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Committee on Public Health
Committee on Industry, Research and Energy

2025/0406(COD)

14.7.2026

AMENDMENTS
1413 - 1731

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 1413
Christine Anderson

Proposal for a regulation
Article 4

Text proposed by the Commission	*Amendment*
Article 4	***deleted***
High impact health biotechnology strategic projects	
1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:	
(a) the project is a biotechnology development accelerator that fulfils the conditions laid down in Article 5;	
(b) the project is a centre of excellence for advanced therapies, including for advanced therapy medicinal products that fulfils the conditions laid down in Article 6;	
(c) the project contributes to an EU biotechnology late-stage capital booster pilot, fulfilling the conditions laid down in Article 23;	
(d) the project contributes to the development of trusted testing environments for advanced biotechnology innovations, fulfilling the conditions laid down in Article 32(1) or is a health biotechnology data quality accelerator, fulfilling the conditions laid down in	

Article 33.

(e) the project contributes to the EU Biothreat Radar fulfilling the conditions laid down in Article 41(1) or it is a biodefence capability high impact strategic project fulfilling the conditions laid down in Article 42(1).

2. The Commission may adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

Or. en

Amendment 1414
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation ***and*** enhance the translation of research into market applications shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:	1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation***,*** enhance the translation of research into market applications***, or support the scale-up, commercial deployment and industrialisation of biotechnology solutions within the Union, or on the basis of objective supply vulnerability or***

resilience criteria, a significant contribution to strengthening the security, continuity, independence and resilience of supply of critical biological medicinal products in the Union, shall be recognised by the Commission as high impact health biotechnology strategic projects, including***, in particular, projects addressing areas of major public health and socioeconomic burden and persistent innovation gaps, including mental health conditions, where they demonstrate strong systemic and catalytic potential within the Union's biotechnology ecosystem, and*** in the following cases:

Or. en

Amendment 1415
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel, Morten Løkkegaard

Proposal for a regulation
Article 4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:	1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation***, strengthen industrial and biomanufacturing capacity, structured cooperation between large industrial players and SMEs, start-ups or scale-ups*** and enhance the translation of research into market applications***, or support the scale-up, commercial deployment and industrialisation of biotechnology solutions within the Union, including where relevant for disease prevention,*** shall be recognised by the Commission as high impact health

biotechnology strategic projects, including in the following cases:

Or. en

Justification

High-impact status should not be limited to projects focused on early innovation or research translation. Projects that scale up, commercialise or industrialise biotechnology solutions can be equally systemic for the Union's biotechnology ecosystem. To that end, this clarifies that high impact health biotechnology strategic projects may include projects supporting scale-up, commercial deployment and industrialisation, in addition to innovation and research translation.

Amendment 1416
Waldemar Buda, Kosma Złotowski

Proposal for a regulation
Article 4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:	1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications***, or which make a significant contribution to strengthening Union biomanufacturing capacity, security and continuity of supply, resilience of health-related value chains, or the reduction of strategic dependencies in the production of biological medicinal products, including biosimilar medicinal products,*** shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:

Or. en

Amendment 1417
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 4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications shall be recognised by the Commission as high impact ***health*** biotechnology strategic projects, including in the following cases:	1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation***, enhance cooperation between large industrial undertakings and SMCs, SMEs, universities, university hospitals, clinical-translational research infrastructures, start-ups or scale-ups*** and enhance the translation of research into market applications***, including through conducting cross-border clinical studies and developing innovative curative or disease-eradicating therapies,*** shall be recognised by the Commission as high impact biotechnology strategic projects, including in the following cases:

Or. en

Amendment 1418
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II**,** projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate ***by virtue of their scale, scope*** or cross-border ***relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem*** to accelerate innovation and enhance the translation of research into market applications shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:	1. To enable access to the support measures laid down in Section 2 of Chapter II projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects ***and fulfil the conditions on article 3 (2a)***, ***and*** which***, in addition,*** demonstrate ***a clearly substantiated Union-wide systemic impact, based on objective and verifiable indicators, including scalability, ecosystem-wide spillovers,*** or cross-border ***effects, which cannot be adequately achieved through health strategic projects alone*** to accelerate innovation and enhance the translation of research into market applications ***and significant Union public interest benefits including patient access*** shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:

Or. en

Justification

Research commercialisation does not necessarily improve patient access; funded projects must show tangible benefits for access and public health.

Amendment 1419
Sirpa Pietikäinen

Proposal for a regulation
Article 4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to	1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to

accelerate innovation and enhance the translation of research into market applications shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:	accelerate innovation***, enhance cooperation between large industrial undertakings and SMCs, SMEs, universities, university hospitals, clinical-translational research infrastructures, start-ups or scale-ups and patient organisations*** and enhance the translation of research into market applications shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:

Or. en

Amendment 1420
Giorgio Gori

Proposal for a regulation
Article 4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:	1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation***, structure cooperation between large industrial players and SMEs, start-ups or scale-ups*** and enhance the translation of research into market applications***, including where relevant to disease prevention,*** shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:

Or. en

Amendment 1421

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

Proposal for a regulation
Article 4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:	1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation ***strengthen industrial and biomanufacturing capacity, structure cooperation between large industrial players and SMEs, start-ups or scale-ups*** and enhance the translation of research into market applications shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:

Or. en

Amendment 1422
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as ***health*** biotechnology strategic projects***,*** which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to	1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as biotechnology strategic projects which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to

accelerate innovation and enhance the translation of research into market applications shall be recognised by the Commission as high impact ***health*** biotechnology strategic projects, including in the following cases:	accelerate innovation***, enhance cooperation between large industrial undertakings and SMCs, SMEs, universities, university of applied sciences, RTO's, start-ups or scale-ups*** and enhance the translation of research into market applications shall be recognised by the Commission as high impact biotechnology strategic projects, including in the following cases ***and guided by***:

Or. en

Amendment 1423
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:	1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation***, structure cooperation between large industrial players and SMEs, start-ups or scale-ups*** and enhance the translation of research into market applications***, including where relevant to disease prevention,*** shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:

Or. en

Amendment 1424
Ruggero Razza

Proposal for a regulation
Article 4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to ***accelerate*** innovation and ***enhance*** the translation of research into market applications shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:	1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem ***and the capacity to generate long-term benefits for industrial competitiveness, economic security and the Union's resilience with a view*** to ***accelerating*** innovation and ***enhancing*** the translation of research into market applications shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:

Or. it

Amendment 1425
Ondřej Krutílek

Proposal for a regulation
Article 4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications shall be recognised by the Commission as high impact health	1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications***, or support the scale-up, commercial deployment and***

biotechnology strategic projects, including in the following cases:	***industrialisation of biotechnology solutions within the Union,*** shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:

Or. en

Amendment 1426
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:	1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications***, or support the scale-up, commercial deployment and industrialisation of biotechnology solutions within the Union,*** shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:

Or. en

Amendment 1427
Monika Beňová

Proposal for a regulation
Article 4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*

1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:	1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases***. Project may be eligible where the project promoter is itself an SME or a start-up, non-profit or academic entity***:

Or. en

Justification

It is important to clarify start up or a small enterprise can have high impact on the sector, in order to avoid situation where large companies or consortia dominate the market by gate keeping access to resources and infrastructure. With AI enabled approaches often very small and innovative approaches provide the most disruptive or high impact solutions.

Amendment 1428
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 4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation ***and*** enhance the	1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation**,** enhance the

translation of research into market applications shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:

translation of research into market applications***, or support the scale-up, commercial deployment and industrialisation of biotechnology solutions within the Union,*** shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:

Or. en

Amendment 1429
Kristoffer Storm

Proposal for a regulation
Article 4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:	1. To enable access to the support measures laid down in Section 2 of Chapter II, projects located in the Union fulfilling the criteria to be recognised as health biotechnology strategic projects, which demonstrate by virtue of their scale, scope or cross-border relevance, a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation***, structure cooperation between large industrial players and SMEs, start-ups or scale-ups*** and enhance the translation of research into market applications shall be recognised by the Commission as high impact health biotechnology strategic projects, including in the following cases:

Or. en

Amendment 1430
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 4 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the project is a centre of excellence for advanced therapies, including for advanced therapy medicinal products that fulfils the conditions laid down in Article 6;	(b) the project is a centre of excellence for advanced therapies, including for advanced therapy medicinal products that fulfils the conditions laid down in Article 6 ***and their biosimilar versions, as applicable***;

Or. en

Amendment 1431
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 4 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the project is a ***centre*** of excellence for advanced therapies, including for advanced therapy medicinal products that fulfils the conditions laid down in Article 6;	(b) the project is a ***network*** of excellence for advanced therapies, including for advanced therapy medicinal products that fulfils the conditions laid down in Article 6;

Or. en

Amendment 1432
Kateřina Konečná

Proposal for a regulation
Article 4 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) the project contributes to the EU Biothreat Radar fulfilling the conditions laid down in Article 41(1) or it is a biodefence capability high impact strategic project fulfilling the conditions laid down in Article 42(1).	(e) the project contributes to the EU Biothreat Radar fulfilling the conditions laid down in Article 41(1) or it is a biodefence capability high impact strategic project fulfilling the conditions laid down in Article 42(1). ***Where a project is recognised as a high-impact health biotechnology strategic project, the project promoter shall demonstrate, on the basis of an evidence***

dossier accompanying the application, the project's expected contribution to addressing an unmet medical need or to improving patient-relevant clinical benefit. The Commission shall publish a summary of that demonstration, with due regard to the protection of commercially confidential information.

Or. en

Amendment 1433
Michalis Hadjipantela

Proposal for a regulation
Article 4 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) Where a project is recognised as a high-impact health biotechnology strategic project, the project promoter shall demonstrate, on the basis of an evidence dossier accompanying the application, the project's expected contribution to addressing an unmet medical need or to improving patient-relevant clinical benefit. The Commission shall publish a summary of that demonstration, with due regard to the protection of commercially confidential information.

Or. en

Amendment 1434
Peter Agius

Proposal for a regulation
Article 4 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) Where a project is recognised as a high-impact health biotechnology

strategic project, the project promoter shall demonstrate, on the basis of an evidence dossier accompanying the application, the project's expected contribution to addressing an unmet medical need or to improving patient-relevant clinical benefit. The Commission shall publish a summary of that demonstration, with due regard to the protection of commercially confidential information.

Or. en

Amendment 1435
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 4 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) the project has been recognised as a strategic project under Regulation (EU) …/… [Critical Medicines Act; reference to be added after adoption, cf. COM(2025) 102 final] and concerns critical biological medicinal products, their active substances, or key inputs necessary for their manufacture, provided that the Commission determines that the project has significant Union-level relevance for the security, continuity or resilience of supply.

Or. en

Amendment 1436
Giorgio Gori

Proposal for a regulation
Article 4 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*

(ea) the project contributes to the collection and access to high-quality epidemiological surveillance and vaccine effectiveness data, including through the use of interoperable electronic health data in accordance with the European Health Data Space, and promotes coordinated early engagement with developers, with a view to strengthening disease prevention and crisis preparedness.

Or. en

Amendment 1437
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 4 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) the project contributes to the collection and access to high-quality epidemiological surveillance and vaccine effectiveness data, including through the use of interoperable electronic health data in accordance with the European Health Data Space, and promotes coordinated early engagement with developers, with a view to strengthening disease prevention and crisis preparedness.

Or. en

Amendment 1438
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 4 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) the project demonstrates a critical contribution to EU manufacturing capacity for vaccines, antimicrobials and

related APIs, diagnostics and medical countermeasures, including dual use, contributing to the EU's global health and antimicrobial resistance objectives, including addressing by addressing either civilian health security or military medical readiness, or both;

Or. en

Amendment 1439
Waldemar Buda, Kosma Złotowski

Proposal for a regulation
Article 4 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) the project has been recognised as a strategic project under Regulation (EU) …/… [Critical Medicines Act; reference to COM(2025) 102 final] and concerns critical biological medicinal products, including biosimilar medicinal products, their active substances, or key inputs necessary for their manufacture.

Or. en

Amendment 1440
Sirpa Pietikäinen

Proposal for a regulation
Article 4 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) the project is built around translational infrastructures, including molecular imaging or radiopharmaceutical capabilities, where these enable target validation, biomarker development, patient stratification, treatment response assessment and clinical translation across the

biotechnology value chain.

