) an assessment phase performed by the reporting Member State within 21 days from the submission date. The assessment phase shall end when the reporting Member State circulates the draft assessment report;
- (b) a review phase performed within three days from the end of the assessment phase, involving all the Member States concerned, and;
- (c) a coordination phase performed within four days from the end of the review phase.

During the assessment phase, the reporting Member State shall develop a draft assessment report and circulate it to all the Member States concerned.

During the review phase, all Member States concerned shall review the application on the basis of the draft assessment report and shall share considerations for their Member State that are relevant to the application.

Considerations may only be raised on:

- one or more grounds referred to in Article 19(2) of this Regulation.
- on matters that would lead the ethics committee issuing negative opinion.

During the consolidation phase, the reporting Member State shall take due account of the considerations of the other Member States concerned when finalizing the assessment report and shall record how the considerations have been addressed. The reporting Member State shall submit the final assessment report to the sponsor and all the other Member States concerned by the reporting date.’

(b) paragraph 5 is deleted;

(c) paragraph 6 is replaced by the following:

‘6. Between the validation date and the reporting date, only the reporting Member State may request additional information from the sponsor, taking into account the considerations referred to in paragraph 4.

For the purpose of obtaining and reviewing this additional information from the sponsor in accordance with the third and fourth subparagraph, the reporting Member State may extend the period referred to in the first subparagraph of paragraph 3 by a maximum of 14 days.

The sponsor shall submit the requested additional information within the period set by the reporting Member State. This period shall not extend beyond seven days from the receipt of the request.

Upon receipt of the additional information, the Member States concerned shall review any additional information provided by the sponsor and shall share any unaddressed considerations relevant to the application. The review shall be performed within a maximum of three days from the receipt of the additional information and further consolidation shall be performed within a maximum of seven days from the receipt of additional information from the sponsor. When finalising the assessment report, the reporting Member State shall take due account of the considerations of the other Member States concerned and shall record how the considerations have been dealt with.’;

(18) Article 19 is amended as follows:

(a) paragraphs 1 and 2 are replaced by the following:

- ‘1. Each Member State concerned shall notify the sponsor through the EU portal as to whether the substantial modification is authorised, whether it is authorised subject to conditions, or whether authorisation is refused.

Notification shall be done by way of a single decision within five days from the reporting date.

Where the conclusion of the reporting Member State is that the substantial modification is acceptable or acceptable subject to compliance with specific conditions, that conclusions shall be deemed to be the conclusions of the Member State concerned.

A substantial modification subject to condition may be implemented unless the Member State concerned specified that the condition is suspensive. Unless otherwise specified, the fulfilment of the condition does not require a submission of a request for another substantial modification.

Notwithstanding the first subparagraph, a Member State concerned may disagree with that conclusion of the reporting Member State only on the following grounds, provided that the consideration was raised during the process pursuant to Article 18(4) and it considers that it was not sufficiently addressed:

- (a) when it considers that participation in the clinical trial would lead to a subject receiving an inferior treatment than in normal clinical practice in the Member State concerned;
 - (b) infringement of its national law as referred to in article 90.
2. Where the Member State concerned disagrees with the conclusion on the basis of the second subparagraph, it shall communicate its disagreement, together with a detailed justification, through the EU portal, to the Commission, to all Member States and to the sponsor.

A Member State concerned shall refuse to authorise a substantial modification if it disagrees with the conclusion of the reporting Member State as regards Part I of the assessment report on any of the grounds

referred to in the second paragraph or where an ethics committee has issued a negative opinion which, in accordance with the law of that Member State concerned, is valid for the entire Member State. That Member State shall provide for an appeal procedure in respect of such refusal.’

(19) Article 20 is amended as follows:

(a) paragraphs 1 and 2 are replaced by the following:

‘1. Within four days from the submission of the application dossier, the Member State concerned shall notify the sponsor through the EU portal of the following:

- (a) whether the substantial modification concerns an aspect covered by Part II of the assessment report;
- (b) whether the application dossier is complete in accordance with Annex II;
- (c) in case of parallel modification to Part I, whether the submission is acceptable taking into account the requirements of Article 16a.

‘2. Where the Member State concerned has not notified the sponsor within the period referred to in paragraph 1, the substantial modification applied for shall be deemed to concern an aspect covered by Part II of the assessment report and the application dossier shall be deemed to be complete and, when applicable, the parallel substantial modification shall be deemed to be acceptable taking into account the requirements of Article 16a.’

(b) in paragraph 3, the two first subparagraphs are replaced by the following:

‘Where the Member State concerned finds that the substantial modification does not concern an aspect covered by Part II of the assessment report or that the application dossier is not complete, or, where applicable, that the parallel substantial modification is not acceptable, it shall inform the sponsor thereof through the EU portal and shall set a maximum of five days for the sponsor to comment on the application or to complete the application dossier through the EU portal.

Within 14 days from the submission date the reporting Member State shall notify the sponsor as to whether or not the application complies with the requirements set out in paragraph 1 points (a), (b), and if applicable, (c).’

(c) in paragraph 5, the second and third subparagraphs are replaced by the following:

‘Notification shall be done by way of a single decision within 28 days from the submission date.

A substantial modification subject to condition may be implemented unless the Member State concerned specified that the condition is suspensive. Unless otherwise specified, a fulfilment of the condition does not require a submission of a request for another substantial modification.’

(d) in paragraph 6, the second, third and fourth subparagraphs are replaced by the following:

‘For the purpose of obtaining and reviewing this additional information from the sponsor, the Member State concerned may extend the period referred to in the paragraph 5, second subparagraph, by a maximum of 14 days.

The sponsor shall submit the requested additional information within the period set by the Member State concerned, which shall not exceed seven days from the receipt of the request.

Upon receipt of the additional information, the Member State concerned shall complete its assessment within a maximum seven days.’;

(20) in Article 21, paragraph 1 is replaced by the following:

‘1. Where a substantial modification relates to aspects covered by Parts I and II of the assessment report, the application for an authorisation of that substantial modification shall be validated in accordance with Articles 17 and 20.’;

(21) Article 22 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. Each Member State concerned shall assess, for its own territory, the aspects of the substantial modification which are covered by Part II of the assessment report and submit, through the EU portal, that report, including its conclusion, to the sponsor within 28 days from the submission date. If the reporting Member State requested additional information regarding aspects covered by Part I of the assessment report as per Article 21(2) in conjunction with Article 18(6), or when a Member State concerned requests additional information from the sponsor regarding Part II aspects of the application, Member States concerned may extend this period by 14 days.’

(b) paragraph 2 is deleted;

(c) paragraph 3 is replaced by the following:

‘3. The sponsor shall submit the requested additional information within the period set by the Member State concerned, which shall not exceed seven days from the receipt of the request.

Upon receipt of the additional information, the Member State concerned shall complete its assessment within a maximum of seven days from the submission of the requested information by the sponsor.

Where the sponsor does not provide the requested additional information within the period set by the Member State concerned the application shall be deemed to have lapsed in that Member State.

The request for additional information and the additional information shall be submitted through the EU portal.’

(22) Article 23 is amended as follows:

(a) in paragraph 1, the third subparagraph is replaced by the following:

‘A substantial modification subject to condition may be implemented unless the Member State concerned specified that the condition is suspensive. Unless otherwise specified, a fulfilment of the condition does not require a submission of a request for another substantial modification.’

- (b) in paragraph 2, the second subparagraph, is replaced by the following:

‘Notwithstanding the first subparagraph, a Member State concerned may disagree with the conclusion of the reporting Member State only on the following grounds, provided that the consideration was raised during the process pursuant to Article 18(4) and it considers that it was not sufficiently addressed:

 - (a) when it considers that participation in the clinical trial would lead to a subject receiving an inferior treatment than in normal clinical practice in the Member State concerned;
 - (b) infringement of its national law as referred to in Article 90.’
- (23) Article 25 is amended as follows:
- (a) paragraph 1 is amended as follows:
 - (i) in the first subparagraph, point (e) is replaced by the following:

‘(e) justification as to why the clinical trial is a minimal-intervention or low-intervention clinical trial, in cases where this is claimed by the sponsor.’;
 - (ii) the second subparagraph is replaced by the following:

‘The list of required documentation and information for Part I is set out in Part I of Annex I. The list of required documentation for Part II is set out in Part II of Annex I.’;
 - (b) the following paragraphs 1a, 1b and 1c are inserted:

‘1a. The requirements for Part I may be adapted for minimal-intervention or low-intervention clinical trials.’

‘1b. The sponsor shall use harmonised templates, where such templates are available, for the submission of documents for Part II of the application dossier necessary for the authorisation of the clinical trial, in accordance with the requirements described in Article 7(1) of this Regulation.

1c. To draw up and update, when necessary, harmonised templates to be used by sponsors, the Commission shall be empowered to adopt implementing acts in accordance with Article 88. The harmonised templates may include standardised sections for documents referred to in Article 7(2) and in Annex I.’
 - (c) the following paragraph 2a is inserted:

‘2a. The requirements referred to in paragraph 2 may be adapted for minimal-intervention and low-intervention clinical trials.’
 - (d) the following paragraphs 8 and 9 are added:

‘8. An application dossier for an authorisation of a clinical trial or for an authorisation of a substantial modification may rely on health data accessed under Chapter IV of Regulation (EU) 2025/327 of the European Parliament and of the Council*

9. National competent authorities and ethics committees shall ensure that the persons validating or assessing the initial application and substantial

modification requests only documents which are listed in Part I and Part II of Annex I and Annex II.’

- * Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (OJ L, 2025/327, 5.3.2025. ELI: <http://data.europa.eu/eli/reg/2025/327/oj>).

(24) the following Chapters IVa and IVb are inserted:

‘Chapter IVa

INVESTIGATIONAL MEDICINAL PRODUCT CORE DOSSIER

Article 27a

Establishment of an investigational medicinal product core dossier

1. At the time of submission of a clinical trial application referred to in Articles 5 and 11 the sponsor may request through the EU portal the establishment of an investigational medicinal product core dossier. To this end, the sponsor shall provide data and information referred to in point (Ga) of Part I of Annex I.
2. The sponsor shall submit the request for the establishment of the investigational medicinal product core dossier to all Member States concerned of the initial trial. The sponsor may extend this request to other Member States than the Member States concerned. The reporting Member State of the initial clinical trial shall become the depositary Member State.
3. The depositary Member State shall verify the completeness and suitability of the core dossier for the purposes of the initial clinical trial. At the latest by the time when the conclusion of the assessment of Part I is due in accordance with Article 6(3) the depositary Member State shall notify the sponsor and the other core dossier competent Member States through the EU portal of the establishment of the investigational medicinal products core dossier where the assessment is positive.
4. The investigational product core dossier shall be relied upon by the reporting Member State and the Member States concerned in the process of authorising the initial clinical trial referred to in paragraph 1.
5. Once established, the investigational medicinal product core dossier shall be referred to in all subsequent applications concerning the clinical trial in the context of which the investigational medicinal products core dossier was established and any other corresponding clinical trial.

Article 27b

Maintenance and changes of the investigational medicinal products core dossier

1. The sponsor shall keep the investigational medicinal product core dossier updated and shall review it at least once per year. When the sponsor identifies a necessity to update the investigational products core dossier, paragraph 2 applies.

2. When new information, relevant to maintain the suitability and completeness of an established investigational product core dossier becomes known to the sponsor, the sponsor shall submit to the depositary Member State, through the EU portal, a request for a change of the investigational medicinal product core dossier.
3. In case of a new application for an authorisation of a new corresponding clinical trial, the reporting Member State of that clinical trial together with the depositary Member State shall assess the suitability of the investigational product core dossier for the purpose of the authorisation of the trial application, that is;
 - (a) whether the investigational product core dossier is complete as regards the information on the characteristics and knowledge about the investigational medicinal products;
 - (b) if appropriate, the compliance with the requirements concerning the manufacturing and import of investigational medicinal products set out in Chapter IX;
 - (c) whether the investigator's brochure and the IMPD is adequate and complete for the scope of use as proposed by the sponsor in the application in accordance point Ga, Part I of Annex I.

The reporting Member State of the corresponding clinical trial shall communicate the results of its assessment to the depositary Member State.

If the investigational product core dossier does not contain all the information necessary for the authorisation of the clinical trial, the reporting Member State may request the sponsor to change the investigational product core dossier.

The sponsor shall in such situations request a change of the investigational medicinal product core dossier in accordance with paragraph 2.

4. After receiving the request for a change to the core dossier, independently of whether a change is submitted in the context of an assessment of an application related to a corresponding clinical trial or independently, the depositary Member State shall verify whether the core dossier, once changed, will continue to fulfil the requirements listed in paragraph 3 points (a), (b) and (c). The Member State concerned with the core dossier shall not duplicate the assessment of the depositary Member State. The depositary Member State may consult the Member State concerned as appropriate.
5. If a request for a core dossier change is submitted in the context of an ongoing assessment related to a corresponding clinical trial, the timeline for change of the core dossier shall allow for timely approval of the clinical trial.
6. The sponsor shall assess whether a change to the investigational product core dossier makes it necessary to submit a substantial modification in corresponding clinical trials that are ongoing.

Article 27c

Procedural aspects related to the establishment and maintenance of the investigational medicinal products core dossier

The Commission shall set out the detailed rules governing the submission of a request for the establishment of an investigational product core dossier, its assessment and maintenance by means of implementing acts, including the rules for cooperation between the core dossier competent Member States and the change of depositary Member State. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88.”

Chapter IVb

REGULATORY SANDBOXES AND USE OF AI

Article 27d

Regulatory sandbox

1. The Commission may, pursuant to the procedure set out in paragraph 7, establish and operate a regulatory sandbox at Union level that provides a controlled and time-limited framework to enable, under real-world conditions, the testing of innovative approaches in clinical trials to which the full application of certain requirements of this Regulation is not possible or appropriate and which therefore may require adaptations.
2. The regulatory sandbox under this Regulation may encompass approaches to the authorisation and conduct of the clinical trials and where appropriate, maybe be implemented in coordination and synergies with the regulatory sandboxes established pursuant to Regulation (EU) 2024/1689 with full involvement of competent authorities supervising the sandbox under Regulation (EU) 2024/1689 and in accordance with the relevant procedures and rules for participating in those AI regulatory sandboxes.
3. The activities within a regulatory sandbox shall take place pursuant to a specific plan, for eligible clinical trials, which may be conducted under enhanced regulatory oversight of the Member States concerned. The plan shall clearly identify the requirements of this Regulation that are temporarily adapted or derogated from in the sandbox and that may relate to, as necessary, to source data and documentation requirements, recruitment and informed consent procedures, monitoring and reporting requirements, trial design rules, investigational medicines handling rules, safety reporting rules, site requirements. The plan shall also identify the roles and responsibilities of sponsors, investigators, and manufacturers.
4. A regulatory sandbox may be established only if the following conditions are met:
 - (a) it is not possible to authorise or conduct a clinical trial in full compliance with the requirements of this Regulation due to innovative approaches in the clinical trial or due to the specificity of the investigational medicinal product;
 - (b) the approaches referred to in point (a) are expected to contribute to at least one of the following objectives:
 - (i) increasing the robustness of the data generated in the trial;

- (ii) considerably decreasing clinical trial length, and increasing the efficiency of the clinical trial;
 - (iii) enabling new technologies and approaches in the development of medicinal products that have the potential to positively and distinctively contribute to better prevention, diagnosis, and treatment, as well as increase adherence to treatment plans or improve the efficiency of the provision of health care;
 - (c) the sandbox provides safeguards to ensure the safety, well-being, and fundamental rights of clinical trial participants, data robustness, and maintained integrity of the clinical trials within the sandbox.
5. The regulatory sandbox shall not affect the supervisory or corrective powers of the Member States concerned and shall operate under the direct supervision of the competent authorities in the Member State concerned for activities that take place on its territory.
 6. Before setting up a sandbox, the Commission shall request an opinion of the CTAG.
 7. The Commission may establish a regulatory sandbox by means of implementing acts, after taking into consideration opinions referred to in paragraph 6. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88.
 8. Member States shall notify the Commission of any risk to health and safety or fundamental rights or integrity and robustness of data identified during the operation of a sandbox. In these cases, the Commission may, by means of implementing acts, suspend or revoke a regulatory sandbox.
 8. Without prejudice to Article 114(1) of [Regulation (EU) .../... of the European Parliament and the Council *[reference to be added after adoption cf. COM(2023) 193 final]*, where in the context of a regulatory sandbox under Article 113 of Regulation (EU) .../... of the European Parliament and the Council *[reference to be added after adoption cf. COM(2023) 193 final]* is considered that new regulatory approaches in clinical trial are necessary for the product development, the Commission may consider to establish a regulatory sandbox under this Regulation to complement the regulatory sandbox established under Regulation (EU) .../... of the European Parliament and the Council *[reference to be added after adoption cf. COM(2023) 193 final]*.

Article 27e

Use of Artificial Intelligence in Clinical Trials

1. For those clinical trials where the sponsor plan to use AI models or systems, the sponsor shall evaluate the benefits and risks related to patient safety and data robustness of the use of the AI in the context of a specific clinical trial for a specific purpose taking into account the guidelines laid down in Article 37 of Regulation [...] [Biotech Act].
2. The sponsor shall provide information in the protocol on the specific purpose of the use of AI models or systems and the description of the process in the context of the specific clinical trial.

3. When the investigation of a medicinal product in a clinical trial is combined with a performance study of an AI in vitro diagnostic medical device or a clinical investigation of an AI medical device, the provisions of Article 14 on coordinated assessment for authorising combined studies shall apply.
4. In cooperation with the CTAG and, where appropriate, the Medical Device Coordination Group, the Artificial Intelligence Board, the Agency shall develop guidelines referred to in paragraph 1 of this Article.

**** Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006, COM/2023/193final**

(25) Article 28 is amended as follows:

- (a) paragraph 2 is deleted.
- (b) in paragraph 3, the last sentence is deleted.

(26) in Article 29(1), the following subparagraph is added:

‘The communication in the context of an interview between the investigator and the subject or the investigator and the subject and its legally designated representative, as applicable, may be done remotely through use of electronic means. The record of the informed consent procedure may have an electronic form and shall be signed relying on electronic identification means complying with Regulation (EU) No 910/2014 of the European Parliament and of the Council* or the equivalent standards.

* Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC, OJ L 257, 28.8.2014.ELI: <http://data.europa.eu/eli/reg/2014/910/oj>.”

(27) in Article 30(3), point (c) is replaced by the following:

‘(c) the clinical trial is a minimal-intervention clinical trial;’

(28) in Article 31(1), point (e) is deleted;

(29) in Article 32 (1), point (e) is deleted;

(30) in Article 33, the following second paragraph is inserted:

‘Women who become pregnant or begin breastfeeding while participating in a clinical trial shall not be automatically excluded from participation in the clinical trial.’

(31) in Article 41, the following paragraph 5 is added:

‘5. Reporting requirements of adverse events and serious adverse events for minimal-intervention and low-intervention clinical trials shall be simplified by

applying a risk-based approach. Any such adaptation should be clearly stated and justified in the protocol by the sponsor.:

- (32) in Article 48, point (a) is replaced by the following:
‘(a) whether the clinical trial is a minimal-intervention or low-intervention clinical trial;’;
- (33) the following Article 50a is inserted:

‘Article 50a

Delivery of investigational and auxiliary medicinal products through a dispensing pharmacy, an authorised person or directly to the subject

When justified in the protocol, the delivery of investigational medicinal products and auxiliary medicinal products to the clinical trials subjects may be ensured at a distance under the supervision of the investigator.

In case of a minimal-intervention and a low-intervention clinical trial, the distribution of the investigational medicinal products can be ensured in a Member State where the clinical trial has been authorised, under the responsibility of the investigator, through the dispensing pharmacies or by persons authorised to supply medicinal products to the subject.

The protocol and investigator’s brochure shall describe the arrangements for direct delivery to subjects or through dispensing pharmacies or persons authorised to supply to the patients, including the roles and responsibilities of all parties involved and procedures for secure handling, storage.

The direct delivery to subjects shall comply with the guidelines referred to in paragraph 1 of Article 63a.’:

- (34) in Article 51(1), first subparagraph is replaced by the following:
‘Investigational medicinal products shall be traceable. They shall be stored, returned and/or destroyed as appropriate and proportionate to ensure the safety of the subject and the reliability and robustness of the data generated in the clinical trial, in particular, taking into account whether the investigational medicinal product is an authorised investigational medicinal product, and whether the clinical trial is a minimal-intervention or low-intervention clinical trial.’;
- (35) in Article 53(2), the first sentence is replaced by the following:
‘The sponsor shall submit to the Member States concerned, through the EU portal, inspection reports of third country authorities concerning the clinical trial and relevant to subject safety.’
- (36) in Article 57, the first subparagraph is replaced by the following:
‘The sponsor and the investigator shall keep a clinical trial master file. The clinical trial master file shall at all times contain the essential documents relating to that clinical trial which allow verification of the conduct of a clinical trial and the quality of the data generated, taking into account all characteristics of the clinical trial, including in particular whether the clinical trial is a minimal-intervention or low-intervention clinical trial.’;
- (37) Article 61 is amended as follows:

- (a) paragraph 6 is replaced by the following:
- ‘6. Member States shall make the processes set out in paragraph 5 subject to appropriate and proportionate requirements to ensure subject safety and reliability and robustness of the data generated in the clinical trial while taking into account the guidelines referred to in paragraph 7. They shall subject the processes to regular inspections.’;
- (b) the following paragraph 7 is added:
- ‘7. The inspection working groups referred to in Article 142, point (k) of Regulation (EU) .../... of the European Parliament and the Council [*reference to be added after adoption cf. COM(2023) 193 final*]*, in agreement with the Commission, may draw up guidelines on general principles applicable to the processes set out in paragraph 5, including for auxiliary medicinal products, and revise them as necessary in order to take account of technical and scientific progress.

*Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006, COM/2023/193final.’

- (38) in Article 63, paragraph 4 is replaced by the following:
- ‘4. The Member States shall ensure compliance with the requirements of this Article by means of inspections. Articles 188, with exception of its paragraph 3 and 4, and 189 of Directive (EU) .../... [*reference to be added after adoption cf. COM(2023) 192 final*]* and article 52 of Regulation (EU) .../... of the European Parliament and the Council [*reference to be added after adoption cf. COM(2023) 193 final*]** apply mutatis mutandis.

* Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC COM/2023/192final

** Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006, COM/2023/193final’

- (39) the following Article 63a is inserted:

‘Article 63a
Distribution

1. The distribution of investigational medicinal shall comply with standards that shall ensure their quality and integrity. The Commission shall adopt delegated acts supplementing this Regulation by determining the standards of good distribution practices for investigational and auxiliary medicinal products taking into account the input of the inspection working groups referred to in Article 142, point (k) of Regulation (EU) .../... of the European Parliament and the Council [*reference to be added after adoption cf. COM(2023) 193 final*], and update them if necessary to take account of scientific and technical progress.
 2. Where the competent authority of the Member State considers it necessary, in particular where there are grounds for suspecting non-compliance with the requirements of this Article, it may carry out inspections to verify the compliance.
 3. Arrangements for inspections referred to in Article 63(1) apply mutatis mutandis to inspections of good distribution practices for investigational and auxiliary medicinal products.’;
- (40) in Article 76, paragraph 3 is replaced by the following:
- ‘3. Member States shall not require any additional use of the system referred to in paragraph 1 from the sponsor for minimal or low-intervention clinical trials, if any possible damage that could be suffered by a subject resulting from the use of the investigational medicinal product in accordance with the protocol of that specific clinical trial on the territory of that Member State is covered by the applicable compensation system already in place.’;
- (41) Article 78 is amended as follows:
- (a) paragraph 1 is replaced by the following:
- ‘1. The national competent authorities shall organize inspections in order to supervise compliance with this Regulation.
- Member States shall appoint inspectors to perform the inspections in order to supervise compliance with this Regulation.
- The competent authority of the Member State shall have in place a system of supervision that shall include the following measures:
- (a) announced, and where appropriate, unannounced on-site inspections;
 - (b) remote inspections conducted where justified;
 - (c) compliance control;
 - (d) the effective follow up of the measures referred to in points (a), (b) and (c).’;

(b) paragraph 6 is replaced by the following:

“6. Following an inspection, the Member State under whose responsibility the inspection has been conducted, shall draw up an inspection report. That Member State shall make the inspection report available to the inspected entity and the sponsor of the relevant clinical trial and shall submit the inspection report through the EU portal within 90 days after conducting the inspection.”;

(c) paragraphs 8, 9 and 10 are added:

- ‘8. Upon a request by one or more competent authorities of the Member State, the inspection referred to in paragraph 1 may be carried out jointly by the inspectors from more than one Member State and the inspectors from the Agency.
- 9. Member States may delegate to another Member State or the Agency the conduct of a good clinical practice inspection. The Commission may adopt a delegated act in accordance with Article 89 to supplement this Regulation by laying down the procedures applicable to joint inspections and delegation of inspections.
- 10. This Article does not apply to the good manufacturing practice inspections and the good distribution practices inspections related to application of this Regulation, in accordance with Articles 63 and 63a respectively.’;

(42) Article 79 is replaced by the following:

Article 79

Union controls

- 1. The Commission may conduct controls in order to verify:
 - (a) whether the Member States correctly supervise compliance with this Regulation;
 - (b) whether regulatory system applicable to clinical trials conducted outside the Union ensures that the clinical trials references in the applications for marketing authorisations in the Union are designed, implemented and reported on what good clinical practice and ethical principle are concerned, on the basis of principles that are equivalent to the ones established in this Regulation;
 - (c) whether the regulatory system applicable to clinical trials conducted outside the Union ensures that Article 25(5) of this Regulation is complied with .
- 1a. In order to perform the Union controls referred to in paragraph (1) point (a), the Commission may verify whether competent authorities and ethics committees have in place adequate and effective mechanisms to ensure compliance with this Regulation as regards in particular the requirements related to:
 - (a) validation of the clinical trial application as referred to in Articles 5(3), 17(2) and Article 20;
 - (b) scientific and ethical review as referred to in Article 4, Articles 6(1), 7(1), 8, 9 and 10, assessment of substantial modifications as referred to in Articles 17 to 22, safety assessment referred to in Article 44;
 - (c) communication and coordination with other Member States as referred to in Articles 5 to 8, Article 14, Article 17 to 19, Article 22 and 23;
 - (d) manufacturing and import of investigational medicinal products as referred to in Articles 61 and 63(4);

- (e) application of corrective measures and penalties as referred to in Article 77 and 94;
 - (f) conduct inspections as referred to in Articles 78, 63 and 63a.
2. The Commission shall organise the controls referred to in paragraph 1 in cooperation with the national authorities and shall carry them out in a manner that avoids unnecessary administrative burden.
 3. When performing the controls referred to in paragraph 1, the Commission shall consult the relevant best practices.
 4. The Commission, in carrying out the controls referred to in paragraph 1, may be supported by experts from the competent authorities or ethics committees.
 5. Following each control, the Commission shall:
 - (a) prepare a draft report on the findings and, where appropriate, include recommendations addressing the shortcomings identified;
 - (b) send a copy of the draft report referred to in point (a) to the clinical trials national authority concerned for its comments;
 - (c) take the comments referred to in point (b) into account in preparing the final report; and
 - (d) submit the final report through the EU portal.”;
- (43) the following Article 79a is inserted:

Article 79a

Obligations as regards Union controls

Member States shall cooperate with the Commission in respect of the performance of the Union controls referred to in Article 79 (1). In particular, they shall:

- (a) ensure that the necessary technical assistance and the relevant documentation, upon justified request, is being provided to the Commission as well as provide any other support that the Commission requests to enable it to perform controls efficiently and effectively, including facilitating access to all premises or any part thereof, to personnel (interviews) and data, including IT systems of the competent authority that is relevant for the execution of their duties.
 - (b) take appropriate follow-up measures to remedy the shortcomings identified through those Commission controls;’
- (44) Article 81 is amended as follows:
- (a) paragraph 2 is replaced by the following:
 - ’2. The EU database shall be established to enable cooperation between the competent authorities of the Member States concerned to the extent that it is necessary for the application of this Regulation and to search for specific clinical trials. It shall also enable communication between sponsors and Member States concerned and reporting Member State as appropriate for the purpose of swift regulatory procedures. It shall enable sponsors to refer to previous submissions of an application for authorisation of a clinical trial or a substantial modification. It shall also enable citizens of the Union to have access to clinical information about

medicinal products. To this end all data held in the EU database shall be in an easily searchable format, all related data shall be grouped together by way of the EU trial number, and hyperlinks shall be provided to link together related data and documents held on the EU database and other databases managed by the Agency.’;

(b) paragraph 9 is replaced by the following:

‘9. The sponsor shall permanently update in the EU database information on any changes to the clinical trials which are not substantial modifications but are relevant for the supervision of the clinical trial. The sponsor shall also update the EU portal to satisfy the condition to which an authorisation decision is subject to. An update may trigger a corrective measure from the reporting Member State or the Member State concerned requiring from the sponsor to submit a substantial modification concerning this change. The Member State concerned may issue such corrective measure within 7 days from the date of the update. The sponsor shall submit the substantial modification within period defined in the corrective measure by the Member State.’;

(45) Article 83 is replaced by the following:

‘Article 83

Competent authorities and ethics committees

1. Member States shall designate one national contact point to which they confer responsibility for the implementation and practical application of this Regulation. The Commission shall publish a list of national contact points.
2. Each Member State shall communicate the contact point referred to in paragraph 1 to the Commission. Member States shall ensure that competent authorities and ethics committees:
 - (a) have the necessary powers to perform all the necessary regulatory actions and inspections, pursuant to this Regulation.
 - (b) have, or have access to, a sufficient number of suitably qualified and experienced personnel, human and financial resources, operational capacity, and expertise, including technical expertise, for the effective and efficient performance of their tasks they have been made responsible for pursuant to this Regulation.’;

(46) the following Article 83a is inserted:

‘Article 83a

Communication and coordination between competent authorities and between ethics committees

1. Where more than one competent authority and ethics committee are responsible for performing regulatory activities or inspections in a Member State for the purpose of applying this Regulation, Member States shall ensure efficient and effective coordination among all the competent authorities and ethics committees concerned in order to guarantee the consistency and

effectiveness of the regulatory activities or inspections performed on their territory.

