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Committee on Industry, Research and Energy

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AMENDMENTS
1732 - 2047

Draft report
Vytenis Povilas Andriukaitis, Wouter Beke
(PE789.987v01-00)

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)

Proposal for a regulation
(COM(2025)1022 – 2025/0406(COD))

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Amendment 1732
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 15 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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. ***In promoting and facilitating such networks, the Commission and Member States shall ensure broad geographic participation across the Union.***

Or. en

Justification

Without a geographic balance obligation, networkparticipation risks concentrating among well-represented clusters, reinforcingexisting imbalances. The amendment is deliberately non-prescriptive. It sets anoutcome expectation without categorising regions or imposing quotas.

Amendment 1733
Jérémy Decerle, Christophe Grudler

Proposal for a regulation
Article 15 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission and the Member States shall promote and facilitate the cooperation and the establishment of	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.

networks among promoters of health biotechnology strategic projects, of high impact health biotechnology strategic projects and other relevant actors ***building on European excellence reference networks dedicated to therapeutic areas***. 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.

Or. en

Amendment 1734
Ruggero Razza

Proposal for a regulation
Article 15 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) facilitate synergies between innovation ecosystems at local, regional and Union levels;	(a) facilitate synergies between innovation ecosystems ***by promoting complementarity between the respective areas of technological expertise*** at local, regional and Union levels;

Or. it

Amendment 1735
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 15 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) provide transparent, open, and non-discriminatory cross-border access at market prices to research organisations, SMEs, start-ups and scale-ups, healthcare	(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

providers, and industrial actors from across the Union;	the Union***, subject to appropriate safeguards for the protection of intellectual property and confidential business information, and including access to shared validation platforms and reference infrastructures for non-animal methodologies (NAMs)***;

Or. en

Justification

When referring to networks and clusters, shared validation platforms and infrastructures for non-animal NAMs shall also be referenced.

Amendment 1736
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 15 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(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;	(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***, subject to appropriate safeguards for the protection of intellectual property and confidential business information***;

Or. en

Amendment 1737
Anja Hazekamp, Anthony Smith, Sebastian Everding, Lynn Boylan

Proposal for a regulation
Article 15 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*

(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;	(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***, including access to shared validation platforms and reference infrastructures for non-animal methodologies***;

Or. en

Amendment 1738
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 15 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(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;	(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***, including access to shared validation platforms and reference infrastructures for non-animal methodologies***;

Or. en

Amendment 1739
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 15 – paragraph 2 – point f

Text proposed by the Commission	*Amendment*
(f) promote the development of infrastructure and digital platforms, and	(f) promote ***and enable*** the development of infrastructure and digital platforms, and AI-enabled technologies

AI-enabled technologies supporting biotechnology and biomanufacturing.	supporting biotechnology and biomanufacturing.

Or. en

Amendment 1740
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 15 – paragraph 2 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) support, where appropriate, the establishment of cross-border innovation hubs or networks of excellence in therapeutic areas characterised by major public health and socioeconomic burden and persistent innovation gaps, including mental health, with a view to facilitating multi-country clinical research, shared data infrastructures, scientific and regulatory support, workforce development, and implementation readiness across the Union.

Or. en

Amendment 1741
Ruggero Razza

Proposal for a regulation
Article 15 – paragraph 2 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) promote collaboration between universities, scientific healthcare and research institutes, public research organisations and industry with a view to expediting technology transfer and the economic exploitation of research findings;

Or. it

Amendment 1742
Sirpa Pietikäinen

Proposal for a regulation
Article 15 – paragraph 2 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) facilitate cooperation involving molecular imaging and radiopharmaceutical infrastructures, and cross-cutting translational research ecosystems in strategic fields such as immunology.

Or. en

Justification

This addition would strengthen the connection between academic discovery, clinical expertise, translational infrastructure, regulatory knowledge and industrial development.

Amendment 1743
Aurelijus Veryga

Proposal for a regulation
Article 15 – paragraph 2 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) facilitate and support collaboration with clusters and partners at international level to ensure world-class excellence

Or. en

Amendment 1744
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 15 – paragraph 2 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) facilitate and support collaboration with clusters and partners at international level to ensure world-class excellence.

Or. en

Amendment 1745
Ruggero Razza

Proposal for a regulation
Article 15 – paragraph 2 – point f b (new)

Text proposed by the Commission	*Amendment*
	(fb) promote the exchange of expertise in the areas of intellectual property, licensing, patent certifications and access to international markets.

Or. it

Amendment 1746
Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 15 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The networks referred to in this Article may, where relevant, support cooperation between biotechnology clusters, hospitals, universities, research infrastructures, biobanks, patient registries, genomic initiatives, clinical research infrastructures and interconnected and interoperable ERNs, in particular for rare diseases, rare cancers, paediatric conditions and other complex diseases. Such cooperation shall aim to strengthen translational research, clinical trial readiness, patient

recruitment, (including the possibility of cross-border clinical trial access), cross-border access to expertise and the development and deployment of innovative and/or advanced therapies across the Union.

Or. en

Amendment 1747
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 15 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. University hospitals and university hospital alliances shall be eligible to establish and coordinate networks under this Article; such networks shall be able to coordinate cross-border patient recruitment and harmonised clinical protocols for rare ATMP indications;

Or. en

Justification

Coordination of cross-border patient recruitment and harmonised clinical protocols for rare ATMP indications addresses one of the key operational barriers to development and clinical implementation, as patient populations and expertise are often dispersed across multiple Member States.

Amendment 1748
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 15 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Where deemed appropriate and relevant, the network shall also exchange with entities from third countries.

Or. en

Amendment 1749
Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 15 a (new)

Text proposed by the Commission	*Amendment*
	Article15a
	Cross-border infrastructure and patient access
	1. Promoters of high-impact biotechnology projects recognised under this Chapter may, in cooperation with the relevant ERNs, sponsors and patient representatives, establish and scale Union- wide, interoperable infrastructures, including patient registries, genomic data repositories, and biobanks for rare diseases, in full compliance with Regulation (EU) 2025/327 of the European Parliament and of the Council on the European Health Data Space (EHDS). 2. These projects may also Operate under established clear and simplified pathways for patient access to clinical trials and authorised treatments also, in collaboration with national contact points for cross-border healthcare and access to clinical trials to facilitate the recognition of clinical assessments and reimbursement, in line with Directive 2011/24/EU

Or. en

Amendment 1750
Christophe Clergeau, Tomislav Sokol, Vytenis Povilas Andriukaitis, Marta Temido, Michalis Hadjipantela, Sirpa Pietikäinen, Ondřej Krutílek, Marcos Ros Sempere, Tilly Metz

Proposal for a regulation

Article 15 a (new)

Text proposed by the Commission	*Amendment*
	Article15a
	Cross-border infrastructure and patient access
	The following paragraph is added to article 15a of the draft report:
	3. The projects referred to in this Article may, where relevant, draw on established population and longitudinal cohorts as a basis for the recruitment of participants and for the design and conduct of interventional studies and clinical trials, including studies nested within such cohorts, with a view to advancing personalised and preventive approaches to health. Such use shall be consistent with Regulation (EU) No 536/2014, with Regulation (EU) 2016/679, with Regulation (EU) 2025/327 and with applicable Union law on data protection and data governance.

Or. en

Justification

This amendment builds on amendment 115 from the rapporteurs, by clearly identifying population and longitudinal cohorts as health infrastructures and add a paragraph to underline the the interventional / recruitment dimension of established cohorts as a basis for nested interventional studies and trials. The reference to Regulation (EU) 2016/679 reflects the personal-data processing involved.

Amendment 1751
Monika Beňová

Proposal for a regulation
Article 16 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Health biotechnology strategic projects and high impact health biotechnology strategic projects recognised in accordance with this	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.	Regulation that receive financial support in accordance with Union programmes shall offer open, non-discriminatory, transparent, ***proportionate*** and criteria-based access ***under fair and reasonable conditions*** to their facilities, equipment, services***,*** training programmes***, data infrastructures, trusted testing environments and data quality accelerators*** for users, including SMEs, start-ups and scale-ups and other industrial actors, research organisations***, academic institutions*** or training institutions. ***Where appropriate and in accordance with applicable State aid rules, access conditions may include reduced, cost-based or preferential arrangements for start-ups, scale-ups, academic institutions and non-profit developers.***

Or. en

Justification

EU-funded biotech infrastructure should not become a closed club. Start-ups should not get weaker rules, but they must get real, affordable and proportionate access to the facilities, datasets, testing environments and data quality accelerators built with Union support in order to promote innovation and real start up culture in the EU.

Amendment 1752
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 16 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
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-	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 ***that are funded through or directly supported by***

ups and other industrial actors, research organisations or training institutions.	***Union financial support under this Regulation,*** for users, including SMEs, start-ups and scale-ups and other industrial actors, research organisations or training institutions.

Or. en

Amendment 1753
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 16 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
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.	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***, healthcare institutions*** or training institutions.

Or. en

Amendment 1754
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 16 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) any safeguards necessary for the protection of security, confidentiality or economic-security interests, in particular those referred to in paragraph [3].	(c) any safeguards necessary for the protection of ***intellectual property,*** security, confidentiality or economic-

security interests, in particular those referred to in paragraph [3].

Or. en

Justification

Limiting the obligation explicitly toUnion-funded components removes the ambiguity without narrowing the policyintent. Art. 16(2)(c) lists security, confidentiality and economic-securityinterests but not intellectual property. IP is legally distinct from thoseterms and may not be captured by them.

Amendment 1755
Monika Beňová

Proposal for a regulation
Article 16 – paragraph 2 – point 1 b (new)

Text proposed by the Commission	*Amendment*
	(1b) (d) the need to ensure that access conditions, fees, documentation requirements and administrative procedures do not create disproportionate barriers for SMEs, start-ups, scale-ups and academic institutions.

Or. en

Amendment 1756
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 17 – paragraph 1

Text proposed by the Commission	*Amendment*
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	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

maintain thereafter a strategic mapping of the biotechnology ecosystem in the Union.	the biotechnology ecosystem in the Union ***and no later than 12 months after the entry into force of this regulation a mapping of relevant third countriey clusters and centres of excellence of relevance***.

Or. en

Amendment 1757
Ondřej Krutílek

Proposal for a regulation
Article 17 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
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:	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***, taking into account the specific characteristics of pharmaceutical and health biotechnology supply chains, including product-, technology- and process-specific requirements, as well as their integration with international and transatlantic supply chains and dependencies involving trusted third-country partners***. It shall cover in particular the following areas:

Or. en

Amendment 1758
Ondřej Knotek, Viktória Ferenc, Marie-Luce Brasier-Clain, Valérie Deloge, Ton Diepeveen, Laurent Castillo, Aleksandar Nikolic, András Gyürk, Margarita de la Pisa Carrión

Proposal for a regulation
Article 17 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
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:	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***, taking into account the specific characteristics of pharmaceutical and health biotechnology supply chains, including product-, technology- and process-specific requirements, as well as their integration with international and transatlantic supply chains and dependencies involving trusted third-country partners***. It shall cover in particular the following areas:

Or. en

Amendment 1759
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 17 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
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:	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***, taking into account the specific characteristics of pharmaceutical and health biotechnology supply chains, including product-, technology- and process-specific requirements, as well as their integration with international and transatlantic supply chains and dependencies involving trusted third-country partners***. It shall cover in particular the following areas:

Or. en

Amendment 1760
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 17 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
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***:***	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***, taking into account the specific characteristics of pharmaceutical and health biotechnology supply chains, including product-, technology- and process-specific requirements, as well as their integration with international and transatlantic supply chains and dependencies involving trusted third-country partners***. It shall cover in particular the following areas

Or. en

Justification

Ensures that the strategic mapping exercise reflects the specific characteristics of pharmaceutical and health biotechnology supply chains, rather than treating them as a homogeneous category.It is important that the mapping takes into account product-, technology- and process-specific requirements, as well as the role of international and transatlantic supply chains and dependencies on trusted third-country partners.This will help provide a more accurate assessment of capacities, dependencies, gaps and systemic challenges across the Union's biotechnology and biomanufacturing value chains.

Amendment 1761
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 17 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*

(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;***	(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***; The strategic mapping shall be conducted and presented in a manner that prevents the disclosure or use of information on industrial capacity and infrastructure in a way that could undermine security, competitiveness, trade secrets and commercially sensitive information, global supply chain resilience or the legitimate commercial interests of economic operators. To that end, the Commission shall ensure appropriate aggregation, anonymisation and confidentiality safeguards, in accordance with Union law.***

Or. en

Amendment 1762
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 17 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(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***;***	(a) industrial capacity and infrastructures, including on critical intermediates and key ***inputs***, relevant to biotechnology research, development, testing and manufacturing***, including capacities, supply-chain vulnerabilities and regulatory or market-access barriers relevant to critical or essential biological medicinal products, infrastructure operated by established biotechnology companies***, and assessment of their distribution, interconnections and potential gaps***.***

Or. en

Justification

Ensures that the strategic mapping captures the full range of existing industrial capacity and infrastructure in the Union's biotechnology ecosystem. The mapping should capture capacities operated by established biotechnology companies, not only emerging actors or new infrastructure. Excluding existing industrial capacity would produce an incomplete picture of the Union's strengths, gaps and investment needs

Amendment 1763
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 17 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(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;	(a) industrial capacity and infrastructures***, as well as supply vulnerabilities on APIs, critical intermediaries and imported relevant goods***, including on critical intermediates and key input, relevant to biotechnology research, development, testing, and manufacturing, and assessment of their distribution, interconnections and potential gaps;

Or. en

Amendment 1764
Ondřej Knotek, Viktória Ferenc, Marie-Luce Brasier-Clain, Valérie Deloge, Ton Diepeveen, Laurent Castillo, Aleksandar Nikolic, András Gyürk

Proposal for a regulation
Article 17 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) industrial capacity and infrastructures, including on critical intermediates and key ***input***, relevant to biotechnology research, development, testing**,** and manufacturing, and assessment	(a) industrial capacity and infrastructures, including on critical intermediates and key ***inputs***, relevant to biotechnology research, development, testing and manufacturing***, including capacities and infrastructures operated by established biotechnology companies***, and

of their distribution, interconnections and potential gaps;	assessment of their distribution, interconnections and potential gaps;

Or. en

Amendment 1765
Ondřej Krutílek

Proposal for a regulation
Article 17 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(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;	(a) industrial capacity and infrastructures, including on critical intermediates and key input, relevant to biotechnology research, development, testing, and manufacturing, ***including capacities and infrastructures operated by established biotechnology companies,*** and assessment of their distribution, interconnections and potential gaps;

Or. en

Amendment 1766
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 17 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(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;	(a) industrial capacity and infrastructures, including on critical intermediates and key ***inputs***, relevant to biotechnology research, development, testing and manufacturing***, including capacities and infrastructures operated by established biotechnology companies***, and assessment of their distribution, interconnections and potential gaps;

Or. en

Amendment 1767
Ondřej Krutílek

Proposal for a regulation
Article 17 – paragraph 2 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) to identify and assess strategic supply-chain dependencies and related investment needs, in particular those concerning critical biotechnology inputs and products derived from biological materials, with a view to strengthening the Union's resilience, while taking into account the entire biotechnology lifecycle, including the role of established biotechnology companies, industrial scale-up, commercial deployment and integration within international and transatlantic value chains.

Or. en

Amendment 1768
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 17 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(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;	(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***, taking into account the attractiveness of the sector in terms of quality working conditions and adequate wage policy***;

Or. en

Amendment 1769
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 17 – paragraph 2 – point e

Text proposed by the Commission	*Amendment*
(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.	(e) use of data and AI, by assessing access to data, computing and digital infrastructures for biotechnology and identifying opportunities to foster responsible ***ethical and*** AI-enabled innovation and mitigate related risks***, used in a manner that guarantees full human oversight promotes transparency regarding the intended purpose and limitations of AI systems, and includes appropriate safeguards against discriminatory outcomes and bias***.

Or. en

Amendment 1770
Aura Salla

Proposal for a regulation
Article 17 – paragraph 2 – point e

Text proposed by the Commission	*Amendment*
(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.	(e) use of data and AI, by assessing access to data, computing***, including quantum computing,*** and digital infrastructures for biotechnology and ***biomanufacturing, including industrial data spaces, and by*** identifying opportunities to foster responsible AI-enabled innovation***, biological data standards enabling efficient data sharing and use,*** mitigate related risks ***and strategic dependencies***.

Or. en

Justification

Biotechnology and biomanufacturing should be better integrated into the EU's digital and AI strategies. Strategic mapping should therefore assess not only general access to data and computing capacity, but also the availability of industrial data spaces, biological data standards and advanced computing capabilities, including quantum computing.

Amendment 1771
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 17 – paragraph 2 – point e

Text proposed by the Commission	*Amendment*
(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.	(e) use of data and AI, by assessing access to data, computing***, including quantum computing,*** and digital infrastructures for biotechnology and ***biomanufacturing, including industrial data spaces, and by*** identifying opportunities to foster responsible AI-enabled innovation***, biological data standards enabling efficient data sharing and use*** and mitigate related risks.

Or. en

Justification

Biotechnology and biomanufacturing should be fully integrated into the EU's digital and AI strategies. Strategic mapping should therefore assess not only general access to data and computing capacity, but also the availability of industrial data spaces, biological data standards and advanced computing capabilities, including quantum computing, that are needed to enable efficient data sharing, modelling and process optimisation.

Amendment 1772
Ruggero Razza

Proposal for a regulation
Article 17 – paragraph 2 – point e

Text proposed by the Commission	*Amendment*

(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***.	(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 ***encourage its use in research, development and biomanufacturing activities***.

Or. it

Amendment 1773
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 17 – paragraph 2 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) energy needs, grid and infrastructure requirements, permitting risks and access to renewable and low-carbon energy necessary for biotechnology and biomanufacturing scale-up, including where relevant their potential contribution to reducing greenhouse gas emissions, including methane emissions, in line with the Union's 2030 climate and energy targets, the 2040 climate target and the objective of climate neutrality at the latest by 2050.