Or. en

Justification

This addition would signal that strategic biotechnology projects should be assessed not only by their manufacturing or industrial scale, but also by their ability to connect the capabilities required for clinical translation.

Amendment 1441
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 4 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) the project supports cross-border impact and contributes to reducing fragmentation in the Union's biotechnology ecosystem, in line with the objectives set out in Article 3(1);

Or. en

Amendment 1442
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 4 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) the project aims to connect research, industrial and financing actors, thus supporting the reduction of fragmentation in the Union's biotechnology system.

Or. en

Amendment 1443
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 4 – paragraph 1 – point e b (new)

Text proposed by the Commission	*Amendment*
	(eb) the project contributes to the collection and access to high-quality epidemiological surveillance and vaccine effectiveness data, including through the use of interoperable electronic health data in accordance with the European Health Data Space, and promotes coordinated early engagement with developers, with a view to strengthening disease prevention and crisis preparedness;

Or. en

Justification

Wording is added to allow for a project at EU level to support (including financing) for generation of surveillance and vaccine effectiveness data. Articles 32 and 33 set out additional conditions for the strategic projects listed in Article 4(1). However, further development would be needed to define how a surveillance data project could be structured (e.g. as a public–private partnership) before such conditions could be applied to project (eb). It should be noted that Article 4(2) allows the Commission to establish such conditions at a later stage through implementing acts.

Amendment 1444
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 4 – paragraph 1 – point e b (new)

Text proposed by the Commission	*Amendment*
	(eb) the project contributes to ecosystem multiplier effects, including the capacity to connect research, industry, clinical, regulatory, manufacturing, data and financing actors, in line with Articles 3(1) and 20(3);

Or. en

Amendment 1445
Waldemar Buda, Kosma Złotowski

Proposal for a regulation
Article 4 – paragraph 1 – point e b (new)

Text proposed by the Commission	*Amendment*
	(eb) the project significantly contributes to the development, modernisation or expansion of capacities for biological medicinal products, including biosimilar medicinal products.

Or. en

Amendment 1446
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 4 – paragraph 1 – point e c (new)

Text proposed by the Commission	*Amendment*
	(ec) the project contributes to innovation translation capacity, including through the development, validation, standardisation, regulatory acceptance and uptake of New Approach Methodologies, where scientifically appropriate, in line with Article 3(1), points (b) and (c), and Article 32;

Or. en

Amendment 1447
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation

Article 4 – paragraph 1 – point e d (new)

Text proposed by the Commission	*Amendment*
	(ed) the project contributes to workforce development, skills, quality jobs and the Union's biotechnology talent base, in line with Article 3(1), point (d);

Or. en

Amendment 1448
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 4 – paragraph 1 – point e e (new)

Text proposed by the Commission	*Amendment*
	(ee) the project contributes to Union strategic autonomy, supply security and a resilient biotechnology and biomanufacturing capacity, in line with Articles 3(1), point (a), 24 and 25;

Or. en

Amendment 1449
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 4 – paragraph 1 – point e f (new)

Text proposed by the Commission	*Amendment*
	(ef) the project includes data and digital readiness, including interoperability, trustworthy artificial intelligence and secure data infrastructures, in line with Articles 32 and 33;

Or. en

Amendment 1450
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 4 – paragraph 1 – point e g (new)

Text proposed by the Commission	*Amendment*
	(eg) the project contributes to the availability, security of supply, resilience, substitution, repurposing or development of therapeutic alternatives for critical medicines or medicinal products of common interest within the meaning of Regulation (EU) …/… [Critical Medicines Act];

Or. en

Amendment 1451
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 4 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. In assessing whether a project demonstrates the strong systemic and catalytic potential referred to in paragraph 1, the Commission shall give particular consideration to projects involving partners, infrastructures or implementation activities in at least three Member States. Projects involving fewer Member States may be recognised where the applicant demonstrates a clear Union added value, including through their expected cross-border impact, scalability, contribution to Union strategic autonomy, or relevance for patients, healthcare systems or biotechnology ecosystems in several Member States.

Or. en

Amendment 1452
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 4 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Where appropriate, the Commission may recognise groups of geographically concentrated high impact health biotechnology strategic projects, together with associated infrastructures, clinical centres, accelerators and manufacturing facilities, as constituting an EU Biotech Flagship Zone.

Or. en

Amendment 1453
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 4 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Where appropriate, the Commission may recognise high impact health biotechnology strategic projects, together with associated infrastructures, clinical centres, accelerators and manufacturing facilities.

Or. en

Amendment 1454
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation

Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission may adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).	2. The Commission may adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications***, or support the scale-up, commercial deployment and industrialisation of biotechnology solutions within the Union, including where mature biotechnology companies adopt and integrate new technologies, such as data-driven tools, AI and advanced manufacturing processes, to support competitiveness, scale-up and industrialisation within the Union.***. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

Or. en

Justification

Both emerging and established biotechnology activities contribute to the Union's biotechnology ecosystem, including where mature companies adopt and integrate new technologies to support competitiveness and scale-up, and boost Union resilience.

Amendment 1455
Ondřej Krutílek

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission may adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential	2. The Commission may adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential

within the Union’s biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

within the Union’s biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications***, or support the scale-up, commercial deployment and industrialisation of biotechnology solutions within the Union, including where mature biotechnology companies adopt and integrate new technologies, such as data-driven tools, AI and advanced manufacturing processes, to support competitiveness, scale-up and industrialisation within the Union***. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

Or. en

Amendment 1456
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission may adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union’s biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).	2. The Commission may adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union’s biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications ***or support the scale-up, commercial deployment and industrialisation of biotechnology solutions within the Union, including where mature biotechnology companies adopt and integrate new technologies, such as data-driven tools, AI and advanced manufacturing processes, to support competitiveness, scale-up and industrialisation within the Union***. These implementing acts shall be adopted in accordance with the examination procedure

referred to in Article 65(2).

Or. en

Amendment 1457
Ondřej Knotek, Viktória Ferenc, Marie-Luce Brasier-Clain, Valérie Deloge, Laurent Castillo, Aleksandar Nikolic, András Gyürk

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission may adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation ***and*** enhance the translation of research into market applications. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).	2. The Commission may adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation***,*** enhance the translation of research into market applications***, or support the scale-up, commercial deployment and industrialisation of biotechnology solutions within the Union, including where mature biotechnology companies adopt and integrate new technologies, such as data-driven tools, AI and advanced manufacturing processes, to support competitiveness, scale-up and industrialisation within the Union***. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

Or. en

Amendment 1458
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*

2. The Commission may adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation ***and*** enhance the translation of research into market applications. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).	2. The Commission may adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation***,*** enhance the translation of research into market applications***, or support the scale-up, commercial deployment and industrialisation of biotechnology solutions within the Union, including where mature biotechnology companies adopt and integrate new technologies, such as data-driven tools, AI and advanced manufacturing processes, to support competitiveness, scale-up and industrialisation within the Union***. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

Or. en

Amendment 1459
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission may adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).	2. The Commission may adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications. ***Environmental and socio-economic impact, including high-quality job creation located in the EU, as well as the preservation of essential industrial capacities should be duly taken into account when defining strong systemic and catalytic potential within the***

	Union's biotechnology ecosystem These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

Or. en

Amendment 1460
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission may adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).	2. The Commission may adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications ***including, in particular, where projects address rare diseases, rare cancers, ultra-rare conditions or advanced therapies requiring cross-border patient pools, specialised infrastructure or shared clinical expertise***. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

Or. en

Amendment 1461
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission ***may*** adopt	2. The Commission ***shall*** adopt

implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).	implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2). ***). Prior to the adoption of those implementing acts, the Commission shall conduct timely and transparent consultations with patient organisations and shall take due account of the input received.***

Or. en

Justification

Strategic health biotechnology projects have the potential to contribute positively to strengthening the Union's health biotechnology ecosystem. However, it is essential to ensure that robust scrutiny and accountability mechanisms are in place. To that end, clear, transparent and measurable criteria for the designation and evaluation of such projects should be established and consistently applied across all Member States. Those criteria should aim to ensure that supported initiatives effectively address unmet medical needs and deliver tangible added value for patients, including by promoting the development of products that improve patient care and contribute to equitable access across the Union. In order to reinforce transparency and accountability, relevant stakeholders, in particular patient organisations, should be appropriately consulted in the development of such criteria or related guidance

Amendment 1462
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission ***may*** adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology	2. The Commission ***shall*** adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology

ecosystem to accelerate innovation and enhance the translation of research into market applications. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

ecosystem to accelerate innovation***,*** ***strengthen industrial and biomanufacturing capacity,*** and enhance the translation of research into market applications. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

Or. en

Amendment 1463
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission may adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).	2. The Commission may adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation***,*** ***strengthen industrial and biomanufacturing capacity*** and enhance the translation of research into market applications. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

Or. en

Amendment 1464
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*

2. The Commission ***may*** adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).	2. The Commission ***shall, without undue delay,*** adopt implementing acts to detail the conditions set out in paragraph 1, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

Or. en

Amendment 1465
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission ***may*** adopt implementing acts to ***detail the conditions set out in*** paragraph 1***, to clarify in which cases a project is to be deemed to have a strong systemic and catalytic potential within the Union's biotechnology ecosystem to accelerate innovation and enhance the translation of research into market applications***. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).	2. The Commission ***shall*** adopt implementing acts to ***specify the procedural aspects for the application of*** paragraph 1 ***without modifying, supplementing or expanding the criteria set out in this Article or Article 3(2a)***. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2). ***Given their exceptional nature, high impact health biotechnology strategic projects shall be limited in number.***

Or. en

Amendment 1466
Ruggero Razza

Proposal for a regulation
Article 4 – paragraph 2 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	These criteria shall take account of the project's technological maturity and contribution to Europe's industrial development as well as its long-term economic viability and capacity to generate benefits for the entire European biotechnology ecosystem.

Or. it

Amendment 1467
Romana Jerković

Proposal for a regulation
Article 4 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Projects promoted by universities, public research organisations, hospitals, European Research Infrastructures, European Reference Networks or other non-profit entities shall be eligible for recognition as Health Biotechnology Strategic Projects on the same conditions as commercial entities where they fulfil the criteria laid down in this Regulation. The non-commercial nature of a project shall not in itself constitute grounds for refusing recognition.

Or. en

Amendment 1468
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 4 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Applications concerning projects falling within the scope of Regulation

(EU) 2015/2283 shall be declared inadmissible.

Or. en

Amendment 1469
François-Xavier Bellamy, Céline Imart

Proposal for a regulation
Article 4 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Applications concerning projects falling within the scope of Regulation EU 2015/2283 shall be declared inadmissible.

Or. en

Amendment 1470
Christine Anderson

Proposal for a regulation
Article 4 a (new)

Text proposed by the Commission	*Amendment*
	Article4a
	Objective eligibility for simplified procedures
	1. A health biotechnology project shall be eligible for the simplification measures set out in this Chapter where it:
	(a) falls within the scope of this Regulation;
	(b) is conducted by a natural or legal person established in the Union;
	(c) complies with applicable Union and national law;
	(d) does not seek to benefit from accelerated procedures, regulatory sandboxes or Union financial support in relation to activities excluded under

Article 40a; and

(e) provides sufficient information to allow the competent authority to determine the applicable procedure.

2. Member States shall not impose additional administrative conditions for access to simplified procedures unless such conditions are necessary and proportionate for the protection of human health, animal health, the environment, ethics, biosecurity or data protection.

3. Eligibility under this Article shall not confer a right to authorisation, market access, Union funding or derogation from applicable substantive requirements.

Or. en

Amendment 1471
Michele Picaro, Aurelijus Veryga

Proposal for a regulation
Article 4 a (new)

Text proposed by the Commission	*Amendment*
	Article 4a
	Indicative pre-evaluation of (high impact) strategic projects
	1. Project promoters may request competent authorities an indicative, non-binding pre-evaluation as to whether a proposed initiative is likely to qualify as a (high impact) strategic project under this Regulation.
	2. The pre-evaluation shall provide high-level feedback on eligibility and relevant procedural aspects within a reasonable timeframe and shall not prejudge any formal designation decision.
	3. The Commission may adopt guidance on the scope, procedure and timelines of the pre-evaluation mechanism.