2. Within those Member States, the competent authorities shall cooperate with each other. They shall communicate information to each other for the effective implementation of the regulatory activities and inspections provided for in this Regulation.’;

(47) Article 85 is replaced by the following:

‘Article 85

Clinical Trials Coordination and Advisory Group

1. A Clinical Trials Coordination and Advisory Group (CTAG) is hereby established.
2. Each Member State shall appoint to the CTAG, for a three-year term which may be renewed once, one member and one alternate each with expertise in the field of clinical trials. The members of the CTAG shall be chosen for their competence and experience in the field of clinical trials. They shall represent the competent national authorities and the ethics committees of the Member States. The names and affiliations of members and alternates shall be made public by the Commission. The alternates shall represent and vote for the members in their absence.
3. For the purpose of the fulfilment of their tasks, CTAG members shall be able to rely on the contribution of experts from national competent authorities and ethics committees. These experts shall participate in CTAG meetings where relevant.
4. The CTAG shall use its best endeavors to reach consensus. If such consensus cannot be reached, the CTAG shall decide by a majority of its members. Members with diverging positions may request that their position and the grounds on which they are based are recorded.
5. The CTAG shall in particular have the following tasks:
 - (a) to support the exchange of information between the Member States and the Commission on the experience acquired with regard to the implementation of this Regulation;
 - (b) to assist the Commission in providing the support referred to in the second paragraph of Article 84;
 - (c) to prepare recommendations on criteria regarding the selection of a reporting Member State;
 - (d) to provide strategic steering on a common approach for the application of this Regulation and on the support of the clinical trials ecosystem in the Union;
 - (e) to contribute to the development of guidance aiming to ensure effective and harmonised implementation of this Regulation.
 - (f) to contribute to the development of guidelines on the use of the artificial intelligence models and systems in clinical trials in accordance with Article [xx] Regulation (EU) .../... [European Biotech Act]*;

- (g) to provide advice, either of its own initiative or at the request of the Commission, in the assessment of any issue related to the implementation of this Regulation;
 - (h) to contribute to harmonised administrative practice with regard to clinical trials in the Member States;
 - (i) to provide a recommendation before setting up a regulatory sandbox.
6. The CTAG shall be chaired by a representative of the Commission. The chair shall not take part in votes of the CTAG.
 7. The CTAG may issue recommendations and opinions on matters related to clinical trials and shall endorse any guidance related to the application of this Regulation. The Commission shall publish the guidelines endorsed by the CTAG.
 8. The CTAG shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State. Any item of the agenda of the meeting shall be placed at the request of the Commission or a Member State.
 9. The secretariat shall be provided by the Commission.
 10. The CTAG shall draw up its rules of procedure. The rules of procedure shall be made public.
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(48) Article 93 is replaced by the following:

'Article 93

Data protection

1. When carrying out their tasks pursuant to this Regulation, sponsors are required to process personal data, including genetic data or data concerning health for the following purposes:
 - (a) for the submission of applications in accordance with Articles 5, 11, 14 and 16;
 - (b) to perform research activities in the context of a clinical trial in accordance with the protocol as authorised by the national competent authorities in accordance with point D, Part I of Annex I;
 - (c) to perform safety operations and reporting in accordance with Articles 41 to 43 and 52 to 54;
 - (d) to record, process, handle and store information in accordance with Article 56;
 - (e) to perform archiving in accordance with Article 58;
 - (f) to submit to the EU portal the summary of the results of the clinical trial, the lay summary, the clinical study report and, where applicable, raw data, in accordance with Article 37(4).

2. When carrying out their tasks pursuant to this Regulation, investigators are required to process personal data, including genetic data or data concerning health for the following purposes:
 - (a) to perform research activities in the context of a clinical trial in accordance with the protocol as authorised by the national competent authorities in accordance with point D, Part I, Annex I;
 - (b) to perform safety reporting in accordance with Articles 41 and 54;
 - (c) to record, process, handle and store information in accordance with Article 56;
 - (d) to perform archiving in accordance with Article 58.
3. Sponsors and investigators shall make available personal data, including genetic data or data concerning health:
 - (a) to the competent authorities of the Member States for the purposes of oversight activities, including inspections, in accordance with Article 78;
 - (b) to the Commission for the purposes of controls, in accordance with Article 79.
4. For the processing assessment leading to the authorisation of clinical trial applications and operations referred to in this Article, sponsors and investigators are controllers within the meaning of Article 4(7) of Regulation (EU) 2016/679.
5. Personal data, including genetic data or data concerning health, shall be retained as long as required pursuant to Article 58 and in accordance with the conditions laid down therein.
6. Personal data collected and processed in accordance with this Regulation may be further processed by the same controller for the purposes of other clinical trials conducted under this Regulation, or for scientific research with the aim of protecting public health, improving standard of care and fostering the innovation capacity of European medical research.
7. By derogation from Article 9(4) of Regulation (EU) 2016/679, Member States may not maintain or introduce further conditions, including limitations, with regard to the processing of personal data, including genetic data or data concerning health in the context of clinical trials carried out in accordance with this Regulation.
8. Processing of personal data referred to in this Article shall be subject to appropriate technical and organisational measures to ensure the protection of the rights and freedoms of data subject. In particular, the controller shall obtain informed consent of the subject in accordance with Article 29 of this Regulation. The controllers shall also apply confidentiality rules concerning access to records and personal data of subjects and apply further safeguards that are appropriate for a specific clinical trial as requested in point D, Part I of Annex I (ak), (al), (am).

(49) Article 97 is replaced by the following:

“Article 97

Review

Five years after the date referred to in Article 99, second subparagraph, and every ten years thereafter, the Commission shall present a report to the European Parliament and to the Council on the application of this Regulation. That report shall include an assessment of the impact that the Regulation has had on scientific and technological progress, comprehensive information on the different types of clinical trials authorised pursuant to this Regulation, and the measures required in order to maintain the competitiveness of European clinical research. The report shall also assess progress made by monitoring as a key performance indicator the number of addition multinational clinical trials authorised in the Union over the 5-year period of the reporting, compared to the average number of such clinical trials authorised per year in the Union as of 2025;

The Commission shall, if appropriate, present a legislative proposal based on that report in order to update the provisions set out in this Regulation”

(50) in Article 98, paragraph 1 is replaced by the following:

‘1. This Regulation, as applicable on [Publication Office: please insert the date of the day before the date of application of Biotechnology Regulation] shall continue to apply to the procedures for authorisation, substantial modification of addition of a Member State concerned of a clinical trial where the request for the authorisation has been submitted before the date of entry into application as referred in Article 67(3), point (a), of Regulation [...] [European Biotech Act].’

(51) the following Article 98a is inserted;

‘Article 98a

Development plan for the EU Portal and database

The Agency shall be responsible for reporting, on the development, maintenance and, where relevant, adjustment of the EU portal in terms of timing, budgetary compliance and quality.

This would include a submission, after consulting the Commission, of a revised development plan for EU Portal and database to the Agency’s Management Board 1 month after entry into force of Regulation (EU).../... of the European Parliament and of the Council [include reference to Biotech Act proposal].* The development plan shall ensure that all required system functionalities are available by the date of application as defined in Article [...] of Regulation (EU).../... [Biotech Act proposal].

The summary of the development plan with key milestones and timelines [once approved by the Management Board of the Agency] shall be made publicly available at the website of the Agency.’

*Biotechnology proposal

(52) Annex I is amended in accordance with Annex I to this Regulation.

Amendments to Regulation (EU) 2019/6

Regulation (EU) 2019/6 is amended as follows:

- (1) in Article 3, the following paragraph 3 is inserted:

“The Union GMO legislation shall not apply to veterinary medicinal products containing or consisting of genetically modified organisms that are authorised or manufactured in accordance with this Regulation. The administration of veterinary medicinal products shall not bring the treated animal or their products under the scope of the GMO rules.”
- (2) in Article 4, the following points (45), (46) and (47) are added:
 - (45) “zoonosis’ means any disease and/or infection which is naturally transmissible directly or indirectly between animals and humans
 - (46) “‘veterinary medicinal products containing or consisting of genetically modified organisms’ means veterinary medicinal products that contain or consist of genetically modified organisms as defined in Article 2 point (2) of Directive 2001/18/EC” excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC”;
 - (47) “‘regulatory sandbox’ means a time-limited regulatory framework that enables the development, placing on the market or use, under regulatory supervision, of innovative technologies, methods or products related to animal health which are directly or indirectly related to the development, manufacturing or use of veterinary medicinal products and which are not regulated under Union legislation”;
- (3) in Article 8, paragraph 5 is deleted;
- (4) Article 9 is amended as follows:
 - (a) the following paragraph 2a is inserted:

‘2a. In case of clinical trials with veterinary medicinal products containing or consisting of genetically modified organisms, the competent authorities shall assess potential adverse effects on human health and the environment, having regard to the specific characteristics of the product and in accordance with the principles for environmental risk assessment set out in Annex II. Where appropriate, the implementation of risk mitigation measures shall be required’.
 - (b) in paragraph (3), the following subparagraph is added:

‘During this period, where the trial concerns a veterinary medicinal product containing or consisting of genetically modified organisms, the competent authorities may consult with the bodies set up by the Union or Member States in accordance with under Directive 2001/18/EC, in particular in case of novel questions or first-in-class veterinary medicinal products. The consulted bodies shall ensure protection of commercially confidential information and security of exchange of information.’
 - (c) In paragraph (4), the following subparagraph is added:

‘In the context of the sponsor’s obligation to determine that there are no environmental grounds precluding the conduct of the study, in case of clinical trials with veterinary medicinal products containing or consisting of genetically modified organisms, where a risk to the environment or human health is identified, mitigation measures shall be implemented before the start of the trial, having regard to the specific characteristics of the product, the magnitude of the possible hazard and likelihood of that adverse effect occurring.’

- (5) In Article 28, paragraph 2 is replaced by the following:

‘During the process of examination of applications for marketing authorisations for veterinary medicinal products containing or consisting of genetically modified organisms, the Agency may hold consultations with the bodies set up by the Union or Member States in accordance with Directive 2001/18/EC, in particular for first-in-class products or when a novel question arises. The consulted bodies shall ensure protection of commercially confidential information and security of exchange of information.’

- (6) The following Article 40a is inserted:

‘Article 40a

Extension of the supplementary protection certificate concerning biotechnology medicinal products treating zoonoses developed and authorised in the Union

1. Where a marketing authorisation is granted by the Union to a veterinary medicinal product developed by means of a biotechnology process referred to in paragraphs 2(a) of Article 42 of Regulation (EU) 2019/6 that is intended to diagnose, treat or prevent zoonotic diseases, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009⁷⁴ of the European Parliament and of the Council, or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs 1 and 2 of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:
 - (a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union;
 - (b) the veterinary medicinal product has a mechanism of action distinctly different and shows a level of safety and efficacy which at least equivalent to that of any authorised veterinary medicinal product in the Union for the same zoonotic disease; and
 - (c) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.
2. The Agency shall assess compliance with the conditions referred to in paragraph 1 as part of the marketing authorisation procedure concerned.

⁷⁴ Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1

3. Where compliance is confirmed, the Agency's opinion shall issue a statement to that effect.
4. A copy of the statement referred to in paragraph 3 shall be included in the application for a certificate lodged under article 7 of of Regulation (EC) No 469/2009.

(7) Article 61 is replaced by the following:

'Article 61

Variations that do not require assessment

1. Marketing authorisation holders shall be entitled to implement variations included in the list established in accordance with Article 60(1), under the conditions specified therein.
2. Where a variation referred to in paragraph (1) affects the summary of product characteristics, the labelling or package leaflet, the marketing authorisation holder shall record the change in the product database within 30 days after its implementation.

The competent authority that granted the marketing authorisation or, in the case of veterinary medicinal products authorised under the centralised procedure, the Commission following an opinion by the Agency, shall amend the marketing authorisation in accordance with the change recorded by the marketing authorisation holder in the product database.

For veterinary medicinal products authorised under the centralised procedure, the amendment of the marketing authorisation shall be made by means of implementing acts which shall be adopted in accordance with the examination procedure referred to in Article 145(2).

3. Where a variation as referred to in paragraph (1) does not affect the summary of product characteristics, labelling or package leaflet, the marketing authorisation holder shall record the change in the product database within one year after its implementation.
4. Variations implemented by marketing authorisation holders in circumvention of the conditions laid down in the implementing act referred to in Article 60(1) shall not be valid.'

(8) the following Chapter IX is added:

'CHAPTER IX

REGULATORY SANDBOX

Article 136a

Regulatory sandbox

1. The Commission may set up a regulatory sandbox in accordance with the procedure set out in paragraphs 2 and 4 for innovative technologies, methods or products related to animal health which are directly or indirectly related to the development, manufacturing or use of veterinary medicinal products and

which are not regulated under other Union legislation, where the following conditions are met:

- (a) it can be expected that those technologies, methods or products will have a positive impact on animal health without unacceptable negative impacts on human health or the environment;
 - (b) the development, placing on the market or use of the technologies, methods or products concerned is hindered by the lack of a harmonised legal framework.
2. Developers of technologies, methods or products related to animal health which are directly or indirectly related to the development, manufacturing or use of veterinary medicinal products and which are not regulated under other Union legislation may send an application to the Agency requesting the development of a regulatory sandbox. The Agency shall assess applications received and, based on its assessment, may submit a recommendation to the Commission which shall include all of the following:
- (a) a justification for the regulatory sandbox, including a description of the proposed technologies, methods or products to be included;
 - (b) identification of existing regulatory challenges;
 - (c) estimation of potential benefits and potential risks to animal or human health or the environment;
 - (d) mapping of existing expertise available to the Agency required to address potential benefits and risks referred to in point (c). Where no relevant expertise is readily available to the Agency, it shall present a plan on how it intends to address the points identified under point (c);
 - (e) a proposal for the duration of the regulatory sandbox.
3. Upon receipt of the Agency's recommendation, the Commission shall take a decision, by means of an implementing act, in accordance with the examination procedure referred to in Article 145(2). Where the Commission agrees to the establishment of a regulatory sandbox, the implementing act shall specify the duration of the regulatory sandbox.
4. After a regulatory sandbox is established, the Agency shall take the following measures:
- (a) develop and make publicly available technical and scientific requirements for technologies, methods or products developed under the regulatory sandbox, taking due account of the potential risks of thereof for human and animal health and the environment;
 - (b) develop rules of procedure which ensure that the confidentiality of information exchanged is maintained;
 - (c) provide relevant scientific advice;
 - (d) assess the benefits and risks of technologies, methods or products developed under the regulatory sandbox and, where it considers that the benefits outweigh the risks, it shall address to the Commission a recommendation for their placing on the market or use.

The Agency shall levy a fee from the applicants in accordance with Article 4 of Regulation (EU) 2024/568⁷⁵ for the activities referred to in points c) and d) of the first subparagraph. The applicable amounts shall be published on the website of the Agency.

5. The Commission may, by means of an implementing act, authorise the placing on the market or the use of the technologies, methods or products developed under a regulatory sandbox in accordance with the examination procedure referred to in Article 145(2).

Technologies, methods or products developed under a regulatory sandbox shall not be placed on the market or used until they have been authorised by the Commission.

6. Where a serious risk to public or animal health or to the environment associated with the use of technologies, methods or products developed under a regulatory sandbox is identified by national competent authorities, they shall swiftly inform the Agency. Pending the adoption of a Commission decision pursuant to paragraph 8, national competent authorities may take interim measures, including the suspension of their placing on the market, the suspension of use, or recall measures.
7. Where the Agency is notified of a serious risk in accordance with paragraph 6, it shall swiftly assess the referred matter and, where appropriate, any possible impact for similar technologies, methods or products placed on the market which have been developed or used under a regulatory sandbox. In its assessment, the Agency shall consider the benefits for animal health and the identified risks.
8. Where the assessment referred to in paragraph 7 concludes that the benefit-risk balance is negative and there are no satisfactory risk mitigation measures that can be implemented, the Agency shall recommend the suspension or withdrawal of authorisation for placing on the market or use. The Commission shall take a decision, by means of an implementing act, in accordance with the examination procedure referred to in Article 145(2).
9. Following the assessment referred to in paragraphs 7, the Agency may recommend the Commission to put an end to the regulatory sandbox. The Agency's recommendation shall advise on appropriate actions concerning the technologies, methods or products in development under the regulatory sandbox. The Commission may, by means of an implementing act, terminate a regulatory sandbox in accordance with the examination procedure referred to in Article 145(2).
10. Two years before the end of the period of validity of an established regulatory sandbox, the Agency shall submit an assessment report on the progress of the regulatory sandbox to the Commission, including recommendations for a regulatory framework after the end of the regulatory sandbox. Where

⁷⁵ Regulation (EU) 2024/568 of the European Parliament and of the Council of 7 February 2024 on fees and charges payable to the European Medicines Agency, amending Regulations (EU) 2017/745 and (EU) 2022/123 of the European Parliament and of the Council and repealing Regulation (EU) No 658/2014 of the European Parliament and of the Council and Council Regulation (EC) No 297/95 (OJ L OJ L 568, 14.2.2024)

appropriate, it may recommend the extension of the duration of the regulatory sandbox.

11. The Commission shall review the assessment report referred to in paragraph 10 and may take appropriate actions as regards the regulatory requirements for the marketing or use of technologies, methods or products under the scope of the regulatory sandbox after the termination thereof. Where appropriate, the Commission may extend the duration of a regulatory sandbox, by means of an implementing act, in accordance with the examination procedure referred to in Article 145(2).
12. The Agency shall keep a registry of regulatory sandboxes established in accordance with this Regulation. It shall prepare and publish each year a report on the implementation of the regulatory sandbox.'

- (9) Article 146 is replaced by the following:

'Article 146

Amendments to Annex II

'The Commission is empowered to adopt delegated acts in accordance with Article 147(2) in order to amend Annex II to take due account of technical and scientific progress.'

- (10) Annex II to Regulation (EU) 2019/6 is amended in accordance with Annex III to this Regulation.

Article 60

Amendments to Regulation (EU) 2024/795

Regulation (EU) 2024/795 is amended as follows:

- (a) in Article 2, the following paragraph 9 is added:
- '9. Health biotechnology strategic projects, including high-impact health biotechnology strategic projects recognised in accordance with Regulation [...] [European Biotech Act] shall be deemed to contribute to the STEP objectives referred to in paragraph 1, point (a)(iii) or point (b), as appropriate.
- (b) in Article 4, paragraph 7 is replaced by the following:
- '7. Strategic projects recognised in accordance with the relevant provisions of the Regulation (EU) 2024/1735, Regulation (EU) 2024/1252, Regulation [...] [Critical Medicines Act] and health biotechnology strategic projects, including high-impact health biotechnology strategic projects recognised in accordance with Regulation [...] [European Biotech Act] that fall within the scope of Article 2 of this Regulation and that receive a contribution under the programmes referred to in Article 3 of this Regulation may also receive a contribution from any other Union programme, including funds under shared management, provided that those contributions do not cover the same costs. The rules of the relevant Union programme shall apply to the corresponding contribution to the strategic project. The cumulative funding shall not exceed the total eligible costs of the strategic project. The support from the different

Union programmes may be calculated on a pro rata basis in accordance with the documents setting out the conditions for support.’;

- (c) in Article 6(1), point (c) is replaced by the following:
- ‘(c) details of projects that have been recognized as strategic projects under Regulation (EU) 2024/1735, Regulation (EU) 2024/1252 and Regulation [...] [Critical Medicines Act] and as health biotechnology strategic projects, including as high-impact health biotechnology strategic projects under Regulation [...] [European Biotech Act], to the extent that they fall within the scope of Article 2 of this Regulation.’.

Article 61

Amendment to Regulation (EU) 2024/1938

Regulation (EU) 2024/1938 is amended as follows:

- (1) In Article 3, the following point (60) is added:
- ‘(60) ‘regulatory sandbox’ means a regulatory framework which allows to develop, assess and test innovative or adapted regulatory solutions within a controlled environment pursuant to a specific plan, for a limited time and under regulatory supervision and which facilitates the development, assessment, authorisation or monitoring of innovative activities or substances which are likely to fall within the scope of this Regulation.’
- (2) in Article 13, the following paragraph 3a is inserted:
- ‘3a. The Commission may adopt implementing acts, setting out time limits for the provision, by the competent authorities consulted in accordance with paragraph 2, of a reply on the regulatory status of a substance, product or activity.
- Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).’
- (3) in Article 69(2), the first subparagraph is replaced by the following:
- ‘The Commission may adopt implementing acts setting out time limits for the SCB, to issue its opinions on the regulatory status of a substance, product or activity, in accordance with Article 13(3), first subparagraph.
- The Commission may adopt implementing acts setting out criteria and procedures for the consultation of advisory bodies established under other relevant Union legislation in relation to the performance of the SCB tasks, including time limits for those bodies to issue their opinions in the framework of such consultation.
- Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2)
- (4) the following Article 39a is inserted:

Article 39a

SoHO regulatory sandboxes

1. On a substantiated request from a SoHO entity, a Member State may set up regulatory sandboxes that provide a time limited controlled environment to

facilitate the development and testing of innovative products, services, processes or substances in the field of SoHO, under the supervision of one or more competent authorities and where the following conditions are met:

- (a) the characteristics or methods of those innovations and technologies are expected to distinctively contribute to the safety, quality, including the effectiveness of the SoHO or the SoHO activity or to provide a major contribution to patient access to treatment;
 - (b) the application of the requirements of this Regulation would impede or significantly delay the development of those innovations and technologies, due to scientific or regulatory challenges arising from the characteristics or methods related to that innovation or technology.
2. Member States may jointly set up the regulatory sandboxes referred to in paragraph 1. The Commission shall support such cooperation in accordance with Article 72 (1).
3. The regulatory sandbox shall seek to allow the assessment of the innovations referred to in paragraph 1 in a real-world environment under strict regulatory supervision, to ensure that the necessary evidence and data is generated to demonstrate their safety quality, including effectiveness in view of their distribution.
4. The regulatory sandbox may include clearly described derogations from the requirements set out in this Regulation. Those derogations may entail adapted, enhanced, waived or deferred requirements. Each derogation shall be limited to what is apt and strictly necessary to attain the objectives pursued and shall be duly justified and specified in the sandbox plan referred to in paragraph [6].
- However, the regulatory sandbox shall not include derogations from the provisions on standards concerning voluntary and unpaid nature of SoHO donations laid down in Article 54.
5. The regulatory sandboxes shall be conducted under the supervision of the SoHO competent authorities, and, where appropriate, in cooperation with competent authorities acting in accordance with other relevant Union legislative acts in the area of health or national legislation.
6. The activities within the regulatory sandbox shall take place in accordance with a specific regulatory sandbox plan developed by the SoHO competent authorities. The sandbox plan shall:
- (a) be informed by data provided by, and established following consultations with, the developers of the concerned innovations;
 - (b) identify the participants in the regulatory sandbox and their respective roles;
 - (c) identify the requirements of this Regulation that cannot be complied with, from which derogations are considered necessary and the adapted, enhanced, waived or deferred requirements entailed by such derogations;
 - (d) include appropriate measures to mitigate potential risks to health and to the environment;
 - (e) establish the duration of the regulatory sandbox.

- (f) explain the monitoring framework for the regulatory sandboxes including what aspects will be reported on, the frequency of reporting and data sources.
7. When establishing the regulatory sandbox, the SoHO competent authorities shall consult, where appropriate, the SCB, including by requesting scientific, technical or regulatory advice for the design of the sandbox plan. The SCB shall provide support and shall seek to foster a common approach for the design and the implementation of the regulatory sandboxes referred to in this Article.

For the purposes of the support to SoHO competent authorities referred to in the first subparagraph, the SCB may:

- (a) request information and data from holders of authorisations of SoHO preparations, leveraging information on the EU SoHO platform established under article 74 of this Regulation, developers, independent experts and researchers, representatives of healthcare professionals and patients and may engage with them in preliminary discussions;
 - (b) collaborate with the Foresight Panel for Emerging Health Innovation referred to in article 38 of Regulation (EU) .../...[European Biotech Act].
8. When setting up the regulatory sandbox, the SOHO competent authorities shall provide detailed, non-confidential information to the Commission, regarding the regulatory framework governing the specific regulatory sandbox set out in a regulatory sandbox plan. The Commission shall publish the information received, on the EU SoHO platform established under article 74 of this Regulation.
9. Upon the termination of the regulatory sandbox, the competent authorities shall submit to the SCB and to the Commission a detailed report on the regulatory sandbox and any possible follow up concerning in particular changes in the regulatory framework for the innovations or categories of innovations concerned, based on the learnings from the regulatory sandbox. The SCB shall publish the information received.

The information referred to in the first subparagraph may also be provided at regular intervals during the implementation of the sandbox.

10. A SoHO preparation resulting from an innovation developed as part of a regulatory sandbox may be distributed for human application only where authorised in accordance with Article 38(1). The initial validity of such authorisation shall not exceed the duration of the regulatory sandbox. The authorisation may be extended by the competent authority at the request of the relevant SoHO entity.
11. The regulatory sandboxes shall not affect the enforcement and monitoring responsibilities of the SoHO competent authorities pursuant to this Regulation and to other Union legislation.
12. Participants in the regulatory sandbox, in particular the developer shall remain liable under applicable national legislation for any harm inflicted on third parties as a result from the testing taking place in the regulatory sandbox. They shall inform the national SoHO competent authorities without undue delay of any information which might entail the amendment of the regulatory sandbox

or concerns the quality, safety or efficacy of products developed as part of a regulatory sandbox.

13. In case of identification of risks to public health or safety concerns or the environment associated with the use of the innovation covered by a regulatory sandbox, the sandbox participants shall immediately inform the SoHO competent authorities of the action taken to prevent those risks. The SoHO competent authorities shall take immediate and adequate temporary corrective measures, including to suspend, revoke or restrict the scope of the regulatory sandbox and shall inform the SCB and the Commission thereof.

CHAPTER [X]

FINAL PROVISIONS

Article 62

Monitoring

The Commission shall publish and keep up to date a list of health biotechnology strategic projects and high impact health biotechnology strategic projects.

Article 63

Evaluation

1. No sooner than [*insert date, five years after the date of entry into application of this Regulation...*], the Commission shall evaluate this Regulation in light of the general objective that it pursues and referred to in Article 1(1)]and present a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee, and the Committee of the Regions, in particular on the impact of this Regulation and progress towards that objective.
2. The Member States shall, upon request, provide the Commission with any relevant information they have and that the Commission may need for its assessment pursuant to in paragraph 1.

Article 64

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 43(2) shall be conferred on the Commission for a period of five years from [*insert date of entry into force of this Regulation*]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Articles 43(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Articles 43(2), shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 65

Committee procedure

1. The Commission shall be assisted by the Standing Committee on Biotechnology. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 66

Handling of confidential information

1. Information acquired in the course of implementing this Regulation shall be used only for the purposes of this Regulation and shall be protected by the relevant Union and national law.
2. Member States and the Commission shall ensure the protection of trade and business secrets and other sensitive, confidential and classified information obtained and processed in application of this Regulation, including recommendations and measures to be taken, in accordance with Union and relevant national law.
3. The Commission and Member States shall ensure that classified information provided or exchanged pursuant to this Regulation is not downgraded or declassified without the prior written consent of the originator in accordance with relevant Union or national law.
4. The Commission and the national authorities, their officials, employees and other persons working under the supervision of those authorities shall ensure the confidentiality of information obtained in carrying out their tasks and activities in

accordance with relevant Union or national law. This obligation also applies to all representatives of Member States, observers, experts and other participants attending meetings of the Steering Group.