Or. en

Amendment 1774
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 17 – paragraph 2 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) therapeutic areas characterised by a high public health and socioeconomic

burden but persistent innovation gaps, including mental health conditions, by assessing barriers related to clinical development, access to risk-tolerant capital, data infrastructures, regulatory uncertainty, cross-border scale-up and real-world implementation.

Or. en

Amendment 1775
Christophe Clergeau, Vytenis Povilas Andriukaitis, Marta Temido, Michalis Hadjipantela, Sirpa Pietikäinen, Ondřej Krutílek, Marcos Ros Sempere, Tilly Metz

Proposal for a regulation
Article 17 – paragraph 2 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) population and longitudinal cohorts and exposome data resources, by mapping their availability, characteristics and interoperability, and by assessing their potential to serve exposome research and to support the design and conduct of interventional studies and clinical trials within the Union.

Or. en

Justification

New point, extending the strategic-mapping content list in Article 17(2). It follows the rapporteur's additions of point (ea) on emerging technologies (Amendment 118) and point (eb) on ERNs (Amendment 119). Entire text is new and shown in bold.

Amendment 1776
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 17 – paragraph 2 – point e a (new)

Text proposed by the Commission	*Amendment*

	(ea) clinical research infrastructures, university hospitals, health data infrastructures, advanced therapy manufacturing facilities and clinical trial networks.

Or. en

Amendment 1777
Aurelijus Veryga

Proposal for a regulation
Article 17 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	3. The strategic mapping shall be based on information from relevant Union bodies and agencies, and, where appropriate, industry stakeholders and research organisations***, including existing Union and regulatory data repositories and dossiers, such as the European Medicines Verification System (EMVS), marketing authorisation and regulatory submission data, pharmacovigilance, manufacturing authorisation and inspection-related datasets***. The Commission may request Member States to submit data necessary for this purpose ***only where such information is not already available through existing sources***, ***and with a clearly defined purpose serving the objectives of the Act*** 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.

Or. en

Amendment 1778
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 17 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	3. The strategic mapping shall be based on information from relevant Union bodies and agencies, and, where appropriate, industry stakeholders and research organisations***, including existing Union and regulatory data repositories and dossiers, such as the European Medicines Verification System (EMVS), marketing authorisation and regulatory submission data, pharmacovigilance, manufacturing authorisation and inspection-related datasets***. The Commission may request Member States to submit data necessary for this purpose***, only where such information is not already available through existing sources***, 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.

Or. en

Amendment 1779
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 17 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The strategic mapping shall include an assessment of biotechnology-specific workforce shortages, including in regulatory science, clinical research, advanced manufacturing, quality management, data science, artificial intelligence, New Approach Methodologies (NAMs), bioinformatics, intellectual property, technology transfer

and entrepreneurship. It shall also assess barriers to cross-border mobility, recognition of skills and professional experience, unequal access to upskilling and reskilling programmes, gender gaps and regional disparities in access to biotechnology skills development.

Or. en

Amendment 1780
Christophe Clergeau, Vytenis Povilas Andriukaitis, Marta Temido, Michalis Hadjipantela, Sirpa Pietikäinen, Ondřej Krutílek, Marcos Ros Sempere, Tilly Metz

Proposal for a regulation
Article 17 – paragraph 5 – introductory part

Text proposed by the Commission	*Amendment*
5. The results of the strategic mapping shall be used for the following purposes:	5. ***The strategic mapping shall be subject to a dynamic monitoring and may include, where relevant, clinical networks, ERNs, registries, biobanks, population and longitudinal cohorts and diagnostic infrastructures.*** The results of the strategic mapping shall be used for the following purposes:

Or. en

Justification

This amendment builds on the rapporteur's Amendment 121, which already opens Article 17(5) to "clinical networks, ERNs, registries, biobanks and diagnostic infrastructures". We propose a new element to insert "population and longitudinal cohorts" into that list.

Amendment 1781
Ondřej Knotek, Viktória Ferenc, Marie-Luce Brasier-Clain, Valérie Deloge, Laurent Castillo, Aleksandar Nikolic, András Gyürk, Margarita de la Pisa Carrión

Proposal for a regulation
Article 17 – paragraph 5 – point a a (new)

Text proposed by the Commission	*Amendment*

(aa) to identify and assess strategic supply-chain dependencies and related investment needs, in particular those concerning critical biotechnology inputs and products derived from biological materials, with a view to strengthening the Union's resilience, while taking into account the entire biotechnology lifecycle, including the role of established biotechnology companies, industrial scale-up, commercial deployment and integration within international and transatlantic value chains.

Or. en

Amendment 1782
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 17 – paragraph 5 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) to identify and assess strategic supply-chain dependencies and related investment needs, in particular those concerning critical biotechnology inputs and products derived from biological materials, with a view to strengthening the Union's resilience, while taking into account the entire biotechnology lifecycle, including the role of established biotechnology companies, industrial scale-up, commercial deployment and integration within international and transatlantic value chains.

Or. en

Amendment 1783
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 17 – paragraph 5 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) to identify and assess strategic supply-chain dependencies and related investment needs, in particular those concerning critical biotechnology inputs and products derived from biological materials, with a view to strengthening the Union's resilience, while taking into account the entire biotechnology lifecycle, including the role of established biotechnology companies, industrial scale-up, commercial deployment and integration within international and transatlantic value chains.

Or. en

Justification

This amendment ensures that the results of the strategic mapping are used to identify and assess strategic supply-chain dependencies and related investment needs, particularly for critical biotechnology inputs and products derived from biological materials. It clarifies that project prioritisation, policy and funding decisions, and Steering Group advice should reflect the entire biotechnology lifecycle, including established companies, industrial scale-up, commercial deployment and international and transatlantic value chains, with a view to strengthening the Union's competitiveness and resilience.

Amendment 1784
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 17 – paragraph 5 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) address gaps and duplications identified in the mapping process.

Or. en

Amendment 1785
Wouter Beke

Proposal for a regulation
Article 17 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. The findings of the strategic mapping referred to in this Article, including any identification of gaps in biotechnology clusters or biomanufacturing ecosystems across the Union, shall be used solely for informational and analytical purposes. They shall not be used to establish geographical quotas, territorial allocation keys, or any form of mandatory geographical distribution for the recognition of projects or the allocation of Union financial support under this Regulation. Where the mapping reveals structural investment gaps in particular regions of the Union, the Commission shall address those gaps, as appropriate, through the cohesion policy instruments referred to in Regulation (EU) 2021/1060, which shall remain the primary instrument for addressing territorial disparities, and not through the project recognition and support mechanisms established by this Regulation.

Or. en

Amendment 1786
Waldemar Buda, Kosma Złotowski

Proposal for a regulation
Article 17 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. The strategic mapping shall also identify Union-based manufacturing capacities, quality-control infrastructure, key inputs, supply-chain vulnerabilities and investment needs relevant to biological medicinal products, including

biosimilar medicinal products, with particular regard to opportunities for the expansion, modernisation and diversification of manufacturing capacities across the Union, with a view to ensuring geographical balance and strengthening biotechnology ecosystems across all regions of the Union.

Or. en

Amendment 1787
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka, Kamila Gasiuk-Pihowicz

Proposal for a regulation
Article 17 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. The strategic mapping shall also identify Union-based manufacturing capacities, quality-control infrastructure, key inputs, active substances, supply-chain vulnerabilities and regulatory or market-access barriers relevant to critical or essential biological medicinal products, including critical established biological medicinal products.

Or. en

Amendment 1788
Ruggero Razza

Proposal for a regulation
Article 17 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. The strategic mapping shall also include an assessment of Europe's ability to transform research into industrial production, including identifying the main challenges around technology

transfer and the exploitation of intellectual property.

Or. it

Amendment 1789
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 18 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	The provisions of this Regulation regarding the permit granting process, the priority status of ***biotechnology strategic projects, of high impact*** biotechnology strategic projects***, of pan-European*** high impact biotechnology projects and support for such projects shall apply without prejudice to more favourable provisions laid down in other Union rules. ***When implementing support measures under this Chapter, the Commission and the Member States shall, where appropriate, take into account their contribution to public value, including prevention, timely and equitable patient access, the availability, accessibility and affordability of medicines, treatments and health biotechnology products, supply security, quality jobs, social dialogue, sustainability, geographical cohesion, ethical standards and a high level of protection of human and animal health and the environment.***

Or. en

Amendment 1790
Letizia Moratti, Fulvio Martusciello, Massimiliano Salini

Proposal for a regulation

Article 18 a (new)

Text proposed by the Commission	*Amendment*
	Article18a
	Immediate Market Availability
	1. Immediately upon a positive opinion of the Committee for Medicinal Products for Human Use ("CHMP"), a medicinal product shall be available on the market at a price communicated by the marketing authorisation holder ("EAS price"), without constituting reimbursement by Member States.
	2. Member States shall ensure that no legal, administrative or procedural obstacle prevents the placing on the market of the medicinal product referred to in paragraph 1 outside the public reimbursement system, including through private payment and private or supplementary health insurance schemes.
	3. Availability under this Article shall be without prejudice to, and shall not delay, the initiation or conduct of national pricing and reimbursement procedures, which Member States and the marketing authorisation holder may pursue in parallel.
	4. The EAS price shall not affect the outcome of any subsequent pricing and reimbursement negotiation.

Or. en

Justification

The proposal aims to facilitate earlier patient access to medicinal products across the Union by allowing products to be placed on the market immediately following a positive opinion of the Committee for Medicinal Products for Human Use (CHMP), at a price communicated by the marketing authorisation holder (EAS price). The proposal also guarantees that early market availability does not interfere with, delay or influence subsequent national pricing and reimbursement procedures or their outcomes.

Amendment 1791

Letizia Moratti, Fulvio Martusciello, Massimiliano Salini

Proposal for a regulation
Article 18 b (new)

Text proposed by the Commission	*Amendment*
	Article18b
	Early Access Scheme for medicinal products
	1. For medicinal products, an Early Access Scheme ("EAS") shall be established.
	2. Eligibility for the EAS shall be determined at Union level, compatible with EU Joint Clinical Assesment and confirmed at the time of the Committee for Medicinal Products for Human Use ("CHMP") opinion.
	3. A medicinal product shall be eligible where it meets all of the following conditions:
	(a) no satisfactory alternative treatment is available, as established in the context of the orphan designation or CHMP assessment;
	(b) the condition represents an unmet medical need, demonstrated by clinically relevant benefit in terms of morbidity, mortality, disease progression or quality of life.
	4. Within 30 days, the marketing authorisation holder may notify its intention to participate in the EAS and shall communicate a single EAS list price applicable during the duration of the Scheme. Such price shall remain fixed for the duration of the EAS.
	5. Within 30 days of such notification, participating Member States shall confirm participation. Upon confirmation, supply and procurement shall commence at national level under the EAS price.
	6. The EAS shall have a fixed duration of up to 12 months from initiation. During

this period, national pricing and reimbursement procedures may be initiated and conducted in parallel, without suspension or modification of national competences.

7. Within the EAS period:

(a) the marketing authorisation holder shall submit a pricing and reimbursement dossier within 3 months of EAS initiation;

(b) Member States shall initiate pricing and reimbursement negotiations within 5 months of dossier submission;

(c) final reimbursement decisions shall be adopted within 4 months of initiation of negotiations.

9. Where no agreement on pricing and reimbursement is reached within the EAS period, an EU-level conciliation mechanism shall be made available to facilitate resolution of disputes between the marketing authorisation holder and Member States.

10. In the case of successful conclusion of national pricing and reimbursement procedures within the EAS period, the product shall transition to full commercial availability.

11. The final reimbursed price may include, where applicable, volume-based arrangements, outcome-based schemes, or expenditure caps. The marketing authorisation holder shall reimburse Member States for any difference between the EAS list price and the final reimbursed price.

12. By [OP please insert the date = 3 years from the date of application] the Commission shall present a report to the European Parliament, the Council on the application of this Article. This report shall be based, among others, on the information provided by the orphan drug market autorization holders the initiation. The Commission shall, if appropriate, present legislative proposals based on that

evaluation to expand, amend, or delete this Article.

Or. en

Justification

The proposal aims to improve timely and equitable access to medicinal products across the Union by addressing delays occurring after marketing authorisation. It introduces coordinated mechanisms to reduce fragmentation in pricing and reimbursement processes, while preserving Member States' competences, thereby ensuring faster patient access to innovative and life-saving therapies, in particular for unmet and rare medical needs.

Amendment 1792
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 19 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The Network may involve representatives of patient organisations and experts nominated by European Reference Networks with expertise in rare diseases, advanced therapies, regulatory science, artificial intelligence and biotechnology manufacturing.

Or. en

Amendment 1793
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 19 – paragraph 2

Text proposed by the Commission	*Amendment*
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,	2. The Network shall assist and support the developers of health biotechnology products, in particular ***academic institutions and nonprofits organisations,*** SMEs, start-ups and scale-

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.

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. ***The Network shall also ensure the structured involvement, where relevant, of patients, clinicians and hospital pharmacists, reflecting the multidisciplinary expertise required across the lifecycle of advanced therapies.***

Or. en

Amendment 1794
Ondřej Krutílek

Proposal for a regulation
Article 19 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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***, including those related to supply-chain resilience, critical biotechnology inputs, and products derived from biological materials, as well as related investment needs***.

Or. en

Amendment 1795
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 19 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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***, including those related to supply-chain resilience, critical biotechnology inputs, and products derived from biological materials***.

Or. en

Justification

The Support Network should help project promoters identify opportunities linked to supply-chain resilience, critical inputs, biological materials and related investment needs. Such support is necessary for projects to move beyond regulatory navigation and address the practical conditions for scale-up, resilience and continuity of supply

Amendment 1796
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 19 – paragraph 2

Text proposed by the Commission	*Amendment*
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	2. The Network shall assist and support the developers of health biotechnology products, in particular SMEs, start-ups and scale-ups***, academic developers, public-sector innovators and not-for-profit research organisations where appropriate***, the promoters of biotechnology projects, including health

promoters') in identifying the relevant applicable rules and funding, scaling-up and networking opportunities.	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.

Or. en

Amendment 1797
Ruggero Razza

Proposal for a regulation
Article 19 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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***, the protection of intellectual property,*** networking opportunities ***and access to international markets***.

Or. it

Amendment 1798
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 19 – paragraph 3 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) facilitate access to coordinated scientific and regulatory advice, in cooperation with the European Medicines Agency and national competent

authorities, particularly for SMEs, academic developers and developers of advanced therapy medicinal products, orphan medicinal products and personalised medicines.

Or. en

Amendment 1799
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 19 – paragraph 3 – point e

Text proposed by the Commission	*Amendment*
(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;	(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; ***and including facilities supporting advanced therapy medicinal products, radiopharmaceuticals and advanced diagnostics;***

Or. en

Amendment 1800
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 19 – paragraph 3 – point f

Text proposed by the Commission	*Amendment*

(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;	(f) support biotechnology actors in the responsible and effective integration of AI, by providing sector-specific guidance and promoting best practices and standards for ***ethical and*** trustworthy AI***, including transparency, traceability, human oversight and mechanisms enabling independent verification of compliance with Union rules***, in coordination with the bodies established under Regulation (EU) 2024/1689, and by providing ***legal certainty through regulatory*** support ***and targeted assistance***, in particular to SMEs, start-ups***,*** scale-ups***, and SMCs, to facilitate innovation, investment, and market uptake across the Union***;

Or. en

Amendment 1801
Aurelijus Veryga

Proposal for a regulation
Article 19 – paragraph 3 – point f

Text proposed by the Commission	*Amendment*
(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;	(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, and by providing information and support, in particular to SMEs, start-ups and scale-ups***, in coordination with the bodies established under Regulation (EU) 2024/1689 and the Agency in order to ensure consistency of available guidance***;

Or. en

Amendment 1802
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation

Article 19 – paragraph 3 – point f

Text proposed by the Commission	*Amendment*
(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;	(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, and by providing information and support, in particular to SMEs, start-ups and scale-ups***, in coordination with the bodies established under Regulation (EU) 2024/1689, and the Agency in order to ensure consistency of available guidance***;

Or. en

Amendment 1803
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 19 – paragraph 3 – point g

Text proposed by the Commission	*Amendment*
(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;	(g) facilitate liaison and exchanges among project promoters ***as well as with other relevant stakeholders across the health biotechnology ecosystem, including patients and healthcare professionals,*** with a view to fostering networking and cooperation, including to support networks of health biotechnology clusters referred to in Article 15;

Or. en

Amendment 1804
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 19 – paragraph 3 – point h a (new)

Text proposed by the Commission	*Amendment*
	(ha) provide dedicated support to healthcare providers, including university hospitals, in the conduct of investigator-initiated clinical trials and other non-commercial research, including guidance on regulatory pathways, cost management and cross-border coordination;

Or. en

Justification

Theamendment addresses a structural gap in the current support framework under theBiotech Act, which focuses primarily on SMEs and commercial actors whileunder-recognising healthcare providers as key innovation actors. Universityhospitals are central to Europe's biotech ecosystem, serving as primaryinfrastructures for clinical trials, data generation and translational research,particularly through investigator-initiated studies.

Amendment 1805
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 19 – paragraph 3 – point i a (new)

Text proposed by the Commission	*Amendment*
	(ia) Support the exchange of best practices on patient-centred innovation, including approaches facilitating access to innovative health biotechnology solutions addressing unmet medical needs, including, where appropriate, through collaborative procurement mechanisms as provided for in the Critical Medicines Act (CMA). Such exchanges shall involve patient organisations, in order to ensure that patient perspectives and experiences are duly taken into account.

Or. en

Amendment 1806
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 19 – paragraph 3 – point i a (new)

Text proposed by the Commission	*Amendment*
	(ia) support exchanges of best practices concerning patient-centred innovation, including approaches that facilitate access to innovative health biotechnology solutions addressing unmet medical needs, including through collaborative procurement mechanisms where relevant as foreseen by the Critical Medicines Act (CMA). Such exchanges shall also involve patient organisations in order to incorporate patient perspectives and experiences.

Or. en

Justification

The Regulation should not only strengthen the Union's competitiveness in biotechnology, but also improve patient outcomes, access to innovative treatments, and the sustainability of healthcare systems. Including patient representatives in this network would help ensure that support for SMEs, start-ups, scale-ups and innovators reflects patient priorities and addresses unmet medical needs, as well as access barriers and other challenges faced by patients across Europe.