Or. en

Amendment 1472
Christine Anderson

Proposal for a regulation
Article 5

Text proposed by the Commission	*Amendment*
Article 5	***deleted***
Biotechnology development accelerators	
1. To enable access to the support measures laid down in Section 2 of Chapter II, the Commission shall recognise projects located in the Union as high impact health biotechnology strategic projects in the form of biotechnology development accelerators, only where they comply with the conditions laid down in Article 4(1), and they fulfil at least three of the following conditions:	
(a) provide trusted testing or demonstration facilities replicating real-world biomanufacturing processes, including good manufacturing practices (GMPs) compliant processes, or their enabling technologies, for process testing, validation, and small batch manufacturing, including for the investigational medicinal products for early stages of clinical trials; such enabling technologies may include digital technologies, with specific applicability in biotechnology and biomanufacturing;	
(b) aim to operate state-of-the-art equipment, laboratories and technical expertise to support biotechnology and biomanufacturing processes and provide access thereof;	
(c) aim to support hands-on and work-based training programmes aligned with the Union's skills and workforce development objectives in the	

biotechnology and biomanufacturing sectors or in relation to enabling technologies, such as digital technologies, with specific applicability in biotechnology and biomanufacturing;

(d) conduct applied research in biotechnology or biomanufacturing, or in relation to enabling technologies, with specific applicability in biotechnology and biomanufacturing;

(e) seek to engage in partnerships among industry, academia, and public authorities to ensure the integration of research, innovation, and training in biotechnology and biomanufacturing or their enabling technologies.

Or. en

Amendment 1473
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 5 – paragraph 1 – introductory part

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 as high impact health biotechnology strategic projects in the form of biotechnology development accelerators, only where they comply with the conditions laid down in Article 4(1), and they fulfil at least ***three*** of the following conditions:	1. To enable access to the support measures laid down in Section 2 of Chapter II, the Commission shall recognise projects located in the Union as high impact health biotechnology strategic projects in the form of biotechnology development accelerators, only where they comply with the conditions laid down in Article 4(1), and they fulfil ***condition (a) and*** at least ***two*** of the following conditions:

Or. en

Amendment 1474
Michele Picaro, Kristoffer Storm

Proposal for a regulation

Article 5 – paragraph 1 – introductory part

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 as high impact health biotechnology strategic projects in the form of biotechnology development accelerators, only where they comply with the conditions laid down in Article 4(1), and they fulfil at least ***three*** of the following conditions:	1. To enable access to the support measures laid down in Section 2 of Chapter II, the Commission shall recognise projects located in the Union as high impact health biotechnology strategic projects in the form of biotechnology development accelerators, only where they comply with the conditions laid down in Article 4(1), and they fulfil ***condition (a) and*** at least ***two*** of the following conditions:

Or. en

Amendment 1475
Ruggero Razza

Proposal for a regulation
Article 5 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) provide trusted testing or demonstration facilities replicating real-world biomanufacturing processes, including good manufacturing practices (GMPs) compliant processes, or their enabling technologies, for process testing, validation, ***and*** small batch manufacturing, including for the investigational medicinal products for early stages of clinical trials; such enabling technologies may include digital technologies, with specific applicability in biotechnology and biomanufacturing;	(a) provide trusted testing or demonstration facilities replicating real-world biomanufacturing processes, including good manufacturing practices (GMPs) compliant processes, or their enabling technologies, for process testing, validation, small batch manufacturing ***and rapidly scaling up production processes with a view to production on a commercial scale***, including for the investigational medicinal products for early stages of clinical trials; such enabling technologies may include digital technologies, with specific applicability in biotechnology and biomanufacturing;

Or. it

Amendment 1476
Ruggero Razza

Proposal for a regulation
Article 5 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) aim to operate state-of-the-art equipment, laboratories and technical expertise to support biotechnology and biomanufacturing processes and provide access ***thereof***;	(b) aim to operate state-of-the-art equipment, laboratories and technical expertise to support biotechnology and biomanufacturing processes and provide ***SMEs with*** access ***thereto***;

Or. it

Amendment 1477
Ruggero Razza

Proposal for a regulation
Article 5 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) aim to support hands-on ***and work-based*** training programmes aligned with the Union's skills and workforce development objectives in the biotechnology and biomanufacturing sectors or in relation to enabling technologies, such as digital technologies, with specific applicability in biotechnology and biomanufacturing;	(c) aim to support ***continuous*** hands-on training***, professional development and workforce reskilling*** programmes ***in cooperation with industry and the research community, which are*** aligned with the Union's skills and workforce development objectives in the biotechnology and biomanufacturing sectors or in relation to enabling technologies, such as digital technologies, with specific applicability in biotechnology and biomanufacturing;

Or. it

Amendment 1478
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 5 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*

(c) aim to support hands-on and work-based training programmes aligned with the Union's skills and workforce development objectives in the biotechnology and biomanufacturing sectors or in relation to enabling technologies, such as digital technologies, with specific applicability in biotechnology and biomanufacturing;	(c) aim to ***contribute to the creation and maintenance of high-quality jobs in the EU and*** support hands-on and work-based training programmes aligned with the Union's skills and workforce development objectives in the biotechnology and biomanufacturing sectors or in relation to enabling technologies, such as ***non-animal and*** digital technologies, with specific applicability in biotechnology and biomanufacturing;

Or. en

Justification

Amendment drafted with the Eurogroup for Animals

Amendment 1479
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 5 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) seek to engage in partnerships among industry, academia, and public authorities to ensure the integration of research, innovation, and training in biotechnology and biomanufacturing or their enabling technologies.	(e) seek to engage in partnerships among industry***, non profit organisations***, academia, and public authorities to ensure the integration of research, innovation, and training in biotechnology and biomanufacturing or their enabling technologies.

Or. en

Amendment 1480
Ruggero Razza

Proposal for a regulation
Article 5 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) seek to engage in partnerships among industry, academia, ***and*** public authorities to ensure the integration of research, innovation, and training in biotechnology and biomanufacturing or their enabling technologies.	(e) seek to engage in partnerships among industry, academia, public authorities ***and healthcare facilities*** to ensure the integration of research, innovation, and training in biotechnology and biomanufacturing or their enabling technologies.

Or. it

Amendment 1481
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 5 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) structured long-term cooperation between large industrial actors and small and medium-sized enterprises, start-ups or scale-ups, which may include co-development activities, early-stage licensing arrangements, shared access to infrastructure, joint talent development programmes, or systematic spin-out or spin-in mechanisms.

Or. en

Amendment 1482
Kristoffer Storm

Proposal for a regulation
Article 5 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) structured long-term cooperation between large industrial actors and small and medium-sized enterprises, start-ups or scale-ups, which may include co-development activities, early-stage

licensing arrangements, shared access to infrastructure, joint talent development programmes, or systematic spin-out or spin-in mechanisms;

Or. en

Amendment 1483
Ruggero Razza

Proposal for a regulation
Article 5 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) provide support services designed to safeguard intellectual property, to facilitate European patent procedures and patent certifications and to harness innovations for industrial use.

Or. it

Amendment 1484
Christine Anderson

Proposal for a regulation
Article 5 a (new)

Text proposed by the Commission	*Amendment*
	Article 5a
	Reduction of administrative burden
	1. Member States shall review administrative requirements applicable to health biotechnology projects with a view to eliminating duplication, shortening inactive periods, allowing digital submission, reusing existing assessments and reducing fixed compliance costs, in particular for SMEs, start-ups and scale-ups.
	2. Where competent authorities request additional information, such requests

shall be reasoned, proportionate, limited to what is necessary for the assessment and, where possible, consolidated into a single request.

3. Member States shall make publicly available clear guidance on applicable procedures, timelines, documentation requirements, fees and remedies.

Or. en

Amendment 1485
Christine Anderson

Proposal for a regulation
Article 6

Text proposed by the Commission	*Amendment*
Article 6	***deleted***
Centres of excellence for advanced therapies	
1. To enable access to the support measures laid down in Section 2 of Chapter II, the Commission shall recognise projects located in the Union as high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products (ATMPs), only where they comply with the conditions laid down in Article 4[(1) and reinforce the Union's capability in the area of advanced therapies, by fulfilling all of the conditions set out in paragraph 2 of this Article.	
2. The centres referred to in paragraph 1 shall fulfil all of the following conditions:	
(a) specialise in at least one advanced therapy, such as cell and gene therapies;	
(b) provide or coordinate advanced infrastructures including downstream processing, delivery models and the	

manufacturing of therapies referred to in point (a);

(c) integrate quality, regulatory science, and safety testing functions supporting Union-wide development of advanced therapies;

(d) establish structured cooperation among clinical centres, research organisations, industrial developers of biotechnology products, investors and regulators;

(e) provide multiple services enabling the transition of advanced therapies from laboratory research to commercial manufacturing, including:

(i) provide acceleration programmes to transform innovative ideas into viable business propositions;

(ii) provide incubation programmes assisting early-stage companies requiring GMP infrastructure, technical and regulatory expertise;

(iii) carry out networking and partnership facilitation to foster alliances;

(iv) ensure access to clinical and hospital settings, including for paediatric patients, for testing, clinical validation, and feedback;

(v) provide education and training for researchers, clinicians, and developers; and

(vi) ensure the possibility of cross-border access to users from any Member State.

3. The Commission may adopt implementing acts to detail the conditions listed in paragraph 2 of this Article, with a view to ensure a consistent approach in their implementation across the Member States. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

Or. en

Amendment 1486
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 6 – title

Text proposed by the Commission	*Amendment*
Centres of excellence for advanced therapies	Centres of excellence for ***development of innovative and/or*** advanced therapies ***including for rare or life-threatening or seriously debilitating diseases***

Or. en

Amendment 1487
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 6 – title

Text proposed by the Commission	*Amendment*
Centres of excellence for advanced therapies	***Networks*** of excellence for advanced therapies

Or. en

Justification

As there is no physical centre, the use of this terminology may be misleading. Referring instead to a network would more accurately reflect the structure and functioning of the initiative.

Amendment 1488
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 6 – paragraph 1

Text proposed by the Commission	*Amendment*
1. To enable access to the support	1. To enable access to the support

measures laid down in Section 2 of Chapter II, the Commission shall recognise projects located in the Union as high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products (ATMPs), only where they comply with the conditions laid down in Article 4[(1) and reinforce the Union's capability in the area of advanced therapies, by fulfilling all of the conditions set out in paragraph 2 of this Article.	measures laid down in Section 2 of Chapter II, the Commission shall recognise projects located in the Union***, which may be implemented by public entities, private entities, or through public-private partnerships (PPPs),*** as high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products (ATMPs), only where they comply with the conditions laid down in Article 4[(1) and reinforce the Union's capability in the area of advanced therapies, by fulfilling all of the conditions set out in paragraph 2 ***or 2a*** of this Article. ***Centres of excellence for advanced therapies may take the form of a network of organisations established in one or more Member States. The conditions set out in paragraph 2 may be fulfilled jointly by the entities forming such a network.***

Or. en

Amendment 1489
Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 6 – 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 as high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products (ATMPs), only where they comply with the conditions laid down in Article 4[(1) and reinforce the Union's capability in the area of advanced therapies, by fulfilling all of the conditions set out in paragraph 2 of this Article.	1. To enable access to the support measures laid down in Section 2 of Chapter II, the Commission shall recognise projects located in the Union as high impact health biotechnology strategic projects in the form of centres of excellence for ***innovative and/or*** advanced therapies ***for rare or life-threatening or seriously debilitating diseases***, including for advanced therapy medicinal products (ATMPs), only where they comply with the conditions laid down in Article 4[(1) and reinforce the Union's capability in the area of ***innovative and/or*** advanced therapies, by fulfilling all of the conditions set out in paragraph 2 of this

Article. ***These centres of excellence can be structured among other things as public institutions and their networks, including ERNs, joint ventures, public-private partnerships or deeply integrated partnerships between different entities.***

Or. en

Amendment 1490
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 6 – 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 as high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products (ATMPs), only where they comply with the conditions laid down in Article 4[(1) and reinforce the Union's capability in the area of advanced therapies, by fulfilling all of the conditions set out in paragraph 2 of this Article.	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 ***which may be implemented by public entities, private entities, or through public-private partnerships (PPPs),*** as high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products (ATMPs), only where they comply with the conditions laid down in Article 4[(1) and reinforce the Union's capability in the area of advanced therapies, by fulfilling all of the conditions set out in paragraph 2 of this Article.