Article 67

Entry into force and application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.
2. It shall apply as of the day of entry into force.
3. By way of derogation from paragraph 2:
 - (a) Article 58, points (5) to (12) and points (15) to (24) shall apply as of [OP, *please insert date: six months after entry into force of this Regulation*];
 - (b) Article 58, point (13) shall apply as of [OP, *please insert date: nine months after entry into force of this Regulation*];
 - (c) Article 58, point (25) shall apply as of [OP, *please insert date: nine months after entry into force of this Regulation*].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg,

For the European Parliament
The President

For the Council
The President

LEGISLATIVE FINANCIAL AND DIGITAL STATEMENT- AGENCIES

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1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing a framework of measures for strengthening Europe's biotechnology and biomanufacturing sectors and amending Regulations (EU) No 536/2014 ('Clinical Trials Regulation'), (EC) No 1394/2007 (ATMP), (EU) 2024/1938 (SoHO), (EU) 2019/6 (Veterinary Medicine Products Regulation), and Regulation (EC) No 178/2002 (General Food Law) ('EU Biotech Act')

1.2. Policy area(s) concerned

Priority Area: Competitiveness, prosperity and security

Health, Biotech, Agriculture and Bioeconomy

1.3. Objective(s)

1.3.1. General objective(s)

- (i) to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector, from research to production,
- (ii) to create the conditions for the development and timely placing on the Union market, of biotechnology innovations, products and services,
- (iii) while safeguarding high standards for the protection of human health, animal health, patients and consumers, the environment, ethics, quality, food and feed safety, and biosecurity.

1.3.2. Specific objective(s)

This general objective translates into the following specific objectives:

- (i) strengthen the biotechnology sector and reinforce the Union's research, development and production capabilities, by establishing a framework for the recognition of, and support measures for, strategic health biotechnology projects and high impact strategic health biotechnology projects (pillar 1);
- (ii) support funding of, investments in, and access to capital for, biotechnology companies and projects, including through the setting up of an EU health biotechnology investment pilot to fill the gap in spending on biotechnology innovation (pillar 2);
- (iii) improve the EU manufacturing capacity of, and expertise in biosimilars, including through international cooperation (pillar 3);
- (iv) facilitate the application of AI into the Union's biotechnology and health technology manufacturing ecosystems and frameworks, in line with the Regulation (EU) 2024/1689 (pillar 4);
- (v) ensure a legislative framework that encourages innovation and takes account of technological and scientific developments and progress, by establishing provisions for health biotechnology products (pillar 5);
- (vi) prevent the misuse of biotechnologies and strengthen biodefence capabilities (pillar 6).

(vii) enable the effectiveness of the measures under the pillars 1 to 6 through a legislative framework conducive to the use of biotechnology innovations, by amending Union legislation in particular on clinical trials, veterinary medicinal products, food and feed safety and related legislation (pillar 7).

1.3.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

Overall, the Biotech Act is expected to support a smooth function of the Union internal market and the resilience and competitiveness of the Union biotechnology and biomanufacturing sector, while allowing allow end-users - including patients - to benefit from the availability of innovative technologies in the EU.

The Biotech Act will have the following expected results:

- - regulatory procedures to place products on the market are predictable, simplified and shorter, with reduced administrative burden;
- - innovation is supported by specific regulatory procedures that are fit for technological and scientific progress;
- - operators have better access to funding throughout the different stages of their development;
- - the EU's capabilities in research, development and production are reinforced, including for biodefence
- - availability of a skilled biotechnology workforce in the Union is improved;
- - there are clear rules preventing the misuse of biotechnologies.

1.3.4. Indicators of performance

Specify the indicators for monitoring progress and achievements.

Progress towards the objectives of the Biotech Act will be monitored using a set of quantitative and qualitative indicators. This assessment will draw on the strategic mapping of the Union's biotechnology ecosystem, to be established and maintained by the Commission.

Such monitoring shall be based on key performance indicators such as the increase in the number of clinical trials in the Union over the period of five years, as this indicator reflects both the attractiveness of the Union and the capacity of the European regulatory system to support clinical research with maintained high data quality and patients' safety standards.

1.4. The proposal/initiative relates to:

☒ a new action

☐ a new action following a pilot project / preparatory action¹

¹ As referred to in Article 58(2), point (a) or (b) of the Financial Regulation.

☒ the extension of an existing action

“ a merger or redirection of one or more actions towards another/a new action

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative

In the short term, the initiative requires the Commission to complete the strategic mapping of the Union's biotechnology ecosystem within six months of entry into force and to initiate the establishment of the new governance and support structures foreseen in the Regulation, including the EU Health Biotechnology Support Network, the Emerging Innovation Foresight Panel and the European Health Biotechnology Steering Group. The Commission would also proceed with adopting the necessary implementing and delegated acts, including those detailing the criteria and procedures for the recognition of health biotechnology strategic projects and high-impact health biotechnology strategic projects. In parallel, Member States must designate national single points of contact and begin applying the streamlined regulatory procedures.

The Commission and the Agencies will have to update and/or develop new tools and ways of operation to implement workflows resulting from the amendments to EU legislative frameworks in the health and food area. These amendments aim at simplifying regulatory procedures and creating regulatory environments conducive to innovation.

In the medium term, the strategic mapping would be updated and used to guide the selection of projects and the deployment of Union support, as well as further developments in Union policy for biotechnology.

1.5.2. Added value of EU involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this section 'added value of EU involvement' is the value resulting from EU action, that is additional to the value that would have been otherwise created by Member States alone.

Reasons for action at EU level (ex-ante)

European companies are not competitive enough and face several market and regulatory barriers. Whilst several Member States have taken action to boost innovation in this field, many bottlenecks persist, and improvements are not expected to achieve the necessary levels for the Union to compete at a global scale.

Important regulatory barriers identified stem from EU legislation, therefore the proposed amendments seek to simplify EU legislations, enhance their legal clarity and certainty and make them fit to scientific and technological development.

Furthermore, the market drivers are occurring across the EU, affecting the functioning of the Union single market and EU's businesses competitiveness in the Union and globally. These hurdles result from insufficient capacity of EU companies to access private finance at a competitive scale, especially at later stages of development. Biotechnology clusters in the EU are scattered across Member States, without cross-border connections and continental scale, thus not able to compete globally. Compounded by the low level of storage, access and sharing of data in the area of biotechnology - including cross-borders -, the development and deployment

of AI solutions for biotechnology in the Union are not reaching their full potential. Finally, the gap in developing and retaining an adequately skilled workforce has been observed across the Union. These challenges are systemic, transnational in nature and cannot be addressed effectively through isolated national measures alone.

Expected generated EU added value (ex-post)

A harmonised but simplified EU regulatory framework, supported by strengthened collaboration in selected policy areas (access to capital, skills, AI and data) is expected to ensure all patients, users and citizens can benefit from these innovations to same extent in the EU, a level playing field for operations in the Union single market as well as to enhance the overall competitiveness of the EU. Coordinated EU action will generate economies of scale, reduce duplication of efforts, increase legal certainty for entrepreneurs operating across borders, and unlock cross-border investments, infrastructures and skills development that Member States acting alone could not achieve. It will also reinforce the EU's strategic autonomy in a critical technological area foster the development of adequate biosecurity capabilities.

1.5.3. *Lessons learned from similar experiences in the past*

Developments in the biotechnology sector over the last decades shows that Europe's strong scientific base does not automatically translate into industrial competitiveness. Fragmented and complex regulatory frameworks, slow and divergent procedures, limited access to risk-tolerant capital, insufficient data sharing and interoperability, shallow public equity markets, and persistent skills shortages have repeatedly hindered the ability of EU innovators to scale and commercialise their technologies. Past efforts have also demonstrated that lack of coordinated EU action leads to duplication, delays, and missed opportunities for deploying biotechnology at scale, while emerging technologies such as AI raise regulatory and biosecurity challenges that cannot be adequately addressed at national level.

Experience from other strategic sectors saw targeted EU-level initiatives, combining regulatory simplification, coordinated investment, and infrastructure support, being deployed to address systemic bottlenecks - such as in the case of the Net-Zero Industry Act and the Critical Raw Materials Act. The same lessons apply to biotechnology: only a coherent and integrated EU approach can unlock the sector's full potential, strengthen competitiveness, and accelerate the safe deployment of biotechnology innovative across the Single Market.

1.5.4. *Compatibility with the multiannual financial framework and possible synergies with other appropriate instruments*

In order to maximise its positive impact, the Biotech Act will build upon the strong knowledge base. The objectives of the Biotech Act may be supported under the future European Competitiveness Fund, in particular under the Health, Biotech, Agriculture and Bioeconomy Window. Horizon Europe may also be leveraged to complement the Biotech Act's objective of bringing biotechnology products to the market by supporting all stages of research and development of innovative ideas.

1.5.5. *Assessment of the different available financing options, including scope for redeployment*

N/A

1.6. Duration of the proposal/initiative and of its financial impact

☐ limited duration

- ☐ in effect from [DD/MM]YYYY to [DD/MM]YYYY
- ☐ financial impact from YYYY to YYYY for commitment appropriations and from YYYY to YYYY for payment appropriations.

☒ unlimited duration

- Implementation with a start-up period from 2028 to 2029,
- followed by full-scale operation.

1.7. Method(s) of budget implementation planned²

☒ Direct management by the Commission

- ☒ by its departments, including by its staff in the Union delegations;
- ☒ by the executive agencies
- ☐ Shared management with the Member States

☒ Indirect management by entrusting budget implementation tasks to:

- ☐ third countries or the bodies they have designated
- ☐ international organisations and their agencies (to be specified)
- ☒ the European Investment Bank and the European Investment Fund
- ☐ bodies referred to in Articles 70 and 71 of the Financial Regulation
- ☐ public law bodies
- ☒ bodies governed by private law with a public service mission to the extent that they are provided with adequate financial guarantees
- ☒ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that are provided with adequate financial guarantees
- ☐ bodies or persons entrusted with the implementation of specific actions in the common foreign and security policy pursuant to Title V of the Treaty on European Union, and identified in the relevant basic act
- ☒ bodies established in a Member State, governed by the private law of a Member State or Union law and eligible to be entrusted, in accordance with sector-specific rules, with the implementation of Union funds or budgetary guarantees, to the extent that such bodies are controlled by public law bodies or by bodies governed by private law with a public service mission, and are provided with adequate financial guarantees in the form of joint and several Soho by the controlling bodies or equivalent financial guarantees and which may be, for each action, limited to the maximum amount of the Union support.

Comments:

² Details of budget implementation methods and references to the Financial Regulation may be found on the BUDGpedia site: <https://myintracomm.ec.europa.eu/corp/budget/financial-rules/budget-implementation/Pages/implementation-methods.aspx>.

The proposal envisions two main vehicles for biotechnology investment in the EU:

Support to High Impact Health Biotechnology Strategic Projects

High Impact Health Biotechnology Strategic projects will boost the European ecosystem by expanding shared pilot facilities open to SMEs and academia alike, financially supporting Member State innovation procurement to create predictable demand for innovative products, and harnessing the potential of data and AI for Biotechnology

A Biotechnology Investment Pilot

The Pilot aims to provide a full lifecycle approach to biotechnology finance by supporting both the intermediate equity approach for biotechnology equity investments and venture loans into the sector. This would enable European innovators to move from discovery to industrial scale by bridging the most capital-intensive stages of development. A company may, for instance, start with early-stage backing from a VC fund, then access tailored venture loans to build production capacity, securing co-investment along the financing journey. By linking these steps, the Pilot ensures that Europe's biotechnology champions can grow, manufacture and stay anchored in Europe.

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

The proposal relies on existing legislations and initiatives in the European Commission and the European Medicines Agency, which will facilitate monitoring of several indicators. For these, continuous data/information will be available.

In addition, five years after the Regulation's entry into application, and every five years thereafter, the Commission will evaluate its implementation, effectiveness and impact.

2.2. Management and control system(s)

2.2.1. *Justification of the budget implementation method(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed*

The actions for establishing a framework of measures for strengthening Europe's biotechnology and biomanufacturing sector will be implemented through direct and indirect management, using the implementation modes offered by the Financial Regulation, mainly being grants and procurement for the direct management mode. Direct management allows to establish grant agreements/contracts with beneficiaries/contractors directly engaged in activities that serve Union policies. The Commission ensures direct monitoring over the outcome of the actions financed. The payment modalities of the actions funded will be adapted to the risks pertaining to the financial transactions.

In order to ensure the effectiveness, efficiency and economy of the Commission controls, the control strategy will be oriented towards a balance of ex-ante and ex-post checks and focus on three key stages of grant/contract implementation, in accordance with the Financial Regulation and/ or the specific contractual provisions:

- Selection of proposals/award the contract to tenders that fit the policy objectives;
- Operational, monitoring and (ex ante) technical desk reviews that cover project implementation, public procurement, pre-financing, interim and final payments, management of guarantees;
- Ex-post controls at the beneficiaries will also be carried out on a sample of transactions. The selection of these transactions will combine a risk assessment and a random selection.

The annual EU subsidy will be transferred to the Agencies in accordance with their payment needs and upon their requests. The Agencies will be subject to administrative controls including budgetary control, internal audit, annual reports by the European Court of Auditors, the annual discharge for the execution of the Union budget and possible investigations conducted by OLAF to ensure, in particular, that the resources allocated to the Agencies are put to proper use. Through its representation in the Agencies' Management Board and Audit Committee, the Commission will receive audit reports and ensures that adequate actions are defined and timely implemented by the Agencies to address the issues identified. All payments will remain pre-financing payments until the Agencies' accounts have been audited by the European Court of Auditors and the Agencies has submitted its final accounts. If necessary, the Commission will recover unspent amounts of the instalments paid to the Agencies.

For provisions of this Regulation that require long-term coordination and large-scale public and private investment (i.e. for high impact health biotechnology strategic projects), the Commission may propose European Partnerships where the Union together with private and/or public partners, acting in full compliance with competition rules, commit to jointly supporting the development and implementation of a programme activities, including those related to market, regulatory or policy uptake.

The activities of the Agencies will also be subject to the supervision of the Ombudsman in accordance with Article 228 of the Treaty. These administrative controls provide a number of procedural safeguards to ensure that account is taken of the interests of the stakeholders.

2.2.2. *Information concerning the risks identified and the internal control system(s) set up to mitigate them*

The main risks relate to the Agencies' performance and independence in implementing the tasks entrusted to them. Underperformance or impaired independence could hamper the achievement of the objectives of this initiative and also reflect negatively on the Commission's reputation.

The Commission and the Agencies have put in place internal procedures that aim at covering the risks identified above. The internal procedures are in full compliance with the Financial Regulation and include anti-fraud measures and cost-benefit considerations.

First and foremost, sufficient resources should be made available to the Agencies in both financial and staffing terms to achieve the objectives of this initiative.

Furthermore, quality management will include both the integrated quality-management activities and risk-management activities within the Agencies. A risk review is conducted annually, with risks being assessed at a residual level, i.e. taking into account controls and mitigations already in place. Conducting self-assessments (as part of the EU Agencies benchmarking programme), annual reviews of sensitive functions and ex-post controls also fall within this area, as does maintain a register of exceptions.

To preserve impartiality and objectivity in every aspect of the Agencies' work, a number of policies and rules on management of competing interests have been put in place and will be regularly updated, describing specific arrangements, requirements and processes applying to the Agencies' Management Board, scientific committee members and experts, the Agencies' staff and candidates, as well as consultants and contractors. The Commission will be informed timely of relevant management and independence issues encountered by the Agencies and will react upon notified issues timely and adequately.

The proposal also envisages that the Commission promotes Biotechnology Investment Pilot for biotechnology investment in the EU.

The main risks are the following:

- Risk of not fully achieving the objectives of the Regulation due to insufficient uptake or quality/delays in the implementation of the selected projects or contracts;
- Risk of inefficient or non-economic use of investments awarded;

• Reputational risk for the Commission, if fraud or criminal activities are discovered; only partial assurance can be drawn from the third parties' internal control systems due to the rather large number of heterogeneous contractors and beneficiaries, each operating their own control system.

The Commission will allocate the necessary human and financial resources for the proper implementation of this Regulation and will put in place internal procedures that aim at covering the risks identified above. The internal procedures will be in full compliance with the Financial Regulation and include anti-fraud measures and cost-benefit considerations.

2.2.3. *Estimation and justification of the cost-effectiveness of the controls (ratio between the control costs and the value of the related funds managed), and assessment of the expected levels of risk of error (at payment & at closure)*

The Commission's and the Agencies' internal control strategies take into consideration the main cost drivers, and the efforts already taken over several years to reduce the cost of controls, without compromising the effectiveness of controls. The existing control systems proved to be able to prevent and/or to detect errors and/or irregularities, and in case of errors or irregularities, to correct them.

In the past five years, the Commission's yearly costs of controls under indirect management represented less than 1% of the annual budget spent on subsidies paid to the EMA and EFSA. The Agencies allocated less than 0,5% (EMA) and 5% (EFSA) of their total annual budget on control activities centring around integrated quality management, audit, anti-fraud measures, finance and verification processes, corporate risk management and self-assessment activities.

2.3. Measures to prevent fraud and irregularities

Preventing and detecting fraud is a key governance issue and a common control objective for all Commission's departments who have, in practical terms, the obligation to put in place the appropriate management and internal control procedures designed to deter, detect, correct or sanction irregularities and fraud, in line with articles 317 and 325 TFEU and article 36 FR.

As for its activities in indirect management, the Commission shall take appropriate measures ensuring that the financial interests of the European Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportional and deterrent penalties. To this effect, the Commission adopted an anti-fraud strategy, latest update of April 2019 (COM(2019)176), covering preventive, detective and corrective measures. The Commission or its representatives and the European Court of Auditors shall have the power of audit, on the basis of documents and on-the-spot, over all grant beneficiaries, contractors and subcontractors who have received Union funds. OLAF shall be authorised to carry out on-the-spot checks and inspections on economic operators concerned indirectly by such funding.

As regards the European Medicines Agency, the anti-fraud measures are provided for in Article 69 of Regulation (EC) No 726/2004 and the framework financial Regulation (2019/715). The Executive Director and the Management Board of the Agency will take the appropriate measures in accordance with the Internal Control

Principles applied across all EU institutions. In line with the Common Approach and Article 42 of the framework financial Regulation, an anti-fraud strategy has been developed and is followed by the Agency. The Agency's Anti-fraud strategy covers 3-year period and is accompanied by a corresponding action plan, outlining both specific focus areas and actions for the next years, and several continuous actions that are carried out every year, such as a specific standalone fraud risk assessment, with the identified fraud risks included in the overall Agency risk register. Anti-fraud trainings are organised as part of the induction training and via mandatory anti-fraud e-learning training for newcomers. Staff are made aware of how to report any suspects of wrongdoings and disciplinary procedures are in place as per the rules of the Staff Regulations.

As regards the European Food Safety Authority, the anti-fraud measures are provided for in Article 25 of Regulation (EC) No 178/2002 and the framework financial Regulation (2019/715). The Management Board will take the appropriate measures in accordance with the Internal Control Principles applied across all EU institutions. In line with the Common Approach and Article 42 of the framework financial Regulation, an anti-fraud strategy has been developed and is followed by the Authority. The Authority's Anti-fraud strategy is accompanied by a corresponding action plan, outlining both specific focus areas and actions for the next years, and several continuous actions that are carried out every year, such as a specific standalone fraud risk assessment, with the identified fraud risks included in the overall Agency risk register. Mandatory anti-fraud trainings are organised as part of the awareness anti-fraud sessions. Staff are made aware of how to report any suspects of wrongdoings and disciplinary procedures are in place as per the rules of the Staff Regulations.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff. ¹	from EFTA countries ²	from candidate countries and potential candidates ³	From other third countries	other assigned revenue
2	Support expenditure of the programme	Non-diff	YES	YES	YES	NO
2	Union contribution to the European Medicines Agency	Non-diff.	YES	YES	YES	NO
2	Union contribution to the European Food Safety Agency	Diff.	YES	YES	YES	NO
4	20 01 02 01 - Headquarters and Representation offices - officials and temporary staff	Non-diff.	NO	NO	NO	NO
4	20 02 01 and 20 02 02 – External personnel – Headquarters and Representation offices	Non-diff.	NO	NO	NO	NO
4	20 02 06 02 - Conference and meeting costs	Non-diff.	NO	NO	NO	NO
4	20 02 06 01 - Missions, conferences and representation expenses	Non-diff.	NO	NO	NO	NO

¹ Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.

² EFTA: European Free Trade Association.

³ Candidate countries and, where applicable, potential candidates from the Western Balkans.

3.2. Estimated financial impact of the proposal on appropriations

3.2.1. Summary of estimated impact on operational appropriations

- The proposal/initiative does not require the use of operational appropriations
- ☒ The proposal/initiative requires the use of operational appropriations, as explained below

3.2.1.1. Appropriations from voted budget

Amounts are indicative and do not prejudice the outcome of the ongoing negotiations on the next MFF.

EUR million (to three decimal places)

DG: SANTE			Year	Year	Year	Year	Year	Year	Year	TOTAL MFF 2028-2034
			2028	2029	2030	2031	2032	2033	2034	
Operational appropriations										
Programme Budget line	Commitments	(1a)	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.
	Payments	(2a)	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.
Appropriations of an administrative nature financed from the envelope of specific programmes										
Budget line - Technical Assistance -Support credits		(3)	2,626	2,626	2,626	2,626	2,626	2,626	2,626	18,382
TOTAL appropriations	Commitments	=1a+1b+3	2,626	2,626	2,626	2,626	2,626	2,626	2,626	18,382
for DG SANTE	Payments	=2a+2b+3	2,626	2,626	2,626	2,626	2,626	2,626	2,626	18,382

EU contribution to decentralised agencies

EUR million (to three decimal places)

[Agency]: <EMA .>	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL 2028 - 2034	POST 2034 annual expenditure)
Budget line: EMA / EU Budget contribution to the agency	10,055	8,153	2,196	2,240	2,285	2,330	2,377	29,635	2,425

EUR million (to three decimal places)

EFSA	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL 2028- 2034	POST 2034(annual expenditure)
Budget line: EFSA/ EU Budget contribution to the agency	0,882	1,800	1,836	1,872	1,910	1,948	1,987	12,235	2,027

For EFSA and EMA for the first year only 50 % of the average staff costs are taken into account as it is expected that not all positions will be filled from the beginning of the year

Without prejudice to the negotiations on the next MFF, the appropriations allocated to the agencies from 2028 onwards will be compensated via redeployments from programmes under the 2028-2034 MFF. If a compensatory reduction is needed, the resources allocated to the agencies and their funding streams and sources may need to be revised.

EUR million (to three decimal places)

			Year	Year	Year	Year	Year	Year	Year	TOTAL MFF 2028-2034
			2028	2029	2030	2031	2032	2033	2034	
TOTAL operational appropriations (including contribution to EMA and EFSA)	Commitments	(4)	10,938	9,953	4,032	4,112	4,194	4,278	4,364	41,870
	Payments	(5)	10,938	9,953	4,032	4,112	4,194	4,278	4,364	41,870
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	2,626	2,626	2,626	2,626	2,626	2,626	2,626	18,382
TOTAL appropriations under HEADING SANTE of the multiannual financial framework	Commitments	=4+6	13,564	12,579	6,658	6,738	6,820	6,904	6,990	60,252
	Payments	=5+6	13,564	12,579	6,658	6,738	6,820	6,904	6,990	60,252

Without prejudice to the negotiations on the next MFF, the appropriations allocated to the agencies from 2028 onwards will be compensated via redeployments from programmes under the 2028-2034 MFF. If a compensatory reduction is needed, the resources allocated to the agencies and their funding streams and sources may need to be revised.

EUR million (to three decimal places)

Heading of multiannual financial framework	4	‘Administrative expenditure’

DG: SANTE		Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL MFF 2028- 2034
Human resources		6,371	6,371	6,371	6,371	6,371	6,371	6,371	44,597
Other administrative expenditure		0,010	0,010	0,010	0,011	0,011	0,011	0,011	0,075
TOTAL DG SANTE	Appropriations	6,381	6,381	6,381	6,382	6,382	6,382	6,382	44,672

TOTAL appropriations under HEADING 4 of the multiannual financial framework	(Total commitments = Total payments)	6,381	6,381	6,381	6,382	6,382	6,382	6,382	44,672

– Amounts are indicative and do not prejudice the outcome of the ongoing negotiations on the next MFF.

TOTAL HEADING 1 to 4 C1

	Year 2028		Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL MFF 2028-2034
TOTAL appropriations under HEADINGS 1 to 4	Commitments	19,945	18,960	13,039	13,120	13,202	13,286	13,372	104,924
of the multiannual financial framework	Payments	19,945	18,960	13,039	13,120	13,202	13,286	13,372	104,924

* Figures in the table above are all strictly indicative pending the outcome of the 2028-2034 MFF negotiations which cannot be prejudged.

3.2.2. Estimated output funded from operational appropriations (not to be completed for decentralised agencies)

The output funded from operational appropriations cannot be calculated as the outcome of the 2028-2034 MFF negotiations, still ongoing at time of completing the LFDS, cannot be prejudged.

3.2.3. *Summary of estimated impact on administrative appropriations (not to be completed for decentralised agencies)*

- “ The proposal/initiative does not require the use of appropriations of an administrative nature
- x The proposal/initiative requires the use of appropriations of an administrative nature, as explained below

– 3.2.3.1 Appropriations from voted budget

VOTED APPROPRIATIONS	Year	Year	Year	Year	Year	Year	Year	TOTAL 2028 - 2034	POST
	2028	2029	2030	2031	2032	2033	2034		2034(annual expenditure)
HEADING 4									
Human resources	6,371	6,371	6,371	6,371	6,371	6,371	6,371	44,597	6,371
Other administrative expenditure	0,010	0,010	0,010	0,011	0,011	0,011	0,011	0,075	0,011
Subtotal HEADING 4	6,381	6,381	6,381	6,382	6,382	6,382	6,382	44,672	6,382
Outside HEADING 4									
Human resources	2,626	2,626	2,626	2,626	2,626	2,626	2,626	18,382	2,626
Other expenditure of an administrative nature	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000
Subtotal outside HEADING 4	2,626	2,626	2,626	2,626	2,626	2,626	2,626	18,382	2,626
TOTAL	9,007	9,007	9,007	9,008	9,008	9,008	9,008	63,054	9,008

- * Figures in the tables above are all strictly indicative pending the outcome of the 2028-2034 MFF negotiations which cannot be prejudged.

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3.2.4. *Estimated requirements of human resources (not to be completed for decentralised agencies)*

- “ The proposal/initiative does not require the use of human resources
- ☒ The proposal/initiative requires the use of human resources, as explained below

3.2.4.1. Financed from voted budget

Estimate to be expressed in full-time equivalent units (FTEs)¹

TOTAL VOTED APPROPRIATIONS + EXTERNAL ASSIGNED REVENUES	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	POST 2034(annual expenditure)
Establishment plan posts (officials and temporary staff)								
20 01 02 01 (Headquarters and Commission's Representation Offices)	29	29	29	29	29	29	29	29
20 01 02 03 (EU Delegations)	0	0	0	0	0	0	0	0
01 01 01 01 (Indirect research)	0	0	0	0	0	0	0	0
01 01 01 11 (Direct research)	0	0	0	0	0	0	0	0
Other budget lines (specify)	0	0	0	0	0	0	0	0
• External staff (in Full Time Equivalent unit: FTE)								
20 02 01 (AC, END from the 'global envelope')	9	9	9	9	9	9	9	9
20 02 03 (AC, AL, END and JPD in the EU Delegations)	0	0	0	0	0	0	0	0
Admin. Support line [XX.01.YY.YY] [2]	- at Headquarters	0	0	0	0	0	0	0
	- in EU Delegations	0	0	0	0	0	0	0
01 01 01 02 (AC, END - Indirect research)	0	0	0	0	0	0	0	0
01 01 01 12 (AC, END - Direct research)	0	0	0	0	0	0	0	0
Other budget lines (specify) - Heading 4	0	0	0	0	0	0	0	0
Other budget lines (specify) - Outside Heading 4	26	26	26	26	26	26	26	26
TOTAL	64	64	64	64	64	64	64	64

* Figures in the tables above are all strictly indicative pending the outcome of the 2028-2034 MFF negotiations which cannot be prejudged.

Considering the overall strained situation in Heading 4, in terms of both staffing and the level of appropriations, the human resources required will be only partly met by staff from the DG who are already assigned to the management of the action and/or have been redeployed within the DG.