Amendment 1807
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 19 – paragraph 3 – point i a (new)

Text proposed by the Commission	*Amendment*
	(ia) provide targeted support to innovators in therapeutic areas facing persistent scientific, regulatory or commercial barriers, including mental health innovation, notably where products or interventions combine pharmacological, psychotherapeutic,

digital or other non-pharmacological elements.

Or. en

Amendment 1808
Laurent Castillo, Aleksandar Nikolic, Valérie Deloge, Julie Rechagneux, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 19 – paragraph 3 – point i a (new)

Text proposed by the Commission	*Amendment*
	(ia) support exchanges of best practices concerning patient-centred innovation, including approaches that facilitate access to innovative health biotechnology solutions addressing unmet medical needs, in particular through collaborative purchasing mechanisms.

Or. fr

Amendment 1809
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 19 – paragraph 3 – point i a (new)

Text proposed by the Commission	*Amendment*
	(ia) facilitate cooperation with European Reference Networks established pursuant to Directive 2011/24/EU, where relevant for rare and complex diseases.

Or. en

Amendment 1810
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation

Article 19 – paragraph 3 – point i a (new)

Text proposed by the Commission	*Amendment*
	(ia) support the development of the "fifth freedom" for research, innovation, knowledge, data and education

Or. en

Amendment 1811
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 19 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The Network shall facilitate technology transfer and knowledge exchange between universities, research organisations, healthcare providers, biotechnology developers and manufacturing facilities in order to accelerate the translation of research into clinical application and manufacturing within the Union.

Or. en

Amendment 1812
Ruggero Razza

Proposal for a regulation
Article 19 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. provide guidance on Union and national procedures pertaining to the protection of industrial property, patents, licensing and the economic exploitation of innovations developed in the Union;

Or. it

Amendment 1813
Ruggero Razza

Proposal for a regulation
Article 19 – paragraph 3 b (new)

Text proposed by the Commission	*Amendment*
	3b. foster dialogue between innovating businesses, investors, universities and public research organisations with a view to expediting the commercialisation of biotechnology innovations developed in the Union;

Or. it

Amendment 1814
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 19 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	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. ***It shall not duplicate existing Union or national advisory structures and shall not impose additional reporting obligations on developers, project promoters or Member States.***

Or. en

Amendment 1815
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 19 – paragraph 5 – subparagraph 1

Text proposed by the Commission	*Amendment*
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 strenghten existing national and European networks that support SMEs, start-ups and scale-ups, and innovators.	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 strenghten existing national and European networks that support SMEs, start-ups and scale-ups, and innovators. ***Eligible members shall include national biotechnology industry associations, cluster organisations and other relevant private sector bodies as well as patient organisations and other relevant public or private sector bodies, provided they meet the published selection criteria, as well as where appropriate, specialist expertise on rare diseases, advanced therapies, AI, data, biomanufacturing and regulatory science, including ERN-nominated experts.***

Or. en

Justification

The Regulation should not only strengthen the Union's competitiveness in biotechnology, but also improve patient outcomes, access to innovative treatments, and the sustainability of healthcare systems. Including patient representatives in this network would help ensure that support for SMEs, start-ups, scale-ups and innovators reflects patient priorities and addresses unmet medical needs, as well as access barriers and other challenges faced by patients across Europe.

Amendment 1816
Manuela Ripa

Proposal for a regulation
Article 19 – paragraph 5 – subparagraph 1

Text proposed by the Commission	*Amendment*

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 ***strenghten*** existing national and European networks that support SMEs, start-ups and ***scale-ups***, and innovators.	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 ***SMCs,*** SMEs, start-ups and ***scale-ups***, and innovators. ***Eligible members shall include national biotechnology industry associations, cluster and patient organisations and other relevant public or private sector bodies, provided they meet the published selection criteria, as well as where appropriate, specialist expertise on rare diseases, advanced therapies, AI, NAMs, data, biomanufacturing and regulatory science, including ERN-nominated experts.***

Or. en

Amendment 1817
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Article 19 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Commission ***may*** support the Network through Union funds, programmes, and instruments, in accordance with the objectives established in their respective basic acts.	6. The Commission ***shall*** support the Network through Union funds, programmes, and instruments, in accordance with the objectives established in their respective basic acts.

Or. en

Amendment 1818
Waldemar Buda, Kosma Złotowski

Proposal for a regulation
Article 19 – paragraph 7

Text proposed by the Commission	*Amendment*
7. Member States shall take all necessary measures to facilitate the fulfilment of the tasks of the Network.	7. Member States shall take all necessary measures to facilitate the fulfilment of the tasks of the Network***, in particular with regard to the objective needs of SMEs, start-ups and scale-ups and to the reduction of administrative and regulatory burdens they encounter***.

Or. en

Amendment 1819
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka, Kamila Gasiuk-Pihowicz

Proposal for a regulation
Article 19 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	7a. The EU Health Biotechnology Support Network shall also provide support to project promoters developing or manufacturing critical established biological medicinal products, including assistance in identifying applicable regulatory pathways, scientific advice procedures, funding opportunities, strategic project recognition routes and relevant support measures under this Regulation, the Critical Medicines Act and Union funding programmes.

Or. en

Amendment 1820
Waldemar Buda, Kosma Złotowski

Proposal for a regulation
Article 19 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	7a. The Network shall also provide support to project promoters developing or

manufacturing biological medicinal products, including biosimilar medicinal products, by assisting them in identifying applicable regulatory pathways, scientific advice procedures, funding opportunities, strategic project recognition routes and relevant support measures under this Regulation and Union funding programmes.

Or. en

Amendment 1821
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 20 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Steering group shall support the exchange of best practices on national approaches to the financing and reimbursement of authorised standard-of-care treatments used in multinational clinical trials, with a view to identifying barriers to cross-border clinical research and facilitating the conduct of multinational clinical trials, without prejudice to Member States' competence for the organisation and financing of healthcare systems.

Or. en

Amendment 1822
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 20 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Steering Group shall facilitate the conversion of research and innovation

	findings into industrial application and market penetration in the field of biotechnology, including by encouraging alignment between research efforts, financing, and demand-driven measures, and by pinpointing obstacles to scaling up and to the establishment of markets across the Union

Or. en

Amendment 1823
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu

Proposal for a regulation
Article 20 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The mapping shall also assess, where relevant, Union capacities for exposome-informed biotechnology research and innovation, including biomonitoring, environmental health data, One Health indicators, NAMs, health data infrastructures and advanced analytics relevant to prevention and early warning.

Or. en

Amendment 1824
Peter Agius

Proposal for a regulation
Article 21 – paragraph 1

Text proposed by the Commission	*Amendment*
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***')***.	1. The Steering Group shall be composed of***:***

a. one representative from each Member ***State;***

b. one representative of the Commission***,*** ***who shall*** chair ***the Steering Group;***

c. two representatives of patient organisations operating at Union level, of whom at least one shall represent patients living with chronic and long-term conditions for which biotechnology-derived medicinal products represent a primary or essential treatment;

d. one representative of healthcare-professional associations operating at Union level.

The representatives referred to in points (c) and (d) shall be members in their own right and shall participate fully in the deliberations of the Steering Group. They shall be appointed by the Commission for a renewable term of three years, following an open call for expressions of interest, on the basis of transparent and objective criteria including independence, expertise relevant to the conditions and technologies within the scope of the Steering Group's work, and demonstrated capacity to represent the perspectives of the constituency concerned.

Conflict-of-interest requirements applicable to those representatives shall be applied proportionately, having regard to the specific subject matter under deliberation, and shall not exclude representatives on grounds, such as membership of a patient or healthcare-professional organisation, or routine receipt of disease-related educational support, unrelated to the matter at hand.

Representatives appointed under points (c) and (d) shall be remunerated and reimbursed for travel and subsistence on terms equivalent to those applicable to other members of the Steering Group, and shall have access to the training, documentation and administrative support necessary to participate effectively.

Or. en

Amendment 1825
Kateřina Konečná

Proposal for a regulation
Article 21 – paragraph 1

Text proposed by the Commission	*Amendment*
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***')***.	1. The Steering Group shall be composed of***:***
	(a) one representative from each Member ***State;***
	(b) one representative of the Commission***, who shall*** chair ***the Steering Group;***
	(c) two representatives of patient organisations operating at Union level, of whom at least one shall represent patients living with chronic and long-term conditions for which biotechnology-derived medicinal products represent a primary or essential treatment;
	(d) one representative of healthcare-professional associations operating at Union level.
	The representatives referred to in points (c) and (d) shall be members in their own right and shall participate fully in the deliberations of the Steering Group. They shall be appointed by the Commission for a renewable term of three years, following an open call for expressions of interest, on the basis of transparent and objective criteria including independence, expertise relevant to the conditions and technologies within the scope of the Steering Group's work, and demonstrated capacity to represent the perspectives of the constituency concerned.
	Conflict-of-interest requirements applicable to those representatives shall

be applied proportionately, having regard to the specific subject matter under deliberation, and shall not exclude representatives on grounds, such as membership of a patient or healthcare-professional organisation, or routine receipt of disease-related educational support, unrelated to the matter at hand.

Representatives appointed under points (c) and (d) shall be remunerated and reimbursed for travel and subsistence on terms equivalent to those applicable to other members of the Steering Group, and shall have access to the training, documentation and administrative support necessary to participate effectively.

Or. en

Amendment 1826
Wouter Beke, Ingeborg Ter Laak, Angelika Niebler, Adam Jarubas, Aura Salla, Jessica Polfjärd, Liesbet Sommen, Paulo Cunha, Sérgio Humberto, Sirpa Pietikäinen, Manuela Ripa, Willemien Koning, Andrea Wechsler, Dolors Montserrat, Oliver Schenk, Elena Nevado del Campo, András Tivadar Kulja, Niels Flemming Hansen

Proposal for a regulation
Article 21 – paragraph 1

Text proposed by the Commission	*Amendment*
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').	1. The Steering Group shall be composed of representatives from all Member States and the Commission***, as well as a representative from the Advisory group on biosecurity as established in Article 52 and a representative from the Foresight Panel for Emerging Health Innovation as established in Article 37***. It shall be chaired by a representative of the Commission (the 'Chair').

Or. en

Amendment 1827

Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain, Margarita de la Pisa Carrión

Proposal for a regulation
Article 21 – paragraph 1

Text proposed by the Commission	*Amendment*
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')***.	1. The Steering Group shall be composed of representatives from all Member States and the Commission. It shall be chaired by a representative of ***a Member State on a rotating basis every six months. Representatives of the pharmaceutical sector and the health biotechnology industry shall be regularly consulted, as appropriate***.

Or. en

Amendment 1828
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 21 – paragraph 1

Text proposed by the Commission	*Amendment*
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')***.	1. The Steering Group shall be composed of representatives from all Member States and the Commission. It shall be ***co-chaired*** by a representative of the Commission ***and by a representative of the Member States, who shall be elected by and from among the representatives of the Member States***.

Or. en

Amendment 1829
Dario Nardella, Georgia Tramacere

Proposal for a regulation
Article 21 – paragraph 1

Text proposed by the Commission	*Amendment*
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')**.**	1. The Steering Group shall be composed of representatives from all Member States and the Commission***, and from representative organisations of the pharmaceutical and health biotechnology industries***. It shall be chaired by a representative of the Commission (the 'Chair')

Or. en

Justification

For future looking biotech regulatory environment, the experience from the industry is useful. Industry would be represented but without voting rights (unlike Member States and the Commission).

Amendment 1830
Kristoffer Storm

Proposal for a regulation
Article 21 – paragraph 1

Text proposed by the Commission	*Amendment*
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').	1. The Steering Group shall be composed of representatives from all Member States and the Commission ***, and from representatives of the pharmaceutical and health biotechnology industries***. It shall be chaired by a representative of the Commission (the 'Chair').

Or. en

Amendment 1831
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 21 – paragraph 1

Text proposed by the Commission	*Amendment*
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').	1. The Steering Group shall be composed of representatives from all Member States and the Commission***, and from representatives of the pharmaceutical and health biotechnology industries***. It shall be chaired by a representative of the Commission (the 'Chair').

Or. en

Amendment 1832
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 21 – paragraph 1

Text proposed by the Commission	*Amendment*
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').	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') ***and count with representatives of civil society, patient and consumer associations***.

Or. en

Amendment 1833
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 21 – paragraph 1

Text proposed by the Commission	*Amendment*
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').	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'). ***The Steering Group shall strive for gender balance.***

Or. en

Justification

Amendment drafdet by the Deutsche Stiftung Weltbevölkerung (DSW)

Amendment 1834
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 21 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The Sterring Group may invite observers, representatives of the industry, academia, European Reference Networks, patient organisations, SMEs, EMA, HERA AND social partners

Or. en

Amendment 1835
Ruggero Razza

Proposal for a regulation
Article 21 – paragraph 2

Text proposed by the Commission	*Amendment*
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	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 ***by involving, where***

Member State. The Commission and the Member States shall have voting rights.	***appropriate, the competent authorities for health, research, industry, innovation and economic development with a view to ensuring that this Regulation is implemented consistently***. The Commission and the Member States shall have voting rights.

Or. it

Amendment 1836
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 21 – paragraph 2

Text proposed by the Commission	*Amendment*
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***.	2. Each Member State shall nominate a ***permanent*** member and an alternate member***, with strategic expertise relevant for the implementing the different measures set out in this Regulation,*** 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. ***Each*** Member States shall have ***one vote***.

Or. en

Amendment 1837
Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 21 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*

	2a. The Steering Group shall include as permanent members with advisory capacity the Chair of the 24 ERNs Coordinators Group and accredited European-level patient organisations. The Steering Group may also invite other observers, including representatives of industry, academia, SMEs, social partners, EMA, HERA, the EIB Group and independent ethic and scientific experts.

Or. en

Amendment 1838
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 21 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	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. ***The Steering Group shall establish structured arrangements for consulting industry representatives, research organisations and other relevant stakeholders on matters within its remit, including through technical workshops and written consultations, at least once per year.***

Or. en

Justification

A structured mechanism with a minimum annual frequency ensures that implementation guidance reflects reality without granting industry neither any formal membership nor voting rights.

Amendment 1839

Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 21 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	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 ***Co-Chairs*** may invite external experts to attend meetings of the Steering Group. ***To fulfil its tasks, the steering grop shall, where relevant, also consult through joint meetings with patient and consumer organisations, healthcare professional organisations and industry representatives.***

Or. en

Amendment 1840
Wouter Beke, Ingeborg Ter Laak, Angelika Niebler, Adam Jarubas, Angelika Winzig, Aura Salla, Jessica Polfjärd, Liesbet Sommen, Paulo Cunha, Sérgio Humberto, Sirpa Pietikäinen, Manuela Ripa, Willemien Koning, Andrea Wechsler, Dolors Montserrat, Oliver Schenk, Elena Nevado del Campo, András Tivadar Kulja, Niels Flemming Hansen

Proposal for a regulation
Article 21 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The Steering Group shall establish appropriate arrangements to identify and regularly consult the best available experts with relevant scientific, technical, clinical and regulatory expertise. Such consultation shall support the Steering Group in carrying out its tasks and contribute to ensuring that its recommendations and activities are informed by the latest scientific evidence, technological developments and international best practices.

Or. en

Amendment 1841
Sirpa Pietikäinen

Proposal for a regulation
Article 21 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The Steering Group shall establish appropriate arrangements to identify and regularly consult globally the best available experts with relevant scientific, technical, clinical and regulatory expertise. Such consultation shall support the Steering Group in carrying out its tasks and contribute to ensuring that its recommendations and activities are informed by the latest scientific evidence, technological developments and international best practices.

Or. en

Amendment 1842
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 21 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The members appointed to the steering group and its sub group or sub groups shall make a declaration of their financial and other interests and update it annually and whenever necessary.

Or. en

Amendment 1843
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 21 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	4. The Steering Group shall meet ***regularly*** 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.

Or. en

Amendment 1844
Wouter Beke, Ingeborg Ter Laak, Angelika Niebler, Adam Jarubas, Angelika Winzig, Aura Salla, Jessica Polfjärd, Liesbet Sommen, Paulo Cunha, Sérgio Humberto, Sirpa Pietikäinen, Willemien Koning, Andrea Wechsler, Dolors Montserrat, Oliver Schenk, Elena Nevado del Campo, András Tivadar Kulja, Niels Flemming Hansen

Proposal for a regulation
Article 21 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The Steering Group may establish a dedicated working group on Union AI infrastructure and AI model validation to support trustworthy AI and data management practices.

Or. en

Amendment 1845
Wouter Beke, Ingeborg Ter Laak, Angelika Niebler, Adam Jarubas, Angelika Winzig, Aura Salla, Jessica Polfjärd, Liesbet Sommen, Paulo Cunha, Sérgio Humberto, Sirpa Pietikäinen, Manuela Ripa, Willemien Koning, Andrea Wechsler, Dolors Montserrat, Oliver Schenk, Elena Nevado del Campo, Niels Flemming Hansen

Proposal for a regulation

Article 21 – paragraph 5 – point a

Text proposed by the Commission	*Amendment*
(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;	(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 ***biotechnology strategic projects, high impact*** biotechnology strategic projects and ***Pan-European*** high impact biotechnology strategic projects***, with a view to strengthening the Union's competitiveness and supporting the timely translation and uptake of safe and effective biotechnology innovation, in particular in the field of health, for the benefit of patients***;

Or. en

Amendment 1846
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 21 – paragraph 5 – point a

Text proposed by the Commission	*Amendment*
(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;	(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***, in particular by ensuring that the needs and perspectives of patients, including with regard to timely access to innovative health biotechnology products and services, are being taken into account***;

Or. en

Justification

The involvement of patient representatives in discussions about strategic projects across Europe to ensure that the strategic project also lead to improved access, affordability and health outcomes would be key as there iis a need to reflect on and promote purpose-driven investment models to ensure that research and innovation address unmet and neglected medical needs, while supporting equitable access for patients across Europe.