Or. en

Amendment 1491
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 6 – 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 as high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products (ATMPs), only where they comply with the conditions laid down in Article 4[(1) and reinforce the Union's capability in the area of advanced therapies, by fulfilling all of the conditions set out in paragraph 2 of this Article.	1. To enable access to the support measures laid down in Section 2 of Chapter II, the Commission shall recognise projects located in the Union as high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products (ATMPs), only where they comply with the conditions laid down in Article 4[(1) and reinforce the Union's capability in the area of advanced therapies, by ***supporting the pathway from research to clinical development, manufacturing scale-up and market uptake, by*** fulfilling all of the conditions set out in paragraph 2 of this Article.

Or. en

Amendment 1492
Aurelijus Veryga

Proposal for a regulation
Article 6 – 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 as high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products (ATMPs), only where they comply with the conditions laid down in Article 4[(1) and reinforce the Union's capability in the area of advanced therapies, by fulfilling all of the conditions set out in paragraph 2 of this Article.	1. To enable access to the support measures laid down in Section 2 of Chapter II, the Commission shall recognise projects located in the Union as high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products (ATMPs), only where they comply with the conditions laid down in Article 4[(1)***]*** and reinforce the Union's capability in the area of advanced therapies***, by supporting the pathway from research to clinical development, manufacturing scale-up and market uptake***, by fulfilling all of the conditions set out in paragraph 2 of this Article.

Or. en

Amendment 1493
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 6 – 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 as high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products (ATMPs), only where they comply with the conditions laid down in Article 4[(1) and reinforce the Union's capability in the area of advanced therapies, by fulfilling all of the conditions set out in paragraph 2 of this Article.	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***, including networks of organisations established in one or more Member States,*** as high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products (ATMPs), only where they comply with the conditions laid down in Article 4[(1) and reinforce the Union's capability in the area of advanced therapies, by fulfilling all of the conditions set out in paragraph 2 of this Article.

Or. en

Amendment 1494
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 6 – 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 as high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products (ATMPs), only where they comply with the conditions laid down in Article 4[(1) and reinforce the Union's capability in the area of advanced therapies, by fulfilling all of the conditions	1. To enable access to the support measures laid down in Section 2 of Chapter II, the Commission shall recognise projects located in the Union as high impact health biotechnology strategic projects in the form of centres of excellence for ***innovative and/or*** advanced therapies ***for rare or life-threatening or seriously debilitating diseases***, including for advanced therapy medicinal products (ATMPs), only where they comply with the conditions laid down in Article 4[(1) and reinforce the Union's

set out in paragraph 2 of this Article.	capability in the area of advanced therapies, by fulfilling all of the conditions set out in paragraph 2 of this Article.

Or. en

Amendment 1495
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 6 – 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 as high impact health biotechnology strategic projects in the form of ***centres*** of excellence for advanced therapies, including for advanced therapy medicinal products (ATMPs), only where they comply with the conditions laid down in Article 4[(1) and reinforce the Union's capability in the area of advanced therapies, by fulfilling all of the conditions set out in paragraph 2 of this Article.	1. To enable access to the support measures laid down in Section 2 of Chapter II, the Commission shall recognise projects located in the Union as high impact health biotechnology strategic projects in the form of ***networks*** of excellence for advanced therapies, including for advanced therapy medicinal products (ATMPs), only where they comply with the conditions laid down in Article 4[(1) and reinforce the Union's capability in the area of advanced therapies, by fulfilling all of the conditions set out in paragraph 2 of this Article.

Or. en

Amendment 1496
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 6 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Centres of excellence for advanced therapies shall cooperate with European Reference Networks established pursuant to Article 12 of Directive 2011/24/EU, National Contact Points and national healthcare providers to facilitate the timely identification and referral of

eligible patients, support cross-border participation in clinical trials where appropriate, and improve access to advanced therapies through established pathways for planned cross-border healthcare, without prejudice to Member States' responsibilities for the organisation, financing and delivery of health services and medical care.

Or. en

Amendment 1497
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Article 6 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Centres of excellence for advanced therapies may take the form of a network of organisations established in one or more Member States. The conditions set out in paragraph 2 may be fulfilled jointly by the entities forming such a network.

Or. en

Amendment 1498
Ruggero Razza

Proposal for a regulation
Article 6 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The centres of excellence shall also promote coordinated activities for the purposes of technology transfer, the management of intellectual property and support to help patent innovations in the field of advanced therapies.

Or. it

Amendment 1499
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 6 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. The centres referred to in paragraph 1 shall fulfil ***all*** of the following conditions:	2. The centres referred to in paragraph 1 shall ***support the Union-wide development of advanced therapies and shall*** fulfil ***four*** of the following conditions:

Or. en

Amendment 1500
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 6 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. The centres referred to in paragraph 1 shall fulfil all of the following conditions:	2. The centres referred to in paragraph 1 ***shall support the Union-wide development of advanced therapies and*** shall fulfil all of the following conditions:

Or. en

Amendment 1501
Kristoffer Storm

Proposal for a regulation
Article 6 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. The centres referred to in paragraph 1 shall fulfil ***all*** of the following	2. The centres referred to in paragraph 1 shall fulfil ***condition (c) and at least four***

conditions:	of the following conditions:

Or. en

Amendment 1502
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 6 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. The centres referred to in paragraph 1 shall fulfil ***all*** of the following conditions:	2. The centres referred to in paragraph 1 shall fulfil ***condition (c) and at least four*** of the following conditions:

Or. en

Amendment 1503
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 6 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. The ***centres*** referred to in paragraph 1 shall fulfil all of the following conditions:	2. The ***networks*** referred to in paragraph 1 shall fulfil all of the following conditions:

Or. en

Amendment 1504
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 6 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) specialise in at least one advanced	(a) specialise in at least one ***innovative***

therapy, such as cell and gene therapies;	***or*** advanced therapy, such as cell and gene therapies ***or in at least one rare or life-threatening disease or seriously debilitating disease, including rare cancers and paediatric conditions***;

Or. en

Amendment 1505
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 6 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) specialise in at least one advanced therapy, such as cell ***and*** gene therapies;	(a) specialise in at least one ***modality of*** advanced therapy, such as cell ***or*** gene therapies ***as defined by Regulation (EC) No 1394/2007***;

Or. en

Amendment 1506
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 6 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) specialise in at least one advanced therapy, such as cell ***and*** gene therapies;	(a) specialise in at least one ***modality of*** advanced therapy, such as cell ***or*** gene therapies;

Or. en

Amendment 1507
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 6 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) provide ***or*** coordinate advanced infrastructures including downstream processing, delivery models ***and*** the manufacturing of therapies referred to in point (a);	(b) provide***,*** coordinate ***or facilitate access to*** advanced infrastructures ***for product development, process development, manufacturing and distribution*** including downstream processing, delivery models ***or*** the manufacturing of therapies referred to in point (a)***, including by making such manufacturing infrastructure accessible to other developers of advanced therapies, subject to appropriate safeguards for the protection of intellectual property and confidential business information***;

Or. en

Amendment 1508
Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 6 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) provide or coordinate advanced infrastructures including downstream processing, delivery models and the manufacturing of therapies referred to in point (a);	(b) ***for innovative and/or advanced therapies*** provide or coordinate ***state of the art*** advanced infrastructures***,*** including downstream processing, delivery models and the manufacturing of ***innovative or advanced*** therapies referred to in point (a); ***including by making such manufacturing infrastructure accessible to other developers of innovative or advanced therapies, subject to appropriate safeguards for the protection of intellectual property and confidential business information;***

Or. en

Amendment 1509
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 6 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) provide ***or*** coordinate advanced infrastructures including downstream processing, delivery models and the manufacturing of therapies referred to in point (a);	(b) ***(b)*** provide***,*** coordinate ***or facilitate access to*** advanced infrastructures ***for product development, process development, manufacturing and distribution,*** including downstream processing, delivery models and the manufacturing of therapies referred to in point (a);

Or. en

Amendment 1510
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 6 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) provide or coordinate advanced infrastructures including downstream processing, delivery models and the manufacturing of therapies referred to in point (a);	(b) ***for innovative or advanced therapies*** provide or coordinate advanced infrastructures including downstream processing, delivery models and the manufacturing of therapies referred to in point (a);

Or. en

Amendment 1511
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 6 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) integrate quality, regulatory science, and safety testing functions supporting Union-wide development of	(c) integrate quality, regulatory science, and safety testing functions***, as well as long-term patient monitoring,***

advanced therapies;	***pharmacovigilance and registry-based evidence generation where appropriate,*** supporting Union-wide development of advanced therapies;

Or. en

Amendment 1512
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 6 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) integrate quality, regulatory science, and safety testing functions supporting Union-wide development of advanced therapies;	(c) integrate quality, regulatory science, and safety testing functions***, prioritising the use of NAMs,*** supporting Union-wide development of advanced therapies;

Or. en

Justification

Amendment drafted with the Eurogroup for Animals

Amendment 1513
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 6 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) integrate quality, regulatory science, and safety testing functions supporting Union-wide development of advanced therapies;	(c) integrate quality, regulatory science, and safety testing functions supporting Union-wide development of advanced ***and/or innovative*** therapies;

Or. en

Amendment 1514
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 6 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) integrate quality, regulatory science, and safety testing functions ***supporting Union-wide development of advanced therapies***;	(c) integrate quality ***assurance, quality control, analytical capacity, pre-clinical efficacy***, regulatory science, and safety testing functions;

Or. en

Amendment 1515
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 6 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) integrate quality, regulatory science, and safety testing functions ***supporting Union-wide development of advanced therapies;***	(c) integrate quality ***assurance, quality control, analytical capacity, pre-clinical efficacy***, regulatory science, and safety testing functions

Or. en

Amendment 1516
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 6 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) establish structured cooperation among clinical centres, research organisations, industrial developers of biotechnology products, investors ***and*** regulators***;***	(d) ***These Centres of Excellence shall*** establish structured cooperation among ***public institutions, university hospitals, academic medical centres, their cross-border networks,*** clinical centres, research organisations, industrial developers of biotechnology products, investors***,***

regulators***, European Reference Networks where appropriate, joint ventures, public-private partnerships and other deeply integrated partnerships, while maintaining the core objective of reducing fragmentation, avoiding duplication and establishing globally competitive European centres for health biotechnology and advanced therapies.***

Or. en

Amendment 1517
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 6 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) establish structured cooperation among clinical centres, research organisations, industrial developers of biotechnology products, ***investors and*** regulators;	(d) establish structured cooperation among clinical centres, research organisations, ***European Reference Networks established pursuant to Article 12 of Directive 2011/24/EU,*** industrial developers of biotechnology products, ***relevant financing partners,*** regulators***, health technology assessment bodies, payers and patient organisations***;

Or. en

Amendment 1518
Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 6 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) establish structured cooperation among clinical centres, research organisations, industrial developers of biotechnology products, investors and regulators***;***	(d) establish structured cooperation among clinical centres, research organisations, industrial developers of biotechnology products, investors***, patient representatives*** and regulators ***and, where***

relevant, European Reference Networks.