¹ Please specify below the table how many FTEs within the number indicated are already assigned to the management of the action and/or can be redeployed within your DG and what are your net needs.

24 additional establishment plan posts which are required to implement the proposal and 4 SNEs (in FTEs) to be covered with additional staff to be financed under heading 4. 26 CAs will be financed from appropriations of an administrative nature financed from the envelope of specific programmes. 5ADs, 4 CAs and 1 SNE posts to be covered by current staff available in the Commission services.

The staff required to implement the proposal (in FTEs):

	To be covered by current staff available in the Commission services	Exceptional additional staff*		
		To be financed under Heading 4 or Research	To be financed from BA line	To be financed from fees
Establishment plan posts	5 ADs	19 ADs 5 ASTs	N/A	
External staff (CA, SNEs, INT)	4 CAs (FIV) and 1 SNE	4 SNEs	20 CAs FGIV 6 CAs FGIII	

The provisions of the Biotech Act, focused on health and food applications in the biotechnology sector, were developed by a temporary taskforce in DG SANTE with support of line units fully resourced to other tasks across different directorates. To fully implement the Act's provisions — which aim to streamline and future proof the regulatory system, enhance research, development, manufacturing and financing of biotechnology products, enable use of AI, foster skills and safe use of biotechnology — additional dedicated personnel will be needed, as presented in the table above and detailed below.

Description of tasks to be carried out by SANTE:

Officials and temporary staff	24 FTEs (AD profiles) to: • Manage the workload related to the revision and implementation of the following legislation ○ Amendment to Regulation (EU) 2024/1938 (SoHO): handle increased number of cases concerning the development of novel nologysandboxes in the field of SoHO. ○ Amendments to Regulation (EC) No 1394/2007 on Advanced Therapeutic Medicinal Products (ATMPs): draft delegated acts in relation to what constitute an ATMP in line with amendments to Regulation (EC) No 1394/2007 foreseen by this Regulation. ○ Amendments to Regulation (EU) No 536/2014 ('Clinical Trials Regulation'): prepare the delegated acts and implementing acts related to the changes of CTR, support the work of expert groups developing

	guidance and best practices, coordinate with relevant authorities for coherence with other regulatory frameworks, monitor the preparedness of Member States for the harmonised implementation of the changes to the CTR, monitor and steer the changes to the Clinical Trials Information System. ○ Amendments to Regulation (EC) No 178/2002 ('General Food Law'): comment on behalf of the Commission prior to the commencement of a proposed regulatory sandbox and of any adaptations thereof; Develop of implementing acts , review annual reports of Member States that have set up regulatory sandboxes, proceed to the necessary adaptations of the applicable legislative framework where required. • Manage a panel of experts advising the Commission on new biotechnology developments i.e., Foresight Panel for Emerging Health Innovation. • Set up and manage the regulatory sandboxes for novel health biotechnology products not falling in any other legislation in the area of health. • Develop implementing acts as needed, detail criteria, draft call for proposals and follow the implementation of High Impact Health Biotechnology strategic projects on: biotechnology research and development, availability of late-stage capital, AI biotechnology applications and biosecurity. • Draft call for proposals and follow the implementation of innovative and precommercial procurement projects, the establishment of an EU Health Biotechnology Support Network of local antennas supporting biotechnology undertakings; • Provide policy and legal guidance to and coordinate with: ○ EMA on AI systems Deployment and Use in the Lifecycle of Medicinal Products. ○ Implementing partners on the management of the Biotechnology Investment Pilot. ○ Member States on the supervision of economic operators handling potential biosecurity risk products. 5 (AST profiles) to: • Provide administrative and logistic support to experts' meetings of the Advisory Group on Biosecurity and Artificial Intelligence and to meetings of Member States and the Commission in the European Health Biotechnology Steering Group. • Support the process of projects selection and assessment for High Impact Health Biotechnology strategic projects and assist with information management. • Develop and maintain a Union Regulatory Status Repository to assist developers in navigating cases of health biotechnology products.
External staff	5 SNEs and 24 CAs (FGV) to support ADs with: • Expert selection and appointment and dissemination of discussion papers produced

	by the Foresight Panel for emerging health innovation, support content preparation of panels meetings. • Setting up and management of Regulatory Sandbox for novel health biotechnology products not falling in any other legislation in the area of health • Commenting on proposed regulatory sandboxes in the framework of the General Food Law and with the development of implementing and delegated acts. • Drafting of calls for proposal for High Impact Health Biotechnology Strategic Projects and follow their implementation, in different areas (biotechnology research and development, availability of late-stage capital, AI biotechnology applications and biosecurity) and for the establishment of the and the EU Health Biotechnology Support Network. • Providing technical content development of the AI-Biotechnology Support Module and its continued maintenance and update with information to be disseminated by the Biotechnology Support Network. • Ensuring coordination in management of funding and liaison with implementing partners in the context of the EU Biotechnology Investment Pilot. • Drafting of guidelines on the enforcement of biosecurity provision to be enforced in cooperation with Member States and relevant delegated or implementing acts, monitor and analyse landscape to identify promising technologies and to support ADs in developing and following calls for capability projects. • Preparing meeting content and support management of the meetings of the Advisory Group on Biosecurity and Artificial Intelligence and the European Health Biotechnology Steering Group. 6 CAs (FGIII) to: • Provide administrative support to the organisation of the experts' meetings of the Foresight Panel for emerging health innovation. • Promote and facilitate the networking and cooperation among projects and maintain updated lists of High Impact Health Biotechnology Strategic Project. • Support with workflow of queries and management of information of the EU Health Biotechnology Support Network.

3.2.5. *Overview of estimated impact on digital technology-related investments (not to be completed for decentralised agencies)*

Compulsory: the best estimate of the digital technology-related investments entailed by the proposal/initiative should be included in the table below.

Exceptionally, when required for the implementation of the proposal/initiative, the appropriations under Heading 4 should be presented in the designated line.

The appropriations under Headings 1-3 should be reflected as "Policy IT expenditure on operational programmes". This expenditure refers to the operational budget to be used to re-use/ buy/ develop IT platforms/ tools directly linked to the implementation of the initiative and their associated investments (e.g. licences, studies, data storage etc). The information provided in this table should be consistent with details presented under Section 4 "Digital dimensions".

TOTAL Digital and IT	Year	Year	Year	Year	Year	Year	Year	TOTAL MFF

appropriations	2028	2029	2030	2031	2032	2033	2034	2028 - 2034
HEADING 4								
IT expenditure (corporate)	0	0	0	0	0	0	0	0
Subtotal HEADING 4	0	0	0	0	0	0	0	0
Outside HEADING 4								
Policy IT expenditure on operational programmes	0	0	0	0	0	0	0	0
Subtotal outside HEADING 4	0	0	0	0	0	0	0	0
TOTAL	0	0	0	0	0	0	0	0

3.2.6. *Compatibility with the current multiannual financial framework (not to be completed for decentralised agencies)*

The proposal/initiative:

- ☒ can be fully financed through redeployment within the relevant heading of the multiannual financial framework (MFF)

The initiative will be fully financed via redeployments from programmes under the 2028-2034 MFF

- " requires use of the unallocated margin under the relevant heading of the MFF and/or use of the special instruments as defined in the MFF Regulation
- " requires a revision of the MFF

3.2.7. *Third-party contributions (not to be completed for decentralised agencies)*

The proposal/initiative:

- does not provide for co-financing by third parties
- ☒ provides for the co-financing by third parties estimated below:

Appropriations in EUR million (to three decimal places)

	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	Total
Specify the co-financing body								

TOTAL appropriations co-financed								

3.2.8. Estimated human resources and the use of appropriations required in EMA

Staff requirements (full-time equivalent units)

[Agency]: <EMA .>	Year	Year	Year	Year	Year	Year	Year	POST
	2028	2029	2030	2031	2032	2033	2034	2034
Temporary agents (AD Grades)	5	5	5	5	5	5	5	5
Temporary agents (AST grades)	2	2	2	2	2	2	2	2
Temporary agents (AD+AST) subtotal	7	7	7	7	7	7	7	7
Contract staff	5	5	5	5	5	5	5	5
Seconded National Experts								
Contract agents and SNE subtotal	5	5	5	5	5	5	5	5
TOTAL staff	12	12	12	12	12	12	12	12

Appropriations covered by the EU budget contribution in EUR million (to three decimal places)

[Agency]: <EMA .>	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL 2028 - 2034	POST 2034(annual expenditure)
Title 1: Staff expenditure	1,055	2,153	2,196	2,240	2,285	2,330	2,377	14,635	2,425
Title 2: Infrastructure and operating expenditure (IT investments) =	9,000	6,000						15,000	
Title 3: Operational expenditure								0,000	

TOTAL of appropriations covered by the EU Budget	10,055	8,153	2,196	2,240	2,285	2,330	2,377	29,635	2,425

IT investments: EMA currently maintains the Clinical Trials Information System (CTIS) development and maintenance. This Regulation contains major new provisions directly impacting CTIS and need its strengthening. The core objectives of the amendments to the Clinical Trials Regulation (EU 526/2014) will be implementable only following significant IT developments and establishment of new workflows. We anticipate that these new provisions will necessitate fundamental redesign and build of CTIS followed by long-term maintenance including technology refresh.

Overview/summary of human resources and appropriations (in EUR million) required by the proposal/initiative in a decentralised agency

[Agency]: <EMA .>	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL 2028 - 2034	POST 2034
Temporary agents (AD+AST)	7	7	7	7	7	7	7		12
Contract agents	5	5	5	5	5	5	5		5
Seconded National Experts	0	0	0	0	0	0	0		
Total staff	12	12	12	12	12	12	12		12
Appropriations covered by the EU Budget	10,055	8,153	2,196	2,240	2,285	2,330	2,377	29,635	2,425
Appropriations covered by fees	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000
Appropriations co-financed (if applicable)	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000
TOTAL appropriations	10,055	8,153	2,196	2,240	2,285	2,330	2,377	29,635	2,425

Appropriations covered by fees: Veterinary sandboxes established in this Regulation will be supported by fees, however being a completely new use case for which EMA will not be able to establish the fee level before the coming into effect of this Regulation, it is impossible to establish an amount and assess the level of contribution at this stage.

Without prejudice to the negotiations on the next MFF, the appropriations allocated to the agencies from 2028 onwards will be compensated via redeployments from programmes under the 2028-2034 MFF. If a compensatory reduction is needed, the resources allocated to the agencies and their funding streams and sources may need to be revised.

Description of tasks to be carried out by the European Medicines Agency (EMA):

Officials and temporary staff	The Biotech Act proposal will contain major new provisions on the management of Clinical Trials. These include multiple new workflows, parallel submissions, amended dossier requirement, a core product dossier and extension to combined studies including in-vitro diagnostics, among others. The requested 5 ADs will be: Managing the significantly increased daily operations of Clinical Trial

	Information System (CTIS) including the access and tasks of its >20,000 users and close to 3000 initial clinical trial applications and thousands of substantial modification applications. • Identifying, designing, reviewing and ensuring oversight of the delivery process for new functionalities and modules in CTIS in line with relevant legal provisions. • Monitoring the performance of the contractor, • Working with CTIS subject matter experts and stakeholders, to prioritise and validate CTIS technical specifications, in line with relevant legal provisions. • Performing CTIS testing activities, including for the new functionalities and modules. • Planning and performing change management activities. • Performing communication, engagement and training of all relevant stakeholders (e.g. sponsors, Member State regulatory bodies). • Maintaining the training materials up to date. • Monitoring the KPIs of the IT system and the CTR for regular reporting • Delivering reports when requested • Regulatory compliance check of the IT system 2 AST will: • Support AD organization of meetings with sponsors and/or experts and drafting minutes. • Support and coordinate engagement with CTIS subject matter experts and stakeholders. Support and coordinate communication and training activities with sponsors, member state authorities, ethics bodies etc.
External staff	The requested 5 FTE will be supporting ADs in: • Overall support to the ADs, and as appropriate, in the case of national experts, they provide expertise • Implementation of the development plan • Contribute to coordination tasks • Maintaining continuous availability and operation of CTIS. • Managing post-delivery maintenance, providing support to relevant

	stakeholders (e.g. IT and business service desk). - performing continuous monitoring of the CTIS function and performance. - Providing programme and project management. - Response to queries from stakeholders - Support the development of CTIS training material - Stakeholder communication (e.g. CTIS Forum and other events) The extra resources are absolutely necessary since timely implementation of the amendments targeting competitiveness are dependent on substantial IT development that would need to be set up in short time.

3.2.9. Estimated human resources and the use of appropriations required in EFSA

Staff requirements (full-time equivalent units)

[Agency]: <EFSA>	Year	Year	Year	Year	Year	Year	Year	POST
	2028	2029	2030	2031	2032	2033	2034	2034
Temporary agents (AD Grades)	5	5	5	5	5	5	5	5
Temporary agents (AST grades)	1	1	1	1	1	1	1	1
<i>Temporary agents (AD+AST) subtotal</i>	6	6	6	6	6	6	6	6
Contract staff	8	8	8	8	8	8	8	8
Seconded National Experts								
<i>Contract agents and SNE subtotal</i>	8	8	8	8	8	8	8	8
TOTAL staff	14	14	14	14	14	14	14	14

Overview/summary of human resources and appropriations (in EUR million) required by the proposal/initiative in a decentralised agency

[Agency]: <EFSA>	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL 2028 - 2034	POST 2034(annual expenditure)
Title 1: Staff expenditure	0,882	1,800	1,836	1,872	1,910	1,948	1,987	12,235	2,027
Title 2: Infrastructure and operating expenditure								0,000	
Title 3: Operational expenditure								0,000	
TOTAL of appropriations covered by the EU Budget	0,882	1,800	1,836	1,872	1,910	1,948	1,987	12,235	2,027

[Agency]: <EFSA>	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL 2028 - 2034	POST 2034
Temporary agents (AD+AST)	6	6	6	6	6	6	6		6
Contract agents	8	8	8	8	8	8	8		8
Seconded National Experts	0	0	0	0	0	0	0		
Total staff	14	14	14	14	14	14	14		14
Appropriations covered by the EU Budget	0,882	1,800	1,836	1,872	1,910	1,948	1,987	12,235	2,027
Appropriations covered by fees	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000
Appropriations co-financed (if applicable)	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000
TOTAL appropriations	0,882	1,800	1,836	1,872	1,910	1,948	1,987	12,235	2,027

Without prejudice to the negotiations on the next MFF, the appropriations allocated to the agencies from 2028 onwards will be compensated via redeployments from programmes under the 2028-2034 MFF. If a compensatory reduction is needed, the resources allocated to the agencies and their funding streams and sources may need to be revised.

Description of tasks to be carried out by the European Food Safety Agency (EFSA):

Officials and temporary staff	Currently, there are a lot of delays during the EU risk assessment as EFSA receives low quality dossiers, for which it has to frequently stop the EU risk assessment process and request applicants to provide clarifications and/or additional information. To enhance innovation and to ensure that applicants, and especially SMEs, submit high quality/comprehensive application dossiers it is imperative to support them at pre-submission phase. This will ensure that the EU risk assessment finishes within the time provided increasing the applicants' chances of reaching the market as quickly as they can (while keeping funding from investors). Currently EFSA provides pre-submission advice only as regards what an application dossier needs to contain (administrative/regulatory aspects). Given the restricted scope of pre-submission advice (PSA), the uptake of the existing PSA is limited; applicants primarily need support on the scientific aspects of preparing a dossier. The provisions of the Biotech Act will significantly increase EFSA workload, in particular due to the enlarged scope of PSA which will now cover <u>also scientific advice</u> (i.e. what kind of studies, advice on the appropriate study design depending on the subject matter at issue, etc). Given the considerable attractiveness of the proposed changes for applicants, especially for SMEs, this is expected to result in a significant increased uptake of pre-submission advice (PSA) especially by SMEs both in terms of numbers of requests for pre-submission advice but also in the breadth and coverage of advice to be given. <u>As regards numbers,</u> EFSA expects about 200 requests per year across all authorisation domains in the food chain – which are many and diverse – both for new products/substances and renewals where applicable (e.g. novel foods, food additives/enzymes/flavourings, feed additives, plant protection products, maximum residue limits of pesticides, GM food and feed, food contact materials, health claims,

	addition of vitamins and minerals and other substances to foods, etc). As <u>regards the breadth and coverage of the advice to be given</u>, EFSA will now be required to carry out a closer evaluation of the request at hand and provide tailor-made advice covering both administrative/regulatory aspects but also scientific aspects on each individual case. Thus, the requested -5 ADs are necessary to: - Prepare and provide tailor-made pre-submission advice consisting of scientific advice including on the type and design of studies to be submitted in support of an application/notification and on the content of the application/notification at hand. The scientific advice will be particularly demanding as it needs to be specific to the needs of each individual application taking also into account the profile of the applicant at hand (e.g. SME that has no experience with applications) as well as the subject matter (type of product, applicable sectoral legislation, type of approval, e.g. new or renewal etc). This includes additional tasks such as: ○ coordinate with subject matter units for the needed tasks, involvement of working group Experts, Panel experts, who might also later be involved in dossier assessment; In this respect, additional research and work would need to be carried out as regards previous scientific outputs of the EFSA of all 11 Panels across all authorisation procedures in the food chain, data requirements set out in sectoral legislation and all relevant scientific guidances, where such exist as well as the latest scientific information that may be relevant for the applicant concerned; ○ coordinate with Member State experts in the relevant EFSA networks/fora but also with other EU agencies where needed – in the area of pesticides where the approval system of active substances is semi-decentralised this will need additional effort to coordinate with the relevant MS authorities to ensure the provision of PSA from EFSA and from the MS authorities in a consistent manner; ○ exchange with the requestor (on acceptability, requests for clarifications); ○ regular consultation with EFSA’s legal department to provide advice in line with the applicable rules (remit of pre-submission advice, public disclosure of the advice

	given once corresponding valid applications are made etc.) ensure the clarity and consistency of the pre-submission advice to all requestors across all authorisation procedures, especially where applicants would need to apply for more than 1 authorisation process for placing products on the market (application for novel foods and subsequently application for a health claim); ○ coordinate the timely handling of all PSA requests in a manner that provides added value to the applicants and ensure that high quality dossiers are subsequently submitted. - promotion of the pre-submission advice provided by EFSA upon request among applicants and particularly SMEs, who are often one-time applicant and have no experience on how to prepare application dossiers for risk assessment purposes; - to effectively explain the ‘pre-submission advice (PSA)’ process to potential requestors; - to ensure appropriate training to the subject matter units and/or relevant experts both on the required content of dossiers and on the scientific front taking into account the EFSA scientific guidance documents and data requirements laid down in the sector specific legislation. The permanent 5 AD positions will ensure clarity and consistency in the provision of PSA, maintain the uptake of PSA to ensure that high quality dossiers are later submitted that would accelerate the risk assessment process and that the knowledge is retained within EFSA in the most effective manner. 1 Assistant staff (AST) is needed for: - organization of tele-meetings with the requestor and/or experts (if needed) and drafting minutes; - developing a knowledge database and ensuring its maintenance, monitoring, reporting, auditing of the requests; - following up on the continuous improvement of the service and support IT tool improvements; - supporting applicants on the characteristics of the service and the IT Tools; - disseminating the service among applicants and SMEs, supporting the publication of summary in Open EFSA, publication of full advice at the time of a validated dossier.
External staff	Given the expected considerable increased uptake of the PSA in the

early years of entry into application of this enlarged service, the permanent staff would need the support of 8 CAs (FGIV) to set in motion the relevant process and the establishment/maintenance in terms of content of a knowledge database for future use for all the tasks outlined and for all authorisation procedures across the food chain for which EFSA is responsible to provide scientific advice. More specifically:

- perform reception and triage of the request;
- analyse the request and ensure appropriate understanding what is needed to provide tailor-made advice;
- liaise with the technical units and identify the relevant and appropriate profile of scientific experts (either from the established panels or their working groups or even from the reserve list of experts) that could support the scientific aspects of PSA depending on each individual request; ensure their participation, analysis and input to the provision of the PSA;
- perform literature review and preparatory work to support the scientific experts and ensure also the provision of PSA on administrative/regulatory aspects;
- exchanges with the requestor (on acceptability, requests for clarifications) and setting up where appropriate PSA meetings;
- review of written replies and summaries to ensure consistency;
- ensure that the replies provided are introduced into a knowledge database to keep records of past advice for future use depending on the relevant needs of the requests at hand;
- drafting of the written advice to be sent to the requestor, finalisation of the advice and ensure that public disclosure of the PSA advice does not contain personal data or other confidential information.

If such staffing is not guaranteed and given the considerable increase of PSA that is expected, EFSA would not be able to deliver on the PSA advice without moving staff from its ‘core business’ – which is the provision of risk assessment – to the pre-submission phase. **This will result in even more delays** than currently occur in the delivery of scientific outputs, **defeating the very purpose of the Biotech act**, which is to stimulate innovation and ensure that the time to the market for innovators is reduced.

Therefore, it is absolutely imperative for ensuring the objectives of the Biotech act to guarantee the EFSA additional resources so as to avoid any **direct negative impact on the timeliness and speed of delivery of scientific opinions..**

3.3. Estimated impact on revenue

- The proposal/initiative has no financial impact on revenue.
- The proposal/initiative has the following financial impact:
 - on own resources
 - on other revenue
 - please indicate, if the revenue is assigned to expenditure lines

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative ²						
		Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034
Article								

For assigned revenue, specify the budget expenditure line(s) affected.

[...]

Other remarks (e.g. method/formula used for calculating the impact on revenue or any other information).

[...]

4. DIGITAL DIMENSIONS

4.1. Requirements of digital relevance

High-level description of the requirements of digital relevance and related categories (data, process digitalisation & automation, digital solutions and/or digital public services)

Reference to the requirement	Requirement description	Actors affected or concerned by the requirement	High-level Processes	Categories
Article [3] 1b Health Biotechnology Strategic Projects	Scaling-up or upgrading critical research and technology infrastructures underpinning the development,	Member State authorities, Research organisations, Biotechnology industry actors	Technical documentation, Data generation, Data processing	Data, Digital Solution

² As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 20% for collection costs.

	testing and validation of biotechnology products, including but not limited to pilot or testing infrastructures for biomanufacturing, data and digital platforms;			
<i>Article [3] 1c Health Biotechnology Strategic Projects</i>	accelerating innovation and technology deployment through one or more of the following features: (i) introducing or scaling up breakthrough innovations in biotechnology that have the potential to strengthen the Union's industrial competitiveness, including AI-enabled technologies and tools;	Commission, Member State authorities, Research organisations, Biotechnology industry actors	Technical documentation, Data generation, Data processing	Data, Digital Solution
<i>Article [4] 1d High Impact Health Biotechnology Strategic Projects</i>	the project contributes to the development of trusted testing environments for AI-enabled biotechnology innovations, fulfilling the conditions laid down in Article [36], paragraph [1] or it is Biotechnology Data Quality	Commission, Member State authorities, Research organisations, Biotechnology industry actors	Data generation, Data processing	Data, Digital Solution

	Accelerator High Impact Project, fulfilling the conditions laid down in Article [37]			
<i>Article [5] a Biotechnology Development Accelerator</i>	it provides trusted testing or demonstration facilities replicating real-world biomanufacturing processes, including general manufacturing practices (GMPs) compliant processes, or their enabling technologies, for process testing, validation, and small batch manufacturing, including for the initial phases of clinical trials; such enabling technologies may include digital technologies, including AI with specific applicability in biotechnology and biomanufacturing;	Commission, Member State authorities, Research organisations, Biotechnology industry actors	Data generation, Data processing	Data, Digital Solution
<i>Article [5] c Biotechnology Development Accelerator</i>	it aims to support hands-on and work-based training programmes aligned with the Union's skills and workforce development objectives in the biotechnology and biomanufacturing	Commission, Member State authorities, Research organisations, Biotechnology industry actors	Technical documentation, Information exchange	Data, Digital Solution

	sectors or in relation to enabling technologies, such as digital technologies including AI, with specific applicability in biotechnology and biomanufacturing;			
<i>Article [5] d Biotechnology Development Accelerator</i>	it conducts applied research in biotechnology or biomanufacturing, or in relation to enabling technologies, such as digital technologies including AI, with specific applicability in biotechnology and biomanufacturing	Research organisations, Biotechnology industry actors	Data generation, data processing	Data, Digital Solution
<i>Article [11] 7 Single Points of Contact</i>	Member States shall promote the reuse of existing data, studies and authorisations in order to avoid duplication of procedures, reduce administrative burden and ensure consistency of decision-making. For that purpose, they shall ensure that, when assessing an application, competent authorities duly take into account all relevant studies, assessments and valid permits or	Member State authorities	Reuse of existing data	Data

	authorisations already carried out or issued for the same project or its components, provided that they remain applicable and up to date.			
<i>Article [15] 2e Networks of Health Biotechnology Clusters</i>	Such networking and cooperation should aim to: e) promote the development of interoperable infrastructure and digital platforms, and AI-enabled technologies supporting biotechnology and biomanufacturing	Commission, Member State authorities, Research organisations, Biotechnology industry actors	Information exchange	Data
<i>Article [16] 6a Access Principles and Security Safeguards</i>	access by a non-associated third country or by a non-associated third-country entity to sensitive information is prevented and the employees or other persons involved have national security clearance issued by a Member State or an associated country, where appropriate;	Non-associated third country, Non-associated third-country entity, Member States, Associated countries	Access to data	Data
<i>Article [16] 6b Access Principles and Security Safeguards</i>	intellectual property arising from, and the results of, the activities related to the access to infrastructures and datasets remain within the legal entity that is	Non-associated third country, Non-associated third-country entity, Member States, Associated	Access to infrastructures and datasets	Data

	granted access, during and after such access, are not subject to control or restriction by a non-associated third country or by a non-associated third-country entity, and are neither exported outside the Union or outside associated countries nor accessible from outside the Union or outside associated countries without the approval of the Member State or the associated country in which the legal entity is established and in accordance with the objectives of this Regulation	countries		
<i>Article [17] 2e Strategic Mapping of the Union's Biotechnology Ecosystem</i>	use of data and artificial intelligence, by assessing access to data, computing and digital infrastructures for biotechnology and identifying opportunities to foster responsible AI-enabled innovation and contribute to the mitigation of related risks.	Union bodies and agencies, industry stakeholders and research organisations	Mapping	Data
<i>Article [21] 5a Composition and</i>	facilitate the exchange of information and	Members of the Steering Group,	Information exchange	Data, Digital Public Service

<i>Functioning of the Steering Group</i>	best practices among Member States, the Commission, and relevant stakeholders in relation to the recognition and the implementation of health biotechnology strategic projects and high impact health biotechnology strategic projects;	Commission, Member State authorities, research organisations, biotechnology industry actors		
<i>Article [21] 5h Composition and Functioning of the Steering Group</i>	facilitate the coordination and information exchange among the Member States on enforcement of the biosecurity provisions in this regulation and other emerging biosecurity topics as provided for in Article	Commission, Member State authorities	Information exchange	Data, Digital public service
<i>Article [29]b Health Biotechnology Strategic Projects for Biosimilars</i>	it contributes to the research, development and marketing authorisation of biosimilar products, and where appropriate to strengthen the use of platform technologies. It includes analytical methodologies that would reduce the need for clinical data for biosimilar	Member State authorities	Use of platform technologies	Data

	medicinal products, without affecting their quality, safety and efficacy.			
<i>Article [31]</i> <i>Guidance on the deployment and use of systems based on advanced technologies, including AI, in the lifecycle of medicinal products</i>	The European Medicines Agency ('the Agency') shall develop guidance on the deployment and use of artificial-intelligence systems ('AI systems') and of general-purpose AI models in the lifecycle of medicinal products development, including during pre-clinical research, clinical development and trials, manufacturing and post-authorisation monitoring. Such guidance shall comply with relevant EU legislation and shall be developed and updated in cooperation with the Commission.	Commission, EU Agencies, Member State authorities, industry stakeholders and research organisations	Technical documentation	The European Medicines Agency ('the Agency') shall develop guidance on the deployment and use of artificial-intelligence systems ('AI systems') and of general-purpose AI models in the lifecycle of medicinal products development, including during pre-clinical research, clinical development and trials, manufacturing and post-authorisation monitoring. Such guidance shall comply with relevant EU legislation and shall be developed and updated in cooperation with the Commission.
<i>Article [32]1</i>	A project located	Commission,	Data	Data