Amendment 1847
Ruggero Razza

Proposal for a regulation
Article 21 – paragraph 5 – point a

Text proposed by the Commission	*Amendment*
(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;	(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 ***while identifying the prevailing administrative and regulatory barriers encountered by the Member States and devising recommendations to help overcome these***;

Or. it

Amendment 1848
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 21 – paragraph 5 – point a

Text proposed by the Commission	*Amendment*
(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	(a) facilitate the exchange of information and best practices among Member States, the Commission, and relevant stakeholders***, including civil society organisations,*** in relation to the recognition and the implementation of

high impact health biotechnology strategic projects;	health biotechnology strategic projects and high impact health biotechnology strategic projects***, taking account of patient needs***;

Or. en

Amendment 1849
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 21 – paragraph 5 – point a

Text proposed by the Commission	*Amendment*
(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;	(a) facilitate the exchange of information and best practices among Member States, the Commission, and relevant stakeholders***, including social partners,*** in relation to the recognition and the implementation of health biotechnology strategic projects and high impact health biotechnology strategic projects;

Or. en

Amendment 1850
Ruggero Razza

Proposal for a regulation
Article 21 – paragraph 5 – point b

Text proposed by the Commission	*Amendment*
(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;	(b) discuss, at least once a year, the progress in the recognition of health biotechnology strategic projects and high impact health biotechnology strategic projects***, including on the basis of indicators regarding authorisation timeframes and the potential of the projects to attract investment, advance industrial development and contribute to the objectives of this Regulation,*** and

provide advice including to overcome systemic challenges faced by such projects;

Or. it

Amendment 1851
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 21 – paragraph 5 – point b

Text proposed by the Commission	*Amendment*
(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;	(b) discuss, at least once a year, the progress in the recognition of health biotechnology strategic projects and high impact health biotechnology strategic projects**,** provide advice including to overcome systemic challenges faced by such projects ***and where necessary, facilitate coordination of respective actions aiming to attain the objectives of this Regulation***;

Or. en

Amendment 1852
Ruggero Razza

Proposal for a regulation
Article 21 – paragraph 5 – point c

Text proposed by the Commission	*Amendment*
(c) provide advice for supporting the federation and networking of biotechnology clusters, as provided for in Article [15[(4)];	(c) provide advice for supporting the federation and networking of biotechnology clusters, as provided for in Article [15[(4)] ***by promoting complementarity between their respective areas of technological expertise, the shared use of infrastructure and the exchange of best organisational practices***;

Or. it

Amendment 1853
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 21 – paragraph 5 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) facilitate coordination between the Commission, the EIB Group, national promotional banks and institutions and relevant implementing partners on portfolio-based financing for eligible biotechnology projects, in particular in the areas of rare diseases, orphan medicinal products and advanced therapy medicinal products, including through diversified investment portfolios, risk-sharing, credit enhancement, debt-based instruments and blended finance, while taking into account relevant clinical, scientific and infrastructure assets, including ERNs, patient registries, natural history data, biobanks, clinical research infrastructures, manufacturing capacity, stockpiling requirements and supply-chain constraints;

Or. en

Amendment 1854
Ruggero Razza

Proposal for a regulation
Article 21 – paragraph 5 – point f

Text proposed by the Commission	*Amendment*
(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.	(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 ***by encouraging the use of joint exercises,***

training activities and the exchange of best practices to strengthen the Union's preparedness.

Or. it

Amendment 1855
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 21 – paragraph 5 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) monitor, in cooperation with the Commission and Member States, the impact of international partnerships and globally integrated value chains on the resilience and sustainability of the Union's biosimilar supply, including risks linked to reduced supplier diversity, and, where appropriate, provide advice to the Commission and facilitate coordination among Member States to support diversified supply structures and the long-term sustainability of biosimilar competition within the internal market;

Or. en

Amendment 1856
Wouter Beke, Ingeborg Ter Laak, Angelika Niebler, Adam Jarubas, Angelika Winzig, Aura Salla, Jessica Polfjärd, Liesbet Sommen, Paulo Cunha, Sérgio Humberto, Sirpa Pietikäinen, Manuela Ripa, Willemien Koning, Andrea Wechsler, Dolors Montserrat, Oliver Schenk, Elena Nevado del Campo, András Tivadar Kulja, Niels Flemming Hansen

Proposal for a regulation
Article 21 – paragraph 5 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) facilitate strategic coordination and the exchange of information between relevant Union agencies, expert groups

and advisory bodies, with a view to identifying horizontal regulatory and implementation challenges affecting the Union biotechnology ecosystem, while fully respecting their respective mandates and independence.

Or. en

Amendment 1857
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 21 – paragraph 5 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) monitor the consistent application of the recognition criteria and support measures under this Regulation across Member States and provide guidance to ensure a coherent approach across the Union.

Or. en

Justification

The proposed point (fa) addresses divergence risk in recognition criteria and support measures application across Member States anchoring a monitoring and guidance function within the Steering Group's existing tasks.

Amendment 1858
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 21 – paragraph 5 – point f b (new)

Text proposed by the Commission	*Amendment*
	(fb) facilitate coordination between the Commission, the European Investment Bank Group, national promotional banks and institutions and relevant implementing partners on portfolio-based

financing for eligible biotechnology projects, in particular in areas characterised by long development timelines, complex value chains or recognised market failures, including rare diseases, orphan medicinal products, advanced therapy medicinal products and priority vaccines and antimicrobials, through diversified investment portfolios, risk-sharing mechanisms, credit enhancement, debt-based instruments and blended finance, taking into account the relevant clinical, scientific, manufacturing and infrastructure capacities of the Union, including European Reference Networks, patient registries, natural history data, biobanks, clinical research infrastructures, manufacturing capacity, stockpiling arrangements and supply-chain considerations.

Or. en

Justification

Portfolio-based financing isparticularly well suited to areas where individual projects face highdevelopment risk but where a diversified portfolio of projects can deliver anacceptable risk-adjusted return for institutional and private investors.Priority vaccines and antimicrobials, alongside rare diseases, orphan medicinal products andadvanced therapy medicinal products, present the combination of longdevelopment timelines, complex value chains and recognised market failures thatjustify a coordinated, portfolio-based approach at Union level. Tasking theEuropean Health Biotechnology Steering Group with this coordinating roleensures policy coherence between the Investment Pilot, the EuropeanBiotechnology Scale-Up Fund and national financing instruments, and complementsthe existing incentives under Union legislation on medicinal products for humanuse.

Amendment 1859
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 21 – paragraph 5 – point f b (new)

Text proposed by the Commission	*Amendment*

(fb) ensure structured consultation of relevant patient organisations, including organisations representing cancer patients and rare disease communities, and, where appropriate, of the European Medicines Agency and national competent authorities, in relation to access outcomes across Member States, cross-border implementation of this Regulation, affordability and equity considerations, and patient involvement in health-related artificial intelligence governance.

Or. en

Amendment 1860
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 21 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. The Steering Group may establish a dedicated working group on Union biomanufacturing capacity to support mapping, identify key bottlenecks and supply chain vulnerabilities, and facilitate coordination between manufacturing capacity, clinical expertise and strategic investment priorities, in cooperation with Member States, HERA, EMA and relevant stakeholders, including industry, patient organisations, health technology assessment bodies and public payers.

Or. en

Amendment 1861
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 21 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Steering Group may establish subgroups for the purpose of this Regulation.	6. The Steering Group may establish subgroups for the purpose of this Regulation. ***One subgroup focusing on transparency and engagement with patient organisations shall be created with the objective of facilitating dialogue on the implementation of this Regulation, monitoring its impact on patients, and providing input on activities and initiatives developed under the Act.***

Or. en

Amendment 1862
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 21 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Steering Group may establish subgroups for the purpose of this Regulation.	6. The Steering Group may establish subgroups for the purpose of this Regulation. ***A subgroup on engagement with civil society organisations shall be established to monitor the Regulation's contribution to improved patient outcomes, the addressing of unmet medical needs, and the sustainability and resilience of healthcare systems across the Union.***

Or. en

Amendment 1863
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 21 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Steering Group may establish subgroups for the purpose of this Regulation.	6. The Steering Group***, at the proposal of the co-chair or any of its members,*** may establish***, on a case by case basis, one or more*** subgroups for the purpose of this Regulation.

Or. en

Amendment 1864
Kateřina Konečná

Proposal for a regulation
Article 21 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. Where the Steering Group establishes working groups, subgroups or other ad hoc bodies to support the performance of its tasks, each such body shall include, as members in their own right:
	(i) at least one person with relevant lived experience of a chronic or long-term condition for which biotechnology-derived medicinal products represent a primary or essential treatment;
	(ii) at least one representative of an organisation representing patients living with such conditions, operating at Union level; and
	(iii) at least one representative of healthcare-professional associations operating at Union level.
	The persons referred to in points (i), (ii) and(iii) shall participate on terms equivalent to those laid down in this paragraph for the representatives appointed under points (c) and (d), including as regards appointment criteria, conflict-of-interest rules, remuneration, training and administrative support.

The Steering Group may, by reasoned decision published with its agenda, depart from the first subparagraph where the subject matter of a working group, subgroup or ad hoc body is exclusively technical and bears no foreseeable connection to patient-relevant clinical benefit, access to medicinal products, or the conditions under which biotechnology-derived medicinal products are made available to patients in the Member States.

Or. en

Amendment 1865
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 21 a (new)

Text proposed by the Commission	*Amendment*
	Article21a
	Establishing the Single European Regulatory Space: International Regulatory Cooperation and Mutual Recognition for Biotechnology Supply Chains
	1. The Commission and the European Medicines Agency (EMA), in cooperation with Member States, shall promote better leveraging the benefits of international regulatory cooperation with trusted partner jurisdictions to strengthen the EU's biotechnology ecosystem, supply chain resilience and timely patient access in the Union.
	2. The Commission shall pursue the negotiation, conclusion, expansion and effective implementation of Mutual Recognition Agreements (MRAs) and other reliance arrangements covering the mutual recognition of Good Manufacturing Practice (GMP) inspections, manufacturing oversight,

batch certification, import testing and quality assurance systems. Priority shall be given to jurisdictions participating in the Pharmaceutical Inspection Co-operation Scheme (PIC/S) whose standards of quality, safety and manufacturing oversight are assessed as equivalent to those applicable under Union law, in particular the EEA/EFTA States and the United Kingdom.

3. The arrangements referred to in paragraph 2 shall aim to reduce unnecessary duplication of inspections, import testing, certification; facilitate the reliable movement of biotechnology products, biological medicinal products, vaccines, advanced therapy medicinal products and critical inputs; support preparedness for shortage mitigation and prevention and public health emergencies; strengthen the competitiveness and export capacity of Union biotechnology undertakings, including SMEs and scale-ups; and reduce avoidable waste linked to duplicative procedures or supply-chain delays.

Or. en

Justification

See proposed recital 4b for the justification.

Amendment 1866
Christine Anderson

Proposal for a regulation
Article 22

Text proposed by the Commission	*Amendment*
[...]	***deleted***

Or. en

Amendment 1867
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 22 – title

Text proposed by the Commission	*Amendment*
EU ***health*** biotechnology investment ***pilot***	EU biotechnology investment ***facility***
	(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)

Or. en

Amendment 1868
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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 Biotechnology investment ***facility*** (‘the ***facility***). The ***facility*** is established for an initial period of two years, after which it shall be reviewed.
	The review shall assess the effectiveness of the facility in achieving the objectives set out in paragraph 4, evaluate the adequacy of its scope and instruments, and shall include recommendations on its continuation, modification or scaling up. The Commission shall present the findings of the review to the European Parliament and to the Council.

Or. en

Justification

The two-year duration creates uncertainty about continuity that may deter the long-term investment commitments, particularly from institutional investors such as pension funds, that the facility is designed to catalyse. A structured review with parliamentary reporting gives institutional investors a clearer signal on the future trajectory and clarity on the political and financial backing for the project.

Amendment 1869
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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. ***The review shall assess the effectiveness of the pilot in achieving the objectives set out in paragraph 4, evaluate the adequacy of its scope and instruments, and shall include recommendations on its continuation, modification or scaling up. The Commission shall present the findings of the review to the European Parliament and to the Council***

Or. en

Justification

The pilots address a structural financing gap: in Q4 2025, European ATMP companies received approximately USD 0.5 billion in capital raisings, against USD 2 billion in North America. The Late-Stage Capital Booster is particularly relevant for ATMPs, where the gap is most acute at manufacturing scale-up and where European companies are most exposed to acquisition or relocation outside the Union. The current text does not specify the content or consequences of the review, nor the relationship of the pilots to successor instruments under

the next Multiannual Financial Framework, despite the European Competitiveness Fund being identified as a key budgetary anchor for 2028 to 2034.

Amendment 1870
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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. ***The review shall examine the pilot’s effectiveness in meeting the objectives set out in paragraph 4, assess whether its scope and instruments are adequate, and include recommendations on its continuation, modification, or scaling up. The Commission shall submit the review findings to the European Parliament and the Council.***

Or. en

Justification

A structured review with parliamentary reporting gives institutional investors a clearer signal on trajectory.

Amendment 1871
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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. ***Where the EU Health Biotechnology Investment Pilot has proven to be successful, the Commission shall evaluate the pilot and, where appropriate, optimise it and extend its duration for a further period of two years.***

Or. en

Amendment 1872
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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 ***four*** years,***.*** It shall be reviewed ***for optimisation and extension after two years***.

Or. en

Amendment 1873

Kristoffer Storm

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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 ***four*** years***.*** It shall be reviewed ***for optimisation and extension after two years***.

Or. en

Amendment 1874
Morten Løkkegaard, Katri Kulmuni, Sophie Wilmès

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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 ***four*** years, after which it shall be reviewed.

Or. en

Justification

Longer time frame to support long term investments and a better foundation for assessing the pilot.

Amendment 1875
Michalis Hadjipantela

Proposal for a regulation
Article 22 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. 1. The Commission shall, together with the European Investment Bank Group, the European Investment Fund or other implementing partners, establish a European Biotechnology Scale-Up Fund (EBSF) to support companies and projects falling within the scope of this Regulation.
	2. The EBSF shall form part of the EU Health Biotechnology Investment Pilot referred to in Article 22 and shall be designed to mobilise and pool Union, national, institutional and private capital for investment in healt biotechnology companies and projects established or active in the Union.
	3. As a 'fund-of-funds', the EBSF shall pursue the following objectives:
	(a) to increase the availability of long-term risk finance for health biotechnology companies and projects across the Union, in particular at growth, late-stage development, industrial scale-up and manufacturing stages;
	(b) to support the development, scaling and retention in the Union of innovative health biotechnology companies, technologies, intellectual property, manufacturing capacity and skilled employment;
	(c) to mobilise private and institutional investment, including from pension funds, occupational pension schemes, insurance undertakings, long-term savings vehicles, strategic investors and other private financial actors;

(d) to provide indirect financing through commitments to specialised biotechnology venture capital funds and growth funds, and, where appropriate, through co-investment mechanisms alongside such funds; (e) to diversify investment risk across a portfolio of health biotechnology companies, projects, technologies and development stages;

(f) to strengthen the Union's competitiveness, resilience, strategic autonomy and capacity to translate scientific excellence into patient-ready health biotechnology products.

4. The EBSF shall support the full lifecycle of health biotechnology companies and projects, including SMEs, start-ups, scale-ups, mid-caps and other biotech companies contributing to the objectives of this Regulation.

5. The EBSF may provide support through, inter alia:

(a) commitments to specialised European health biotechnology venture capital funds, growth funds or other investment vehicles;

(b) co-investment alongside such funds in eligible health biotechnology companies and projects;

(c) risk-sharing mechanisms, including first-loss, subordinated or guarantee instruments, where necessary to mobilise private and institutional capital;

(d) blended finance, quasi-equity, debt, venture debt or other suitable financing instruments;

(e) advisory, technical and capacity-building support for fund managers, financial intermediaries, project promoters and investee companies.

6. In designing and implementing the EBSF, the Commission and the implementing partners shall ensure that its structure is capable of attracting private and institutional capital at scale.

To that end, the Fund-of-Funds shall include appropriate governance, risk-sharing, reporting, ethical and transparency arrangements that enable participation by pension funds, insurance undertakings and other long-term institutional investors.

7. The governance of the EBSF shall ensure professional, independent and market-oriented investment decision-making. Strategic investors participating in the Fund-of-Funds shall not receive privileged access to commercially sensitive information, preferential acquisition rights or any influence over individual investment decisions.

8. Eligibility criteria for support from the EBSF shall be designed to ensure that supported companies and projects make a meaningful contribution to the Union's health biotechnology ecosystem. Such criteria may include requirements relating to establishment in the Union, research and development activity in the Union, contribution to Union industrial capacity, manufacturing, clinical development, intellectual property generation, strategic resilience or patient access.

9. The EBSF shall be developed in coordination with relevant Union financing instruments, including those under the Savings and Investment Union, the European Innovation Council, InvestEU, the Strategic Technologies for Europe Platform and any successor programmes under the Multiannual Financial Framework.

10. The Commission shall ensure that the EBSF is established for a period consistent with the long development cycles of health biotechnology. The EBSF shall be reviewed no later than five years after its establishment, with a view to assessing its effectiveness, its capacity to mobilise private and institutional capital, and the need to make it permanent. By [two years after the date of application of

this Regulation], and every two years thereafter, the Commission shall report to the European Parliament and to the Council on the implementation of this Article. The report shall include information on capital mobilised, investments supported, leverage achieved, participation of institutional investors, geographical distribution, company-stage distribution, contribution to Union competitiveness and any barriers to further capital mobilisation

Or. en

Amendment 1876
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 22 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The Commission and EIB will review the administrative processes for EIB submissions and pilot novel administrative and financing frameworks. The experiences will be captured in a report with guidance for the EIB financing processes.

Or. en

Amendment 1877
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 22 – paragraph 2

Text proposed by the Commission	*Amendment*
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	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.	direct and indirect financing, 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. ***Implementing partners, including the EIB Group, may carry out equity and quasi-equity operations under the pilot, acting on behalf of or in coordination with the Union, in accordance with their respective mandates, applicable basic acts and Union rules on State aid and competition.***

Or. en

Amendment 1878
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 22 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. The ***facility*** shall support the full lifecycle of companies and projects in the area of biotechnology***, in particular in the area of health***, 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. ***The facility shall also support non-profit and academic health biotechnology developers, including hospital-led translational research projects and investigator-initiated development programmes.*** It shall complement and be developed in a coordinated manner with other EU financing instruments.