Or. en

Amendment 1519
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 6 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) establish structured cooperation among clinical centres, research organisations, industrial developers of biotechnology products, investors and regulators;	(d) establish structured cooperation among clinical centres, research organisations, industrial developers of biotechnology products, investors***, health technology assessment bodies, patient organisation*** and regulators;

Or. en

Amendment 1520
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 6 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) establish structured cooperation among clinical centres, research organisations, industrial developers of biotechnology products, investors and regulators;	(d) establish structured cooperation among clinical centres, research organisations, ***healthcare professionals involved in the preparation and administration of advanced therapies,*** industrial developers of biotechnology products, investors and regulators;

Or. en

Amendment 1521
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 6 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) establish structured cooperation among clinical centres, research organisations, industrial developers of biotechnology products, investors and regulators;	(d) establish structured cooperation among clinical centres, research organisations, industrial developers of biotechnology products, investors and regulators***, health technology assessment (HTA) bodies, payers and patient organisations***;

Or. en

Amendment 1522
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 6 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) establish structured cooperation among clinical centres, research organisations, industrial developers of biotechnology products, investors and regulators;	(d) establish structured cooperation among clinical centres, research organisations, industrial developers of biotechnology products, investors and regulators***, health technology assessment bodies, payers and patient organisations***;

Or. en

Amendment 1523
Aurelijus Veryga

Proposal for a regulation
Article 6 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) establish structured cooperation among clinical centres, research organisations, industrial developers of biotechnology products, investors and regulators;	(d) establish structured cooperation among clinical centres, research organisations, industrial developers of biotechnology products, investors***, health technology assessment bodies, patient***

organisation and regulators;

Or. en

Amendment 1524
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 6 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) establish structured cooperation among clinical centres, research organisations, industrial developers of biotechnology products, investors and regulators;	(d) establish structured cooperation among clinical centres, research organisations, industrial developers of biotechnology products, investors***, patient representatives*** and regulators;

Or. en

Amendment 1525
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 6 – paragraph 2 – point e – introductory part

Text proposed by the Commission	*Amendment*
(e) provide multiple services enabling the transition of advanced therapies from laboratory research to commercial manufacturing, including:	(e) provide multiple services enabling the transition of advanced therapies from laboratory research to ***clinical development, industrial validation and*** commercial manufacturing, including ***such as***:

Or. en

Amendment 1526
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 6 – paragraph 2 – point e – introductory part

Text proposed by the Commission	*Amendment*
(e) provide multiple services enabling the transition of advanced therapies from laboratory research to ***commercial*** manufacturing, including:	(e) provide multiple services enabling the transition of advanced therapies from laboratory research to ***clinical development,*** manufacturing, ***regulatory assessment and patient access,*** including:

Or. en

Amendment 1527
Aurelijus Veryga

Proposal for a regulation
Article 6 – paragraph 2 – point e – introductory part

Text proposed by the Commission	*Amendment*
(e) provide multiple services enabling the transition of advanced therapies from laboratory research to commercial manufacturing, including:	(e) provide multiple services enabling the transition of advanced therapies from laboratory research to ***clinical development, industrial validation and*** commercial manufacturing, including:

Or. en

Amendment 1528
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 6 – paragraph 2 – point e – introductory part

Text proposed by the Commission	*Amendment*
(e) provide multiple services enabling the transition of advanced therapies from laboratory research to commercial manufacturing, including:	(e) provide multiple services enabling the transition of ***innovative and/or*** advanced therapies from laboratory research ***through clinical research*** to commercial manufacturing, including:

Or. en

Amendment 1529
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 6 – paragraph 2 – point e – introductory part

Text proposed by the Commission	*Amendment*
(e) provide multiple services enabling the ***transition*** of advanced therapies from laboratory research to commercial manufacturing, including:	(e) provide multiple services enabling the ***translation*** of advanced therapies from laboratory research to commercial manufacturing, including ***one of the following***:

Or. en

Amendment 1530
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 6 – paragraph 2 – point e – introductory part

Text proposed by the Commission	*Amendment*
(e) provide multiple services enabling the transition of advanced therapies from laboratory research to commercial manufacturing, ***including***:	(e) provide multiple services enabling the transition of advanced therapies from laboratory research to commercial manufacturing, ***such as***:

Or. en

Amendment 1531
Kristoffer Storm

Proposal for a regulation
Article 6 – paragraph 2 – point e – introductory part

Text proposed by the Commission	*Amendment*
(e) provide multiple services enabling the transition of advanced therapies from	(e) provide multiple services enabling the transition of advanced therapies from

laboratory research to commercial manufacturing, ***including***:	laboratory research to commercial manufacturing, ***such as***:

Or. en

Amendment 1532
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 6 – paragraph 2 – point e – point i

Text proposed by the Commission	*Amendment*
(i) provide acceleration programmes to transform innovative ideas into viable business propositions;	(i) provide acceleration programmes to transform innovative ideas into viable ***development and*** business propositions***, including regulatory, manufacturing and market access strategies***;

Or. en

Amendment 1533
Aurelijus Veryga

Proposal for a regulation
Article 6 – paragraph 2 – point e – point i

Text proposed by the Commission	*Amendment*
(i) provide acceleration programmes to transform innovative ideas into viable business propositions;	(i) provide acceleration programmes to transform innovative ideas into viable ***development and*** business propositions***, including regulatory, manufacturing and market access strategies***;

Or. en

Amendment 1534
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 6 – paragraph 2 – point e – point ii

Text proposed by the Commission	*Amendment*
(ii) provide incubation programmes assisting early-stage companies requiring GMP infrastructure, technical and regulatory expertise;	(ii) provide incubation programmes assisting early-stage companies***, SMEs, SMCs and biopharmaceutical mid-caps,*** requiring GMP infrastructure, technical and regulatory expertise;

Or. en

Amendment 1535
Aurelijus Veryga

Proposal for a regulation
Article 6 – paragraph 2 – point e – point ii

Text proposed by the Commission	*Amendment*
(ii) provide incubation programmes assisting early-stage companies requiring GMP infrastructure, technical and regulatory expertise;	(ii) provide incubation programmes assisting early-stage companies***, SMEs, SMCs and biopharmaceutical mid-caps*** requiring GMP infrastructure, technical and regulatory expertise;

Or. en

Amendment 1536
Ruggero Razza

Proposal for a regulation
Article 6 – paragraph 2 – point e – point ii

Text proposed by the Commission	*Amendment*
(ii) provide incubation programmes assisting early-stage companies requiring GMP infrastructure, technical and regulatory expertise;	(ii) provide incubation programmes assisting early-stage companies requiring GMP infrastructure, technical***, patent-related*** and regulatory expertise;

Or. it

Amendment 1537

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

Proposal for a regulation
Article 6 – paragraph 2 – point e – point iv

Text proposed by the Commission	*Amendment*
(iv) ensure access to clinical and hospital settings, including for paediatric patients, for testing, clinical validation, and feedback;	(iv) ensure access to clinical and hospital settings***, cross-border access including for clinical trials for patients***, including for paediatric patients, for testing, clinical validation, and feedback;

Or. en

Amendment 1538
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 6 – paragraph 2 – point e – point iv

Text proposed by the Commission	*Amendment*
(iv) ensure access to clinical and hospital settings, including for paediatric patients, for testing, clinical validation, ***and*** feedback;	(iv) ensure access to clinical and hospital settings, including for paediatric patients, for testing, clinical validation, ***safety*** feedback ***and the generation of registry and real-world evidence***;

Or. en

Amendment 1539
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 6 – paragraph 2 – point e – point iv

Text proposed by the Commission	*Amendment*
(iv) ensure access to clinical and hospital settings, including for paediatric patients, for testing, clinical validation, ***and*** feedback;	(iv) ensure access to clinical and hospital settings, including for paediatric patients, for testing, clinical validation, ***safety*** feedback ***and the generation of registry and real-world evidence***;

Or. en

Amendment 1540
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 6 – paragraph 2 – point e – point v

Text proposed by the Commission	*Amendment*
(v) provide education and training for researchers, clinicians, ***and*** developers; and	(v) provide education and training for researchers, clinicians, developers ***as well as for hospital pharmacists and other healthcare professionals involved in the preparation, handling and administration of advanced therapies***; and

Or. en

Amendment 1541
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 6 – paragraph 2 – point e – point v

Text proposed by the Commission	*Amendment*
(v) provide education and training for researchers, clinicians, and developers; and	(v) provide education and training for researchers, clinicians, ***nurses, pharmacists, laboratory specialists, regulatory experts, HTA experts*** and developers ***involved in advanced therapies***; and

Or. en

Amendment 1542
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 6 – paragraph 2 – point e – point v

Text proposed by the Commission	*Amendment*
(v) provide education and training for researchers, clinicians, and developers; and	(v) provide ***high quality working conditions and*** education and training for researchers, clinicians, and developers; and

Or. en

Amendment 1543
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 6 – paragraph 2 – point e – point vi

Text proposed by the Commission	*Amendment*
(vi) ensure the possibility of cross-border access ***to*** users from any Member State.	(vi) ensure the possibility of cross-border access ***for*** users***, including researchers, developers, healthcare professionals and, where appropriate, patients,*** from any Member State ***to the services of the centre of excellence, in accordance with applicable Union and national law***.

Or. en

Amendment 1544
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 6 – paragraph 2 – point e – point vi

Text proposed by the Commission	*Amendment*
(vi) ensure ***the possibility of*** cross-border ***access to*** users from any Member State***.***	(vi) ensure ***and facilitate timely access to authorised innovative and personalised therapies for rare diseases, through clear and simplified*** cross-border ***diagnosis and treatment pathways for*** users***,*** from any Member State***, to the services of the centre of excellence;***

Or. en

Amendment 1545
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 6 – paragraph 2 – point e – point vi

Text proposed by the Commission	*Amendment*
(vi) ensure the possibility of cross-border access to users from any Member State.	(vi) ensure the possibility of cross-border access to users***, including patients,*** from any Member State ***and EU accession countries***.

Or. en

Amendment 1546
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 6 – paragraph 2 – point e – point vi a (new)

Text proposed by the Commission	*Amendment*
	(via) support long-term patient follow-up and regulatory-grade real-world evidence generation;

Or. en

Amendment 1547
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 6 – paragraph 2 – point e – point vi a (new)

Text proposed by the Commission	*Amendment*
	(via) support long-term patient follow-up and regulatory-grade real-world

evidence generation;

Or. en

Amendment 1548
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, Tomislav Sokol

Proposal for a regulation
Article 6 – paragraph 2 – point e – point vi b (new)

Text proposed by the Commission	*Amendment*
	(vib) support interoperable data infrastructures aligned with the European Health Data Space;

Or. en

Amendment 1549
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 6 – paragraph 2 – point e – point vi b (new)

Text proposed by the Commission	*Amendment*
	(vib) support interoperable data infrastructures aligned with the European Health Data Space;

Or. en

Amendment 1550
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, Tomislav Sokol

Proposal for a regulation
Article 6 – paragraph 2 – point e – point vi b (new)

Text proposed by the Commission	*Amendment*
	(vib) support multinational investigator-initiated clinical trials;

Or. en

Amendment 1551
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 6 – paragraph 2 – point e – point vi c (new)

Text proposed by the Commission	*Amendment*
	(vic) support multinational investigator-initiated clinical trials;

Or. en

Amendment 1552
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 6 – paragraph 2 – point e – point vi d (new)

Text proposed by the Commission	*Amendment*
	(vid) introduce a platform-based regulatory approach; or

Or. en

Amendment 1553
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, Tomislav Sokol

Proposal for a regulation
Article 6 – paragraph 2 – point e – point vi e (new)

Text proposed by the Commission	*Amendment*
	(vie) facilitate timely access to authorised innovative and personalised therapies for rare diseases, through clear and simplified cross-border healthcare pathways.

Or. en

Amendment 1554
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 6 – paragraph 2 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) establish connection between Centres of Excellence with European ERNs and other cross-border health networks, and leverage them for the development of innovative and advanced therapies, particularly in rare and life-threatening diseases requiring highly specialized expertise and infrastructure.

Or. en

Amendment 1555
Peter Agius

Proposal for a regulation
Article 6 – paragraph 2 – point e a (new)

Text proposed by the Commission	*Amendment*

(ea) Provide non-discriminatory access to subjects from all Member States to clinical trials across the EU, though active cross border recruitment processes by the sponsor.

Or. en

Amendment 1556
Michele Picaro, Aurelijus Veryga, Kristoffer Storm

Proposal for a regulation
Article 6 – paragraph 2 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) the proposed capabilities are not adequately available through existing private or public facilities in close geographical proximity;

Or. en

Amendment 1557
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 6 – paragraph 2 – point e b (new)

Text proposed by the Commission	*Amendment*
	(eb) leverage EU data and research infrastructures, including the European Health Data Space and ERNs), to generate real-world data and real-world evidence in a structured, consistent and timely manner. This would require:
	(i) EU-level oversight and governance
	(ii) Adequate and sustainable public funding for ERNs
	(iii) Alignment of methodologies to ensure fit-for-purpose data generation

(iv) expanding, consolidating and integrating disease registries established under ERNs into the EHDS, ensuring their interoperability and systematic use across Member States.

(v) Advancing the acceptance of real-world evidence for regulatory decision-making.

Or. en

Amendment 1558
Peter Agius

Proposal for a regulation
Article 6 – paragraph 2 – point e b (new)

Text proposed by the Commission	*Amendment*
	(eb) Provide equal and not discriminatory access to insured persons across the European Union to any treatments to patients provided within these centres.

Or. en

Amendment 1559
Michele Picaro, Aurelijus Veryga, Kristoffer Storm

Proposal for a regulation
Article 6 – paragraph 2 – point e b (new)

Text proposed by the Commission	*Amendment*
	(eb) representation from the health industry sector in the governance bodies;

Or. en

Amendment 1560
Aurelijus Veryga

Proposal for a regulation
Article 6 – paragraph 2 – point e c (new)

Text proposed by the Commission	*Amendment*
	(ec) operate in compliance with:
	i. Union regulatory requirements applicable to ATMPs pursuant to Regulation (EC) No 1394/2007;
	ii. recognised Good Manufacturing Practice frameworks for ATMPs
	iii. where activities are undertaken pursuant to derogation or exceptional schemes, the requirements set out in Regulation (EC) No 1394/2007 and Article 2 of [please insert revised Directive 2001/83/EC].