<i>Biotechnology testing environments for advanced biotechnology innovations</i>	in the Union that contributes to the development of trusted testing environments for AI-enabled biotechnology innovations shall be recognised as a high-impact health biotechnology strategic project where, in addition to the conditions laid down in Article [6], paragraph [1], it substantially strengthens the Union's capacity for responsible experimentation, development, testing and validation of such innovations and it fulfils all of the following conditions:	Member State authorities	generation, Data processing, setting up testing environments for AI	
<i>Article [33] 2a Biotechnology Data Quality Accelerator</i>	aim to foster the development and deployment of trustworthy and competitive AI applications in health biotechnologies, including large-scale and general-purpose models;	Research organisations, Biotechnology industry actors	Development and deployment of AI solutions	Data
<i>Article [33] 2b Biotechnology Data Quality Accelerator</i>	ensure that datasets are established, managed and processed in accordance with applicable Union legislation on data governance, ethics	Research organisations, Biotechnology industry actors	Data generation, data processing	Data

	and fundamental rights, including Regulation (EU) 2025/327 [European Health Data Space], Regulation (EU) 2016/679 [General Data Protection Regulation].			
<i>Article [33] 2c Biotechnology Data Quality Accelerator</i>	make such datasets, or the metadata and reference annotations thereof, available under fair, reasonable and non-discriminatory conditions, ensuring equitable access for users including research organisations, SMEs and public institutions, in compliance with the provisions of Article [9] of this Regulation.	Research organisations, Biotechnology industry actors	Data access	Data
<i>Article [33] 2d Biotechnology Data Quality Accelerator</i>	contribute to the development of Union standards and quality frameworks for data representativeness, provenance, interoperability and annotation in biotechnology;	Research organisations, Biotechnology industry actors	Data interoperability, Standard Development	Data
<i>Article [33] 2e Biotechnology Data Quality Accelerator</i>	support, where appropriate, the integration of these datasets into Union infrastructures,	Research organisations, Biotechnology industry actors	Infrastructure interoperability, Data integration	Data

	including the European Health Data Space, European Research Area data spaces, or other, including the infrastructures operated by high impact health biotechnology strategic projects.			
<i>Article [33] 2f Biotechnology Data Quality Accelerator</i>	give due consideration to the interoperability with platforms deployed pursuant to the EHDS and other relevant data spaces.	Research organisations, Biotechnology industry actors	Platform interoperability	Data
<i>Article [35] 1 Union Regulatory Status Repository</i>	The Commission shall compile, maintain, develop and make publicly available a Regulatory Status Repository to assist developers in navigating cases of novel biotechnology products ('Regulatory Status Repository').	Member State authorities, Commission	Technical documentation, Information exchange	Data
<i>Article [35] 2 Union Regulatory Status Repository</i>	The Regulatory Status Repository shall contain: a) decisions, opinions, scientific recommendations regarding the regulatory status of a health innovations,	Member State authorities, Commission	Technical documentation, Information exchange	Data

	issued pursuant to the mechanisms laid down in Article 4 of [revised Regulation (EU) 2017/745], Articles 61 and 62 of [revised Regulation (EC) No 726/2004] and Articles 13 and 69 of Regulation (EU) 2024/1938; b) the summaries of the scientific recommendations delivered by the European Medicines Agency in accordance with Article 17 of Regulation (EC) No 1394/2007 on whether a product falls within the definition of an advanced therapy medicinal product or not; c) the discussion papers delivered by the Foresight Panel for Emerging Health Innovation.			
<i>Article [35] 3</i> <i>Union Regulatory Status Repository</i>	Member States shall make publicly available, through the relevant national platforms or registries, decisions, opinions, scientific recommendations, and other outputs issued at national	Member State authorities, Commission	Technical documentation, Information exchange	Data

	level concerning the regulatory status of novel biotechnology products. Member States shall inform the Commission where such information is made available.			
<i>Article [39] Regulatory Sandboxes provided for in the applicable frameworks and Cross Framework Communication</i>	The European Medicines Agency, the MDCG, the SCB and the Foresight Panel, as applicable, shall facilitate dialogue among the authorities responsible for the setting up and the implementation of regulatory sandboxes for novel health biotechnology products. This dialogue shall focus on exchanging mutual learnings and findings, specifically including: (a) promoting knowledge sharing, by facilitating the exchange of information, experiences and best practices, including on regulatory approaches, technological challenges	Member State authorities, Commission	Technical documentation, Information exchange	Data, Digital public service

Article [40] <i>Regulatory sandboxes for novel health biotechnology products not falling under other sandboxes in Union legislation</i>	The Commission may, by means of implementing acts, lay down common principles, criteria and practical arrangements for the assessment of applications received from developers and for the establishment and the supervision of the regulatory sandboxes and for sandbox plans.	Commission	Technical documentation	Digital public service
Article [41] d <i>EU Biothreat Radar High Impact Projects</i>	ensure that sequencing data generated through early detection activities is shared in a timely manner via the European Nucleotide Archive (ENA), to enable access and use by actors across the Union for the development, validation and deployment of advanced pathogen detection and characterisation methods; engage in partnerships among industry, academia, public authorities and defence actors to ensure data sharing and integration of warning systems;	Commission, Member State authorities, Biotechnology industry actors, Research Organisations	Surveillance, data sharing	Data

Article [42] f <i>Biodefence capability high impact strategic project</i>	development, validation and benchmarking of methods for the detection and attribution of genetic engineering, including the creation of open genetic engineering detection tools	Commission, Member State authorities	Health cross border Surveillance, data sharing	Data
Article [44] <i>Verification of Legitimate Need</i>	An economic operator that makes available on the Union market, including through online marketplaces, biotechnology products of concern, shall, for each transaction, verify proof of identity of the prospective customer, record the transaction, including the quantities ordered, and assess whether the customer has a legitimate need.	Economic operator, prospective customer	Identity verification	Data
Article [46] <i>Prevention and Reporting of Misuse</i>	For the purpose of preventing and detecting biotechnology misuse, economic operators and online marketplaces shall	Economic operators, Online marketplaces	Data reporting, Information exchange	Data

	report suspicious transactions,			
<i>Article [48] 2 National Inspection Authorities</i>	Member States shall ensure that the national inspection authority has the resources and investigative powers necessary to perform their tasks, including the power to request information and records, to carry out on-site inspections and, where appropriate, to conduct test purchases, including online.	Commission, Member State authorities	Information exchange	Data
<i>Article [48] 4 National Inspection Authorities</i>	Member States shall ensure the participation of national inspection authorities, as appropriate, in the relevant activities of the Steering Group, in particular for the exchange of information on implementation practices, inspection findings and emerging risks.	Commission, Member State authorities	Information exchange	Data (data flow)
<i>Article [49] Commission Enforcement Support and Monitoring</i>	The Commission may support and monitor national competent authorities in the enforcement of this section, by taking actions such as requesting	Commission	Monitoring, requesting information	Data, Digital public service

	information and records and running training exercises.			
<i>Article [52] Advisory Group on Biosecurity</i>	AI models in biological applications. The Commission, based on advice by the Advisory Group on Biosecurity, and where appropriate, in cooperation with the Steering Group, may issue and regularly update guidance, to assist actors in the supply chain and the competent authorities, and to facilitate cooperation between them.	Commission, Member State authorities, Actors in the supply chain	Monitoring, access to data, Technical guidelines	Data, Digital public service
<i>Article [53] Biological Systemic Risk</i>	The Commission shall monitor systemic risk from AI models in biological applications and propose mitigating actions, based on advice provided by the Scientific Panel, including boosting biodefense capabilities or regulation, including on assessment and mitigation of systemic risk from those models, as appropriate.	Commission, Member State authorities	Monitoring systemic risk	Data
<i>Article [54]</i>	information on how to exchange	Commission, Member State	Information	Data

<i>Monitoring and Guidance</i>	relevant information between competent authorities, national contact points and among Member States;	authorities	exchange	
<i>Article [55] Coordination on Biosecurity and Biosafety</i>	The Steering Group in cooperation with the Commission, facilitates coordination and information exchange on emerging AI-enabled bio-risks;	Commission, Member State authorities	Information exchange, Technical Guidelines	Data, Digital Public Service
<i>Article [56] Amendments to Regulation (EC) No 178/2002 (General Food Law): Article 3</i>	‘regulatory sandbox’ means a controlled environment where participants can test innovative products or substances and related processes as well as data and other regulatory requirements at a pre-market stage under a set of defined rules and monitoring and for a limited period of time.	Commission, Member State authorities	Technical documentation, Information Exchange	Data
<i>Article [56] Amendments to Regulation (EC) No 178/2002 (General Food Law): Article 49a (3) General provisions on regulatory sandboxes</i>	Regulatory sandboxes may be established in relation to the following: (a) all stages of the production, processing and distribution of food with the exception of novel foods, and	Member States	Facilitating the development, testing, and validation of technologies; Testing data requirements Testing alternative regulatory requirements	Technologies, Data

	also of the feed produced for, or fed to food-producing animals; (b) food contact materials, with the exception of plastic recycled materials; (c) products, other than food and feed, containing or consisting of genetically modified organisms as defined in Article 2, point (2), of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC. The making available of products within a regulatory sandbox shall not be regarded as placing on the market. Regulatory sandboxes shall have the following objectives: (a) facilitating the development, testing and validation of technologies, products and substances before they obtain authorisation or		(such as digital labelling instead of actual labels on food products).	

	approval for placing on the market, where so required by Union law; (b) testing data requirements, including the type and design of studies required for conducting a safety and/or efficacy assessment; (c) testing alternative regulatory requirements and appraising their performance as regards the attainment of the objectives of the applicable Union sectoral law in comparison to the existing requirements; in the areas where Union law provides for an approval or authorisation, as well as in the area of food information to consumers			
<i>Article [56] Amendments to Regulation (EC) No 178/2002 (General Food Law): Article 3</i>	‘regulatory sandbox’ means a controlled environment where participants can test innovative products or substances and related processes as well as data and other regulatory requirements at a	Commission, Member State authorities	Technical documentation, Information Exchange	Data

	pre-market stage under a set of defined rules and monitoring and for a limited period of time.			
<i>Article [56] Amendments to Regulation (EC) No 178/2002 (General Food Law): Article 49a (3)General provisions on regulatory sandboxes</i>	Regulatory sandboxes may be established in relation to the following: (a) all stages of the production, processing and distribution of food with the exception of novel foods, and also of the feed produced for, or fed to food-producing animals; (b) food contact materials, with the exception of plastic recycled materials; (c) products, other than food and feed, containing or consisting of genetically modified organisms as defined in Article 2, point (2), of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC. The making available	Member States	Facilitating the development, testing, and validation of technologies; Testing data requirements Testing alternative regulatory requirements (such as digital labelling instead of actual labels on food products).	Technologies, Data

	of products within a regulatory sandbox shall not be regarded as placing on the market. Regulatory sandboxes shall have the following objectives: (a) facilitating the development, testing and validation of technologies, products and substances before they obtain authorisation or approval for placing on the market, where so required by Union law; (b) testing data requirements, including the type and design of studies required for conducting a safety and/or efficacy assessment; (c) testing alternative regulatory requirements and appraising their performance as regards the attainment of the objectives of the applicable Union sectoral law in comparison to the existing requirements; in the areas where Union law			

	provides for an approval or authorisation, as well as in the area of food information to consumers			
Article [56] Amendments to Regulation (EC) No 178/2002 (General Food Law): Article 49a General provisions on regulatory sandboxes	Member States shall monitor and supervise the operation of regulatory sandboxes that they establish and ensure compliance with the regulatory sandbox plan. A participant to an established regulatory sandbox shall immediately inform the competent authorities of the Member State(s) concerned if it considers or has reason to believe that the conditions of the regulatory sandbox plan have not been complied with and/or there are potential risks to public health, animal health or welfare, plant health or to the environment, which may require the revocation of the regulatory sandbox or the amendment of the regulatory sandbox plan to	Member States, Commission	Monitoring and Supervision, Information exchange	Data

	provide for mitigating measures. Participants shall also immediately inform the competent authorities of any other information that concerns the quality, safety or efficacy of the subject matter of the relevant regulatory sandbox. Member States shall immediately notify to the Commission and, where relevant, to the Authority any violation of the conditions set out in the regulatory sandbox plan and/or the identification of any potential risks to public health, animal health or welfare, plant health or to the environment. Member States shall suspend or revoke a regulatory sandbox at any time on their own motion, or at the request of the Commission in accordance with paragraph 9, in either of the following cases: (a) the requirements and conditions			

	governing the regulatory sandbox plan are not met; (b) where necessary to protect public health, animal health or welfare, plant health or the environment and there is no possibility for effective mitigation measures. Member States shall inform the Commission, the Authority and the other Member States without delay of the suspension or revocation of a regulatory sandbox and of the reasons. Where after the setting up of a regulatory sandbox in their territory, a Member State identifies risks to public health, animal health and welfare, plant health and to the environment which can be fully mitigated by amendments to the regulatory sandbox plan, it shall communicate to the Commission, the Authority and the other Member States the draft			

	amendments in accordance with the procedure laid down in Article 49b. Where the Commission considers that one of the cases referred to in paragraph 7 is fulfilled, it shall immediately adopt implementing acts.in accordance with the procedure referred to in Article 58(2) requesting the suspension or the revocation of the regulatory sandbox concerned. However, in emergencies, the Commission may provisionally adopt an implementing act requesting the suspension of the regulatory sandbox concerned after consulting the Member State(s) concerned and informing the other Member States. As soon as possible, and at most within 10 working days, the measure taken shall be confirmed, amended or revoked in accordance with			

	the procedure referred to in Article 58(2) and the reasons for the Commission's decision shall be made public without delay. A Member State may prolong the duration once of a regulatory sandbox for a limited time where this is justified by the need to attain the objective of the specific regulatory sandbox at hand and shall inform the Commission, the Authority and the other Member States thereof. The Commission may, by means of implementing acts, specify common principles or practical arrangements for the establishment and supervision of regulatory sandboxes, including the establishment of sandboxes involving several Member States pursuant to this Article, Article 49b and 49c. Those implementing acts shall be adopted in accordance with the procedure			

	referred to in Article 58(2).			
<i>Article [56] Amendments to Regulation (EC) No 178/2002 (General Food Law): Article 49b</i> <i>Establishment of regulatory sandboxes at national level</i>	Where a Member State deems it appropriate to establish a regulatory sandbox pursuant to Article 49a, it shall communicate to the Commission, the Authority and the other Member States a draft regulatory sandbox plan 60 days prior to the commencement	Commission, EFSA, Member State authorities	Information exchange	Data
<i>Article [56] Amendments to Regulation (EC) No 178/2002 (General Food Law): Article 49c</i> <i>Other responsibilities, monitoring and reporting obligations regarding regulatory sandboxes</i>	Regulatory sandboxes shall not affect the enforcement and monitoring responsibilities of the competent authorities set out in Article 17 and in other sectoral legislation. Participants, with the exception of final consumers, in particular the operator that is the developer of the product or substance concerned, shall remain liable under applicable national legislation for any harm inflicted on third parties as a result from the	Commission, Agency (EFSA), Member State authorities	Monitoring, Information exchange	Data

	testing taking place in the sandbox. Member States shall submit annual reports to the Commission on the results from the implementation of regulatory sandboxes, including good practices developed, lessons learnt and recommendations on their setup and, where relevant, on the application of the relevant sectorial Union legislation. Those reports shall be made publicly available by the Commission. The Authority shall also ensure the necessary revisions of its guidance where relevant and appropriate on the basis of those annual reports.			
<i>Article [58] Amendments to Regulation (EU) No 536/2014 ('Clinical Trials Regulation')</i>	Article 5: Submission of an application through EU portal Article 6: Assessment report by the reporting Member State—Aspects covered by Part I Article 7: Assessment report	Biotechnology industry actors, Commission, Agency, Member States	Submission of an application, Information exchange, access to application	Data, Process automation, EU portal

	- Aspects covered by Part II Article 8: Decision on the clinical trial by Member States to sponsor Article 9: Persons assessing the application Article 14c: Coordinated assessment for the authorisation of combined studies Article 17: Validation of an application for the authorisation of a substantial modification of an aspect covered by Part I of the assessment report Article 19: Decision on the substantial modification of an aspect covered by Part I of the assessment report Article 20: validation, assessment and decision regarding a substantial modification of an aspect covered by Part II of the assessment report Article 21: Substantial modification of aspects covered by Parts I and II of the assessment report			

	Article 25: Data submitted in the application dossier			
<i>Article [58] Amendments to Regulation (EU) No 536/2014 ('Clinical Trials Regulation')/Article 27e: Use of AI in Clinical Trials</i>	Sponsors shall evaluate AI models or AI systems proposed to be used in the context of the lifecycle of the specific clinical trial	Biotechnology industry actors, Commission, Agency, Member States	Evaluation of AI models	Data
<i>Article [58] Amendments to Regulation (EU) No 536/2014 ('Clinical Trials Regulation') Articles 41 –46, 55, 56-58, 79a regarding reporting requirements</i>	Article 41: Reporting of adverse events and serious adverse events by the investigator to the sponsor Article 42: Reporting of suspected unexpected serious adverse reactions by the sponsor to the Agency Article 43: Annual reporting by the sponsor to the Agency Article 44: Assessment by Member States Article 46: Reporting with regard to auxiliary medicinal products Article 48: Monitoring Article 52: Reporting of serious breaches	Biotechnology industry actors, Commission, Agency, Member States	Reporting	Data, EU portal

	Article 55: Investigator's brochure Article 56: Recording, processing, handling and storage of clinical trial information: Article 57: Clinical trial master file Article 58: Archiving of the clinical trial master file Article 79a: Obligations as regards Union controls: Ensure that the necessary technical assistance and the available documentation, upon justified request, is being provided to the Commission as well as any other support that the Commission requests			
<i>Article [58] Amendments to Regulation (EU) No 536/2014 ('Clinical Trials Regulation')</i>	Article 81 is amended: The sponsor shall permanently update in the EU database information on any changes to the clinical trials which are not substantial modifications but are relevant for the	Commission, Agency (EMA), Member States	Reporting	Data, digital solution, process automation, EU portal, EU database

	supervision of the clinical trial. The sponsor shall also update the EU portal to satisfy a condition to which an authorisation decision is subject to.			
<i>Article [58] Amendments to Regulation (EU) No 536/2014 ('Clinical Trials Regulation')</i>	Article 93: Data protection: Sponsors shall comply with Regulation (EU) 2016/679 to process personal data, including data concerning health, in the public interest of health in the context of the entire lifecycle of a clinical trial, from the preparation of the application for the authorisation of the clinical trial to the end of the archiving period	Biotechnology industry actors, Commission, Agency, Member States	Data protection	Data
<i>Article [59] Amendments to Regulation (EU) 2019/6 (Veterinary Medicine Products Regulation)</i>	Article 61 (2). Where a variation as referred to in paragraph (1) affects the summary of product characteristics, labelling or package leaflet, the marketing authorisation holder shall record the change in the product database within 30 days	Commission, Member State authorities, Agency	Information exchange	Data

	after its implementation.			
Article [59] <i>Amendments to Regulation (EU) 2019/6 (Veterinary Medicine Products Regulation)</i>	‘CHAPTER IX REGULATORY SANDBOX Article 136a Regulatory sandbox 5. After a sandbox is established, the Agency shall: a) develop and make publicly available technical and scientific requirements for technologies, methods or products developed under the sandbox, taking due account of the potential risks of thereof for human and animal health and the environment;	Commission, Member State authorities	Technical documentation, Information Exchange	Data
Article [61] <i>Amendments to Regulation (EC) No 2024/1938 Article [39a] 3</i> <i>SoHO regulatory sandboxes</i>	The regulatory sandbox shall aim to allow the assessment of the innovations referred to in paragraph 1 in a real-world environment under strict regulatory supervision, to ensure that the necessary evidence and data is generated to demonstrate their, safety quality, including effectiveness in view of their distribution.	Member State authorities, Commission	Assessment of innovations	Data

Article [61] Amendments to Regulation (EC) No 2024/1398 Article [39a] 7a SoHO regulatory sandboxes	request information and data from holders of authorisations of SoHO preparations, developers independent experts and researchers, representatives of healthcare professionals and patients and may engage with them in preliminary discussions;	Member State authorities, developers, independent experts and researchers, representatives of healthcare professionals and patients	Data access, information exchange, leveraging information published on the EU SoHO platform (art 74.3(b) of Regulation (EU)2024/1938,	Data
Article [63] Evaluation	The national authorities and the economic operators shall, upon request, provide the Commission with any relevant information they have and that the Commission may need for its assessment pursuant to in paragraph 1	Commission, Member State authorities, research organisations, biotechnology industry actors	Information exchange	Data
Article [66] Handling of Confidential Information	Member States and the Commission shall ensure the protection of trade and business secrets and other sensitive, confidential and classified information obtained and processed in application of this Regulation,	Commission, Member States	Information exchange	Data, Digital solution

	including recommendations and measures to be taken, in accordance with Union and relevant national law. The Commission and Member States shall ensure that classified information provided or exchanged pursuant to this Regulation is not downgraded or declassified without the prior written consent of the originator in accordance with relevant Union or national law.			

4.2. Data

High-level description of the data in scope

Type of data	Reference to the requirement(s)	Standard and/or specification (if applicable)
Data required for testing and validation of biotechnology products	<i>Article [3]1 Health Biotechnology Strategic Projects</i> <i>Article [4] 1 High Impact Health Biotechnology Strategic Projects</i> <i>Article [15] 2e Networks of Health Biotechnology Clusters</i> <i>Article [5] Biotechnology Development Accelerator</i> <i>Article [30] Strategic Projects for Biosimilars</i> <i>Article [32] Biotechnology Testing Environments for advanced biotechnology innovations</i> <i>Article [33] 2 Biotechnology Data Quality Accelerator</i> <i>Article [59]</i> <i>Amendments to Regulation (EU) 2019/6 (Veterinary Medicine Products Regulation)</i> <i>Article [61] Amendments to Regulation (EC) No 2024/1938/ Article [39a] 3 SoHO regulatory sandboxes</i> <i>Article [49a] General</i>	N.A.

	<i>provisions on regulatory sandboxes</i>	
Sensitive information, biotechnology datasets	<i>Article [16] Access Principles and Security Safeguards</i>	N.A.
Mapping of existing infrastructures	<i>Article [17] Strategic Mapping of the Union's Biotechnology Ecosystem</i>	N.A.
Guidance on the use and deployment of AI	<i>Article [31] Guidance on the deployment and use of systems based on advanced technologies including AI Systems in the Lifecycle of Medicinal Products</i>	N.A.
Regulatory decisions, opinions, recommendations	<i>Article [35] 1 Union Regulatory Status Repository</i>	N.A.
Personal health data, clinical data	<i>Article [58] Amendments to Regulation (EU) No 536/2014 ('Clinical Trials Regulation')</i>	N.A.
Cross-border surveillance of biological threats	<i>Article [41] EU Biothreat Radar High Impact Projects</i> <i>Article [42] Biodefence capability high impact strategic project</i> <i>Article [44] Verification of Legitimate Need</i> <i>Article [46] Prevention and Reporting of Misuse</i>	One implementing Act/Delegated Act foreseen

	<i>Article [48]</i> <i>National Inspection Authorities</i> <i>Article [49]</i> <i>Commission Enforcement Support and Monitoring</i> <i>Article [52]</i> <i>Advisory Group on Biosecurity</i> <i>Article [53]</i> <i>Biological Systemic Risk</i> <i>Article [54]</i> <i>Monitoring and Guidance</i> <i>Article [55]</i> <i>Coordination on Biosecurity and Biosafety</i>	
Handling of confidential information	<i>Article [66] Handling of Confidential Information</i>	N.A.

Alignment with the European Data Strategy

Explanation of how the requirement(s) are aligned with the European Data Strategy

Article [33] Biotechnology Data Quality Accelerator High Impact Health Biotechnology Strategic Projects will ensure that datasets are established, managed and processed in accordance with applicable Union legislation on data governance, ethics and fundamental rights, including Regulation (EU) 2025/327 [European Health Data Space], Regulation (EU) 2016/679 [General Data Protection Regulation].

Alignment with the once-only principle

Explanation of how the once-only principle has been considered and how the possibility to reuse existing data has been explored

The legal provision allows for the reuse of data and evidence that has already been submitted for the purposes of a first registration.

Explanation of how newly created data is findable, accessible, interoperable and reusable, and meets high-quality standards

Through Union programmes and infrastructures, the Act promotes fair, reasonable and non-discriminatory access to high-quality data resources for researchers, SMEs and public institutions, thereby accelerating innovation while ensuring compliance with Union standards on data protection, ethics and security.

Data flows

High-level description of the data flows

Type of data	Reference(s) to the requirement(s)	Actors who provide the data	Actors who receive the data	Trigger for the data exchange	Frequency (if applicable)
Data required for testing and validation of biotechnology products	Article [3]1 Health Biotechnology Strategic Projects Article [4] 1 High Impact Health Biotechnology Strategic Projects Article [5] Biotechnology Development Accelerator Article [15] 2e Networks	Biotechnology industry actors, Research organizations	Member States, Commission, Agencies (EMA, EFSA)	Testing and validation of innovations	N.A.