Or. en

Amendment 1879

François-Xavier Bellamy, Céline Imart

Proposal for a regulation
Article 22 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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. ***This support shall not apply to companies or projects developing food products falling within the scope of Regulation EU 2015/2283.***

Or. en

Amendment 1880
Nikos Papandreou, Romana Jerković

Proposal for a regulation
Article 22 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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***, from translational research and proof-of-concept to clinical development, industrial scale-up and commercial deployment,*** 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.

Or. en

Amendment 1881
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 22 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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. ***This support shall not apply to projects developing food products falling within the scope of Regulation (EU) 2015/2283.***

Or. en

Amendment 1882
Michalis Hadjipantela

Proposal for a regulation
Article 22 – paragraph 2

Text proposed by the Commission	*Amendment*
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	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***, mid-caps and other biotechnology companies contributing to the objectives of this Regulation,*** through direct and indirect financing, other than direct equity operations, without prejudice to the basic acts to be agreed under the next

coordinated manner with other EU financing instruments.	Multiannual Financial Frameworks. It shall complement and be developed in a coordinated manner with other EU financing instruments.

Or. en

Amendment 1883
Ondřej Krutílek

Proposal for a regulation
Article 22 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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***, as well as established and commercially mature biotechnology companies,*** 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.

Or. en

Amendment 1884
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 22 – paragraph 2

Text proposed by the Commission	*Amendment*
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	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, ***in addition to*** 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.

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.

Or. en

Amendment 1885
Kristoffer Storm

Proposal for a regulation
Article 22 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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, ***in addition to*** 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.

Or. en

Amendment 1886
Sophie Wilmès, Olivier Chastel

Proposal for a regulation
Article 22 – paragraph 2

Text proposed by the Commission	*Amendment*
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	2. The pilot shall support the full lifecycle of companies and projects in the area of health biotechnology, ***in particular*** 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.	Multiannual Financial Frameworks. It shall complement and be developed in a coordinated manner with other EU financing instruments.

Or. en

Amendment 1887
Nikos Papandreou

Proposal for a regulation
Article 22 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. By ... [12 months from the date of entry into force of this Regulation], the Commission shall, together with the European Investment Bank Group, the European Investment Fund and, where appropriate, national promotional banks and institutions and other implementing partners, establish the EBSF to support the scaling-up, late-stage development, industrial deployment and manufacturing capacity of biotechnology companies and projects established or active in the Union. Prior to establishment, the Commission shall assess the appropriate modalities, governance structure and capitalisation of the EBSF.

Or. en

Amendment 1888
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard, Sigrid Friis

Proposal for a regulation
Article 22 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The pilot shall be designed as a mechanism that may use and leverage different funding streams and 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.	to accelerate and catalyse investments into the health biotechnology sector. It may be used to provide Union support through Union programmes. ***The operational design of the pilot shall specify how the following factors are weighted as material risk-reducing elements in investment eligibility assessments conducted by the EIBG or other implementing partners, in accordance with Recitals (44) and (44a): (a) prior regulatory approval granted by a competent authority in a comparable jurisdiction outside the Union; (b) submission for market approval to a relevant regulatory authority; (c) demonstrated manufacturing readiness at industrial scale. Those factors shall be applied consistently to all biotechnology companies assessed under the pilot, irrespective of the sector of application of the biotechnology concerned. The operational design shall ensure that companies meeting one or more of those criteria are not assessed as pre-commercial entities.***

Or. en

Justification

Article 22(3) delegates the operational design of the pilot without statutory constraints on risk-assessment methodology. This amendment operationalises recitals (44) and (44a) at the level of the design mandate and requires consistent application across all sectors, preventing a de facto tiered system that disadvantages sectors such as food and feed biomanufacturing where Union approval timelines significantly exceed those of comparable jurisdictions.

Amendment 1889
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 22 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The pilot shall be designed as a mechanism that may use and leverage different funding streams and 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.

to accelerate and catalyse investments into the biotechnology sector. It may be used to provide Union support through Union programmes.

Or. en

Amendment 1890
Nikos Papandreou, Romana Jerković

Proposal for a regulation
Article 22 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The participation of public contributors in the EBSF shall be structured so that their remuneration is commensurate with the risk they assume. To that end, the investment structure shall include mechanisms ensuring that returns accruing to public contributors are proportionate to their seniority and risk exposure in the capital structure. Any differential risk-sharing arrangement shall be limited to what is necessary and proportionate to address demonstrated market failures and shall be compatible with Union state aid rules.

Or. en

Amendment 1891
Nikos Papandreou, Romana Jerković

Proposal for a regulation
Article 22 – paragraph 4 – point a

Text proposed by the Commission	*Amendment*
(a) support early-stage applied research and innovation, technology transfer and spin-offs, with appropriate financing mechanisms, including equity;	(a) support early-stage applied research and innovation, technology transfer and spin-offs, ***including academic spin-offs, research-intensive SMEs and technology transfer from universities, hospitals and***

research organisations with appropriate financing mechanisms, including equity;

Or. en

Amendment 1892
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 22 – paragraph 4 – point a

Text proposed by the Commission	*Amendment*
(a) support early-stage applied research and innovation, technology transfer and spin-offs, with appropriate financing mechanisms, including equity;	(a) support early-stage applied research and innovation, technology transfer and spin-offs, with appropriate financing mechanisms, including equity***, including spin-offs and translational projects originating from university hospitals and academic medical centres***;

Or. en

Amendment 1893
Aura Salla

Proposal for a regulation
Article 22 – paragraph 4 – point a

Text proposed by the Commission	*Amendment*
(a) support early-stage applied research and innovation, technology transfer and spin-offs, with appropriate financing mechanisms, including equity;	(a) support early-stage applied research and innovation, technology transfer***, demonstration, piloting, scale-up readiness*** and spin-offs, with appropriate financing mechanisms, including equity;

Or. en

Justification

The amendment ensures that the EU Health Biotechnology Investment Pilot supports the full pathway from applied research and innovation to piloting, demonstration and scale-up. This is needed to de-risk biomanufacturing and process infrastructure, improve access to finance

for pilot, demonstration and flagship facilities. It would help European companies translate RDI results into scalable biotechnology and biomanufacturing capacity within the Union.

Amendment 1894
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 22 – paragraph 4 – point a

Text proposed by the Commission	*Amendment*
(a) support early-stage applied research and innovation, technology transfer and spin-offs, with appropriate financing mechanisms, including equity;	(a) support early-stage applied research and innovation, technology transfer***,*** ***demonstration, piloting, scale-up readiness*** and spin-offs, with appropriate financing mechanisms, including equity;

Or. en

Amendment 1895
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 22 – paragraph 4 – point b

Text proposed by the Commission	*Amendment*
(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;	(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***, including for the development of ATMPs targeting ultra-rare conditions where, due to limited patient populations and high development costs, market incentives alone are insufficient to support investment***;

Or. en

Amendment 1896

Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 22 – paragraph 4 – point b

Text proposed by the Commission	*Amendment*
(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***;***	(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***, including in therapeutic areas characterised by a major public health and socioeconomic burden and persistent innovation gaps, such as mental health conditions***

Or. en

Amendment 1897
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 22 – paragraph 4 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) where appropriate, mobilise private and institutional investment through tailored risk-sharing mechanisms specifically designed to address recognised structural market failures, including those affecting the discovery, development and manufacturing of priority vaccines and antimicrobials, as recognised in the Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach (2023/C 220/01), or in any successor instrument;

Or. en

Justification

Standard equity and debt instruments are often poorly suited to projects affected by structural market failures, where expected revenues are uncertain or decoupled from product utility (as is the case for priority antimicrobials, whose responsible-use considerations limit revenue per dose). Tailored risk-sharing mechanisms (including conditional repayment, milestone-based payments, push-and-pull combinations and other instruments) can mobilise private and institutional investment in these areas. The reference to "or any successor instrument" ensures that the provision remains operative if the 2023 Council Recommendation is replaced.

Amendment 1898
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 22 – paragraph 4 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) provide support and finance biosimilar manufacturing projects and human and veterinary vaccines against zoonotic and emerging infectious diseases for which no licensed vaccine is authorised in the Union, with priority given to applicants demonstrating an established Union biologics manufacturing footprint;

Or. en

Amendment 1899
Anja Hazekamp, Anthony Smith, Sebastian Everding, Lynn Boylan

Proposal for a regulation
Article 22 – paragraph 4 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) provide Moonshot programmes to support the development, validation, standardisation, scale-up, market uptake and regulatory integration of NAMs across the full innovation and value chain;

Or. en

Amendment 1900
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard, Sigrid Friis

Proposal for a regulation
Article 22 – paragraph 4 – point c

Text proposed by the Commission	*Amendment*
(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;	(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; ***for the purposes of this point, biotechnology companies that have submitted for market approval to a relevant regulatory authority, or that have obtained regulatory approval in a comparable jurisdiction outside the Union, shall be eligible for scale-up financing on equal terms, irrespective of the sector of application of the biotechnology concerned, including food and feed biomanufacturing, fermentation-derived ingredients and bio-based industrial inputs; disbursement may be structured around defined regulatory and commercial milestones, with tranches linked to submission for market approval, regulatory decision, or attainment of a commercial production threshold, as appropriate;***

Or. en

Justification

The current text does not expressly extend eligibility to companies that have submitted for or hold third-market approval and does not permit milestone-based disbursement. Companies in sectors such as food and feed biomanufacturing face Union approval timelines that routinely exceed those of comparable jurisdictions, creating a regulatory-induced financing gap. Milestone-based disbursement, already applied by the EIB in health biotechnology, is the standard instrument for bridging it, and sits naturally alongside the new Scale-Up Fund (Amendment 164 as proposed by the rapporteurs in the draft report).

Amendment 1901
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 22 – paragraph 4 – point c

Text proposed by the Commission	*Amendment*
(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;	(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***, for the purposes of this point, biotechnology companies that have submitted for market approval to a relevant regulatory authority, shall be eligible for scale-up financing on equal terms, irrespective of the sector of application of the biotechnology concerned, including food and feed biomanufacturing, fermentation-derived ingredients and bio-based industrial inputs***; ***disbursement may be structured around defined regulatory and commercial milestones, with tranches linked to submission for market approval, regulatory decision, or attainment of a commercial production threshold, as appropriate;***

Or. en

Justification

The current text does not expressly extend eligibility to companies that have submitted for or hold third-market approval and does not permit milestone-based disbursement. Companies in sectors such as food and feed biomanufacturing face Union approval timelines that routinely exceed those of comparable jurisdictions, creating a regulatory-induced financing gap.

Amendment 1902
Ondřej Krutílek

Proposal for a regulation
Article 22 – paragraph 4 – point c

Text proposed by the Commission	*Amendment*
(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;	(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 ***, as well as instruments supporting access to capital markets and large-scale financing***;

Or. en

Amendment 1903
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 22 – paragraph 4 – point c

Text proposed by the Commission	*Amendment*
(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***;***	(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***, as well as instruments supporting access to capital markets and large-scale financing***

Or. en

Justification

These changes would ensure that the investment pilot supports companies and projects across the full biotechnology lifecycle, including established and commercially mature biotechnology companies.They aim to clarify that financing should reflect the needs of late-stage development, industrial scale-up, production capacity build-up, commercial expansion and manufacturing capacity, including through access to capital markets and large-scale financing.This will help anchor growth and manufacturing activities in the Union, strengthen industrial capacity and support the Union's strategic autonomy, resilience and competitiveness in health biotechnology.

Amendment 1904
Nikos Papandreou, Romana Jerković

Proposal for a regulation
Article 22 – paragraph 4 – point c

Text proposed by the Commission	*Amendment*
(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;	(c) finance late-stage development initiatives, industrial scale-up and production capacity build-up***, including first industrial deployment and manufacturing readiness where appropriate,*** for companies that contribute to the objectives of this Regulation, through venture loans and other suitable debt or quasi-equity instruments;

Or. en

Amendment 1905
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 22 – paragraph 4 – point c

Text proposed by the Commission	*Amendment*
(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;	(c) finance late-stage development initiatives***, including industrial biomanufacturing projects***, 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;

Or. en

Amendment 1906
Jérémy Decerle, Christophe Grudler

Proposal for a regulation

Article 22 – paragraph 4 – point d

Text proposed by the Commission	*Amendment*
(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;	(d) anchor growth and manufacturing activities in the Union***, including by establishing, maintaining or developing critical capacities and technologies within the Union's health biotechnology value chain,*** in order to gain or maintain strategic autonomy and resilience, as well as boost competitiveness of the sector;

Or. en

Amendment 1907
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 22 – paragraph 4 – point d

Text proposed by the Commission	*Amendment*
(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;	(d) anchor growth and manufacturing activities in the Union***, including the maintenance, modernisation, upgrading and expansion of existing manufacturing capacities,*** in order to gain or maintain strategic autonomy and resilience, ***ensure continuity of supply,*** as well as boost competitiveness of the sector;

Or. en

Amendment 1908
Nikos Papandreou, Romana Jerković

Proposal for a regulation
Article 22 – paragraph 4 – point d

Text proposed by the Commission	*Amendment*
(d) anchor growth and manufacturing activities in the Union in order to gain or maintain strategic autonomy and resilience,	(d) anchor growth and manufacturing activities in the Union ***and contribute to public health resilience, security of supply***

as well as boost competitiveness of the sector;	***and the availability of innovative health biotechnologies,*** in order to gain or maintain strategic autonomy and resilience, as well as boost competitiveness of the sector;

Or. en

Amendment 1909
Margarita de la Pisa Carrión, Paolo Borchia, Laurent Castillo, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 22 – paragraph 4 – point d

Text proposed by the Commission	*Amendment*
(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;	(d) anchor growth and manufacturing activities***, including the expansion and retention of industrial capacities within*** in the Union in order to gain or maintain strategic autonomy and resilience, as well as boost competitiveness of the sector;

Or. en

Amendment 1910
Ondřej Krutílek

Proposal for a regulation
Article 22 – paragraph 4 – point d

Text proposed by the Commission	*Amendment*
(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;	(d) anchor growth and manufacturing activities ***including the expansion and retention of industrial capacities within*** the Union***,*** in order to gain or maintain strategic autonomy and resilience, as well as boost competitiveness of the sector;

Or. en

Amendment 1911
Waldemar Buda, Kosma Złotowski

Proposal for a regulation
Article 22 – paragraph 4 – point d

Text proposed by the Commission	*Amendment*
(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;	(d) anchor growth and manufacturing activities in the Union in order to gain or maintain strategic autonomy and resilience, ***ensure continuity of supply,*** as well as boost competitiveness of the sector;

Or. en

Amendment 1912
Nikos Papandreou, Romana Jerković

Proposal for a regulation
Article 22 – paragraph 4 – point e

Text proposed by the Commission	*Amendment*
(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;	(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; ***this objective should contribute, where appropriate, to the broader aims of the Savings and Investments Union by mobilising long-term European savings towards productive biotechnology investment;***

Or. en

Amendment 1913
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 22 – paragraph 4 – point e

Text proposed by the Commission	*Amendment*
(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;	(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***, notably through investments in European venture capital and private equity funds, fund-of-funds structures that crowd in private capital***;

Or. en

Amendment 1914
Morten Løkkegaard, Katri Kulmuni, Stine Bosse, Sophie Wilmès

Proposal for a regulation
Article 22 – paragraph 4 – point e

Text proposed by the Commission	*Amendment*
(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;	(e) mobilise private investments, including from institutional investors such as pension funds***, occupational pension schemes and long-term savings vehicles***, 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;

Or. en

Amendment 1915
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 22 – paragraph 4 – point f

Text proposed by the Commission	*Amendment*
(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***;***	(f) assist early**-** and growth-stage companies through blended and concessional finance, encompassing equity or debt operations***, including through indirect financing mechanisms such as investments in venture capital and private equity funds***, complementing the direct equity support provided by the European Innovation Council Fund and the Scale-Up Europe Fund under Horizon Europe, including via the development of new products

Or. en

Amendment 1916
Nikos Papandreou, Romana Jerković

Proposal for a regulation
Article 22 – paragraph 4 – point f

Text proposed by the Commission	*Amendment*
(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;	(f) assist early and growth-stage companies through blended and concessional finance***, including risk-sharing instruments capable of crowding in private and institutional capital***, 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;

Or. en

Amendment 1917
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 22 – paragraph 4 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) support the development, validation, scale-up and uptake of New Approach Methodologies, where scientifically appropriate;

Or. en

Amendment 1918
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 22 – paragraph 4 – point g

Text proposed by the Commission	*Amendment*
(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.	(g) provide advisory support throughout the investment cycle, encompassing concrete capacity-building measures***, and including regulatory, clinical trial, reimbursement, health technology assessment, data governance and EHDS-related advisory support***. 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.

Or. en

Justification

For university hospitals, the bottleneck is often not only investment access, but regulatory navigation, trial set-up, data governance, HTA and reimbursement.

Amendment 1919
Nikos Papandreou, Romana Jerković

Proposal for a regulation
Article 22 – paragraph 4 – point g

Text proposed by the Commission	*Amendment*
(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.	(g) provide advisory support throughout the investment cycle, encompassing concrete capacity-building measures***, including investment readiness, regulatory preparedness, market access planning and scale-up support***. 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.

Or. en

Amendment 1920
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 22 – paragraph 4 – point g a (new)

Text proposed by the Commission	*Amendment*
	(ga) strengthen the attractiveness of the Union as a location for clinical research by supporting a regulatory environment that is efficient, predictable and accessible for both commercial and non-commercial trial sponsors. This includes proportionate and streamlined assessment procedures for new indications building on previously authorised platform technologies. Where the underlying technology has already demonstrated safety and quality, regulatory pathways should enable appropriate reliance on existing evidence rather than requiring a complete reassessment for each new rare disease

indication, also through platform approaches.

Or. en

Justification

The design of the regulatory environment is a primary determinant of where clinical research, investment and innovation take place globally. Europe's current challenge is not a lack of scientific excellence, but its inability to translate research into scalable clinical development and commercialisation at competitive speed and scale.