Or. en

Amendment 1561
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 6 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. A centre of excellence for advanced therapies referred to in paragraph 1 may consist of a network of hospitals, including university hospitals, and affiliated clinical sites administering authorised advanced therapy medicinal products to patients. Points (i), (ii) (iii) of paragraph 2(e) shall not apply to centres designated in accordance with this paragraph. The fulfilment of the remaining conditions set out in paragraph 2 shall be assessed at the level of the network as a whole. A centre of excellence under this paragraph shall maintain a patient registry designated under Article 6a.

Or. en

Justification

The Commission proposal's Article 6 is designed for innovation-translation hubs, not for clinical treatment settings. Many ATMP-specialised treatment centres cannot necessarily meet the current cumulative conditions (e.g., acceleration/incubation programmes). Yet, these centres are the most directly linked to patient access and therefore key to solving the "patient volume and data volume" problems in ATMP development. Without an explicit second type of centre, the framework fails to incentivise the full ATMP value chain. This amendment creates two complementary, non-exclusive types: (1) innovation-translation centres (existing Article 6(2)) and (2) clinical-network centres (new Article 6(2a)).

Amendment 1562
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 6 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The centres referred to in paragraph 1 shall include structured and continuous regulatory science engagement, including through embedded regulatory support and expertise involving the European Medicines Agency, national competent authorities or designated regulatory bodies, in order to facilitate early dialogue, upstream regulatory learning and faster convergence of scientific, clinical and regulatory requirements, and the translation of research outcomes into clinical development and clinical application, without affecting the independence of regulatory decision-making.

Or. en

Amendment 1563
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 6 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The centres referred to in paragraph 1 shall include structured and continuous regulatory science engagement, including through embedded regulatory support and expertise involving the European Medicines Agency, national competent authorities or designated regulatory bodies, in order to facilitate early dialogue, upstream regulatory learning and faster convergence of scientific, clinical and regulatory requirements, without affecting the independence of regulatory decision-making.

Or. en

Amendment 1564
Aurelijus Veryga

Proposal for a regulation
Article 6 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The centres referred to in paragraph 1 shall include structured and continuous regulatory science engagement, including through embedded regulatory support and expertise involving the European Medicines Agency, national competent authorities or designated regulatory bodies, in order to facilitate early dialogue, upstream regulatory learning and faster convergence of scientific, clinical and regulatory requirements, without affecting the independence of regulatory decision-making.

Or. en

Amendment 1565
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 6 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Allowing Centres of Excellence to qualify by fulfilling at least four of the conditions in paragraph 2, rather than all of them, is essential to ensure that the framework is also suitable for industry-led initiatives. There is no requirement to consult existing facilities and infrastructure, nor is there any reference to industry involvement in governance, even in an advisory role.

Or. en

Justification

The purpose is to secure regulatory practitioners support to facilitate early dialogue, upstream regulatory learning and faster convergence of scientific, clinical and regulatory requirements, without affecting the independence of regulatory decision-making.

Amendment 1566
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 6 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Centres of excellence shall, where appropriate, contribute to the development of common outcome measures and interoperable clinical registries supporting long-term evidence generation for advanced therapies.

Or. en

Amendment 1567
Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 6 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Commission may issue guidance for the operational implementation of centres of excellence for innovative and/or advanced therapies, including for advanced therapy medicinal products.

Or. en

Amendment 1568
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 6 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. Centres of excellence for advanced therapies shall act as facilitators for the cross-border movement of patients seeking treatment with advanced therapies provided through those centres, without prejudice to the responsibilities of the Member States for the organisation, financing and delivery of health services and medical care. To that end, they shall provide patients and their referring healthcare providers with information and operational support on the legal pathways for planned cross-border healthcare under Directive 2011/24/EU and Regulation (EC) No 883/2004, in coordination with the National Contact Points established under Article 6 of that Directive.

Or. en

Amendment 1569
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 6 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. The Commission shall ensure the coordination and cooperation of the network of centres of excellence referred to in paragraph 1, either directly or through the designation of one or more centres of excellence as coordination hubs. The coordination hub or hubs shall facilitate cooperation, the exchange of knowledge, best practices and expertise among the centres, promote interoperability and complementarity of their infrastructures and services, strengthen links with relevant Union initiatives and infrastructures, pool and analyse the research data of the centres and support the coherent development of advanced therapy capabilities across the Union.

Or. en

Amendment 1570
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 6 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission ***may*** adopt implementing acts to detail the conditions listed in paragraph 2 of this Article, with a view to ensure a consistent approach in	3. The Commission ***shall*** adopt implementing acts to detail the conditions listed in paragraph 2 of this Article, with a view to ensure a consistent approach in

their implementation across the Member States. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).	their implementation across the Member States. ***The implementing acts referred to in this paragraph shall take into account the objectives of accelerating the placing on the market of advanced therapies, accelerating clinical translation, improving quality control, and facilitating patient access, including cross-border access, across the Union.*** These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

Or. en

Amendment 1571
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 6 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission may adopt implementing acts to detail the conditions listed in paragraph 2 of this Article, with a view to ensure a consistent approach in their implementation across the Member States. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).	3. The Commission may adopt implementing acts to detail the conditions listed in paragraph 2 of this Article, with a view to ensure a consistent approach in their implementation across the Member States. ***The implementing acts referred to in this paragraph shall take into account the objectives of accelerating the placing on the market of advanced therapies, accelerating clinical translation, improving quality control, and facilitating patient access across the Union.*** These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

Or. en

Justification

Article 6 responds to the translation gap that has left Europe excellent in basic ATMP research but underrepresented in late-stage development: Europe hosts around 22% of global ATMP developers but is associated with only 58 of the 154 Phase III ATMP trials ongoing globally in Q4 2025. The intent of Article 6, as reflected in recital 43, is to accelerate clinical

translation and placing on the market, improve quality control and facilitate patient access. The Commission's current drafting risks being read as requiring a single physical site fulfilling all conditions, which does not match the way advanced therapy capabilities are organised in the Union, where complementary expertise is distributed across academic hospital centres, manufacturers, companies and investors, often spanning more than one Member State. Express recognition that the conditions in paragraph 2 may be fulfilled jointly by the entities forming a network would allow complementary specialisation and prevent duplication, supporting the Union

Amendment 1572
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 6 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission ***may*** adopt implementing acts to detail the conditions listed in paragraph 2 of this Article, with a view to ensure a consistent approach in their implementation across the Member States. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).	3. The Commission ***shall*** adopt implementing acts to detail the conditions listed in paragraph 2 of this Article, with a view to ensure a consistent approach in their implementation across the Member States. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2). ***Prior to their adoption, the Commission shall conduct timely and transparent consultations with civil society organisations and shall duly take into account the input received.***

Or. en

Amendment 1573
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 6 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission ***may*** adopt implementing acts to detail the conditions listed in paragraph 2 of this Article, with a	3. The Commission ***shall*** adopt implementing acts to detail the conditions listed in paragraph 2 of this Article, with a

view to ensure a consistent approach in their implementation across the Member States. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).	view to ensure a consistent approach in their implementation across the Member States. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

Or. en

Amendment 1574
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 6 a (new)

Text proposed by the Commission	*Amendment*
	Article6a
	Patient registries for advanced therapies
	1. To enable the generation of evidence on authorised advanced therapy medicinal products (ATMPs), competent authorities shall designate patient registries that comply with the technical specifications adopted under paragraph 2 ('designated registries'). Designation may be withdrawn where the registry no longer complies with the technical specifications referred to in paragraph 2. 2. The Commission shall adopt delegated acts in accordance with Article 64(2) to supplement this Regulation by establishing the following: (a) technical requirements applicable to designated registries, including interoperability, coding systems and data governance requirements; (b) the disease- and therapy-specific minimum data elements applicable to designated registries; (c) the conditions under which designated registries shall grant the Commission and the Agency, the competent authorities of the Member States, sponsors or marketing authorisation holders of advanced therapy medicinal products and researchers access to their data. 3. Before adopting

the delegated acts referred to in paragraph 2, the Commission shall consult the Agency and the Member State Coordination Group on Health Technology Assessment ('HTACG') established pursuant to Article 3 of Regulation (EU) 2021/2282. The Agency and the HTACG may consult relevant stakeholders, including patient and consumer groups, healthcare professionals, not-for-profit entities, European Reference Networks (ERNs), and industry representatives. 4. Activities for the establishment and maintenance of designated registries shall be supported under the financial instruments referred to in Chapter III. 5. The processing of personal data under this Article shall be subject to Regulations (EU) 2016/679 and (EU) 2018/1725, as applicable.

Or. en

Justification

EU-level ATMP registries cannot be made mandatory without violating Article 168(7) TFEU (Member States' competence over health systems organisation). A voluntary, incentive-based framework avoids this legal constraint. The proposal draws on the precedent set by the EHDS Regulation (Article 78) on data quality labels for publicly funded datasets. The framework requires only voluntary participation but creates strong incentives through eligibility for Union funding. It also serves the post-authorisation regulatory needs (benefit-risk assessment) and HTA purposes (joint clinical assessments). Participation in designated registries is also linked to the new clinical-network centre designation under Article 6(2a).

Amendment 1575
Christine Anderson

Proposal for a regulation
Article 6 a (new)

Text proposed by the Commission	*Amendment*
	Article 6a
	SME and start-up proportionality
	1. Administrative requirements, fees and documentation obligations applicable to

	SMEs, start-ups, scale-ups, university spin-offs and non-commercial research organisations shall be proportionate to the size, risk profile and stage of development of the project.
	2. Member States shall, where appropriate, provide simplified guidance, pre-submission advice, reduced administrative fees or staged documentation requirements for the entities referred to in paragraph 1.
	3. Simplification under this Article shall not reduce substantive requirements relating to safety, ethics, informed consent, data protection, biosecurity or environmental protection.

Or. en

Amendment 1576
Christine Anderson

Proposal for a regulation
Article 7

Text proposed by the Commission	*Amendment*
Article 7	***deleted***
Designation of the competent authority responsible for assessing applications for recognition of health biotechnology strategic projects and high-impact health biotechnology strategic projects	
1. Member States shall designate an authority ('the designated authority') responsible for assessing applications for recognition of health biotechnology strategic projects and high impact health biotechnology strategic projects.	
2. Member States shall inform the Commission within six months from the entry into force of this Regulation of the authority designated pursuant to paragraph 1.	

Or. en

Amendment 1577
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 7 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall designate an authority ('the designated authority') responsible for assessing applications for recognition of health biotechnology strategic projects and high impact health biotechnology strategic projects.	1. Member States shall designate an authority ('the designated authority') responsible for assessing applications for recognition of health biotechnology strategic projects and high impact health biotechnology strategic projects. ***The designated authority shall be able to assess all the selection criteria, particularly those related to compliance with ethical, environmental and social standards.***

Or. en

Amendment 1578
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 7 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall designate an authority ('the designated authority') responsible for assessing applications for recognition of health biotechnology strategic projects and high impact health biotechnology strategic projects.	1. Member States shall designate an authority ('the designated authority') responsible for assessing applications for recognition of health biotechnology strategic projects and high impact health biotechnology strategic projects. ***The designated authority shall have a primary mandate oriented towards the protection of public health.***

Or. en

Amendment 1579
Ruggero Razza

Proposal for a regulation
Article 7 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall designate an authority ('the designated authority') responsible for assessing applications for recognition of health biotechnology strategic projects and high impact health biotechnology strategic projects.	1. Member States shall designate an authority ('the designated authority') ***with the requisite technical and scientific expertise which shall be*** responsible for assessing applications for recognition of health biotechnology strategic projects and high impact health biotechnology strategic projects.

Or. it

Amendment 1580
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 7 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Member States shall establish clear, coordinated and predictable administrative arrangements, including a Single Point of Contact capable of coordinating permitting, environmental, planning and health-related procedures across competent authorities.

Or. en

Amendment 1581
Aurelijus Veryga

Proposal for a regulation
Article 7 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Member States shall establish clear, coordinated and predictable administrative arrangements, including a Single Point of Contact capable of coordinating permitting, environmental, planning and health-related procedures across competent authorities.

Or. en

Amendment 1582
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 7 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. A Member State may designate more than one authority and shall provide the resources necessary for the successful conclusion of the procedure, in particular through involvement of staff with expertise and knowledge.