	<i>of Health Biotechnology Clusters</i> <i>Article [29] Strategic Projects for Biosimilars</i> <i>Article [32] Article [32]</i> <i>Biotechnology testing environments for advanced biotechnology innovations</i> <i>Article [33] Biotechnology Data Quality Accelerator</i> <i>Article [56] Amendments to Regulation (EC) No 178/2002 (General Food Law): Article [49a] General</i> <i>Article [59] Amendments to Regulation (EU) 2019/6 (Veterinary Medicine Products Regulation)</i> <i>Article [61] Amendments to Regulation (EC) No 2024/1398/ Article [39a] 3 SoHO regulatory sandboxes provisions on regulatory</i>				

	<i>sandboxes</i>				
Reuse of existing data	<i>Article [11] Single Points of Contact</i>	Biotechnology industry actors, Research organizations	Member States, Commission	permit-granting process for strategic biotechnology projects and high impact biotechnology projects	
Guidance on the use and deployment of AI	<i>Article [31] Guidance on the deployment and use of systems based on advanced technologies including AI, in the Lifecycle of Medicinal Products</i>	Member States, Agency (EMA), Commission	Biotechnology industry actors, Research organizations	Guidance for biotechnology industry actors and research organizations on the deployment and use of AI systems and general purpose AI models in the lifecycle of medicinal product development	
Regulatory decisions, opinions, recommendations	<i>Article [35] 1 Union Regulatory Status Repository</i>	Member States, Agency (EMA), Commission	Biotechnology industry actors, Research organizations	Repository will assist developers in navigating cases of novel biotechnology health biotechnology products	
Personal health data, clinical data	<i>Article [58] Amendments to Regulation (EU) No 536/2014 ('Clinical Trials Regulation')</i>	Biotechnology industry actors, Research organizations	Member States, Agency (EMA) Commission	Submission of clinical trial	
Cross-border surveillance of biological	<i>Article [41] EU Biothreat</i>	Biotechnology industry actors,	Member States,	Detection, characterisation,	

threats	<i>Radar High Impact Projects</i> <i>Article [42]</i> <i>Biodefence capability high impact strategic project</i> <i>Article [44]</i> <i>Verification of Legitimate Need</i> <i>Article [46]</i> <i>Prevention and Reporting of Misuse</i> <i>Article [48]</i> <i>National Inspection Authorities</i> <i>Article [49]</i> <i>Commission Enforcement Support and Monitoring</i> <i>Article [52]</i> <i>Advisory Group on Biosecurity</i> <i>Article [53]</i> <i>Biological Systemic Risk</i> <i>Article [54]</i> <i>Monitoring and Guidance</i> <i>Article [55]</i> <i>Coordination on Biosecurity and Biosafety</i>	Research organization s	Commission	identification, analysis and assessment of biological threats	
Handling of	<i>Article [66]</i>	Member	Biotechnolo	Information	

confidential information	<i>Handling of Confidential Information</i>	States, Commission	gy industry actors, Research organizations	acquired in the course of regulation, trade and business secrets	

4.3. Digital solutions

High-level description of digital solutions

Digital solution	Reference(s) to the requirement(s)	Main mandated functionalities	Responsible body	How is accessibility catered for?	How is reusability considered?	Use of AI technologies (if applicable)
Biotechnology testing environments for advanced biotechnology innovations	Article [32] Biotechnology testing environments for advanced biotechnology innovations - high-impact biotechnology strategic projects	Development of trusted testing environments for biotechnology innovations	Commission, Member States			Yes

For each digital solution, explanation of how the digital solution complies with applicable digital policies and legislative enactments

Digital solution #1: Biotechnology testing Environments for advanced biotechnology innovations

Digital and/or sectorial policy (when these are applicable)	Explanation on how it aligns	
AI Act	Development and testing of AI enabled biotechnology solutions is in line with Article 51. It ensures that these systems fulfil the obligations set out in	

	Articles 53-55 of the act.	
EU Cybersecurity framework	Article 10 “Access Principles and Security Safeguards” provides that health biotechnology strategic projects, high impact biotechnology strategic projects, and any other entities operating infrastructures, facilities and services established or supported in accordance with this Regulation shall ensure that access to and the operation of their infrastructures, facilities and services complies, where applicable, with Directive (EU) 2022/2555 of the European Parliament and of the Council (NIS2 Directive), including the relevant cybersecurity risk-management and reporting obligations.	
eIDAS	Individuals and organisations will use electronic identification in line with EU legislation.	
Single Digital Gateway and IMI	N.A.	
Others		

4.4. Interoperability assessment

High-level description of the digital public service(s) affected by the requirements

Digital public service or category of digital public services	Description	Reference(s) to the requirement(s)	Interoperable Europe Solution(s) (NOT APPLICABLE)	Other interoperability solution(s)
Biotechnology Data Quality Accelerator	Biotechnology Data Quality Accelerator, aimed at improving data	Article [33] Biotechnology Data Quality Accelerator	//	

	quality at source, enhancing interoperability and annotation, and fostering the creation, curation, maintenance and use of shared datasets for the development and refinement of AI systems and models in health biotechnology.			
Category of digital public services according to <u>COFOG</u> #1			//	

Digital public service #1 Biotechnology Data Quality Accelerator

Assessment	Measure(s)	Potential remaining barriers (if applicable)
Alignment with existing digital and sectorial policies Please list the applicable digital and sectorial policies identified	The Biotechnology Data Quality Accelerator will operate in accordance with applicable Union legislation on data governance, ethics and fundamental rights, including Regulation (EU) 2025/327 [European Health Data Space], Regulation (EU) 2016/679 [General Data Protection Regulation].	N.A.
Organisational measures for a smooth cross-border digital public services delivery Please list the governance measures foreseen	It will support, where appropriate, the integration of these datasets into Union infrastructures, including the European Health Data Space, European Research Area data spaces, or other, including the infrastructures operated by high impact health biotechnology strategic projects.	N.A.
Measures taken to ensure a shared understanding of the data Please list such measures	Datasets, or the metadata and reference annotations thereof, will be available under fair, reasonable and non-discriminatory conditions, ensuring equitable access for users including research organisations, SMEs and public institutions.	N.A.
Use of commonly agreed open technical specifications and standards Please list such measures	It will contribute to the development of Union standards and quality frameworks for data representativeness, provenance, interoperability	N.A.

	and annotation in biotechnology	

4.5. Measures to support digital implementation

High-level description of measures supporting digital implementation

Description of the measure	Reference(s) to the requirement(s)	Commission role (if applicable)	Actors to be involved (if applicable)	Expected timeline (if applicable)
Adopting guidelines	Article [4] High Impact Health Biotechnology Strategic Projects Article [14] Financial and technical support Article [15] Networks of Health Biotechnology Clusters Article [39] Regulatory Sandboxes provided for in the applicable frameworks and Cross Framework Communication Article [58] Amendments to Regulation (EU) No 536/2014 ('Clinical Trials Regulation'): • Article 37: End of a clinical trial, temporary halt and early termination of a clinical trial and submission of the results • Article 47: Compliance with the protocol and good clinical	Commission will produce guidelines or will be involved in the production of guidelines	Agency (EMA, EFSA), Advisory Groups composed of Member State Representatives	

	• practice • Article 63: Manufacturing and import • Article 85: Clinical Trials Coordination and Advisory Group			
Designing policy implementation pilots	Article [15] Networks of Health Biotechnology Clusters	Commission will participate through the Steering Group	Member States, Biotechnology Industry actors, Research organizations	
Sandboxing	Article [39] Regulatory sandboxes provided for in the applicable frameworks and cross-framework communication Article [40] Regulatory sandboxes or novel health biotechnology products not falling under other sandboxes in Union legislation Article [58] Amendments to Regulation (EU) No 536/2014 ('Clinical Trials Regulation')/Article 85: Clinical Trials Coordination and Advisory Group Article [59] Amendments to Regulation (EU) 2019/6 (Veterinary Medicine Products Regulation) Article 136a: Regulatory	Commission shall encourage setting up regulatory sandboxes for AI biotechnology solutions, Substances of Human Origin	Member States	

	sandbox Article [61] Amendment to Regulation (EU) 2024/1938 (SoHO)/Article 39a: SOHO regulatory sandboxes			

2026-03-17

§ 41**Granskning: Hantering av dygnsvila**

Diarienummer: RJL 2026/231

Beslut

Presidiet

- lämnar ärendet till nämnden för folkhälsa och sjukvård utan eget förslag till beslut.

Sammanfattning

Regionrevisionen har genomfört en granskning av regionens hantering av de nya bestämmelserna om dygnsvila inom hälso- och sjukvården. Syftet med granskningen har varit att bedöma om regionstyrelsen och nämnden för folkhälsa och sjukvård utifrån sina respektive ansvarsområden säkerställt att de nya bestämmelserna om dygnsvila införts och efterlevs på ett ändamålsenligt sätt inom hälso- och sjukvården.

Revisionens samlade bedömning är att regionstyrelsen och nämnden för folkhälsa och sjukvård i allt väsentligt har säkerställt att bestämmelserna införts och efterlevs på ett ändamålsenligt sätt inom hälso- och sjukvården. Samtidigt identifieras förbättringsområden avseende riskanalyser, uppföljning och samlad utvärdering.

Beslutsunderlag

- Tjänsteskrivelse: Granskning av hantering av dygnsvila
- Missiv: Granskning av hantering av dygnsvila
- Rapport: Granskning av hantering av dygnsvila

Beslutet skickas till

Nämnden för folkhälsa och sjukvård

Granskning – Hantering av dygnsvila

Förslag till beslut

Nämnd för folkhälsa och sjukvård

- godkänner tjänsteskrivelsen som svar på revisorernas granskningsrapport.

Sammanfattning

Regionrevisionen har genomfört en granskning av regionens hantering av de nya bestämmelserna om dygnsvila inom hälso- och sjukvården. Syftet med granskningen har varit att bedöma om regionstyrelsen och nämnden för folkhälsa och sjukvård utifrån sina respektive ansvarsområden säkerställt att de nya bestämmelserna om dygnsvila införts och efterlevs på ett ändamålsenligt sätt inom hälso- och sjukvården.

Revisionens samlade bedömning är att regionstyrelsen och nämnden för folkhälsa och sjukvård i allt väsentligt har säkerställt att bestämmelserna införts och efterlevs på ett ändamålsenligt sätt inom hälso- och sjukvården. Samtidigt identifieras förbättringsområden avseende riskanalyser, uppföljning och samlad utvärdering.

Ärendebeskrivning

Nedan redovisas regionens åtgärder och planerade insatser utifrån respektive rekommendation.

- 1. Se över behovet av ytterligare informationsinsatser avseende hanteringen av bestämmelserna avseende dygnsvila till chefer inom hälso- och sjukvården.**

Sedan tidigare pågår ett arbete med att nå mer regiongemensamma arbetssätt kopplat till schema och bemanning. Frågan om dygnsvila kommer integreras i detta mer övergripande arbete istället för att genomföra insatser som kopplar endast till en liten del i helheten. Planerade åtgärder inom detta är:

- Ett uppdaterat och förtydligat stödmaterial av Region Jönköping läns gemensamma arbetssätt för schema och bemanning.
- Tydliggörande av generella principer kopplat till schema och bemanning
- Utbildningsmaterial och -insatser kring schemaläggning generellt där frågor som kompenserande vila och undantag/dispens kommer finnas med.

- Att utbildning om schema och bemanning integreras i chefsintroduktion i relevanta verksamheter
- Att chefer, stödroller såsom schemaläggare och administratörer, ges löpande utbildningar och informationsinsatser för kunskapsuppdatering inom aktuella kollektivantalsförändringar.

2. Säkerställa att riskanalyser/riskbedömningar genomförs i samband med större förändringar.

I de utbildningar och stödmaterial som finns inom Region Jönköpings län framgår att undersökning och riskbedömning ska genomföras inför förändring som ligger utanför den dagliga löpande verksamheten och som kan påverka arbetsmiljön. Ändringar i schema och bemanning kan vara exempel på förändringar av den karaktären. Nedan följer åtgärder som kommer vidtas i syfte att höja kunskapsnivån om den betydelse arbetstidens förläggning har för medarbetarnas hälsa samt vikten av att skapa möjlighet till återhämtning under arbetspassen.

- I stödmaterial och i utbildningsinsatser rörande systematiskt arbetsmiljöarbete tydliggöra orsakerna till varför undersökning och riskbedömning ska genomföras i samband med förändringar av schema och bemanning genom att påvisa de samband som råder mellan medarbetarens möjlighet till återhämtning och dennes och hur arbetstidens förläggning också påverkar hälsa och välmående.
- Utveckla uppföljningen av det systematiska arbetsmiljöarbetet så att den tydligare fångar upp att undersökning och riskbedömning genomförs inför förändringar i schema och bemanning.

3. Säkerställa att det sker regelbunden uppföljning och kontroll av efterlevnaden av de nya bestämmelserna om dygnsvila i schemaläggningen.

Region Jönköpings läns lön och schemasystem har en inbyggd funktionalitet som hindrar att scheman läggs på ett sätt som strider mot bestämmelserna om dygnsvila. Systemet medger dock att behov i verksamheten, så kallade oförutsedda händelser, som föranleder förändringar i schemat kan hanteras inom avtalets ram. Nedan åtgärder planeras för att säkra efterlevnaden och förbättra internkontrollen inom området:

- En regiongemensam rutin införs för uppföljning av verksamheternas följsamhet till de gemensamma arbetssätten och med det också bestämmelserna kring dygnsvila.

- Under 2026 kommer en rapportfunktion i Heroma som förenklar uppföljningen av avvikelser från dygnsvila och kompenserande vila införas.

4. Överväga att genomföra en samlad uppföljning/utvärdering av konsekvenserna av de nya bestämmelserna om dygnsvila och säkerställa att eventuella brister åtgärdas.

Det är viktigt att identifiera orsakerna till verksamheternas upplevda svårigheter med att tillämpa reglerna avseende dygnsvila. Följsamhet till såväl lagar, kollektivavtal och de regiongemensamma regelverk som finns inom området är centralt ur ett arbetsmiljöperspektiv då syftet i sig är att få till ett hälsosammare arbetsliv.

Regionledningskontoret bedömer att det i nuläget inte finns anledning att genomföra en separat utvärdering av nationella bestämmelser som inte kan påverkas lokalt. De ordinarie strukturer för uppföljning som finns bedöms tillräckliga. Men som nämns under rekommendation 2 ovan, behöver rutinen med den årliga uppföljningen inom arbetsmiljö utvecklas och tydliggöras. Den årliga uppföljningen är ett lagkrav som syftar till att undersöka om arbetsmiljöarbetet bedrivs enligt föreskrifterna om systematiskt arbetsmiljöarbete och åtgärda eventuella brister. Uppföljningen genomförs på samtliga nivåer i organisationer.

Region Jönköpings län följer även löpande hur verksamheten utvecklas genom bland annat olika mätetal inom medarbetarområdet och genom en regelbunden medarbetarundersökning. Utifrån de mätetal som följs framgår inte att bestämmelserna haft någon negativ effekt på sjukfrånvaro, personalomsättning eller övertid. Resultatet i årets medarbetarundersökning visar inte heller några tecken på att bestämmelserna skulle haft någon negativ effekt på medarbetarnas hälsa utan snarare tvärtom då flera frågeområden snarare har bättre utfall än tidigare år. Behovet av hyrbemannning har också minskat under 2025. Det finns inte heller, utifrån ett ekonomiskt perspektiv, några tecken på merkostnader kopplat till de nya bestämmelserna.

Beslutsunderlag

- Tjänsteskrivelse: Granskning av hantering av dygnsvila
- Missiv: Granskning av hantering av dygnsvila
- Rapport: Granskning av hantering av dygnsvila

Beslutet skickas till

Regionrevisionen

Regionledningskontoret – HR

Regionledningskontoret – Kansli

Regionledningskontoret – Folkhälsa och sjukvård

Regionfullmäktige

Urban Funck
HR-direktörMarcus Lundgren
Utvecklingschef, HR

Regionrevisionen

Regionfullmäktige

För kännedom till:
Regionstyrelsen
Nämnden för folkhälsa och sjukvård

Granskning av regionens hantering av de nya bestämmelserna om dygnsvila

Från och med 1 oktober år 2023, respektive 1 februari år 2024, är huvudregel att samtliga medarbetare i kommuner och regioner ska ha minst elva timmars sammanhängande dygnsvila under varje 24-timmars period.

Sveriges kommuner och regioner (SKR) gör gällande att det inte är möjligt att komma överens eller besluta om avvikelser från de avtalade bestämmelserna om dygnsvila på lokal nivå. Enligt SKR finns det dock viss möjlighet till undantag från reglerna.

I Region Jönköpings län är regionstyrelsen anställningsmyndighet för samtliga anställda inom och styrelsen ansvarar därigenom för frågor som rör förhållandet mellan regionen som arbetsgivare och arbetstagare. Nämnden för folkhälsa och sjukvård ansvarar för bland annat arbetsmiljö, kompetens och bemanning.

Granskningens syfte är att bedöma om regionstyrelsen och nämnden för folkhälsa och sjukvård utifrån sina respektive ansvarsområden säkerställt att de nya bestämmelserna om dygnsvila införts och efterlevs på ett ändamålsenligt sätt inom hälso- och sjukvården.

Revisorernas bedömning och rekommendationer

Revisionens samlade bedömning utifrån granskningens syfte är regionstyrelsen och nämnden för folkhälsa och sjukvård i allt väsentligt säkerställt att de nya bestämmelserna om dygnsvila införts och efterlevs på ett ändamålsenligt sätt inom hälso- och sjukvården.

Dock bedömer revisionen att det finns förbättringspotential avseende riskanalyser och uppföljning inom området.

Revisorerna rekommenderar Region Jönköpings län att:

- 1. se över behovet av ytterligare informationsinsatser avseende hantering av bestämmelserna avseende dygnsvila till chefer inom hälso- och sjukvården*
- 2. säkerställa att riskanalyser genomförs i samband med större förändringar*
- 3. säkerställa att det sker regelbunden uppföljning och kontroll av efterlevnaden av de nya bestämmelserna om dygnsvila i schemaläggningen*
- 4. genomföra en samlad uppföljning och utvärdering av konsekvenserna av de nya bestämmelserna om dygnsvila och hantering av eventuella brister*

Svar

Regionrevisionen föreslår att regionfullmäktige ger regionstyrelsen och nämnden för folkhälsa och sjukvård i uppdrag att senast 30 april svara på vilka åtgärder, med tillhörande tidplan, som kommer att vidtas till följd av granskningens resultat samt revisorernas rekommendationer.

Jonathan Freyschuss
Ordförande

Johan Stark
Vice ordförande

Detta dokument är elektroniskt signerat och juridiskt bindande.

Signed by: JONATHAN FREYSCHUSS

Date: 2026-01-09 08:09:04

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Ordförande: Jonathan Freyschuss

Signed by: JOHAN ENAR SÖREN STARK

Date: 2026-01-06 04:10:58

BankID refno: 019b9149-1ba4-7cac-8291-0f37f9a20ec6



Vice ordförande: Johan Starck

A decorative background pattern consisting of a large blue triangle on the left and a cluster of grey and green triangles on the right. The main title is centered below these elements.

Granskning av regionens hante- ring av de nya bestämmelserna om dygnsvila

Rapport

Region Jönköpings län

2025-12-15

Antal sidor: 22

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1 SAMMANFATTNING

Azets Revision & Rådgivning har av Region Jönköping läns förtroendevalda revisorer fått i uppdrag att översiktligt granska hanteringen av de nya bestämmelserna om dygnsvila inom hälso- och sjukvården.

Syftet med granskningen har varit att bedöma om regionstyrelsen och nämnden för folkhälsa och sjukvård utifrån sina respektive ansvarsområden säkerställt att de nya bestämmelserna om dygnsvila införts och efterlevs på ett ändamålsenligt sätt inom hälso- och sjukvården.

Vår samlade bedömning utifrån granskningens syfte är regionstyrelsen och nämnden för folkhälsa och sjukvård utifrån sina respektive ansvarsområden i allt väsentligt säkerställt att de nya bestämmelserna om dygnsvila införts och efterlevs på ett ändamålsenligt sätt inom hälso- och sjukvården.

Vår samlade bedömning grundar sig bland annat på att det i planerings- och införandefasen av de nya bestämmelserna om dygnsvila genomfördes strukturerade informationsinsatser, vilka syftade till att öka kunskapen samt förståelsen om regelverket och den praktiska hanteringen av de nya bestämmelserna. Vidare har riktlinjer för schemaläggning samt schemaläggningssystemen anpassats för att stödja korrekt tillämpning av bestämmelserna.

När det gäller riskanalyser noterar vi att flera av de verksamheter som ingick i granskningens urval genomförde riskanalyser inför förändringarna, i enlighet med gällande rutiner. Samtidigt konstaterar vi att riskanalyser inte har genomfördes i samtliga verksamheter som ingick i urvalet, och vi bedömer utifrån det att det även kan finnas en risk för att riskanalyser inte har genomförts i alla verksamheter inom hälso- och sjukvården inför förändringarna. Vidare noterar vi att schemaläggningssystemet innehåller en funktion för att hantera avsteg från reglerna avseende dygnsvila vid akuta situationer som inte kan lösas på annat sätt. Vi noterar att användningen av denna funktion i dagsläget inte följs upp regelbundet. En strukturerad och återkommande kontroll av detta är enligt vår bedömning viktig för att identifiera bakomliggande orsaker till avsteg, bedöma behov av ytterligare stöd eller resurser samt vidta relevanta förebyggande åtgärder.

Avseende uppföljning av införandet och effekterna av de nya bestämmelserna konstaterar vi att regelbunden uppföljning har skett i regionstyrelsens personaldelegation och att hanteringen även omnämns i verksamhetsberättelser inom Folkhälsa och sjukvård. I början av 2025 presenterades även en mer sammanställd utvärdering för personaldelegationen, med övergripande erfarenheter samt statistik över exempelvis sjukfrånvaro och övertid. Denna utvärdering ger enligt vår bedömning en mer samlad bild av utvecklingen efter införandet, men omfattar endast till viss del en strukturerad analys av konsekvenserna av de nya bestämmelserna om dygnsvila. Utifrån granskningen noterar vi att införandet av de nya bestämmelserna har medfört konsekvenser, bland annat utmaningar kopplade till bemanning och ökad administrativ belastning för chefer, vilka enligt vår bedömning inte fullt ut har fångats upp i de uppföljningar som har genomförts. Mot denna bakgrund bedömer vi att det vore fördelaktigt med en mer samlad uppföljning av de faktiska konsekvenserna av införandet av de nya reglerna. Behovet av en mer strukturerad uppföljning och utvärdering har även efterfrågats av verksamhetsföreträdare under granskningen.

I det följande redovisas våra samlade bedömningar av respektive revisionsfråga.

Nej Endast delvis I allt väsentligt Ja 	
Revisionsfråga	Bedömning
Har informationsinsatser avseende bestämmelserna om dygnsvila genomförts för medarbetare och chefer?	I allt väsentligt
Har riskanalyser gällande anpassning av scheman och arbetssätt till följd av de nya bestämmelserna om dygnsvilan genomförts, och har eventuella identifierade risker hanterats på ett ändamålsenligt sätt?	I allt väsentligt
Har styrande dokument, riktlinjer och rutiner för schemalägningsprocessen anpassats till följd av de nya bestämmelserna om dygnsvila?	Ja
Finns det tillräcklig intern kontroll och uppföljning som säkerställer att de nya bestämmelserna om dygnsvila efterlevs?	Endast delvis
Har eventuella konsekvenser på verksamhet, ekonomi och arbetsmiljö som de nya bestämmelserna om dygnsvila kan ha haft följts upp (1), och har eventuella åtgärder vidtagits (2)?	(1) I allt väsentligt (2) Endast delvis

För närmare beskrivning av bakgrunden till våra bedömningar hänvisar vi till respektive avsnitt i revisionsrapporten.

Utifrån våra iakttagelser och bedömningar rekommenderar vi regionstyrelsen samt nämnden för folkhälsa och sjukvård, utifrån sina respektive ansvarsområden, att:

- Se över behovet av ytterligare informationsinsatser avseende hanteringen av bestämmelserna avseende dygnsvila till chefer inom hälso- och sjukvården.
- Säkerställa att riskanalyser/riskbedömningar genomförs i samband med större förändringar.
- Säkerställa att det sker regelbunden uppföljning och kontroll av efterlevnaden av de nya bestämmelserna om dygnsvila i schemaläggningen.
- Överväga att genomföra en samlad uppföljning/utvärdering av konsekvenserna av de nya bestämmelserna om dygnsvila och säkerställa att eventuella brister åtgärdas.

2 BAKGRUND

Azets Revision & Rådgivning har av Region Jönköping läns förtroendevalda revisorer fått i uppdrag att översiktligt granska hanteringen av de sedan 2023 och 2024 nya bestämmelserna om dygnsvila inom hälso- och sjukvården. Uppdraget ingår i revisionsplanen för år 2025.

Från och med 1 oktober år 2023, respektive 1 februari år 2024¹, är huvudregel att samtliga medarbetare i kommuner och regioner ska ha minst elva timmars sammanhängande dygnsvila under varje 24-timmars period. Enligt bestämmelserna ska arbetspass följas av dygnsvila. De nya bestämmelserna infördes för att tillgodose de krav på skyddsregler gällande dygnsvila som finns inom EU:s arbetstidsdirektiv.

Sveriges kommuner och regioner (SKR) gör gällande att det inte är möjligt att komma överens eller besluta om avvikelser från de avtalade bestämmelserna om dygnsvila på lokal nivå. Enligt SKR finns det dock viss möjlighet till undantag från reglerna. Möjligheten uppges vara mycket restriktiv och kan bara bli aktuell i verksamheter som har uppdrag att skydda liv, hälsa och säkerhet. Varje undantag förutsätter att det inte är möjligt att klara bemanningen på annat sätt.

I Region Jönköpings län är regionstyrelsen anställningsmyndighet för samtliga anställda inom Region Jönköpings län och styrelsen ansvarar därigenom för frågor som rör förhållandet mellan regionen som arbetsgivare och arbetstagare. Därtill ska styrelsen tillse att den interna kontrollen är tillräcklig inom sitt område. Nämnden för folkhälsa och sjukvård ansvarar för bland annat arbetsmiljö, kompetens, bemanning och för att den interna kontrollen är tillräcklig inom hälso- och sjukvården.

Revisorerna bedömer i sin risk- och väsentlighetsanalys att det finns en risk för att hanteringen av införandet av de nya bestämmelserna gällande dygnsvila kan ha haft negativa konsekvenser för exempelvis verksamhet, ekonomi och arbetsmiljö. Mot bakgrund av detta har revisorerna beslutat om att genomföra en fördjupad granskning inom området.

2.1 SYFTE, REVISIONSFRÅGOR OCH AVGRÄNSNING

Syftet med granskningen har varit att bedöma om regionstyrelsen och nämnden för folkhälsa och sjukvård utifrån sina respektive ansvarsområden säkerställt att de nya bestämmelserna om dygnsvila införts och efterlevs på ett ändamålsenligt sätt inom hälso- och sjukvården.

Granskningen har omfattat följande revisionsfrågor:

- Har informationsinsatser avseende bestämmelserna om dygnsvila genomförts för medarbetare och chefer?
- Har riskanalyser gällande anpassning av scheman och arbetssätt till följd av de nya bestämmelserna om dygnsvilan genomförts, och har eventuella identifierade risker hanterats på ett ändamålsenligt sätt?

¹ Olika delar av lagstiftningen trädde i kraft vid olika tidpunkter.

- Har styrande dokument, riktlinjer och rutiner för schemalägningsprocessen anpassats till följd av de nya bestämmelserna om dygnsvila?
- Finns det tillräcklig intern kontroll och uppföljning som säkerställer att de nya bestämmelserna om dygnsvila efterlevs?
- Har eventuella konsekvenser på verksamhet, ekonomi och arbetsmiljö som de nya bestämmelserna om dygnsvila kan ha haft följts upp, och har eventuella åtgärder vidtagits?

2.2 AVGRÄNSNING

Granskningen har avgränsats till att omfatta hanteringen av bestämmelserna om dygnsvila för personal inom hälso- och sjukvården. Granskningen avser regionstyrelsen och nämnden för folkhälsa och sjukvård.

2.3 REVISIONSKRITERIER

I granskningen har revisionskriterierna utgjorts av:

- Kommunallagen 6 kap. § 6
- Allmänna bestämmelser 4 kap. 13 §
- Arbetsmiljöverkets föreskrifter och allmänna råd (AFS 2023:1) om systematiskt arbetsmiljöarbete – grundläggande skyldigheter för dig med arbetsgivaransvar
- Reglemente för regionstyrelsen och nämnden för folkhälsa och sjukvård

2.4 METOD

Granskningen har genomförts genom:

- *Dokumentstudier* av bland annat regionstyrelsens reglemente, reglemente för nämnden för folkhälsa och sjukvård, bemanningsbok för schema och bemanning, internkontrollplaner, uppföljningsrapporter och protokoll.
- *Intervjuer* med regionstyrelsen ordförande och vice ordförande, nämnden för folkhälsa och sjukvårds ordförande och vice ordförande, HR-direktör, utvecklingschef, förhandlingschef, sjukvårdsdirektörer, HR-chef för Psykiatri, rehabilitering och diagnostik, HR-chef för Kirurgisk vård samt HR-chef för Medicinsk vård.

Inom ramen för granskningen har intervjuer också genomförts med verksamhetschefer och vårdenhetschefer vid ett urval av verksamheter inom Folkhälsa och sjukvård. De verksamheter som omfattats är operations- och intensivvård (OP-IVA), infektionskliniken, ambulansverksamheten, psykiatriavdelningen samt röntgen. Intervju har också genomförts med representant för Läkarföreningen/huvudskyddsombud som inför samtalet inhämtat synpunkter från flera företrädare inom samma förbund.

De bedömningar som avlämnas i granskningen har utgått ifrån följande bedömningsnivåer:



Samtliga intervjuade har givits möjlighet till att faktakontrollera rapporten.

3 RESULTAT AV GRANSKNINGEN

3.1 ORGANISATION OCH ANSVARSFÖRDELNING

3.1.1 Regionstyrelsen

Enligt *Reglemente för regionstyrelsen*² är styrelsen anställningsmyndighet för samtliga anställda inom Region Jönköpings län. Regionstyrelsen är arbetsgivare och har det övergripande strategiska personal- och kompetensförsörjningsansvaret i regionen, medan respektive verksamhetsnämnd enligt reglementet är ansvarig för bemanning, kompetens och arbetsmiljö inom sina respektive ansvarsområden. När det gäller arbetsmiljö framgår det i rutinen *Uppgiftsfördelning i det systematiska arbetsmiljöarbetet inom Region Jönköpings län - instruktion*³ att det är regiondirektören som fördelar arbetsmiljöuppgifter i tjänstepersonsorganisationen.

Regionstyrelsen ska vidare ha hand om frågor som rör förhållandet mellan regionen som arbetsgivare och dess arbetstagare. Detta kan exempelvis avse reglering av frågor rörande arbetsgivare och arbetstagare genom kollektivavtal samt avgörandet av frågor om tolkning och tillämpning av lag, avtal och andra bestämmelser.

Regionstyrelsen har en personaldelegation som enligt *Reglemente för regionstyrelsens personaldelegation*⁴ ansvarar för att bland annat följa arbetet med strategiska personal- och kompetensförsörjningsfrågor, särskilt följa strategiska personalfrågor inom ramen för programmet för hållbar utveckling – social hållbarhet och följa personalboksutslut med analys och utvärdering inom personalområdet.

3.1.2 Nämnden för folkhälsa och sjukvård

I *Reglemente för nämnden för folkhälsa och sjukvård*⁵ framgår att nämnden har ansvar för organisation, arbetsmiljö, kompetens och bemanning inom sina verksamhetsområden/utgiftsramar. Utöver detta ska nämnden enligt sitt reglemente tillse att den interna kontrollen är tillräcklig och att verksamheten bedrivs på ett i övrigt tillfredsställande sätt. Nämnden ska också följa upp och utvärdera såväl utlagd verksamhet som verksamhet som bedrivs i egen regi.

3.2 INFÖRANDET AV DE NYA BESTÄMMELSERNA OM DYGN SVILA

I november år 2022 fastställde Sveriges Kommuner och Regioner (SKR), Sobona⁶ och de fackliga parterna en ny överenskommelse om regler för dygnsvila. Bakgrunden till överenskommelsen var att EU-kommissionen riktat kritik mot Sverige för att tidigare kollektivavtal inte uppfyllde kraven i EU:s arbetstidsdirektiv, som anger att arbetstagare ska ha minst 11 timmars sammanhängande vila under varje 24-timmarsperiod. De nya bestämmelserna om dygnsvila trädde sedan i kraft den 1 oktober 2023, och från den 1 februari 2024 omfattades även läkare av regleringen.