Amendment 1921
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 22 – paragraph 4 – point g a (new)

Text proposed by the Commission	*Amendment*
	(ga) support mature health biotechnology companies established in the Union that have proven manufacturing capacities and play a significant role in ensuring the security, continuity and resilience of supply of critical health biotechnology products, including through investments in upgrading, modernisation, expansion and long-term sustainability of their production facilities.

Or. en

Amendment 1922
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 22 – paragraph 4 – point g a (new)

Text proposed by the Commission	*Amendment*
	(ga) ensure availability of medicinal products, medical devices when administered together with a medicinal

product and medical countermeasures that are innovative, safe, accessible, available and affordable, thereby promoting equitable access, in accordance with the obligations laid down in Article 14(1) within the Union.

Or. en

Amendment 1923
Kateřina Konečná

Proposal for a regulation
Article 22 – paragraph 4 – point g a (new)

Text proposed by the Commission	*Amendment*
	(ga) ensure availability of Union medicinal products, medical devices and medical countermeasures that are innovative, safe, accessible, available and affordable, thereby promoting equitable access, in accordance with the obligations laid down in Article 14(1).

Or. en

Amendment 1924
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 22 – paragraph 4 – point g a (new)

Text proposed by the Commission	*Amendment*
	(ga) ensure availability of Union medicinal products, medical devices and medical countermeasures that are innovative, safe, accessible, available and affordable, thereby promoting equitable access, in accordance with the obligations laid down in Article 14(1).

Or. en

Amendment 1925
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 22 – paragraph 4 – point g a (new)

Text proposed by the Commission	*Amendment*
	(ga) support the development, manufacturing and scale-up of biosimilars and future follow-on biological medicinal products, where such support strengthens competition, patient access, Union supply resilience and industrial capacity.

Or. en

Amendment 1926
Laurent Castillo, Aleksandar Nikolic, Valérie Deloge, Julie Rechagneux, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 22 – paragraph 4 – point g a (new)

Text proposed by the Commission	*Amendment*
	(ga) guarantee equitable, affordable and ready access to biotechnology medicinal products in all Member States and foster innovative treatments.

Or. fr

Amendment 1927
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 22 – paragraph 4 – point g b (new)

Text proposed by the Commission	*Amendment*
	(gb) support the translation of biotechnology research into commercially

viable innovations by allowing temporary confidentiality periods of up to 24 months for research results generated under projects supported by the facility, where necessary to secure intellectual property protection before publication and facilitate private investment.

Or. en

Justification

To prevent the premature disclosure of strategically valuable biotech and healthcare innovations, the EU Biotechnology Investment Facility, as well as other public funding sources, should introduce confidentiality mechanisms linked to grant funding. Publication of research outputs should be temporarily deferred where necessary to allow appropriate IP protection, financing and industrial partnerships to be secured. This could include confidentiality periods of up to 24 months, ensuring that European startups and research teams have sufficient time to protect their discoveries and attract investment before sensitive technical information becomes publicly available.

Amendment 1928
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 22 – paragraph 4 – point g b (new)

Text proposed by the Commission	*Amendment*
	(gb) promote and support the scaling-up to marketing authorisation of advanced therapy medicinal products developed through hospital exemption.

Or. en

Amendment 1929
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 22 – paragraph 4 – point g b (new)

Text proposed by the Commission	*Amendment*

(gb) ensure transparency and public accountability in the allocation and use of financial support granted under the pilot;

Or. en

Amendment 1930
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 22 – paragraph 4 – point g c (new)

Text proposed by the Commission	*Amendment*
	(gc) promote open platform technology master files approaches for the development of advanced therapy medicinal products.

Or. en

Amendment 1931
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 22 – paragraph 4 – point g d (new)

Text proposed by the Commission	*Amendment*
	(gd) support the coordinated development of combination advanced therapies (ATMP combos) as defined in Article 2, including multi-cellular ATMP combinations, cross-class ATMP combinations, and ATMP-medicinal product combinations, recognising that such combination regimens currently require separate authorisation dossiers for each component and may otherwise be disadvantaged relative to single-product development pathways;

Or. en

Amendment 1932
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 22 – paragraph 4 – point g e (new)

Text proposed by the Commission	*Amendment*
	(ge) facilitate, in coordination with the Committee for Advanced Therapies and the European Medicines Agency, streamlined or joint scientific advice procedures for developers pursuing rational combination regimens involving two or more advanced therapy medicinal products, or an advanced therapy medicinal product and another medicinal product, with a view to reducing duplicative regulatory burden without altering the independent authorisation status of each component.

Or. en

Amendment 1933
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 22 – paragraph 4 – point g f (new)

Text proposed by the Commission	*Amendment*
	(gf) support the repurposing of existing, already-authorised medicinal products for use in combination with advanced therapy medicinal products, within the meaning of the ATMP-medicinal product combination defined in Article 2, including through dedicated financing for the generation of new clinical, non-clinical or real-world evidence required to establish the safety and efficacy of the repurposed product in that combined use; such support shall be available irrespective of whether the repurposed medicinal product remains under patent or regulatory data

protection, is subject to generic or biosimilar competition, or is off-patent, provided that the combination itself contributes to the objectives of this Regulation.

Or. en

Amendment 1934
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 22 – paragraph 4 – point g g (new)

Text proposed by the Commission	*Amendment*
	(gg) support the development, expansion and Union-wide dissemination of specialised biomanufacturing training and skills infrastructure, recognising that the competitiveness and resilience of the Union's health biotechnology sector depend as much on the availability of a highly skilled workforce as on financing, regulatory simplification and manufacturing capacity; to this end, the pilot shall support the establishment or scaling of dedicated biomanufacturing training centres, modelled on demonstrated national examples of workforce development functioning as strategic industrial infrastructure, and shall promote the design and delivery of curricula, apprenticeships and continuous professional training in cell and gene therapy manufacturing, bioprocessing, quality control and related disciplines. In designing and implementing this support, the Commission and the EIBG or other implementing partners shall consult and cooperate with the relevant social partners, including trade unions and employer organisations representing the biotechnology and biomanufacturing workforce, to ensure that skills investment is aligned with job quality, working

conditions, and the long-term employability of workers in the sector.

Or. en

Amendment 1935
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 22 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Within the pilot, the Commission shall establish a dedicated window for ultra-rare disease therapies. In cooperation with the European Reference Networks, the Commission shall select a diversified portfolio of research and development projects on the basis of scientific merit, clinical value and potential for patient impact. The window shall draw on a ring-fenced first-loss or equivalent risk-sharing sub-allocation within the pilot's resources, with a view to catalysing co-investment from private and philanthropic actors and demonstrating the viability of a portfolio-based financing model for areas of high unmet need. Where the European Biotechnology Scale-Up Fund referred to in Article 22c is established, the window may be continued and scaled within that Fund. Selection and implementation shall ensure equitable patient access and full compliance with Union rules on data protection, ethics and patient rights.

Or. en

Amendment 1936
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation

Article 22 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Within six months from the entry into force of this Regulation, the Commission shall issue guidance identifying and describing compatible forms of national support that may be made available, in accordance with Union law, for health biotechnology strategic projects and high-impact health biotechnology strategic projects recognised under this Regulation, including projects related to the manufacturing of critical biological medicinal products. The guidance shall, in particular, cover fiscal, financial and risk-sharing instruments that may be deployed at national level, such as accelerated depreciation schemes, direct grants, guarantees, subsidised loans and tax-compatible support schemes under national law, without prejudice to Articles 107 and 108 TFEU, applicable State aid notification requirements, the General Block Exemption Regulation, de minimis rules and Union competition law.

Or. en

Amendment 1937
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 22 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Within six months from the entry into force of this Regulation, the Commission shall issue guidance identifying and describing compatible forms of national support that may be made available, in accordance with Union law, for health biotechnology strategic projects and high-impact health

biotechnology strategic projects recognised under this Regulation, including projects related to the manufacturing of critical biological medicinal products. The guidance shall, in particular, cover fiscal, financial and risk-sharing instruments that may be deployed at national level, such as accelerated depreciation schemes, direct grants, guarantees, subsidised loans and tax-compatible support schemes under national law, without prejudice to Articles 107 and 108 TFEU, applicable State aid notification requirements, the General Block Exemption Regulation, de minimis rules and Union competition law.

Or. en

Justification

This provision aims to ensure coherence, legal certainty and effective uptake of health biotechnology strategic projects by facilitating coordination between Union-level instruments and compatible national support tools. By mandating the Commission to issue guidance within a defined timeframe, this provision supports timely investment decisions, reduces fragmentation, and promotes predictable and compliant deployment of national instruments. This is particularly important for capital-intensive projects contributing to the manufacturing of critical biological medicinal products in the Union

Amendment 1938
Jérémy Decerle, Christophe Grudler

Proposal for a regulation
Article 22 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Financial support provided under the EU health biotechnology investment pilot shall be conditional on the beneficiary's contribution to establishing, maintaining or developing critical capacities and technologies within the Union's health biotechnology value chain. This condition shall be applied in a proportionate manner, taking into account the nature, size and development

stage of the company or project concerned.

Where financial support is provided by the EU health biotechnology investment pilot, project promoters shall take all appropriate measures, throughout the implementation of the supported project and in accordance with the terms and duration set out in the relevant financing agreement, to maintain the project and its contribution within the European Union's territory.

Or. en

Amendment 1939
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 22 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Where the pilot supports projects involving combination advanced therapies as defined in Article 2, the Commission and the EIBG or other implementing partners shall, insofar as possible, coordinate financing decisions with parallel scientific advice or regulatory support mechanisms available through the Committee for Advanced Therapies and the European Medicines Agency, so as to align the investment cycle of the pilot with the dual (or multiple) authorisation timelines that such combination regimens require. This coordination shall not create a unified marketing authorisation for the combination as such, nor alter the independent regulatory status of each constituent product.

Or. en

Amendment 1940
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 22 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The pilot shall be subject to transparency and reporting requirements. The Commission shall publish, on an annual basis, the list of beneficiaries and projects supported, together with the type and amount of support granted and the corresponding public interest commitments. Beneficiaries shall provide the information necessary to comply with this obligation.

Or. en

Amendment 1941
Margarita de la Pisa Carrión, Paolo Borchia, Laurent Castillo, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 22 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The pilot shall be implemented in a manner that ensures balanced support across the biotechnology lifecycle, taking into account the specific financing needs of companies and projects at different stages of development, including late-stage development, industrial scale-up, commercial expansion and existing manufacturing capacity.

Or. en

Amendment 1942
Ondřej Krutílek

Proposal for a regulation
Article 22 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The pilot shall be implemented in a manner that ensures balanced support across the biotechnology lifecycle, taking into account the specific financing needs of companies and projects at different stages of development, including late-stage development, industrial scale-up, commercial expansion and existing manufacturing capacity.

Or. en

Amendment 1943
Morten Løkkegaard, Katri Kulmuni, Sophie Wilmès

Proposal for a regulation
Article 22 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The Commission shall, together with the European Investment Bank Group (EIBG) or other implementing partners, develop an EU Biotechnology investment pilot for biotech applications outside of health. Where relevant, the development of this may rely on experiences of the EU health biotechnology investment pilot.

Or. en

Amendment 1944
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 22 – paragraph 4 b (new)

Text proposed by the Commission	*Amendment*
	4b. The pilot shall be subject to transparency and reporting requirements. The Commission shall publish, on an annual basis, the list of beneficiaries and projects supported, together with the type and amount of support granted and the corresponding public interest commitments. Beneficiaries shall provide the information necessary to comply with this obligation.

Or. en

Amendment 1945
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 22 – paragraph 4 b (new)

Text proposed by the Commission	*Amendment*
	4b. The Commission, by the end of the pilot, shall publish a list of companies and projects in the area of health biotechnology, including SMEs, start-ups and scale-ups that directly or indirectly received financing through the pilot. The list shall include the type of support companies and projects received,

Or. en

Amendment 1946
Christine Anderson

Proposal for a regulation
Article 23

Text proposed by the Commission	*Amendment*
Article 23	***deleted***

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.

Or. en

Amendment 1947
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 23 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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, ***with a view to establishing a dedicated, specialised and cross-border trading infrastructure for biotechnology securities in the Union,*** and are led by ***private or public sector*** operators***, university hospitals, academic medical centres, non-profit entities, or public-private*** consortia,

with the potential participation of market-infrastructure providers and investors.

Or. en

Justification

Ifthe article remains private sector-led only, it excludes precisely the publicand academic infrastructures (ATMP centres, hospital GMP platforms, clinicaltrial networks and federated health data infrastructures) that should be recognised because they play an essential role in patient access toATMPs particularly for rare diseases that are commercially not viable. It is especially relevant for rare diseases andATMPs, where patient populations and market opportunities are often too limitedto support conventional private investment models. In these areas, cross-bordernon-profit consortia involving university hospitals, academic medical centresand other public research actors may represent the only viable pathway forprogressing promising innovations through late-stage development, validationand scale-up.

Amendment 1948
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 23 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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 ***for biotechnology projects addressing significant public health or societal needs*** in accordance with applicable law, and are led by private-sector operators or consortia, with the potential participation of market-infrastructure providers and investors.

Or. en

Amendment 1949
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Article 23 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The participation in a project referred to in paragraph 1 of entities, investors or activities located in third countries shall not, in itself, preclude the recognition of a project, provided that the project is primarly located in the Union, complies with applicable Union law and contributes to the objectives of this Regulation, including the Union's strategic autonomy, security of supply and resilience.

Or. en

Justification

Many biotechnology supply chains are heavily integrated with trusted international and transatlantic partners, including in established technology areas such as plasma-derived medicinal products.Such integration should not, in itself, prevent projects located in the Union from accessing funding to innovate, scale up or strengthen production capacity, provided that they contribute to the Union's strategic autonomy, security of supply and resilience

Amendment 1950
Ondřej Krutílek

Proposal for a regulation
Article 23 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The participation in a project referred to in paragraph 1 of entities, investors or activities located in third countries shall not, in itself, preclude the recognition of a project, provided that the project is located in the Union, complies with applicable Union law and contributes

to the objectives of this Regulation, including the Union's strategic autonomy, security of supply and resilience.

Or. en

Amendment 1951
Ondřej Krutílek

Proposal for a regulation
Article 23 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(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;	(b) mobilising long-term capital and attracting private investment, including institutional investors, and through private markets, ***for companies and projects across the biotechnology lifecycle, including scale-up, commercial expansion, market consolidation and the expansion or retention of manufacturing and innovation capacities within the Union,*** with credible commitments or structures that support liquidity and follow-on financing;

Or. en

Amendment 1952
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 23 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(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;	(b) ***or*** mobilising long-term capital and attracting private investment, including institutional investors, and through private ***and public*** markets, with credible commitments or structures that support liquidity**,** follow-on financing; ***and the development of specialised public market investors capable of supporting***

biotechnology companies through IPOs and subsequent capital raises;

Or. en

Justification

The Biotech Act should focus on addressing the financing continuum holistically, rather than treating early- and late-stage capital needs as isolated issues, especially if the aim is to address all of Europe's financing gaps in the biotech and healthcare industry. Capital needs to be channelled to areas where market failures are most pronounced, notably both VC and growth equity.

Amendment 1953
Nikos Papandreou, Romana Jerković

Proposal for a regulation
Article 23 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(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;	(b) mobilising long-term capital and attracting private investment, including institutional ***investors, such as pension funds, insurance undertakings and other long-term*** investors, and through private markets, with credible commitments or structures that support liquidity and follow-on financing;

Or. en

Amendment 1954
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Article 23 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) improving cross-border investors' access and issuers' visibility through practical steps and deliverables and demonstrating a credible issuance and	(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

investor pipeline with target numbers and timelines***;***	timelines***, including for issuers seeking to expand, access secondary markets or support follow-on financing.***

Or. en

Justification

Issuer visibility and cross-border investor access should also support companies seeking expansion, secondary-market access or follow-on financing. This is necessary to ensure that capital-market measures serve later-stage biotechnology companies, not only initial growth phases.

Amendment 1955
Ondřej Krutílek

Proposal for a regulation
Article 23 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(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;	(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 ***including for issuers seeking to expand, access secondary markets or support follow-on financing***;

Or. en

Amendment 1956
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 23 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) enhancing biotechnology sector-specific investment expertise through exchange of best practices on these topics ;	(d) enhancing biotechnology sector-specific investment expertise***, including expertise relating to advanced therapies, personalised medicine, regulatory science***

	and clinical development through exchange of best practices on these topics;

Or. en

Amendment 1957
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 23 – paragraph 2 – point e

Text proposed by the Commission	*Amendment*
(e) mobilising private capital through biotechnology accelerators and venture builders, including potential use of risk-sharing mechanisms.	(e) ***or*** mobilising private capital ***through venture capital and private equity funds, as well as*** through biotechnology accelerators and venture builders ***that support company creation and early-stage development across all stages of company development***, including ***early-stage and scale-up financing, and through the*** potential use of risk-sharing mechanisms.

Or. en

Amendment 1958
Nikos Papandreou, Romana Jerković

Proposal for a regulation
Article 23 – paragraph 2 – point e

Text proposed by the Commission	*Amendment*
(e) mobilising private capital through biotechnology accelerators and venture builders, including potential use of risk-sharing mechanisms.	(e) mobilising private capital through biotechnology accelerators and venture builders, including potential use of risk-sharing mechanisms ***with a view to strengthening Europe's specialised biotechnology venture capital ecosystem***.

Or. en

Amendment 1959

Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 23 – paragraph 2 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) contributing to the establishment of a dedicated platform and trading venue or market segment for biotechnology securities in the Union, by developing cross-border listing standards, dedicated market-making arrangements and specialised investor research coverage for biotechnology companies, enabling cross-border listing and investor access for biotechnology companies across the Union, in compliance with applicable Union financial services legislation.

Or. en

Amendment 1960
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 23 – paragraph 2 – point e b (new)

Text proposed by the Commission	*Amendment*
	(eb) promoting innovative financing mechanisms, including public-private partnerships, venture philanthropy and patient-driven investment models, to support the development, clinical translation and equitable access to biotechnologies addressing unmet medical needs, particularly in rare diseases and advanced therapies.