Or. en

Amendment 1583
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 7 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall inform the Commission within ***six*** months from the entry into force of this Regulation of the authority designated pursuant to paragraph 1.	2. Member States shall inform the Commission within ***three*** months from the entry into force of this Regulation of the authority designated pursuant to paragraph 1.

Or. en

Amendment 1584
Ruggero Razza

Proposal for a regulation
Article 7 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The designated authorities shall cooperate with the intellectual property offices of the Member States and the relevant Union bodies with a view to safeguarding and making best use of research findings.

Or. it

Amendment 1585
Christine Anderson

Proposal for a regulation
Article 7 a (new)

Text proposed by the Commission	*Amendment*
	Article 7a
	Mutual recognition and reuse of existing assessments
	1. Competent authorities shall recognise, or where appropriate rely on, studies, assessments, inspections, permits, authorisations, certificates or opinions already carried out or issued by a competent authority in another Member State for the same project, product, process, facility, activity or component, where those studies, assessments, inspections, permits, authorisations, certificates or opinions remain valid, applicable and up to date.
	2. Competent authorities shall not require the resubmission, repetition or duplication of studies, assessments, inspections or documentation solely on the ground that

they were carried out or issued in another Member State.

3. Paragraphs 1 and 2 shall not prevent a competent authority from carrying out an additional assessment where this is necessary and proportionate due to:

(a) material differences in the project, product, process, facility, activity or component concerned;

(b) site-specific environmental, planning, biosafety or public-health conditions;

(c) new scientific evidence or a substantiated safety, biosecurity, ethical or data-protection concern;

(d) the expiry, suspension or withdrawal of the relevant study, assessment, inspection, permit, authorisation, certificate or opinion; or

(e) requirements laid down in Union law or in national law in areas not harmonised by Union law.

4. Where a competent authority refuses to recognise or rely on a study, assessment, inspection, permit, authorisation, certificate or opinion referred to in paragraph 1, it shall provide a written, reasoned explanation identifying the specific deficiencies, material differences or risks justifying that refusal.

5. Member States shall ensure that project promoters have access to effective administrative or judicial remedies against a refusal referred to in paragraph 4.

Or. en

Amendment 1586
Christine Anderson

Proposal for a regulation
Article 8

Text proposed by the Commission	*Amendment*
Article 8	***deleted***
Application for recognition of a health biotechnology strategic projects or a high impact health biotechnology strategic project	
1. An application for the recognition of a project as a health biotechnology strategic project or as a high impact health biotechnology strategic project shall be submitted by the project promoter to the designated authority referred to in Article 7 of a Member State on whose territory the project is located.	
2. The application referred to in paragraph 1 of this Article shall contain the relevant evidence related to the fulfilment of the conditions laid down in Article 3 as regards health biotechnology strategic projects or in Article 4, as regards high impact health biotechnology strategic projects.	

Or. en

Amendment 1587
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission	*Amendment*
1. An application for the recognition of a project as a health biotechnology strategic project or as a high impact health biotechnology strategic project shall be submitted by the project promoter to the designated authority referred to in Article 7 of a Member State on whose territory the project is located.	1. An application for the recognition of a project as a health biotechnology strategic project or as a high impact health biotechnology strategic project shall be submitted by the project promoter to the designated authority referred to in Article 7 of a Member State on whose territory the project is located. ***Member States shall facilitate electronic submission portals.***

Or. en

Amendment 1588
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 8 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The application referred to in paragraph 1 of this Article shall contain the relevant evidence related to the fulfilment of the conditions laid down in Article 3 as regards health biotechnology strategic projects or in Article 4, as regards high impact health biotechnology strategic projects.	2. The application referred to in paragraph 1 of this Article shall contain the relevant evidence related to the fulfilment of the conditions laid down in Article 3 as regards health biotechnology strategic projects or in Article 4, as regards high impact health biotechnology strategic projects. ***Member States shall ensure that the designated authority specifies in advance, in a clear and publicly accessible manner, the documentation and information required to demonstrate compliance with those conditions. Requests for additional information shall be limited to what is necessary and proportionate for the assessment of the application.***

Or. en

Amendment 1589
Kateřina Konečná

Proposal for a regulation
Article 8 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The application referred to in paragraph 1 of this Article shall contain the relevant evidence related to the fulfilment of the conditions laid down in Article 3 as regards health biotechnology strategic projects or in Article 4, as regards high impact health biotechnology strategic projects.	2. The application referred to in paragraph 1 of this Article shall contain the relevant evidence related to the fulfilment of the conditions laid down in Article 3 as regards health biotechnology strategic projects or in Article 4, as regards high impact health biotechnology strategic projects***, in accordance with a standardised format and a common list of***

supporting documentation**. **The Commission shall adopt that format and list by means of implementing acts, after consulting the Steering Group referred to in Article 20.

Or. en

Amendment 1590
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 8 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The application referred to in paragraph 1 of this Article shall contain the relevant evidence related to the fulfilment of the conditions laid down in Article 3 as regards health biotechnology strategic projects or in Article 4, as regards high impact health biotechnology strategic projects.	2. The application referred to in paragraph 1 of this Article shall contain the relevant evidence related to the fulfilment of the conditions laid down in Article 3 as regards health biotechnology strategic projects or in Article 4, as regards high impact health biotechnology strategic projects. ***The Commission shall, by means of implementing acts, establish a common application format and minimum evidentiary requirements for the purposes of this paragraph, to ensure consistent application across Member States.***

Or. en

Amendment 1591
Peter Agius

Proposal for a regulation
Article 8 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The application referred to in paragraph 1 of this Article shall contain the relevant evidence related to the fulfilment of the conditions laid down in Article 3 as	2. The application referred to in paragraph 1 of this Article shall contain the relevant evidence related to the fulfilment of the conditions laid down in Article 3 as

regards health biotechnology strategic projects or in Article 4, as regards high impact health biotechnology strategic projects.	regards health biotechnology strategic projects or in Article 4, as regards high impact health biotechnology strategic projects***, in accordance with a standardised format and a common list of supporting documentation***. ***The Commission shall adopt that format and list by means of implementing acts, after consulting the Steering Group referred to in Article 20.***

Or. en

Amendment 1592
Michalis Hadjipantela

Proposal for a regulation
Article 8 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The application referred to in paragraph 1 of this Article shall contain the relevant evidence related to the fulfilment of the conditions laid down in Article 3 as regards health biotechnology strategic projects or in Article 4, as regards high impact health biotechnology strategic projects.	2. The application referred to in paragraph 1 of this Article shall contain the relevant evidence related to the fulfilment of the conditions laid down in Article 3 as regards health biotechnology strategic projects or in Article 4, as regards high impact health biotechnology strategic projects***, in accordance with a standardised format and a common list of supporting documentation***. ***The Commission shall adopt that format and list by means of implementing acts, after consulting the Steering Group referred to in Article 20.***

Or. en

Amendment 1593
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 8 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The application referred to in paragraph 1 of this Article shall contain the relevant evidence related to the fulfilment of the conditions laid down in Article 3 as regards health biotechnology strategic projects or in Article 4, as regards high impact health biotechnology strategic projects.	2. The application referred to in paragraph 1 of this Article shall contain the relevant evidence related to the fulfilment of the conditions laid down in Article 3 as regards health biotechnology strategic projects or in Article 4, as regards high impact health biotechnology strategic projects***, in accordance with a standardised format and a common list of supporting documentation***. ***The Commission shall adopt that format and list by means of implementing acts, after consulting the Steering Group referred to in Article 20.***

Or. en

Justification

Article 8 establishes a national application route for the recognition of health biotechnology strategic projects, with designated authorities in each Member State receiving and forwarding applications. In the absence of a standardised application format and a common list of supporting documentation, project promoters operating across multiple Member States, in particular SMEs and academic-led consortia, will face divergent national requirements and the assessment processes under Articles 9 and 10 will rest on heterogeneous evidence bases. This amendment introduces, through a Commission implementing act adopted after consultation of the Steering Group, the procedural harmonisation that the single-market and selective-recognition rationale of the Regulation requires. The substantive conditions for recognition, governed by Articles 3 and 4, are not affected. The consultation of the Steering Group, which under Amendment 6 includes representatives of patient organisations and healthcare-professional associations, ensures that the format and documentation requirements give appropriate weight to evidence relevant to the patient criterion in Article 3(1), point (b).

Amendment 1594
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 8 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The application referred to in paragraph 1 of this Article shall contain the relevant evidence related to the fulfilment	2. The application referred to in paragraph 1 of this Article shall contain ***a justification and*** the relevant evidence

of the conditions laid down in Article 3 as regards health biotechnology strategic projects or in Article 4, as regards high impact health biotechnology strategic projects.	related to the fulfilment of the conditions laid down in Article 3 as regards health biotechnology strategic projects or in Article 4, as regards high impact health biotechnology strategic projects.

Or. en

Amendment 1595
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 8 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Notwithstanding paragraph 1, project promoters, especially SMEs, SMCs or start-ups, may request competent authorities an indicative, non-binding pre-evaluation as to whether a proposed initiative is likely to qualify as a high-impact strategic project under this Regulation. The pre-evaluation shall not prejudge any formal designation decision.

Or. en

Amendment 1596
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 8 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Commission shall, by implementing acts, set a common application format and minimum evidence requirements under this paragraph to ensure uniform application across Member States.

Or. en

Amendment 1597
Christine Anderson

Proposal for a regulation
Article 8 a (new)

Text proposed by the Commission	*Amendment*
	Article 8a
	Digital-by-default procedures
	1. Member States shall ensure that documents relevant to procedures under this Chapter may be submitted electronically.
	2. Member States shall work towards interoperable electronic procedures, single submission channels and digital tracking of administrative deadlines.
	3. Digital procedures shall not undermine access to effective remedies, confidentiality, trade secrets, cybersecurity or data protection.

Or. en

Amendment 1598
Christine Anderson

Proposal for a regulation
Article 9

Text proposed by the Commission	*Amendment*
Article 9	***deleted***
Recognition by Member States of health biotechnology strategic projects	
1. The designated authority shall assess the application for the recognition of a project as a health biotechnology strategic project within one month of the receipt of the complete application and	

communicate a reasoned decision to the project promoter. The assessment process shall be fair and transparent.

2. Where the designated authority concludes that the project fulfils the conditions of Article 3, it shall recognise the project as a health biotechnology strategic project.

3. Member States shall ensure that applicants have easy access to information on procedures for the settlement of disputes concerning the recognition process, including, where applicable, alternative dispute resolution mechanisms provided for by national law.

4. Where a project is located on the territory of two or more Member States, the decision recognising the project as a biotechnology strategic project issued by the designated authority of a Member State shall be recognised by the designated authorities of other Member States.

Or. en

Amendment 1599
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 9 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The designated authority shall assess the application for the recognition of a project as a health biotechnology strategic project within one month of the receipt of the complete application and communicate a reasoned decision to the project promoter. The assessment process shall be fair and transparent.	1. The designated authority shall assess the application for the recognition of a project as a health biotechnology strategic project within one month of the receipt of the complete application and communicate a reasoned decision to the project promoter. The assessment process shall be fair and transparent. ***The designated authority shall notify the project promoter within ten working days of receipt whether the application is***

complete. For the purposes of this Article, an application shall be considered complete where it contains all the information required pursuant to Article 8(2). The designated authority shall not request information beyond the scope of a first request for completeness.

Or. en

Justification

The one-month assessment deadline is useful, but without a completeness definition and a cap on information requests, the clock's starting point is vulnerable to stop-the-clock manipulation through successive requests.

The ten working day notification and definition of completeness by reference to Art. 8(2) remove this ambiguity. The prohibition on expanding the scope of information requests mirrors Art. 12(8), creating coherence across the recognition framework.

Amendment 1600
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 9 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The designated authority shall assess the application for the recognition of a project as a health biotechnology strategic project within one month ***of*** the receipt of the complete application and communicate a reasoned decision to the project promoter. The assessment process shall be fair and transparent.	1. The designated authority shall assess the application for the recognition of a project as a health biotechnology strategic project within one month ***without undue delay and in any event no later than 20 days after*** the receipt of the complete application and communicate a reasoned decision to the project promoter. The assessment process shall be fair and transparent. ***The submission of a request for a project to be recognised as a health biotechnology strategic project does not preclude the promoter of the project from simultaneously initiating application procedures with other authorities for the permits needed for the project.***

Or. en

Amendment 1601
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 9 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The designated authority shall assess the application for the recognition of a project as a health biotechnology strategic project within one month of the receipt of the complete application and communicate a reasoned decision to the project promoter. The assessment process shall be fair and transparent.	1. The designated authority shall assess the application for the recognition of a project as a health biotechnology strategic project within one month of the receipt of the complete application and communicate a reasoned decision to the project promoter. The ***designated authority shall confirm within 15 days upon submission whether an application is complete following an initial review of the materials provided. The one-month period shall commence upon such confirmation. The*** assessment process shall be fair and transparent.