² Regionfullmäktige, 2021-08-31

³ 2022-10-06

⁴ Regionfullmäktige, 2021-08-31

⁵ Regionfullmäktige, 2021-08-31

⁶ Sobona är de kommunala företagens arbetsgivarorganisation, som tecknar kollektivavtal och stödjer medlemsföretag i arbetsgivarfrågor.

I avsnitten nedan beskrivs regionens förberedelser inför införandet, liksom hur information om reglerna och deras praktiska hantering förmedlades inom organisationen.

3.2.1 Implementering av förändringarna

Kort efter att den nya överenskommelsen avseende dygnsvila fastställts utarbetade regionens centrala HR-funktion en tidplan för hur förändringarna skulle implementeras. Tidplanen såg ut enligt följande:

- **Februari 2023:** Uppstart för en arbetsgrupp vars uppdrag var att inventera enheter och schemaläggare som berörs av förändringen, planera kommunikation, ta fram exempeldokument/allmänna schemamallar samt planera och genomföra workshops för schemaläggare. Arbetsgruppen bestod av biträdande HR-chefer och systemförvaltare.
- **Mars 2023:** Påbörjande av schemaläggning utifrån de nya bestämmelserna. En workshop genomfördes för både chefer och schemaläggare, och i samband med detta skulle även medarbetare informeras om det pågående arbetet. I mars skulle även eventuella behov av beslut om avveckling/utveckling av befintliga arbetstidsmodeller identifieras.
- **April 2023:** Grundscheman skulle vara klart. I april genomfördes workshops för att kunna fastställa grundscheman.
- **Juni-augusti 2023:** Under sommarperioden erbjöds ordinarie stöd till verksamheterna.
- **1 oktober 2023:** Samtliga medarbetare i regionen ska ha ett planerat schema enligt de nya bestämmelserna⁷.

Därutöver fastställdes även en plan för kommunikationsvägar i implementeringsprocessen, där det tydliggörs genom vilka funktioner informationen ska förmedlas. Ett exempel på ett sådant informationsflöde var att information från förhandlingschef och HR-direktör skulle kommuniceras till den utsedda arbetsgruppen för implementeringsarbetet som i sin tur ansvarade för att informera HR-chefer. HR-cheferna hade därefter uppdraget att föra vidare informationen till verksamhetscheferna. Verksamhetscheferna skulle sedan sprida informationen vidare både till första linjens chefer och inom ramen för lokal samverkan. HR-partner i respektive verksamhet utgjorde enligt planen det närmsta stödet till verksamhetschef och första linjens chefer vid frågor. Slutligen ansvarade första linjens chefer för att informera medarbetare och schemaläggare.

3.2.2 Information och stöd till chefer

I intervju framförs att ett informationstillfälle till samtliga chefer avseende de nya bestämmelserna om dygnsvila genomfördes redan i slutet av år 2022 när den nya överenskommelsen hade fastställts. Vi har tagit del av presentationsmaterialet som användes vid informationstillfället, vilket bland annat beskriver bakgrunden till de nya reglerna, övergripande information om överenskommelsen samt information om schemaläggning. Materialet beskriver även medskick till cheferna om den fortsatta processen, till exempel att cheferna skulle informera medarbetare om förändringarna och inleda en dialog med fackliga representanter.

Under år 2023 genomfördes ytterligare informations- och utbildningsinsatser till chefer i organisationen gällande betydelsen av de nya bestämmelserna, samt hur de skulle påverka det prak-

⁷ Beslutet att läkare skulle omfattas av de nya dygnsvilabestämmelserna från och med 1 februari år 2024 beslutades efter att tidplanen hade tagits fram.

tiska arbetet. Informationsinsatserna genomfördes av regionens förhandlingschef och en systemförvaltare som hade ett särskilt fokus på den praktiska schemalägningsprocessen. I intervjuer framförs att informationstillfällen bokades in i takt med att ny kunskap tillkom och behov uppstod att informera cheferna. Vi har tagit del av presentationsmaterial från dessa tillfällen, där bland annat bakgrunden till bestämmelserna, regler om undantag och dispens, exempel på scheman samt information om kompenserande vila redovisades. Utöver dessa gemensamma informationsstillfällen uppges att förhandlingschef och systemförvaltare genomförde riktade insatser i olika verksamheters ledningsgrupper när detta efterfrågades. Det togs även fram schemamallar som chefer kunde testa att lägga scheman i utifrån de nya bestämmelserna. Därtill genomfördes regelbundet så kallade "Call-ins", vilket var öppna möten/frågestunder där deltagarna kunde lyfta frågor och funderingar. Enligt uppgift kvarstod detta forum även efter att bestämmelserna trädde i kraft i oktober, fram till dess att intresset för deltagande avtog.

I majoriteten av våra intervjuer skildras en positiv upplevelse av informationsinsatserna inför förändringarna. Samtidigt påpekas att både innehåll och tolkningar av regelverket kunde variera mellan olika tillfällen, vilket bidrog till vissa inledande oklarheter. Flera verksamhetschefer och vårdenhetschefer inom hälso- och sjukvården beskriver dessutom att informationen inför och under införandet av det nya regelverket ibland upplevdes som alltför övergripande, vilket försvårade förståelsen för den praktiska tillämpningen i de egna verksamheterna. Detta blev särskilt tydligt mot bakgrund av att olika verksamheter stod inför olika utmaningar och påverkades i olika grad. I intervjuer poängteras dock att HR-partner skulle utgöra det verksamhetsnära stödet i förändringarna.

I intervjuer lyfts att det fortsatt kan finnas ett behov av ytterligare informations- eller utbildningsinsatser avseende hur de nya bestämmelserna påverkar bland annat schemalägningsprocessen. Detta motiveras bland annat utifrån att det anställts nya chefer i organisationen och att viss kunskap kan ha fallit bort. Därtill uttrycks ett intresse av att få ta del av erfarenheter från andra regioner i syfte att jämföra arbetssätt och identifiera eventuella skillnader i hur dygnsvilabestämmelserna har hanterats i relation till Region Jönköpings län.

3.2.3 Information till medarbetare

Som tidigare nämnts uppmanades chefer i slutet av år 2022 att informera medarbetare om de nya bestämmelserna om dygnsvila. Under år 2023 togs även ett särskilt stödmaterial fram som chefer kunde använda på arbetsplatsträffar (APT) för att informera om de nya bestämmelserna. I presentationsmaterialet framgår övergripande information om bestämmelsernas innebörd, bakgrund till förändringen samt svar på praktiska frågor, exempelvis "Kan vi förlägga kortare dygnsvila om både medarbetare och arbetsgivare vill det?". I intervjuer framförs att medarbetare främst informerades om förändringarna via APT samt andra möten på arbetsplatsen.

I intervjuer lyfts vidare att de nya bestämmelserna om dygnsvila skapade frustration bland en del medarbetare, vilka upplevde att exempelvis flexibiliteten i planering av sin egen arbetstid försvann. Det framförs också att det var svårt att skapa förståelse för de förändringarna och deras positiva effekter. Flera chefer lyfter att stödet inte alltid var tillräckligt när det gällde att hantera medarbetarnas oro och frustration. Samtidigt framhålls att frågan med tiden blivit mindre aktuell, även om viss frustration fortfarande kvarstår inom vissa verksamheter, särskilt kopplat till nuvarande schemaplanering.

3.2.4 Riskanalyser inför förändringarna

I *Bilaga till riktlinje för intern kontroll*⁸ framgår att de olika verksamhetsområdena i regionen inom ramen för internkontrollarbetet ska genomföra riskanalyser. I bilagan definieras en risk som en möjlig händelse eller omständighet som kan göra det svårare att uppnå verksamhetens mål eller utföra verksamhetens uppdrag samtidigt som att det sker på ett säkert sätt. Exempel på risker som drivs av yttre omständigheter anges till exempel vara ändrad lagstiftning som ställer nya krav.

I intervjuer framkommer att riskanalyser utifrån ett arbetsmiljöperspektiv ska ha genomförts på verksamhetsnivå inom hälso- och sjukvården inför att de nya bestämmelserna om dygnsvila skulle träda i kraft. Inom ramen för granskningen har vi tagit del av flera exempel på sådana riskanalyser, samt analyser som även omfattat andra delar än arbetsmiljö. I dessa analyser identifierades ett antal risker kopplade till införandet av bestämmelserna, bland annat:

- Risk för övertid vid passbyten som gör passen ännu längre
- Risk för kompetens/personalflykt relaterat till upplevd försämrad arbetsmiljö
- Risk för ökat budgetanslag
- Risk för ökad administrativ belastning
- Risk för patientsäkerhet
- Risk för svårare rekryteringsprocesser
- Risk för psykosocial oro
- Risk för svårigheter att få in personal vid kort bemanning

I respektive riskanalys vi har tagit del av framgår en riskbedömning utifrån sannolikhet, allvarlighet och konsekvens. Därtill anges även förslag till åtgärder samt när dessa åtgärder ska vara genomförda och följas upp. I intervjuer poängteras dock att flera av de risker som identifierades i riskanalyserna inför införandet inte inträffade.

Utifrån intervjuer med verksamhetschefer och vårdenhetschefer inom hälso- och sjukvården framkommer att vissa av de verksamheter som ingick i granskningens urval inte genomförde riskanalyser inför införandet av de nya bestämmelserna. I sammanhanget framförs dock att inte samtliga verksamheter inom hälso- och sjukvården påverkades av förändringarna i större utsträckning, varpå en bedömning gjorts att en riskanalys inte behöver genomföras. Enligt uppgift har ingen samlad uppföljning genomförts av om berörda verksamheter har utfört riskanalyser.

Inom ramen för den årliga uppföljningen av det systematiska arbetsmiljöarbetet för både år 2023 och för år 2024 har arbetet med riskbedömningar följts upp. I uppföljningen år 2023 identifieras riskbedömningar inför förändringar som ett förbättringsområde, vilket grundar sig på att det framkommit att vissa arbetsplatser inom olika verksamhetsområden inte alltid gör riskbedömningar inför större förändringar. I syfte att stärka arbetet framgår det av uppföljningen att en digital utbildning om hur riskbedömning ska genomföras skulle tas fram i början av år 2024. I uppföljningen år 2024 beskrivs arbetet med riskbedömningar ha utvecklats och det anges att de flesta verksamheter genomför riskbedömningar inför förändringar tillsammans med chef och medarbetare/skyddsombud.

⁸ Datum för upprättande saknas.

3.2.5 Bedömning

Vår bedömning är att det **i allt väsentligt** har genomförts informationsinsatser avseende bestämmelserna om dygnsvila för medarbetare och chefer.

Regionstyrelsen har enligt sitt reglemente det övergripande personalansvaret och ska ha hand om frågor som rör förhållandet mellan regionen som arbetsgivare och dess arbetstagare. I ansvaret ingår tolkning och tillämpning av lag, avtal och andra bestämmelser. I samband med införandet av de nya bestämmelserna om dygnsvila var det av central betydelse att både chefer och medarbetare erhöll information om regelverket samt de anpassningar som behövde genomföras. Vi konstaterar att det genomfördes flertalet informationsinsatser till chefer under planerings- och införandefasen av de nya bestämmelserna om dygnsvila. Dessa insatser syftade till att skapa förståelse för bakgrunden till regeländringarna, tydliggöra deras praktiska konsekvenser samt ge cheferna förutsättningar att implementera bestämmelserna på ett korrekt och enhetligt sätt. Utöver detta etablerades regelbundna "call-ins", vilka fungerade som ett forum där chefer kunde ställa frågor och få löpande vägledning. När det gäller information till medarbetare noterar vi att det på övergripande nivå funnits direktiv om att medarbetare ska informeras om förändringarna. Det togs också fram stödmaterial, vilket enligt vår bedömning skapade förutsättningar till att informationen förmedlades på ett enhetligt sätt.

I granskningen har det framkommit att det i samband med införandefasen fanns ett behov av mer verksamhetsanpassad information. Detta då olika delar av organisationen påverkades i varierande grad av förändringarna och därför hade olika behov av stöd. I granskningen lyfts även att det fortfarande kan finnas behov av sådana informationsinsatser i dagsläget, särskilt kopplat till schemaläggning. Mot bakgrund av detta bedömer vi att det vore fördelaktigt att se över behovet av ytterligare riktade informationsinsatser till chefer, i syfte att säkerställa tillräcklig förståelse och stöd i hanteringen av bestämmelserna i det praktiska arbetet.

Vi bedömer att det **i allt väsentligt** genomförts riskanalyser gällande anpassning av scheman och arbetssätt till följd av de nya bestämmelserna om dygnsvilan, samt att dessa har hanterats på ett ändamålsenligt sätt.

Enligt Arbetsmiljöverkets föreskrifter och allmänna råd (AFS 2023:1) ska arbetsgivare när ändringar i verksamheten planeras undersöka om ändringarna medför risker för ohälsa och olycksfall, samt bedöma dessa. I regionen har verksamhetschefer och första linjens chefer inom hälso- och sjukvården har ett uttalat ansvar att genomföra riskbedömningar inför förändringar i verksamheten som en del av det systematiska arbetsmiljöarbetet. Vid vår granskning av ett urval verksamheter inom hälso- och sjukvården konstaterar vi att flera av dem har genomfört riskanalyser inför införandet av de nya bestämmelserna om dygnsvila. Dessa analyser innehöll bedömningar av relevanta risker, tillsammans med förslag på åtgärder samt tidsplaner för när dessa åtgärder ska vara genomförda.

Vi konstaterar att riskanalyser inte har genomförts i samtliga verksamheter som ingick i vårt urval. Mot denna bakgrund bedömer vi att det kan finnas en risk för att riskanalyser inte heller har genomförts i alla verksamheter inom hälso- och sjukvården. Detta kan delvis förklaras av att vissa verksamheter inte ansåg sig vara direkt påverkade av de nya bestämmelserna, men samtidigt konstaterar vi att även verksamheter som faktiskt berördes av förändringarna inte genomfört riskanalyser. Detta kan enligt vår bedömning indikera viss otydlighet eller bristande efterlevnad i arbetssätten för riskhantering. I regionens egen uppföljning av det systematiska arbetsmiljöarbetet har även riskbedömningar identifierats som ett utvecklingsområde, och vi noterar att åtgärder vidtagits utifrån det, vilket vi ser positivt på. För att säkerställa att eventuella risker i samband med större förändringar identifieras och hanteras på ett strukturerat sätt bedömer vi dock att det är av stor vikt att riskanalyser genomförs konsekvent i alla berörda verksamheter.

3.3 EFTERLEVNADEN AV DE NYA BESTÄMMELSERNA OM DYGNSVILA

3.3.1 Anpassning av riktlinjer och rutiner

I intervjuer framförs att det finns särskilt utpekade dokumentägare som är ansvariga för att revidera styrande dokument och riktlinjer i samband med förändringar som påverkar innehållet i dokumenten. I regionen finns en *Handbok för schema och bemanning*⁹ som bland annat beskriver lagar och avtal för schemaläggning, information gällande vila, rast och måltidsuppehåll, arbetsmiljöaspekter vid schemaläggning samt schemamodeller som kan användas. Detta dokument beskrivs vara styrande när det gäller schemaläggning i regionen. Till följd av de nya bestämmelserna har handboken reviderats. Av handboken framgår att alla som arbetar inom Region Jönköpings län ska följa arbetstidslagen (ATL), Allmänna bestämmelser (AB) och lokala kollektivavtal. När det gäller de nya bestämmelserna om dygnsvila framgår följande:

- **Arbetsgivaren ansvarar för att medarbetare får sin dygnsvila och veckovila.** Det anges också att det är chefens ansvar att "bemanna sin enhet på bästa möjliga sätt ur ett patientsäkert, arbetsmiljömässigt, hälsosamt och ekonomiskt perspektiv samt följa gällande avtal".
- **Arbetsgivaren ska förlägga arbetstid så att varje arbetstagare får elva timmars sammanhängande dygnsvila per 24-timmarsperiod.** Det framgår dock att beredskap kan förläggas under arbetstagarens dygnsvila, men om en störning inträffar under beredskapen kan utebliven dygnsvila behöva kompenseras. Vidare anges att dygnsbryt ska framgå i arbetstagares schema och samma dygnsbryt ska gälla för hela beräkningsperioden. Det är arbetsgivare som fastställer när dygnsbrytet är, vanligtvis kl. 06:00, 03:00 eller 19:00 enligt handboken. Inom 24-timmarsperioden ska arbetstagare få sin dygnsvila, och resterande tid kan ordinarie tid eller jour förläggas. I handboken regleras även schemaläggning utifrån veckovila. Det framgår att arbetstagare under varje 7-dagarsperiod ska ha minst 36 timmars veckovila. Enligt Allmänna bestämmelser (AB) kan dock en medarbetares sammanhängande veckovila uppgå till minst 24 timmar vid tillfälliga avvikelser.
- **Oavsett vilken schemalägningsmodell som används ska ansvarig chef kontrollera att rast, dygnsvila och veckovila sker enligt Allmänna bestämmelser (AB).** Flertalet schemalägningsmodeller som kan användas beskrivs, däribland fast schema, terminsschema och individuell

⁹ Datum för upprättande saknas.

schemaplanering. Det anges fördelar med olika typer av modeller samt hur dessa ska hanteras (t.ex. om det krävs avtal utöver AB) och skapas i systemet. Utöver kontroll av att dygnsvila följs ska chef bland annat kontrollera att exempelvis arbetstidsförläggningen är hälsosam samt att kravet för veckoarbetstidsmättet blir korrekt vid blandad dag- och nattjänstgöring eller ren nattjänstgöring.

- **Vid förläggning av arbetstider ska hälsoaspekter beaktas, bland annat att kravet om minst 11 timmars dygnsvila uppfylls.** Andra hälsoaspekter som nämns är att undvika mer än 10 timmar långa pass, och att ett arbetspass som längst får uppgå till 13 timmar.
- **Turbyten mellan medarbetare får inte godkännas om dygnsvilan eller veckovilan påverkas negativt.**

Utöver bemanningshandboken finns även en kompletterande manual för *Schemaläggning av ISP med pass kvar* som mer konkret beskriver hur schema ska läggas utifrån individuell schemaplanering (ISP). Även denna manual har uppdaterats i enlighet med de nya bestämmelserna. I manualen ges exempel på hur avvikelser från kraven på dygnsvila ser ut i Heroma¹⁰. Enligt uppgift finns det även en film på regionens intranät om schemaläggning, vilken också ska ha anpassats utifrån de nya bestämmelserna.

3.3.2 Anpassning av system

Schemaläggning i regionen sker i personal- och lönesystemet Heroma. Enligt *Handbok för schema och bemanning* är det inte möjligt att fastställa ett schema i Heroma om det innebär regelbrott mot dygnsvila och veckovila, med undantag för att beredskap kan förläggas under arbetstagarens dygnsvila. I intervjuer framkommer att denna funktion, det vill säga att det inte går att fastställa ett schema som bryter mot bestämmelserna om dygnsvila, infördes i systemet under oktober år 2025. I intervjuer framförs att systemet dock varnade för regelfel tidigare i de fall bestämmelserna om dygnsvilan inte efterlevdes.

I intervjuer framkommer att det finns möjlighet att göra avsteg från bestämmelserna om dygnsvila vid akuta situationer som inte kan hanteras på annat sätt. I sådana fall kan den schemaläggande personalen markera alternativet "Oförutsedd händelse", vilket möjliggör att ett schema som avviker från dygnsvilo-reglerna kan läggas.

Vid en del intervjuer framförs upplevelser av att schemaläggningssystemet i vissa delar är bristfälligt ur ett användarperspektiv. Detta problem är särskilt tydligt vid planering av kompenserande vila, där systemets tolkning av när sådan vila ska förläggas inte alltid överensstämmer med regionens egen tolkning av regelverket.

3.3.3 Kontroller av efterlevnad

I intervjuer uppges det inte ske några regelbundna kontroller av att schemaläggningen i de olika verksamheterna i hälso- och sjukvården efterlever bestämmelserna avseende dygnsvila, exempelvis av HR-partner eller annan stödfunktion. Ansvar för att schemaläggningen följer bestämmelserna beskrivs åligga cheferna. Det uppges dock att vissa chefer vid tiden efter att de nya bestämmelserna trädde i kraft kunde få återkoppling från HR-partner och/eller biträdande HR-

¹⁰ Heroma är ett personal- och lönesystem.

chef om schemaläggningen inte var i enlighet med de nya bestämmelserna, eller om det gjorts fel tolkningar av exempelvis kompenserande vila. Det har även anställts bemanningscontrollers i syfte att bland annat ge stöd till verksamheterna och kvalitetssäkra schemalägningsprocessen.

I och med den nya funktionen i Heroma som hindrar schemaläggning som bryter mot regler avseende dygnsvilan beskrivs det numera ske en automatisk kontroll av att dygnsvila följs genom funktionen. Det uppges dock inte ske någon särskild uppföljning eller kontroll i de fall chefer har kryssat i "Oförutsedd händelse" för att kunna göra avsteg från bestämmelserna.

3.3.4 Undantag och dispens

3.3.4.1 Undantag

Det finns möjlighet att göra undantag från de nya bestämmelserna om dygnsvilan i enlighet med en *Rutin för ansökan om undantag enligt AB § 13*¹¹. I rutinen framgår att en arbetstagares dygnsvila i undantagsfall kan förkortas till som lägst nio timmar om det finns särskilda skäl i verksamheter med ansvar för liv, hälsa och säkerhet. Även arbetspass och jourpass kan förläggas i direkt anslutning till varandra om det föreligger särskilda skäl i verksamheter med ansvar för liv, hälsa och säkerhet. Vid sådana fall får den sammanlagda arbetstiden som högst uppgå till 20 timmar. Den efterföljande vilan ska i sådant fall vara sammanhängande och som lägst motsvara den sammanlagda arbetstiden.

Enligt rutin för ansökan om undantag ska arbetsgivaren pröva andra möjliga alternativ för att lösa bemanningsbehovet innan något undantag kan komma att tillämpas. Det anges även att undantag ska tillämpas restriktivt och endast efter godkänd ansökan till verksamhetsområdets direktör. Ansökan ska utarbetas i en mall som finns angiven i rutinen. Vid beviljat undantag ska det ske en årlig uppföljning av tillämpning av och orsaker till undantag. Utifrån resultatet, och vid behov, ska en handlingsplan utarbetas för att motverka behov av undantag.

Vid ett flertal intervjuer beskrivs ansökningsprocessen för undantag som svår och tidskrävande. Med anledning av detta uppges det i intervjuer att ett flertal chefer valt att inte ansöka om undantag, trots bemanningsutmaningar. Detta betyder dock inte att undantag har gjorts utan godkännande enligt de intervjuade.

3.3.4.2 Dispens

Regionen kan ansöka om dispens från dygnsvilan hos arbetstidsnämnden¹². Beslut om dispens gäller under en begränsad tidsperiod som högst kan uppgå till tolv månader åt gången. Beslut om dispens förutsätter att det inte är möjligt att bemanna verksamheten inom ramen de nya bestämmelserna. Innan en ansökan om dispens kan prövas av arbetstidsnämnden ska regionstyrelsen godkänna ansökan från verksamheten. Besluten om dispens ska underbyggas av ett flertal delar, däribland en riskbedömning avseende de följder som en beviljad dispens kan medföra för medarbetarna.

Inom Region Jönköpings län har ambulansverksamheten samt Kvinnokliniken Högländssjukhuset Eksjö ansökt om och blivit beviljade dispens från dygnsvilan sedan de nya bestämmelserna trädde

¹¹ 2024-04-05

¹² Arbetstidsnämnden är en partsammansatt nämnd instiftad av SKR och centrala kollektivavtalsparter för att pröva tolkningar och dispensärenden rörande dygnsvilan inom kommuner och regioner.

i kraft. Av regionstyrelsens protokoll från juni år 2024¹³ framgår att regionstyrelsen fattade beslut om att ansöka om dispens för ambulansverksamheten i enlighet med redovisad ansökan. Ansökan gällde för sommarperioden år 2024 (juni-augusti). När det gäller Kvinnokliniken framgår av regionstyrelsens protokoll från juni 2025¹⁴ att regionstyrelsen beslutade om att ansöka om dispens i enlighet med redovisad ansökan. Ansökan avsåg tidsperioden juni-juli 2025.

3.3.5 Bedömning

Vår bedömning är att styrande dokument, riktlinjer och rutiner för schemalägningsprocessen **har** anpassats till följd av de nya bestämmelserna om dygnsvila.

Vi noterar att de riktlinjer som styr schemaläggningen inom hälso- och sjukvården har reviderats och anpassats som en följd av de nya bestämmelserna om dygnsvila. I de uppdaterade riktlinjerna tydliggörs både arbetsgivarens och chefers ansvar för att säkerställa att bestämmelserna efterlevs, samt hur detta ska omsättas i det praktiska schemalägningsarbetet. Riktlinjerna ger därmed ett stöd för hur verksamheterna ska förhålla sig till regelverket.

Vidare konstaterar vi att även schemaläggningssystemet har anpassats i linje med de nya bestämmelserna. Dessa förändringar innebär att systemet i högre grad stödjer korrekt schemaläggning och kan uppmärksamma när schemaläggning riskerar att bryta mot kraven om dygnsvila.

Vår bedömning är att det **endast delvis** finns tillräcklig intern kontroll och uppföljning som säkerställer att de nya bestämmelserna om dygnsvila efterlevs.

Regionstyrelsen och nämnden för folkhälsa och sjukvård ska enligt sina reglementen tillse att den interna kontrollen är tillräcklig inom sina respektive ansvarsområden. Vi noterar att schemaläggningssystemet, från och med hösten 2025, har en inbyggd funktion som förhindrar att scheman läggs på ett sätt som strider mot bestämmelserna om dygnsvila. Enligt vår bedömning utgör detta en central och effektiv kontrollfunktion som både minskar risken för felaktig schemaläggning och stärker verksamhetens möjligheter att säkerställa efterlevnad av gällande regelverk.

I sammanhanget konstaterar vi att systemet medger undantag mot bestämmelserna om dygnsvila genom funktionen "Oförutsedd händelse", vilken kan användas i situationer där avsteg bedöms som nödvändiga. Vi noterar att det i dagsläget inte sker någon regelbunden uppföljning av när denna funktion används. Vi bedömer att en strukturerad och regelbunden kontroll av användningen av denna funktion är av vikt för att kunna identifiera bakomliggande orsaker till avsteg från regelverket, bedöma behov av ytterligare stöd eller resurser samt vidta relevanta förebyggande åtgärder. Avsaknaden av sådan uppföljning kan enligt vår bedömning innebära en risk för att funktionen används på ett sätt som inte är förenligt med syftet att säkerställa dygnsvila, samt att brister i planering eller bemanning inte upptäcks och kvarstår. Vi bedömer utifrån detta att

¹³ Regionstyrelsen 2024-06-11, § 135

¹⁴ Regionstyrelsen 2025-06-03, § 136

det finns ett behov av att stärka kontrollen samt uppföljningen av efterlevnaden av de nya bestämmelserna.

3.4 UPPFÖLJNING AV HANTERINGEN SAMT EFFEKTERNA AV DE NYA BESTÄMMELSERNA

Enligt uppgift har det inte genomförts någon formell uppföljning och/eller utvärdering avseende hanteringen eller eventuella effekter av de nya bestämmelserna om dygnsvila på verksamhetsnivå. På politisk nivå uppges den största delen av uppföljningen avseende hanteringen av de nya bestämmelserna om dygnsvila ha skett i regionstyrelsens personaldelegation. I övrigt uppges uppföljning av eventuella konsekvenser av de nya bestämmelserna ha integrerats i ordinarie verksamhetsuppföljning och inom ramen för det systematiska arbetsmiljöarbetet. I intervjuer framförs att det finns en önskan att det genomförs en formell uppföljning av vilka konsekvenser de nya bestämmelserna medfört för medarbetarna.

I avsnitten nedan beskrivs sådan uppföljning som har gjorts avseende bestämmelserna om dygnsvila, alternativt uppföljning som går att koppla till området, till exempel avseende schemaläggning och arbetsmiljöarbete.

3.4.1 Formell uppföljning

3.4.1.1 Uppföljning i regionstyrelsen

Regionstyrelsen fick på sina sammanträden i juni samt september år 2023¹⁵ uppföljning avseende arbetet med dygnsvila enligt EU:s direktiv. I samband med detta informerade HR-direktör styrelsen om det pågående arbetet för att anpassa verksamheten till de nya bestämmelserna.