Or. en

Amendment 1961
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 23 – paragraph 3 – point c

Text proposed by the Commission	*Amendment*
(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.	(c) include ***transparent*** risk-management, governance and reporting arrangements ***including disclosure of public financial support received and private investment mobilised*** and operate without prejudice to applicable Union financial services legislation and the mandates of competent authorities.

Or. en

Amendment 1962
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 23 – paragraph 3 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) where appropriate, provide for consultation of relevant public authorities, patient organisations and civil society organisations with a view to ensuring that supported activities contribute to public health needs, societal value and public trust.

Or. en

Amendment 1963
Jérémy Decerle, Christophe Grudler

Proposal for a regulation
Article 23 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*

4a. Investments facilitated under the EU biotechnology late-stage capital booster shall be directed towards projects that contribute to the development and strengthening of the Union biotechnology value chain within the European Union's territory.

Where financial support is provided by the EU biotechnology late-stage capital booster, project promoters shall use their best efforts, throughout the implementation of the supported project and in accordance with the terms and duration set out in the relevant financing agreement, to maintain the project and its contribution within the European Union's territory

Or. en

Amendment 1964
Christine Anderson

Proposal for a regulation
Article 23 a (new)

Text proposed by the Commission	*Amendment*
	Article23a
	EU biotechnology late-stage capital access
	1. The Commission may support initiatives facilitating access to late-stage private capital for biotechnology companies in the Union, provided that such initiatives are based on objective, transparent, market-compatible and non-discriminatory criteria.
	2. Support under this Article shall be limited to non-financial facilitation measures, including investor information, cross-border networking, issuer visibility, market transparency, regulatory guidance, exchange of best practices and

measures improving access to private investors.

3. Such initiatives shall pursue at least one of the following objectives:

(a) facilitating cross-border private investment in accordance with Union law;

(b) mobilising long-term private capital, including institutional investors;

(c) improving issuer visibility and investor access across Member States;

(d) enhancing biotechnology sector-specific investment expertise;

(e) facilitating access to private capital for SMEs, start-ups, scale-ups and university spin-offs.

4. Support under this Article shall not involve Union grants, guarantees, loans, equity, quasi-equity, blended finance, concessional finance or other financial instruments.

5. Support under this Article shall not depend on recognition as a strategic project, shall not shield investors from ordinary commercial risk, shall not crowd out private investment and shall not favour incumbent operators over SMEs, start-ups and scale-ups.

Or. en

Amendment 1965
Ruggero Razza

Proposal for a regulation
Article 24 – paragraph 1

Text proposed by the Commission	*Amendment*
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	1. Union programmes may support biotechnology as a strategic technology for the Union's innovation capacity, sovereignty, resilience***, economic security*** and leadership in line with the objectives

Regulations establishing those Union programmes.	set out in the Regulations establishing those Union programmes.

Or. it

Amendment 1966
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 24 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. Union programmes ***shall*** 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.

Or. en

Amendment 1967
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 24 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. Union programmes ***shall*** 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.

Or. en

Amendment 1968

Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 24 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. Union programmes ***shall*** 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.

Or. en

Justification

The possibility for funding and prioritisation should be clearer and more attractive.

Amendment 1969
Aurelijus Veryga

Proposal for a regulation
Article 24 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. The Commission ***shall*** adopt calls, windows or compartments for biotechnology and ***shall*** establish instruments ***and tools*** in the implementation of those programmes, funds and instruments, that support biotechnology companies, projects and initiatives falling within the scope of this Regulation, ***across different stages of development, including commercial-stage and established companies and those contributing to industrial scale-up, commercial deployment, market expansion, industrial capacity, resilience and strategic autonomy within the Union,*** in line with the objectives and rules set out

	in the regulations establishing those programmes, funds and instruments.

Or. en

Amendment 1970
Ondřej Krutílek

Proposal for a regulation
Article 24 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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, ***across different stages of development, including commercial-stage and established companies and those contributing to industrial scale-up, commercial deployment, market expansion, industrial capacity, resilience and strategic autonomy within the Union,*** in line with the objectives and rules set out in the regulations establishing those programmes, funds and instruments.

Or. en

Amendment 1971
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 24 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission may adopt calls, windows or compartments for biotechnology and may establish	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.	instruments in the implementation of those programmes, funds and instruments, that support biotechnology companies, projects and initiatives falling within the scope of this Regulation, ***including dedicated calls, windows or compartments for biotechnology manufacturing capacity, biosimilar development and manufacturing, value-chain resilience and analytical testing infrastructure,*** in line with the objectives and rules set out in the regulations establishing those programmes, funds and instruments.

Or. en

Amendment 1972
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 24 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. The Commission may adopt calls, windows or compartments for biotechnology***, including, where appropriate, dedicated calls supporting translational research, technology transfer and personalised medicine;*** 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.

Or. en

Amendment 1973
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation

Article 24 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. The Commission ***shall*** adopt calls, windows or compartments for biotechnology and ***shall*** establish instruments ***and tools*** 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.

Or. en

Amendment 1974
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 24 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. The Commission ***shall*** adopt calls, windows or compartments for biotechnology and ***shall*** establish instruments ***and tools*** 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.

Or. en

Amendment 1975
Kristoffer Storm

Proposal for a regulation

Article 24 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. The Commission may adopt calls, windows or compartments for biotechnology and may establish instruments ***and tools*** 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.

Or. en

Amendment 1976
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 24 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. The Commission ***shall*** adopt calls, windows or compartments for biotechnology and ***shall*** 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.

Or. en

Amendment 1977
Christine Anderson

Proposal for a regulation
Article 24 – paragraph 3

Text proposed by the Commission	*Amendment*
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***.	3. Companies, projects and initiatives falling within the scope of this Regulation may be ***eligible for*** support from ***existing*** Union programmes and instruments, ***including research and innovation support under Horizon Europe, in accordance with the objectives, eligibility criteria and rules set out in the legal acts establishing those programmes and instruments, and on the basis of objective, transparent and non-discriminatory criteria***. ***This Regulation shall not create new Union financing instruments, guarantees, equity, quasi-equity, blended finance, concessional finance or risk-sharing mechanisms.***

Or. en

Amendment 1978
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 24 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	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***, including projects led by university hospitals, academic medical centres, public research organisations and cross-border non-profit developers***.

Or. en

Amendment 1979
Nikos Papandreou, Romana Jerković

Proposal for a regulation
Article 24 – paragraph 3 – point a (new)

Text proposed by the Commission	*Amendment*
	(a) including by facilitating private investment and supporting projects throughout the biotechnology innovation lifecycle, from translational research to commercial scale-up;

Or. en

Amendment 1980
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 24 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	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***, including where such support contributes to critical industrial capacity, security of supply and strategic autonomy within the Union***.

Or. en

Justification

Member State support should be able to target biotechnology measures that strengthen industrial capacity, security of supply and strategic autonomy. This ensures that State aid can support resilience and leadership in strategic value chains, not only innovation activity

Amendment 1981
Aurelijus Veryga

Proposal for a regulation
Article 24 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	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***, including where such support contributes to industrial capacity, security of supply and strategic autonomy within the Union*****.**

Or. en

Amendment 1982
Ondřej Krutílek

Proposal for a regulation
Article 24 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	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***, including where such support contributes to industrial capacity, security of supply and strategic autonomy within the Union***.

Or. en

Amendment 1983
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 24 – paragraph 4

Text proposed by the Commission	*Amendment*

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.	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***, including where such support contributes to industrial capacity, security of supply and strategic autonomy within the Union***.

Or. en

Justification

Member State support should be able to target biotechnology measures that strengthen industrial capacity, security of supply and strategic autonomy. This ensures that State aid can support resilience and leadership in strategic value chains, not only innovation activity.

Amendment 1984
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 24 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	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. ***Such support should contribute to reducing disparities in access to biotechnology innovation across the Union.***

Or. en

Amendment 1985
Nikos Papandreou, Romana Jerković

Proposal for a regulation
Article 24 – paragraph 4 – point a (new)

Text proposed by the Commission	*Amendment*
	(a) Funding may support investments contributing to the modernisation, digitalisation and sustainability of biotechnology manufacturing;

Or. en

Amendment 1986
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 24 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Companies, projects and initiatives eligible to public funds or receiving public funds within the scope of this regulation shall comply with environmental and social legislation. In case of non-compliance, public funds shall be returned.

Or. en

Amendment 1987
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 24 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The Commission shall facilitate the consistent application of this Article by providing sufficient guidance to Member States on the possibilities offered under existing State aid rules for the granting of State aid.

Or. en

Amendment 1988
Viktória Ferenc, András Gyürk

Proposal for a regulation
Article 24 – paragraph 5

Text proposed by the Commission	*Amendment*
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.	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, ***as well as (high impact) health biotechnology strategic projects for biosimilar development and manufacturing*** in the implementation at national level of the relevant Union programmes that are shared-management basic acts. ***Such support may include, where compatible with the relevant basic acts and State aid rules, the expansion, conversion, upgrading, digitalisation and certification-readiness of existing biomanufacturing sites and related value-chain infrastructure.***

Or. en

Amendment 1989
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 24 – paragraph 5

Text proposed by the Commission	*Amendment*
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.	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, ***as well as (high impact) biotechnology strategic projects for biosimilar development and manufacturing,*** in the implementation at national level of the relevant Union

programmes that are shared-management basic acts. ***Such support may include, where compatible with the relevant basic acts and State aid rules, the expansion, conversion, upgrading, digitalisation and certification-readiness of existing biomanufacturing sites and related value-chain infrastructure.***

Or. en

Amendment 1990
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 24 – paragraph 5

Text proposed by the Commission	*Amendment*
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.	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 ***particular those contributing to the development, manufacturing or supply of biosimilars, in*** the implementation at national level of the relevant Union programmes that are shared-management basic acts.

Or. en

Amendment 1991
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 24 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Where State aid instruments, designed in compliance with Union	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.	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 ***and to health biotechnology strategic projects for biosimilar development and manufacturing*** for support under such instruments***, in particular where those projects contribute to strengthening Union manufacturing capacity, reducing strategic dependencies, improving supply resilience or expanding sustainable access to biological medicinal products*****.**

Or. en

Amendment 1992
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 24 – paragraph 6

Text proposed by the Commission	*Amendment*
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.	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 ***and to health biotechnology strategic projects for biosimilar development and manufacturing*** for support under such instruments***, in particular where those projects contribute to strengthening Union manufacturing capacity, reducing strategic dependencies, improving supply resilience or expanding sustainable access to biological medicinal products***.

Or. en

Amendment 1993
Viktória Ferenc, András Gyürk

Proposal for a regulation
Article 24 – paragraph 6

Text proposed by the Commission	*Amendment*
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**.**	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 ***and to health biotechnology strategic projects for biosimilar development and manufacturing*** for support under such instruments***, in particular where those projects contribute to strengthening Union manufacturing capacity, reducing strategic dependencies, improving supply resilience or expanding sustainable access to biological medicinal products***

Or. en

Amendment 1994
Ruggero Razza

Proposal for a regulation
Article 24 – paragraph 6

Text proposed by the Commission	*Amendment*
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	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.	biotechnology strategic projects for support under such instruments. ***Particular focus shall be devoted to projects which contribute to European production capacity, resilient supply chains and the availability of essential biotechnology products.***

Or. it

Amendment 1995
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 24 – paragraph 6

Text proposed by the Commission	*Amendment*
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.	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 ***in particular strategic projects contributing to expanding sustainable access to biological medicinal products,*** for support under such instruments.

Or. en

Amendment 1996
Kristoffer Storm

Proposal for a regulation
Article 24 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Where State aid instruments, designed in compliance with Union	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.

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 ***priority*** to high-impact health biotechnology strategic projects for support under such instruments.

Or. en

Amendment 1997
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 24 – paragraph 6

Text proposed by the Commission	*Amendment*
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.	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 ***priority*** to high-impact health biotechnology strategic projects for support under such instruments.

Or. en

Amendment 1998
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 24 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. The Commission shall, together with the European Investment Bank Group, the European Investment Fund and, where appropriate, national

promotional banks and institutions and other implementing partners, assess the feasibility of portfolio-based and risk-sharing financing instruments for health biotechnology projects, including orphan medicinal products, advanced therapy medicinal products and rare disease pipelines. Such instruments may include:

(a) diversified research and development project portfolios,

(b) Research-Backed Obligations or equivalent debt-based instruments,

(c) credit enhancement mechanisms,

(d) blended finance and guarantees,

(e) long-tenor European Investment Bank loans;

(f) Union 'patient capital' frameworks designed to mobilise institutional investors, including pension funds and insurance funds, towards long-horizon biotechnology investment, with appropriate prudential and disclosure safeguards;

(g) Union long-horizon procurement contracts for innovative technologies and therapeutic combination products addressing public health emergencies and unmet medical needs,

(h) extended-life venture capital funds with a target life cycle of at least twelve years, supported by Union and national co-investment, in derogation from the standard fund-life conventions of European venture capital.

These financial instruments will be used with a view to mobilising long-term private and institutional capital while preserving public-interest objectives. The assessment shall take into account relevant Union assets, including ERNs, patient registries, natural history data, biobanks, clinical research infrastructures, Union research programmes and the centralised regulatory framework, and shall consider

appropriate transparency, access, affordability and public-return safeguards

Or. en

Amendment 1999
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 24 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. Beneficiaries of financial support under this Article shall take appropriate measures to contribute to the availability and affordability of the resulting health technologies.
	Where high impact health biotechnology strategic projects benefit from financial support under Union funds, programmes and instruments pursuant to this Article, the Commission shall ensure that the conditions applicable to such support are consistent with the access obligations laid down in Article 14(1).]

Or. en

Amendment 2000
Christine Anderson

Proposal for a regulation
Article 24 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. Union or national financial support under this Regulation shall be subject to transparency regarding beneficiaries, beneficial ownership, public contributions, selection criteria, conflicts of interest and expected public-policy objectives. Such support shall not crowd out private investment, shall not shield

investors from ordinary commercial risk and shall not favour incumbent operators over SMEs, start-ups and scale-ups.

Or. en

Amendment 2001
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 24 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. Undertakings benefiting from financial support under this Article shall put in place appropriate arrangements to promote the availability and affordability of the health technologies resulting from that support. Those arrangements shall be described in an access plan, to be submitted to the Commission or to the relevant Member State, as applicable.

Or. en

Justification

Requiring beneficiaries of public funding to commit to access and affordability measures helps ensure public investment delivers public value. An access plan provides a clear framework to monitor these commitments and their contribution to patient access.

Amendment 2002
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 24 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. Beneficiaries of financial support pursuant to this Article shall adopt measures that contribute to the availability and affordability of the

resulting health technologies. These commitments shall be set out in an access plan submitted to the Commission or the Member States as applicable.

Or. en

Amendment 2003
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 24 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. Union and national financial support under this Regulation shall not be granted to activities relating to food products falling within the scope of Regulation (EU) 2015/2283.

Or. en

Amendment 2004
François-Xavier Bellamy, Céline Imart

Proposal for a regulation
Article 24 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. Union and national financial support under this Regulation shall not be granted to activities relating to food products falling within the scope of Regulation EU 2015/2283.

Or. en

Amendment 2005
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 24 – paragraph 6 b (new)

Text proposed by the Commission	*Amendment*
	6b. Without prejudice to the principle of conferral and to the prerogatives of Member States in the field of direct taxation, the Commission can, in coordination with the Member States and through the Open Method of Coordination, facilitate the alignment of national tax incentives supporting biotechnology research and reinvestment, including patent-box regimes for biotechnology intellectual property, capital gains roll-over relief for biotechnology reinvestment, and research and development tax credits

Or. en

Amendment 2006
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 24 – paragraph 6 c (new)

Text proposed by the Commission	*Amendment*
	6c. To support high-risk research and development in areas affected by structural market failure, namely rare and ultra-rare diseases, paediatric conditions and antimicrobial resistance, a Union Risk-Sharing Vehicle, building on the incentives established under Regulation (EC) No 141/2000, with public co-investment can be established. Where Union public co-investment represents 30% or more of the total development cost, transparent pricing obligations, non-exclusive licences for cross-border procurement and priority access conditions for Union patients shall apply,

in accordance with Article 27f(4) of Regulation (EU) 536/2014.

Or. en

Amendment 2007
Christine Anderson

Proposal for a regulation
Article 24 – paragraph 6 c (new)

Text proposed by the Commission	*Amendment*
	6c. The Commission shall publish annually a list of beneficiaries of Union financial support under this Regulation, including the amount and form of support granted, the project objective, the duration of support, and a non-confidential assessment of whether the support contributed to private investment, market entry, SME participation, increased production capacity or reduced administrative burden.

Or. en

Amendment 2008
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 24 – paragraph 6 d (new)

Text proposed by the Commission	*Amendment*
	6d. Union Coordinated Outcome-Based Procurement Mechanism for high-cost advanced therapy medicinal products and innovative technologies shall be established, leveraging the Coordination Group of Member States on Health Technology Assessment established under Regulation (EU) 2021/2282 and the data infrastructure of the European Health

Data Space established under Regulation (EU) 2025/327, designed to distribute financial risk between Union manufacturers and national payers in respect of products characterised by high upfront cost and long-tail efficacy data.

Or. en

Amendment 2009
Wouter Beke, Ingeborg Ter Laak, Angelika Niebler, Adam Jarubas, Aura Salla, Liesbet Sommen, Paulo Cunha, Sérgio Humberto, Sirpa Pietikäinen, Willemien Koning, Andrea Wechsler, Dolors Montserrat, Oliver Schenk, Elena Nevado del Campo, András Tivadar Kulja, Niels Flemming Hansen, Tomislav Sokol

Proposal for a regulation
Article 24 a (new)

Text proposed by the Commission	*Amendment*
	Article24a
	Biosimilar and Biomanufacturing Support Scheme
	1. A Biosimilars and Biomanufacturing Support Scheme ("the Scheme") is hereby established in order to strengthen the resilience, competitiveness, strategic autonomy and affordability of the Union pharmaceutical and biotechnology sector through the development, manufacture and market uptake of biosimilar medicinal products within the Union.
	2. The Scheme shall support activities contributing to:
	a) the development and clinical validation of biosimilar medicinal products;
	b) the establishment, expansion or modernisation of Union-based biomanufacturing capacity;
	c) the reduction of market barriers and investment risks associated with biosimilar development;

d) the diversification and security of supply of critical biologic medicinal products;

3. Financial support under the Scheme may be granted for:

a) analytical comparability and biosimilarity studies;

b) clinical trials and clinical comparability programmes conducted pursuant to Regulation (EU) No 536/2014;

c) process development, scale-up and technology transfer activities;

d) the construction, retrofitting or expansion of facilities for biologics and biosimilars manufacturing within the Union;

e) the development of advanced manufacturing technologies, including continuous bioprocessing and digital manufacturing systems;

f) regulatory science, pharmacovigilance and post-authorisation evidence generation;

g) workforce development and specialised biotechnology training programmes;

h) strategic manufacturing reserve capacity for critical biologic medicinal products.

4. Priority shall be given to projects contributing to:

a) supply chain resilience within the Union;

b) the production of medicines affected by shortages or limited market competition;

c) environmentally sustainable manufacturing processes;

d) cross-border industrial cooperation between Member States;

e) the participation of small and medium-sized enterprises and emerging biotechnology undertakings.

	5. The Commission may support projects under the Scheme through existing Union funding programmes and shall establish dedicated calls, blended finance instruments, innovation procurement mechanisms or accelerated grant procedures for biosimilar-related projects.
	6. The European Investment Bank Group shall be encouraged to support projects falling within the scope of this Article through loans, guarantees, venture debt, risk-sharing mechanisms, blended finance instruments or public-private investment platforms. It may also cooperate with national promotional banks and institutions in order to mobilise additional public and private investment.

Or. en

Amendment 2010
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 25 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. High impact health biotechnology strategic projects ***shall*** 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.

Or. en

Amendment 2011
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Article 25 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. High impact health biotechnology strategic projects ***shall*** 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.

Or. en

Amendment 2012
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 25 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. High impact health biotechnology strategic projects ***shall*** be given ***priority*** 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.

Or. en

Amendment 2013
Kristoffer Storm

Proposal for a regulation
Article 25 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. High impact health biotechnology strategic projects ***shall*** be given ***priority*** 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.

Or. en

Amendment 2014
Ondřej Krutílek

Proposal for a regulation
Article 25 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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***, including instruments supporting liquidity, refinancing and access to public capital markets for established companies,*** and from public-sector or private-sector investors, including through public–public or public–private partnerships.

Or. en

Amendment 2015
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 25 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where high impact health biotechnology strategic projects benefit from financial support under Union funds, programmes and instruments, in	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.	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, ***,including instruments supporting liquidity, refinancing and access to public capital markets for established*** 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.

Or. en

Justification

Established biotechnology companies must also be accounted for in financing design, particularly where liquidity, refinancing and capital-market access are needed for scale-up and long-term investment. Blended financing should therefore be available where it helps strengthen production capacity, resilience and competitiveness in the Union.

Amendment 2016
Nikos Papandreou, Romana Jerković

Proposal for a regulation
Article 25 – paragraph 2

Text proposed by the Commission	*Amendment*
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-	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, ***as well as, where appropriate, from long-term institutional investors,*** from national promotional banks and institutions or from other development or

sector finance institutions and from public-sector or private-sector investors, including through public–public or public–private partnerships.	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.

Or. en

Amendment 2017
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 25 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. Where high impact health biotechnology strategic projects benefit from financial support under Union funds, programmes and instruments***, including Moonshot programmes***, 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.

Or. en

Amendment 2018
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 25 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	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 ***and health biotechnology projects for biosimilar development and manufacturing***.

Or. en

Amendment 2019
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 25 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	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 ***shall*** give particular consideration to actions supporting high-impact health biotechnology strategic projects.

Or. en

Amendment 2020
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Article 25 – paragraph 3

Text proposed by the Commission	*Amendment*
3. When preparing and implementing the annual and multiannual work	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.	programmes of the relevant Union funds, programmes and instruments referred to in paragraph 1, the Commission ***shall*** give particular consideration to actions supporting high-impact health biotechnology strategic projects.

Or. en

Amendment 2021
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 25 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	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 ***shall*** give particular consideration to actions supporting high-impact health biotechnology strategic projects.

Or. en

Amendment 2022
Kristoffer Storm

Proposal for a regulation
Article 25 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	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 ***shall give priority*** to actions supporting high-impact health biotechnology strategic projects.

Or. en

Amendment 2023
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 25 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	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 ***shall give priority*** to actions supporting high-impact health biotechnology strategic projects.

Or. en

Amendment 2024
Wouter Beke

Proposal for a regulation
Article 25 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. When giving particular consideration to actions supporting high-impact biotechnology strategic projects pursuant to paragraph 3, the Commission shall apply merit-based criteria and shall not introduce any form of geographical balance requirement or geographical distribution target as a condition for, or weighting factor in, such consideration. The selection of projects for financial support under Union funds, programmes and instruments shall remain exclusively based on the substantive eligibility and award criteria of those funds, programmes and instruments,

as established by their respective basic acts.

Or. en

Amendment 2025
Dimitris Tsiodras

Proposal for a regulation
Article 25 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	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 ***and health biotechnology strategic projects for biosimilar development and manufacturing,***, including in cooperation with the Steering Group, referred to in Article 20, where appropriate. ***Such strategic guidance shall include, information on eligibility conditions, selection criteria, indicative timelines, relevant contact points and the possibilities for combining Union, national, regional, EIBG and private financing, without prejudice to the applicable basic acts and State aid rules.***

Or. en

Justification

This directly answers the need for clear rules on how projects labelled strategic can access Union, national and regional funding and associated budget lines. It also reduces administrative uncertainty for companies planning long-term manufacturing investment.

Amendment 2026
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 25 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	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, ***and projects for biosimilar development and manufacturing,*** including in cooperation with the Steering Group, referred to in Article 20, where appropriate. ***Such strategic guidance shall include, information on eligibility conditions, selection criteria, indicative timelines, relevant contact points and the possibilities for combining Union, national, regional, EIBG and private financing, without prejudice to the applicable basic acts and State aid rules.***

Or. en

Amendment 2027
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 25 – paragraph 4

Text proposed by the Commission	*Amendment*
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	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.	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. ***Such guidance shall include practical information and tools to assist project promoters in combining Union, European Investment Bank Group (EIBG), national and private financing, including on the applicable eligibility conditions, sequencing of instruments and interplay between Union and national funding streams.***

Or. en

Amendment 2028
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 25 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	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. ***Such guidance shall include practical information and tools to assist project promoters in combining Union, European Investment Bank Group, national and private financing, including on the applicable eligibility conditions, sequencing of instruments and interplay***

between Union and national funding streams.

Or. en

Justification

Article 25 is the provision through which the recognition of a project as a high-impact health biotechnology strategic project translates into financial support under Union funds, programmes and instruments. As currently drafted, that support remains discretionary: projects "may" be given particular consideration, and the Commission "may" give particular consideration when programming. This is particularly consequential for the Centres of Excellence for advanced therapies established under Article 6, which depend on sustained Union financial support to deliver on their objectives of accelerating clinical translation, manufacturing scale-up and patient access. Without an assurance that recognition leads to funding, the strategic projects framework risks becoming a designation without operational consequence, and the Centres of Excellence in particular risk being established without the means to fulfil the conditions set out in Article 6(2)

Amendment 2029
Nikos Papandreou, Romana Jerković

Proposal for a regulation
Article 25 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	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. ***Such coordination shall support the objectives of the Savings and Investments Union by improving access to long-term capital for biotechnology companies established in the Union.***

Or. en

Amendment 2030
Laurent Castillo, Aleksandar Nikolic, Valérie Deloge, Julie Rechagneux, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 25 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The beneficiaries under this Article must comply with the obligations laid down by the Commission, in particular that of prioritising supplies to the Union. If the rules are not complied with, the Commission shall impose effective, proportionate and dissuasive penalties. In the event that public support is granted to health biotechnology strategic projects or high impact health biotechnology strategic projects, the project promoters shall also ensure that the products and services they develop on the basis of, or partly on the basis of, the results of supported activities are affordable, available and accessible for patients within the Union.

Or. fr

Amendment 2031
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 25 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Beneficiaries of financial support under this Article shall take appropriate measures to contribute to the availability and affordability of the resulting health technologies.
	Where high impact health biotechnology strategic projects benefit from financial support under Union funds, programmes

and instruments pursuant to this Article, the Commission shall ensure that the conditions applicable to such support are consistent with the access obligations laid down in Article 14(1).]

Or. en

Amendment 2032
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Article 25 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. When preparing and implementing Union work programmes, the Commission shall ensure that high-impact health biotechnology strategic projects, including cross-border projects, led by cross-border university hospitals, academic medical centres, public research organisations and non-profit developers are eligible for dedicated funding windows.

Or. en

Justification

Without dedicated windows, academic and hospital-led projects may be structurally disadvantaged compared with commercial applicants. Cross-border consortia of university hospitals and academic medical centres are eligible for dedicated funding windows on the same terms as individual institutions. Given the cross-border nature of many rare disease and ATMP development projects, such consortia play a critical role in bringing together the expertise, infrastructure and patient populations necessary to achieve meaningful scale and impact.

Amendment 2033
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 25 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Where high impact health biotechnology strategic projects benefit from financial support under Union funds, programmes and instruments pursuant to this Article, the Commission shall ensure that the conditions applicable to such support are consistent with the access obligations laid down in Article 14(1).

Or. en

Amendment 2034
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 25 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Where high impact health biotechnology strategic projects benefit from financial support under Union funds, programmes and instruments pursuant to this Article, the Commission shall ensure that the conditions applicable to such support are consistent with the access obligations laid down in Article 14(1).

Or. en

Amendment 2035
Kateřina Konečná

Proposal for a regulation
Article 25 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Where high impact health biotechnology strategic projects benefit

from financial support under Union funds, programmes and instruments pursuant to this Article, the Commission shall ensure that the conditions applicable to such support are consistent with the access obligations laid down in Article 14(1).

Or. en

Amendment 2036
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 25 – paragraph 4 b (new)

Text proposed by the Commission	*Amendment*
	4b. Failure to comply with the obligations referred to in paragraph 5 shall be subject to the corrective measures and penalties provided for in Article 14.

Or. en

Amendment 2037
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 25 a (new)

Text proposed by the Commission	*Amendment*
	Article25a
	Biosimilar and Biomanufacturing Support Scheme
	1. A Biosimilar and Biomanufacturing Support Scheme ('the Scheme') is hereby established to strengthen the resilience, strategic autonomy, competitiveness, and affordability of the Union's biotechnology sector, and to support the development

and Union-based manufacture of biosimilar medicinal products.

2. The Scheme shall support the development and clinical validation of biosimilars, the establishment or expansion of Union manufacturing capacity, technology transfer, sustainable manufacturing processes, regulatory science, workforce training, strategic reserve capacity, and preparation for market launch, as well as independent education and awareness activities by patient organisations on biosimilar medicines, in order to improve understanding, trust and uptake, with priority given to projects addressing supply chain resilience, medicine shortages, cross-border cooperation, and participation by SMEs and non-profit actors

3. The Commission shall support projects under the Scheme through existing Union funding programmes, dedicated calls, blended finance instruments and accelerated grant procedures, which may be made subject to proportionate conditions concerning access, supply, affordability and transparency.

4. The European Investment Bank Group shall be encouraged to co-finance projects under this Article through loans, guarantees, venture debt or risk-sharing mechanisms, in cooperation with national promotional banks, in particular to support the supply, affordability and availability of critical biologic and biosimilar medicinal products in the Union.

Or. en

Amendment 2038
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation

Article 26 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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. ***The Steering Group shall also ensure representation of public and non-profit project promoters, including university hospitals and academic medical centres, when coordinating investments.***

Or. en

Amendment 2039
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 26 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	***1.*** 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.

Or. en

Amendment 2040
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 26 – paragraph 1

Text proposed by the Commission	*Amendment*

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.	The Steering Group referred to in Article 20 ***shall*** 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.

Or. en

Amendment 2041
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 26 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	2. Support for strategic projects shall be implemented in a coordinated manner with relevant Union and national funding instruments, including State aid frameworks, the European Investment Bank, the European Innovation Council and future Union financial programmes, in order to ensure consistency, complementarity and equal treatment across Member States.

Or. en

Amendment 2042
Aurelijus Veryga

Proposal for a regulation
Article 26 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Support for strategic projects shall be implemented in a coordinated manner with relevant Union and national funding instruments, including State aid frameworks, the European Investment Bank, the European Innovation Council

and future Union financial programmes, in order to ensure consistency, complementarity and equal treatment across Member States.

Or. en

Amendment 2043
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 26 a (new)

Text proposed by the Commission	*Amendment*
	Article26a
	Innovative purchase of strategic biotechnology tools
	1. Contracting authorities shall have recourse, where the conditions for their use are met, to the innovation partnership referred to in Article 31 of Directive 2014/24/EU, the competitive dialogue referred to in Article 30 of that Directive, or pre-commercial procurement, for the development and, as applicable, subsequent purchase of strategic biotechnology tools that cannot be met by solutions already available on the market.
	2. The Commission shall establish, by means of implementing acts, the criteria for the identification of strategic biotechnology tools for the purposes of this Article, having regard to: (a) whether the tool constitutes a device, technology, platform or component that is necessary or enabling for the development, manufacturing or scale-up of advanced therapy medicinal products within the meaning of Regulation (EC) No 1394/2007, or of other biotechnological products; (b) the existence of a critical dependency, scarcity, or single-source supply risk affecting the availability of that tool within the Union; (c) the contribution of the tool to the Union's

strategic autonomy in the supply of critical health technologies; and (d) the anticipated budgetary impact of the tool, or of the biotechnological products relying on it, on the healthcare systems of one or more Member States.

3. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 64.

4. Where an innovation partnership is established for the purposes of this Article, the contracting authority shall proceed in accordance with Article 31(2) to (5) of Directive 2014/24/EU as regards the structuring of the partnership into successive phases, the setting of intermediate targets, and the definition of arrangements applicable to intellectual property rights.

5. The Commission shall support contracting authorities in the use of the procedures referred to in paragraph 1 by providing technical guidance and, where appropriate, co-financing under relevant Union funding programmes.

Or. en

Amendment 2044
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Article 26 a (new)

Text proposed by the Commission	*Amendment*
	Article26a
	Strategic investment in biotechnology
	1. The Commission shall, in cooperation with the Member States and without prejudice to their competences in the organisation and financing of healthcare systems, support a policy approach that recognises expenditure on innovative health biotechnology as a strategic

investment contributing to health system sustainability, resilience and long-term societal value.2. To that end, the Commission may develop guidance and facilitate the exchange of best practices with Member States on budgetary, accounting and performance-assessment approaches that better reflect the long-term health and economic benefits of innovative biopharmaceuticals, including outcome-based assessment frameworks and multi-year payment or budgeting models, where appropriate. 3. Where relevant, the Commission shall encourage the use of health outcome indicators to support evidence-based policy coordination and monitoring, including in the context of existing Union governance and coordination instruments.

Or. en

Justification

This proposed Article strengthens the effectiveness of the Biotech Act by addressing demand-side conditions for the uptake of innovation. It promotes a strategic, long-term investment perspective on biopharmaceutical spending, encourages outcome-based assessment and flexible budgeting approaches, and supports policy coordination, while fully respecting Member State competences in healthcare organisation and financing.

Amendment 2045
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 26 a (new)

Text proposed by the Commission	*Amendment*
	Article26a
	Coherence and simplification of Union funding instruments
	1. Financial support measures under this Regulation shall be implemented in coherence with existing Union research and innovation funding frameworks, in order to avoid the creation of additional

or duplicative eligibility, application or reporting requirements that may hinder speed and innovation.

2. The Commission shall work with the European Investment Bank and other relevant implementing partners to simplify, accelerate and streamline procedures related to Union financial instruments supporting health biotechnology, including application, assessment and reporting processes.

3. Where appropriate, the Commission may issue guidance or adopt implementing measures to promote procedural alignment, proportionality and efficiency.

Or. en

Amendment 2046
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 26 b (new)

Text proposed by the Commission	*Amendment*
	Article26b
	Pre-commercial procurement and public procurement of innovative solutions
	1. Public authorities shall be encouraged to use pre-commercial procurement and public procurement of innovative solutions, within the meaning given to those instruments in Union guidance on innovation procurement, to act as first buyers or early adopters of advanced biotechnology innovations.
	2. The use of the instruments referred to in paragraph 1 shall pursue the following objectives: (a) the sharing of development risk with developers during the early stages of the innovation cycle; (b) the support of clinical validation and market deployment of eligible products; and (c)

the facilitation of participation by small and medium-sized enterprises and start-ups.

3. Member States shall report to the Commission, on a biennial basis, on the use made of the instruments referred to in paragraph 1 in respect of advanced biotechnology innovations.

Or. en

Amendment 2047
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 26 c (new)

Text proposed by the Commission	*Amendment*
	Article26c
	Outcome-based and delinked payment models
	1. The Commission and Member States may establish, on a voluntary basis, access and financing mechanisms linked to the therapeutic value delivered by advanced biotechnology innovations, including: (a) outcome-based purchasing agreements; (b) risk-sharing arrangements between purchasers and developers; (c) subscription or delinked payment models, in particular for products in respect of which conventional sales-volume-based remuneration does not adequately reflect societal value.
	2. In establishing mechanisms under paragraph 1, the Commission shall establish guidelines for multi-year subscription models designed to increase the predictability of demand while ensuring appropriate use of the products concerned.
	3. Mechanisms established under this Article shall be without prejudice to Article 168(7) TFEU and shall not affect

the competence of Member States to organise and finance their healthcare systems.

4. Beneficiaries of financial support under this Article shall take appropriate measures to contribute to the availability and affordability of the resulting health technologies. Where high impact health biotechnology strategic projects benefit from financial support under Union funds, programmes and instruments pursuant to this Article, the Commission shall ensure that the conditions applicable to such support are consistent with the access obligations laid down in Article 14(1).]

Or. en