3.4.1.2 Uppföljning i personaldelegationen

Vi noterar att det av personaldelegationens protokoll framgår att delegationen i mars år 2023 informerades om att ändringarna i Allmänna bestämmelser (AB) skulle träda i kraft 1 oktober och att det vid tiden pågick ett utbildningsarbete inför införandet¹⁶. Vidare informerades personaldelegationen i maj år 2023 om att det pågick ett samverkansarbete med berörda verksamheter och aktörer på central nivå för att reda ut utmaningarna direktivet medför¹⁷. I september informerades personaldelegationen om att kommunikationen samt arbetet ska genomföras i linjeorganisationen och att HR-partners ska fungera som ett arbetsrättsligt stöd i processen¹⁸. Vidare informeras delegationen om att en regionövergripande arbetsgrupp, vars uppdrag var att identifiera och genomföra insatser för att stödja chef och schemaläggare, hade inrättats. Informationen om arbetet skulle enligt rapporteringen publiceras på en särskild sida på regionens intranät.

Vidare fick personaldelegationen i november år 2023 information om att de nya bestämmelserna även ska vara gällande för läkare från och med första februari 2024¹⁹. Av informationen framgår även att scheman som följer de nya direktiven för övriga yrkeskategorier har implementerats. Det uppgavs inte finnas några planerade undantag vid tiden för uppföljningen.

Rapportering avseende de nya bestämmelserna om dygnsvila till personaldelegationen fortgick även under år 2024. Vid sammanträdet i februari informerades att de nya reglerna började gälla

¹⁵ RS 2023-06-07, § 131 / 2023-09-26, § 187

¹⁶ Personaldelegationen 2023-03-02, § 9

¹⁷ Personaldelegationen 2023-05-10, § 24

¹⁸ Personaldelegationen 2023-09-27, § 36

¹⁹ Personaldelegationen 2023-11-22, § 45

för läkarna den 1 februari och att processen var densamma som tidigare för övriga yrkeskategorier. Det framgick även att regelbundna träffar har genomförts med fackliga organisationer. Vid sammanträdet i maj skedde ytterligare en rapportering och i samband med rapporteringstillfället uppgavs att andelen övertidstimmar har minskat sedan oktober 2023 när bestämmelserna trädde i kraft.

I november år 2024 beslutade personaldelegationen att få en utvärdering över hur arbetet har fortskridit gällande de nya bestämmelserna avseende dygnsvila på nästkommande sammanträde i februari år 2025. Utvärderingen utgjordes av en Powerpointpresentation som beskrev bakgrunden till de nya bestämmelserna samt en redovisning av statistik relaterat till sjukfrånvaro, personalomsättning, övertidstimmar och ej lagstadgad tjänstledighet utan lön²⁰. Av utvärderingen framgår att sjukfrånvaron, personalomsättningen och antal övertidstimmar har varit lägre under år 2024 jämfört med år 2023. När det gäller ej lagstadgad tjänstledighet syns dock en ökning med cirka 7–8 procent mellan 2023 och 2024. Därtill ges information om iakttagelser utifrån dialog med ett antal chefer. Utifrån dessa framgår att införandet av de nya bestämmelserna generellt sett fungerat bra. En del chefer beskriver det som positivt att medarbetare får mer vila mellan sina arbetspass. Däremot anges att det förekommer tidskrävande diskussioner om bestämmelserna på en del enheter, samtidigt som en del chefer fått önskemål om minskad sysselsättningsgrad/tjänstledighet från personalen. På en del enheter upplever medarbetare även kvällshelg som betungande. Vad gäller systemstöd framgår det av utvärderingen att personalsystemet numera ska ge en felsignal om någon försöker bryta mot dygns- eller veckovila. Det framgår även att det har utarbetats ett nytt verktyg som syftar till att säkerställ följsamhet till dygnsvila vid akutbemanning. Verktyget uppgavs vara under testning vid utvärderingens genomförande.

3.4.1.3 Uppföljning genom ordinarie styrning, uppföljning och kontroll

Arbete utifrån de nya bestämmelserna om dygnsvila följs upp och kommenteras i samband med vissa uppföljningsrapporter under åren 2023–2024, när införandet var aktuellt. Nedan redovisas vad som framgår av dessa uppföljningsrapporter.

❖ Nämnden för folkhälsa och sjukvårds verksamhetsberättelser 2023

I Folkhälsa och sjukvårds olika verksamhetsområdens verksamhetsberättelser för år 2023 omnämns införandet och anpassning av verksamheten kopplat till de nya bestämmelserna om dygnsvila. I *Kirurgisk vårds* verksamhetsberättelse framgår att fokus inom HR-området under året har varit på schemaförändringar kopplade till de nya direktiven kring dygnsvila. Det framgår att det pågått ett intensivt arbete med att stötta chefer i hälsosamma scheman utifrån de nya bestämmelserna, och kopplat till detta har det funnits en aktivitet gällande översyn av scheman. Det anges vidare att stöd finns i form av mallar på intranätet, informationsträffar, utvecklat systemstöd och dialog med HR-partner. I *Medicinsk vårds* verksamhetsberättelse anges att implementeringen av nya regler för dygnsvila har genomförts, samt att de flesta verksamheter har lyckats lägga fungerande scheman.

I *Medicinsk vårds* verksamhetsberättelse framkommer även att det genomförts avgångsenkäter för medarbetare som valt att avsluta sin anställning. Där framgår att flertal personer har angivit arbetstiderna som en betydande anledning till att de avslutat sin anställning.

²⁰ Personaldelegationen 2025-02-26, § 7

❖ **Budget och verksamhetsplan samt årsredovisning 2024**

I *Budget och verksamhetsplan 2024* framgår att regionen arbetar med att följa EU:s lagstadgade arbetstidsdirektiv om dygnsvila, samt att regionen har beredskap att möta eventuellt tillkommande resursbehov. När det gäller arbete med scheman fastställs uppdraget "Hållbart arbetsliv" inom ramen för arbetet med målet *Sveriges bästa offentliga arbetsgivare med Sveriges bästa arbetsplatser*, där uppdraget är att "Skapa förutsättningar för att samtliga anställda ska ha ett hållbart arbetsliv och tillsammans med fackliga organisationer arbeta fram hållbara scheman för att öka andelen som heltidsarbetar". I *Årsredovisning 2024* anges att utbildningar inom den organisatoriska och social arbetsmiljön har lanserats för chefer och skyddsombud i syfte att förebygga ohälsa och öka kunskapen om hållbara scheman. Som en central del i arbetet ingår hållbara scheman för att öka kunskapen om vad forskning visar är positivt för medarbetares hälsa. Det anges även att ett regionövergripande arbete för att få en mer gemensam syn i schema och bemanningsfrågor påbörjats. Detta arbete förväntades också få en positiv effekt på långsiktigt hållbar schemaläggning och följsamhet till aktuell skyddslagstiftning och centrala avtal.

❖ **Nämnden för folkhälsa och sjukvårds verksamhetsplaner samt verksamhetsberättelser 2024**

I Folkhälsa och sjukvårds olika verksamhetsområdens verksamhetsplaner för år 2024 omnämns införandet och anpassning av verksamheten kopplat till de nya bestämmelserna om dygnsvila. I både *Psykiatri, rehabilitering och diagnostik* samt *Kirurgisk vårds* verksamhetsplan anges för aktiviteten "Schemaplanera med hållbara och hälsosamma arbetstider" att schemaplanering ska ske på ett sätt så att dygns- eller veckovila inte bryts.

I *Kirurgisk vårds* verksamhetsberättelse för år 2024 anges att arbetet med att se över hållbara och hälsosamma scheman som följer direktiven kring dygnsvila har fortsatt. Det har även fokuserats på att minska övertid utifrån ett hållbarhetsperspektiv. Det anges även att schemaläggning sker utifrån direktiven, samt att ett fåtal kliniker har ansökt och fått beviljat undantag för att förelägga arbete och jour upp till 20 timmar. I *Psykiatri, rehabilitering och diagnostik* framgår att scheman är planerade enligt de nya direktiven kring dygnsvila, samt att uppföljning av övertid och arbetspass längre än 10 timmar sker.

Medicinsk vård anger även att avgångsenkäter har genomförts under år 2024 för medarbetare som valt att avsluta sin anställning. Det framgår att en del är kritiska till vissa delar i sin arbetssituation när det gäller bland annat arbetstider.

3.4.1.4 Uppföljning av det systematiska arbetsmiljöarbetet

Inom ramen för det systematiska arbetsmiljöarbetet tas en årlig uppföljningsrapport fram och redovisas till regionstyrelsen. I *Årlig uppföljning av det systematiska arbetsmiljöarbetet* år 2023 samt år 2024 beskrivs uppföljning, styrkor och förbättringsområden inom olika områden. I dessa nämns inget särskilt avseende dygnsvilan.

3.4.2 Iakttagelser avseende konsekvenser och effekter av förändringarna

Konsekvenser till följd av de nya bestämmelserna avseende dygnsvila uppges i intervjuer skilja sig åt mellan de olika verksamheterna. Detta beskrivs bero på att verksamheterna påverkats av bestämmelserna i olika grad, där det framhålls att verksamheter som bedrivs dygnet runt och/eller verksamheter där personal har beredskap har blivit påverkade i högst grad. Flera intervjuade framhåller dock att det är svårt att isolera konsekvenser, exempelvis relaterat till arbetsmiljö eller

personalomsättning, som en direkt följd av införandet av de nya bestämmelserna då även andra faktorer haft inverkan på verksamheten under samma period.

De största utmaningarna beskrivs vara kopplade till *bemannning och planering*. Exempel som lyfts är att arbetspass behövt justeras eller tas bort, samt att jourpass kortats ned. I flera intervjuer framkommer att schemaläggningen ibland inte överensstämmer med verksamhetens faktiska bemanningsbehov, eftersom planeringen måste anpassas för att följa regelverket. Detta kan skapa ojämn bemanning mellan olika pass. Chefer uppger samtidigt att den administrativa arbetsbördan har ökat, då det krävs mer arbete för att säkerställa att scheman uppfyller kraven.

Det framkommer också att det vid korttidsfrånvaro ibland saknas alternativa lösningar, vilket innebär att övertid hos ordinarie personal blir den enda möjliga åtgärden, en lösning som samtidigt begränsas av de nya reglerna kring dygnsvila. Vidare uppges det i vissa intervjuer att anpassade scheman har skapat behov av ytterligare personal och ökad användning av hyrpersonal inom vissa verksamheter.

När det gäller *arbetsmiljö* framförs det vid intervju att det inom vissa verksamheter har förekommit att medarbetare har valt att avsluta sin avställning i regionen med anledning av följderna av de nya bestämmelserna. Detta beskrivs ha berott på arbetstider och scheman som inte motsvarade enskilda medarbetares behov. I intervjuer betonas att svårigheterna att lägga scheman som både följer bestämmelserna och tillgodoser personalens önskemål. Samtidigt nämns även positiva effekter, såsom ökad möjlighet till återhämtning och mer hållbara arbetstider, exempelvis genom kortare jourpass. Det framhålls dock att anpassade scheman ibland har resulterat i fler arbetspass på helger och helgdagar, vilket upplevts negativt. Bestämmelserna har enligt flera uppgifter även begränsat medarbetarnas möjlighet att påverka sitt schema utifrån egna önskemål, något som lett till missnöje.

När det gäller *ekonomiska konsekvenser* framhålls att det är svårt att särskilt härleda kostnadsökningar till införandet av dygnsvilobestämmelserna. I intervjuer nämns exempelvis att vissa verksamheter, till följd av anpassningarna, fått ett ökat behov av årsarbetare som överskrider budget, samt ett ökat behov av övertid, vilket påverkar ekonomin negativt. Dessa utmaningar beskrivs dock inte vara unika för införandet av dygnsvilan, utan problem som funnits sedan tidigare.

3.4.3 Bedömning

Vi bedömer att konsekvenser på verksamhet, ekonomi och arbetsmiljö som de nya bestämmelserna om dygnsvila har haft **i allt väsentligt** har följts upp, men att åtgärder **endast delvis** har vidtagits.

Regionstyrelsen samt nämnden för folkhälsa och sjukvård ska enligt sina reglementen se till att verksamheten bedrivs på ett tillfredsställande sätt inom sina respektive ansvarsområden. Nämnden ska också följa upp och utvärdera sin verksamhet. Vi noterar att regelbunden uppföljning av hanteringen av de nya bestämmelserna om dygnsvila har genomförts i regionstyrelsens personaldelegation sedan år 2023. Denna rapportering har främst avsett status i införandet och pågående stödsatser. Utöver den formella rapporteringen till personaldelegationen omnämns hanteringen och implementeringen av bestämmelserna även i verksamhetsberättelser inom Folkhälsa

och sjukvård för åren 2023 och 2024. Dessa uppföljningar visar att införandet har beaktats i ordinarie uppföljning, men att uppföljningen i huvudsak varit fragmenterad.

Vi noterar vidare att personaldelegationen i början av 2025 tog del av en mer sammanställd utvärdering i form av en presentation som redovisade såväl övergripande erfarenheter som statistik avseende sjukfrånvaro, personalomsättning, övertidstimmar och tjänstledighet utan lön. Denna utvärdering utgör enligt vår bedömning en mer samlad bild av utvecklingen efter införandet av de nya bestämmelserna, men vi bedömer att utvärderingen endast till viss del omfattar en strukturerad analys av konsekvenserna av de nya bestämmelserna om dygnsvilan. Enligt vår bedömning utgör inte denna rapportering en heltäckande utvärdering av påverkan på exempelvis verksamhet, ekonomi och arbetsmiljö i hälso- och sjukvården.

Utifrån vår granskning konstaterar vi att det förekommer konsekvenser relaterat till dygnsvilan, bland annat i form av utmaningar kopplade till bemanning och ökad administrativ belastning för chefer. Samtidigt är det tydligt att dessa effekter inte fullt ut fångas upp i de uppföljningar som genomförts. Avsaknaden av en sammanhållen analys medför en risk att viktiga konsekvenser är oidentifierade eller att behov av stöd och åtgärder inte hanteras på ett strukturerat sätt. Mot denna bakgrund bedömer vi att det vore fördelaktigt att en mer samlad uppföljning av de faktiska konsekvenserna av bestämmelserna om dygnsvila genomfördes. Enligt vår bedömning skulle en sådan uppföljning ge ett bättre underlag för att prioritera åtgärder, säkerställa en enhetlig tillämpning och stödja verksamheterna i att hantera de utmaningar som kvarstår. Behovet av en mer strukturerad uppföljning/utvärdering har även efterfrågats av verksamhetsföreträdare i samband med granskningen.

Vi vill också framhålla att de nya bestämmelserna har påverkat samtliga regioner i riket i varierande omfattning. Mot denna bakgrund bedömer vi att det även är värdefullt att bevaka och ta del av eventuella nationella utvärderingar av bestämmelserna kring dygnsvila, för att få en bredare bild av konsekvenser och erfarenheter över hela landet.

4 SAMLAD BEDÖMNING OCH REKOMMENDATIONER

Syftet med granskningen har varit att bedöma om regionstyrelsen och nämnden för folkhälsa och sjukvård utifrån sina respektive ansvarsområden säkerställt att de nya bestämmelserna om dygnsvila införts och efterlevs på ett ändamålsenligt sätt inom hälso- och sjukvården.

Vår samlade bedömning utifrån granskningens syfte är regionstyrelsen och nämnden för folkhälsa och sjukvård utifrån sina respektive ansvarsområden i allt väsentligt säkerställt att de nya bestämmelserna om dygnsvila införts och efterlevs på ett ändamålsenligt sätt inom hälso- och sjukvården.

Se inledning samt respektive rapportkapitel för en mer detaljerad beskrivning.

Utifrån våra iakttagelser och bedömningar rekommenderar vi regionstyrelsen samt nämnden för folkhälsa och sjukvård, utifrån sina respektive ansvarsområden, att:

- Se över behovet av ytterligare informationsinsatser avseende hanteringen av bestämmelserna avseende dygnsvila till chefer inom hälso- och sjukvården.
- Säkerställa att riskanalyser/riskbedömningar genomförs i samband med större förändringar.
- Säkerställa att det sker regelbunden uppföljning och kontroll av efterlevnaden av de nya bestämmelserna om dygnsvila i schemaläggningen.
- Överväga att genomföra en samlad uppföljning/utvärdering av konsekvenserna av de nya bestämmelserna om dygnsvila och säkerställa att eventuella brister åtgärdas.

Datum som ovan

Azets Revision & Rådgivning AB

Ludwig Reimer

Certifierad kommunal revisor

Olivia Gonzalez

Verksamhetsrevisor

Liam Alldén

Verksamhetsrevisor

Veronica Hedlund Lundgren

Certifierad kommunal revisor och kvalitetssäkrare

2026-03-17

§ 42**Initiativärende: Tillnyktringsenheten**

Diarienummer: RJL 2026/306

Beslut

Presidiet föreslår nämnden för folkhälsa och sjukvård att

- anse initiativärendet vara besvarat.

Sammanfattning

Maria Högberg, Sverigedemokraterna, har lämnat ett initiativärende med följande förslag.

- Att skyndsamt införa kameraövervakning av entré och korridor på Tillnyktringsenheten för att öka tryggheten
- Att ge personalen bättre förutsättningar att ta del av nödvändig bakgrundsinformation om patienterna för att kunna göra säkrare riskbedömningar
- Att genomföra en revision av avgiftshanteringen för att säkerställa att intäktsbortfall inte upprepas
- Att skärpa rutiner för identitetskontroll vid inskrivning
- Att intensifiera information och utbildning gentemot Polismyndigheten för att säkerställa att rätt personer transporteras till enheten, så att polisens resurser inte slösas

Beslutsunderlag

- Tjänsteskrivelse: Initiativärende – Tillnyktringsenheten
- Beslut NFS 2026-01-20 Initiativärende: Tillnyktringsenheten
- Initiativärende: Tillnyktringsenheten

Beslutet skickas till

Nämnden för folkhälsa och sjukvård

Initiativärende: Tillnyktringsenheten

Förslag till beslut

Förvaltningen lämnar inget förslag till beslut.

Sammanfattning

Maria Högberg, Sverigedemokraterna, har lämnat ett initiativärende med följande förslag.

- Att skyndsamt införa kameraövervakning av entré och korridor på Tillnyktringsenheten för att öka tryggheten
- Att ge personalen bättre förutsättningar att ta del av nödvändig bakgrundsinformation om patienterna för att kunna göra säkrare riskbedömningar
- Att genomföra en revision av avgiftshanteringen för att säkerställa att intäktsbortfall inte upprepas
- Att skärpa rutiner för identitetskontroll vid inskrivning
- Att intensifiera information och utbildning gentemot Polismyndigheten för att säkerställa att rätt personer transporteras till enheten, så att polisens resurser inte slösas

Ärendebeskrivning

Maria Högberg, Sverigedemokraterna, har lämnat ett initiativärende utifrån den uppföljning som är gjord av Tillnyktringsenheten, med följande förslag.

- Att skyndsamt införa kameraövervakning av entré och korridor på Tillnyktringsenheten för att öka tryggheten
- Att ge personalen bättre förutsättningar att ta del av nödvändig bakgrundsinformation om patienterna för att kunna göra säkrare riskbedömningar
- Att genomföra en revision av avgiftshanteringen för att säkerställa att intäktsbortfall inte upprepas
- Att skärpa rutiner för identitetskontroll vid inskrivning
- Att intensifiera information och utbildning gentemot Polismyndigheten för att säkerställa att rätt personer transporteras till enheten, så att polisens resurser inte slösas

Tillnyktringsenheten

Tillnyktringsenheten startade hösten 2020 men pausades sedan under pandemin. Nu har Tillnyktringsenheten varit tillgänglig och i drift dygnet runt sedan sista maj 2024. Uppdraget att bedriva Tillnyktringsenheten tillhör akutkliniken och har en lokal med sju fysiska platser som används i första hand.

Personalens trygghet

Tillnyktringsenheten har kontroll över vilka personer som har tillträde till lokalerna och rutiner för hur man tar emot en individ. Akutkliniken, som inkluderar tillnyktringsenheten, arbetar kontinuerligt med risk för hot och våld genom välkända rutiner för hur man arbetar, hur man bemöter, samt hur man hanterar en situation som inte går att deskalera.

Rutinen beskriver exempelvis:

- Var aldrig ensam när du öppnar entrédörren.
- Se till att alltid bära telefon med överfallslarm.
- Om en patient blir våldsam eller hotar med våld, så att fara föreligger för personalens eller medpatienters liv och hälsa, så ska patienten släppas ut. Tjänstgörande personal har fullt mandat att avgöra när den typen av fara föreligger. Om arbetsmiljön upplevs hotfull ska även ordningsvakt tillkallas. Ansvarig sjuksköterska ska alltid underrättas då patient avviker/avvisas.

Gränsen är lågt satt till när man kontaktar bevakning/polis. Samarbetet med bevakningen har under hela tiden fungerat mycket väl med korta inställelsetider efter kontakt vilket personalen upplever som en trygghet.

Tillnyktringsenhetens lokaler är anpassade för att hantera risk för hot och våld genom att samtliga rum har flera utgångar, expeditionen där övervakning och administration sker är låst samt att ytterdörren är i glas för att personalen ska kunna se vem/vilka som ringer på.

En ansökan om kameraövervakning vid entrén kommer att lämnas in. Kamerans syfte är att täcka det som kan bli en död vinkel utanför ytterdörren.

Ekonomisk styrning

Det som beskrivs i uppföljningen av tillnyktringsenheten rör sig om uteblivna patientavgifter i begränsad omfattning under en begränsad tid som åtgärdades så snart det var möjligt efter att felet uppmärksammats. Rutin för debitering av patientuppgifter finns och följs.

Identitetskontroll

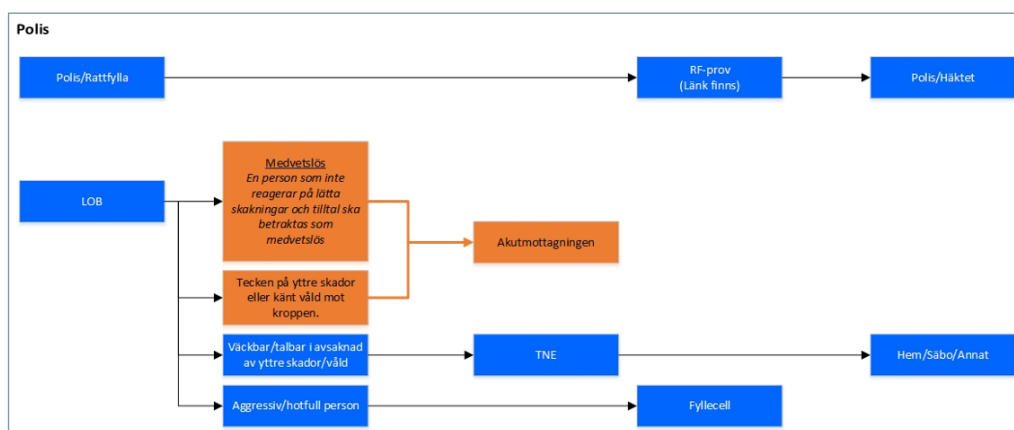
Identitetskontroll och inskrivning av patienter som saknar identifikation och/eller inte är folkbokförda i Sverige följer Region Jönköpings läns ordinarie inskrivningsrutiner.

Rutinen finns tillgänglig på regionens intranät: [Beskrivning hur man gör A- och C-nummer. Vård av personer från andra länder -Regionens intranät](#)

Stöd till Polisen

Polisen avgör själva vilka patienter som är i behov av medicinskt övervakad tillnyktring på tillnyktringsenheten. Rutin och överenskommelse finns och är välkänd. Polismyndigheten ansvarar, på samma sätt som akutkliniken, för att hålla sina medarbetare informerade och uppdaterade i gällande rutiner.

Flödesbilden för vilka patienter som kan transporteras till tillnyktringsenheten förtydligades i samband med övertaget till akutkliniken, och ser ut enligt nedan bild.



Beslutsunderlag

- Tjänsteskrivelse: Initiativärende – Tillnyktringsenheten
- Beslut NFS 2026-01-20 Initiativärende: Tillnyktringsenheten
- Initiativärende: Tillnyktringsenheten

Beslutet skickas till

Maria Högberg (Sverigedemokraterna)
Regionledningskontoret – Folkhälsa och sjukvård

Mats Bojestig
Hälso- och sjukvårdsdirektör

Anette Peterson
Bitr. hälso- och sjukvårdsdirektör

§ 17**Initiativärende: Tillnyktringsenheten**

Diarienummer: RJL 2026/306

Beslut

Nämnden för folkhälsa och sjukvård beslutar att

- ärendet ska beredas.

Sammanfattning

Maria Högberg (Sverigedemokraterna) har initierat ett ärende om Tillnyktringsenheten. I ärendet framförs förslag om att

- skyndsamt införa kameraövervakning av entré och korridor på Tillnyktringsenheten för att öka tryggheten.
- ge personalen bättre förutsättningar att ta del av nödvändig bakgrundsinformation om patienterna för att kunna göra säkrare riskbedömningar.
- genomföra en revision av avgiftshanteringen för att säkerställa att intäktsbortfall inte upprepas.
- skärpa rutiner för identitetskontroll vid inskrivning.
- intensifiera information och utbildning gentemot Polismyndigheten för att säkerställa att rätt personer transporteras till enheten, så att polisens resurser inte slösas.

Beslutsunderlag

- Initiativärende: Tillnyktringsenheten

Beslutet skickas till

Regionledningskontoret – Folkhälsa och sjukvård

Initiativärende | Folkhälsa- och Sjukvårdsnämnden Region Jönköpings län

Tillnyktringsenheten

Bakgrund

Uppföljningen av Tillnyktringsenheten (TNE) för 2025 visar på brister som måste åtgärdas för att garantera en trygg arbetsmiljö och en ansvarsfull hantering av skattemedel. Rapporten pekar på förekomst av hotfulla situationer, administrativt slarv gällande avgifter samt en otydlighet kring vilka som nyttjar tjänsten.

För oss Sverigedemokrater är det en självklarhet att vårdpersonal ska kunna utföra sitt arbete utan rädsla, och att välfärdens resurser ska hanteras med största respekt för skattebetalarna. Mot bakgrund av detta lägger vi fram följande förslag till åtgärder.

1. Garantera personalens trygghet

Det har framkommit att det finns en oro i personalgruppen kopplat till hot och våld, samt en känsla av bristande kontroll över vilka personer som vistas i lokalerna. Att personal upplever otrygghet på sin arbetsplats är oacceptabelt. Den pågående utredningen om kameraövervakning måste skyndsamt övergå i handling.

2. Skärpt ekonomisk styrning

Att regionen under lång tid missat att ta ut patientavgifter på grund av ett "missförstånd" mellan verksamheter vittnar om bristande rutiner. Detta har lett till onödiga inkomstbortfall för regionen. Det krävs en tydligare särredovisning av kostnaderna för att säkerställa att skattemedel används effektivt.

3. Identitetskontroll och välfärdens gränser

Rapporten visar att en del av de inskrivna saknar fastställd identitet eller är folkbokförda i andra län/länder. För att upprätthålla legitimiteten i välfärdssystemet måste vi ha kontroll på vilka som nyttjar våra gemensamma resurser. Det måste säkerställas att regionen får full kostnadstäckning för personer som inte är hemmahörande i länet.

4. Effektivt stöd till Polisen

TNE ska avlasta polisen, inte belasta dem med otydliga rutiner. När polisen tvingas transportera personer som inte uppfyller kriterierna för vård, tas resurser från brottsbekämpning. Samarbetet måste vässas genom tydligare krav och utbildning.

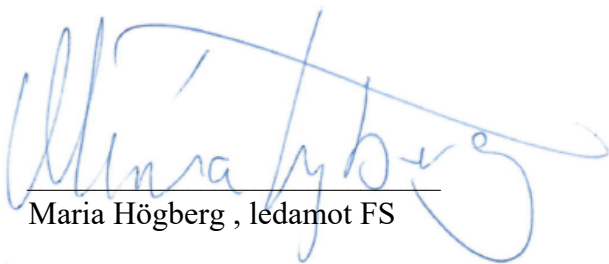
Förslag till beslut:

- **Att** skyndsamt införa kameraövervakning av entré och korridor på Tillnyktringsenheten för att öka tryggheten.
- **Att** ge personalen bättre förutsättningar att ta del av nödvändig bakgrundsinformation om patienterna för att kunna göra säkrare riskbedömningar.
- **Att** genomföra en revision av avgiftshanteringen för att säkerställa att intäktsbortfall inte upprepas.
- **Att** skärpa rutiner för identitetskontroll vid inskrivning.

2026-01-20

- **Att** intensifiera information och utbildning gentemot Polismyndigheten för att säkerställa att rätt personer transporteras till enheten, så att polisens resurser inte slösas.

För Sverigedemokraterna,



Maria Högberg , ledamot FS