Or. en

Amendment 1602
Angelika Winzig

Proposal for a regulation
Article 9 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The designated authority shall assess the application for the recognition of a project as a health biotechnology strategic project within one month of the receipt of the complete application and communicate a reasoned decision to the project promoter. The assessment process shall be fair and transparent.	1. The designated authority shall assess the application for the recognition of a project as a health biotechnology strategic project within one month of the receipt of the complete application and communicate a reasoned decision to the project promoter. The assessment process shall be fair and transparent. ***The designated authority shall consult representatives of the relevant industry in order to assess the commercial viability and market need of each application.***

Or. en

Amendment 1603
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 9 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The designated authority shall assess the application for the recognition of a project as a health biotechnology strategic project within one month of the receipt of the complete application and communicate a reasoned decision to the project promoter. The assessment process shall be fair and transparent.	1. The designated authority shall assess the application for the recognition of a project as a health biotechnology strategic project within one month of the receipt of the complete application and communicate a reasoned decision to the project promoter. The assessment process shall be fair and transparent. ***The designated authority shall consult with industry stakeholders to assess the industrial commercial viability and market need for each application.***

Or. en

Amendment 1604
Kristoffer Storm

Proposal for a regulation
Article 9 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The designated authority shall assess the application for the recognition of a project as a health biotechnology strategic project within one month of the receipt of the complete application and communicate a reasoned decision to the project promoter. The assessment process shall be fair and transparent.	1. The designated authority shall assess the application for the recognition of a project as a health biotechnology strategic project within one month of the receipt of the complete application and communicate a reasoned decision to the project promoter. The assessment process shall be fair and transparent. ***The designated authority shall consult with industry stakeholders to assess the industrial commercial viability and market need for each application.***

Or. en

Amendment 1605
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 9 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The designated authority shall assess the application for the recognition of a project as a health biotechnology strategic project within one month of the receipt of the complete application and communicate a reasoned decision to the project promoter. The assessment process shall be fair ***and*** transparent.	1. The designated authority shall assess the application for the recognition of a project as a health biotechnology strategic project within one month of the receipt of the complete application and communicate a reasoned decision to the project promoter. The assessment process shall be fair***,*** transparent ***and shall take equally into consideration all selection criterions***.

Or. en

Amendment 1606
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 9 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The Commission shall provide a simple, accessible, and user-friendly webpage for project promoters on which at least the following elements shall be clearly listed:
	(a) the contact details and other relevant information on the tasks of Member States' designated authorities;
	(b) information on dedicated Union support for health biotechnology strategic projects; and
	(c) a standard template for the project promoter's request referred in paragraph

2 available in all official languages of the Union.

Or. en

Amendment 1607
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 9 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. The Commission shall adopt implementing acts to provide for the standard template referred to in paragraph 5, point (c), of this Article.

Or. en

Amendment 1608
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 9 – paragraph 1 c (new)

Text proposed by the Commission	*Amendment*
	1c. The Commission shall, following a consultation with relevant stakeholders, including patient and consumer organisations, healthcare professional organisations, public healthcare payers, and industry representatives, issue Union guidelines for a harmonised approach of designated authorities on the designation of heath biotechnology strategic projects.

Or. en

Amendment 1609
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where the designated authority concludes that the project fulfils the conditions of Article 3, it shall recognise the project as a health biotechnology strategic project.	2. Where the designated authority concludes that the project fulfils the conditions of Article 3, it shall recognise the project as a health biotechnology strategic project. ***Such recognition shall be formalised in writing and shall clearly indicate the scope of the project as recognised.***

Or. en

Amendment 1610
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 9 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States shall ensure that applicants have easy access to information on procedures for the settlement of disputes concerning the recognition process, including, where applicable, alternative dispute resolution mechanisms provided for by national law.	3. Member States shall ensure that applicants have easy access to information on procedures for the settlement of disputes concerning the recognition process, including, where applicable, alternative dispute resolution mechanisms provided for by national law. ***Such procedures shall be transparent and conducted within a reasonable timeframe in accordance with national law.***

Or. en

Amendment 1611
Wouter Beke

Proposal for a regulation
Article 9 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*

4a. The assessment referred to in paragraph 1 shall be conducted solely on the basis of the substantive conditions and criteria laid down in this Regulation. The geographical location of a project within the Union shall not be taken into account as a selection or prioritisation criterion. Member States shall not apply any geographical quota or target in the recognition of biotechnology strategic projects.

Or. en

Amendment 1612
Margarita de la Pisa Carrión, Paolo Borchia, Laurent Castillo, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 9 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Common methodological principles and best practices for the assessment of strategic projects should be developed in order to facilitate a consistent and transparent application of this Regulation across the Union, while fully respecting the competence of Member States in the assessment and designation of strategic projects.

Or. en

Amendment 1613
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 9 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Member States shall publish the outcome of each assessment carried out

under this Article and shall transmit the assessment outcome to the Commission for inclusion in an EU level public register to ensure transparency and facilitate consistent implementation across the Union.

Or. en

Justification

Amendment drafted by the BEUC (The European consumer organisation)

Amendment 1614
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 9 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Member States shall publish the outcome of each assessment carried out under this Article and shall transmit the assessment outcome to the Commission for inclusion in an EU-level public register to ensure transparency and facilitate consistent implementation across the Union.

Or. en

Justification

A central EU register would ensure transparent recognition decisions, greater legal certainty and more consistent implementation across the Union.

Amendment 1615
Christine Anderson

Proposal for a regulation
Article 9 a (new)

Text proposed by the Commission	*Amendment*

	Article 9a
	Time-bound administration
	1. Member States shall ensure that competent authorities handle procedures applicable to health biotechnology projects within reasonable and predictable timelines.
	2. The competent authority shall acknowledge the completeness of an application or request missing information within 30 days of receipt.
	3. Incomplete applications shall not be rejected without giving the applicant a reasonable opportunity to remedy the deficiency.
	4. The maximum duration of permit-granting procedures shall be laid down by Member States and published in advance. Extensions shall be justified in writing.

Or. en

Amendment 1616
Christine Anderson

Proposal for a regulation
Article 10

Text proposed by the Commission	*Amendment*
Article 10	***deleted***
Recognition by the Commission of high impact health biotechnology strategic projects	
1. The designated authority shall assess the application for the recognition of a project as a high impact health biotechnology strategic project within one month of the receipt of the complete application and shall communicate its assessment report to the Commission. The assessment process shall be fair and transparent.	

2. Where the designated authority concludes that the project fulfils the conditions of Article 4, the Commission shall, by means of implementing acts, adopt a decision approving or rejecting the application for recognition referred to in paragraph 1 of this Article, based on the assessment referred to in that paragraph and taking into account the views of the Steering Group referred to in Article 20.

3.

By way of derogation from Article 8 and to paragraphs 1 and 2 of this Article, a project may also be recognised as a high impact health biotechnology strategic project in the framework of calls for proposals launched under Union programmes for the purpose of identifying, selecting and funding such projects, in line with the basic acts setting up those programmes.

The Commission shall recognise a project as a high impact health biotechnology strategic project in the context of a call for proposals where it fulfils the conditions set out in Article 4(1) and the specific criteria set out in those calls, based on the evidence submitted by the applicant.

4. The Commission shall adopt implementing acts laying down the format of the assessment report referred to in paragraph 1 of this Article and the procedural rules for the recognition of high impact health biotechnology strategic projects. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

Or. en

Amendment 1617
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 10 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The designated authority shall assess the application for the recognition of a project as a high impact health biotechnology strategic project within one month of the receipt of the complete application and shall communicate its assessment report to the Commission. The assessment process shall be fair and transparent.	1. The designated authority shall assess the application for the recognition of a project as a high impact health biotechnology strategic project within one month of the receipt of the complete application and shall communicate its assessment report to the Commission. The assessment process shall be fair and transparent. ***The designated authority shall notify the project promoter within ten working days of receipt whether the application is complete. For the purposes of this Article, an application shall be considered complete where it contains all the information required pursuant to Article 8(2). The designated authority shall not request information beyond the scope of a first request for completeness.***

Or. en

Justification

Without a Commission decision deadline in Art. 10(1), promoters investing at high impact scale face open-ended uncertainty. Two months from receipt of the assessment report is proportionate and consistent with standard Commission decision-making timelines.

Amendment 1618
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 10 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The designated authority shall assess the application for the recognition of a project as a high impact health biotechnology strategic project within one month of the receipt of the complete	1. The designated authority shall assess the application for the recognition of a project as a high impact health biotechnology strategic project within one month of the receipt of the complete

application and shall communicate its assessment report to the Commission. The assessment process shall be fair and transparent.	application and shall communicate its assessment report to the Commission. The assessment process shall be fair and transparent ***and shall take equally into consideration all selection criterions***.

Or. en

Amendment 1619
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 10 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The designated authority shall assess the application for the recognition of a project as a high impact health biotechnology strategic project ***within one month of*** the receipt of the ***complete application*** and shall communicate its assessment report to the Commission. The assessment process shall be fair and transparent.	1. The designated authority shall assess the application for the recognition of a project as a high impact health biotechnology strategic project ***without undue delay and in any event no later than 20 days after*** the receipt of the ***request.*** and shall communicate its assessment report to the Commission. The assessment process shall be fair and transparent.

Or. en

Amendment 1620
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 10 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where the designated authority concludes that the project fulfils the conditions of Article 4, the Commission shall, by means of implementing acts, adopt a decision approving or rejecting the application ***for recognition*** referred to in paragraph 1 ***of this Article***, based on the assessment referred to in that paragraph	2. Where the designated authority concludes that the project fulfils the conditions of Article 4, the Commission shall, by means of implementing acts, adopt a decision approving or rejecting the application ***within two months of receipt of the assessment report*** referred to in paragraph 1, based on the assessment

and taking into account the views of the Steering Group referred to in Article 20.	referred to in that paragraph and taking into account the views of the Steering Group referred to in Article 20. ***Where a project is recognised as a high impact health biotechnology strategic project in the context of a call for proposals under Union programmes, such recognition shall be considered equivalent to recognition under the standard application route for the purposes of accessing support measures under this Regulation.***

Or. en

Justification

The call-based route equivalence clarification in the recital is necessary to avoid access gaps for promoters recognised through Union programme calls. The two-step national/Commission process is not amended.

Amendment 1621
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 10 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where the designated authority concludes that the project fulfils the conditions of Article 4, the Commission shall, by means of implementing acts, adopt a decision approving or rejecting the application ***for recognition*** referred to in paragraph 1 ***of this Article,*** based on the assessment referred to in that paragraph and taking into account the views of the Steering Group referred to in Article 20.	2. Where the designated authority concludes that the project fulfils the conditions of Article 4, the Commission shall, by means of implementing acts, adopt a decision approving or rejecting the application ***within two months of receipt of the assessment report*** referred to in paragraph 1 based on the assessment referred to in that paragraph and taking into account the views of the Steering Group referred to in Article 20.

Or. en

Justification

Call-based route equivalence is needed to prevent access gaps for promoters recognised under Union programme calls.

Amendment 1622
Kristoffer Storm

Proposal for a regulation
Article 10 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where the designated authority concludes that the project fulfils the conditions of Article 4, the Commission shall, by means of implementing acts, adopt a decision approving or rejecting the application for recognition referred to in paragraph 1 of this Article, based on the assessment referred to in that paragraph and taking into account the views of the Steering Group referred to in Article 20.	2. Where the designated authority concludes that the project fulfils the conditions of Article 4, the Commission shall***, within 3 months***, by means of implementing acts, adopt a decision approving or rejecting the application for recognition referred to in paragraph 1 of this Article, based on the assessment referred to in that paragraph and taking into account the views of the Steering Group referred to in Article 20.

Or. en

Amendment 1623
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 10 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where the designated authority concludes that the project fulfils the conditions of Article 4, the Commission shall, by means of implementing acts, adopt a decision approving or rejecting the application for recognition referred to in paragraph 1 of this Article, based on the assessment referred to in that paragraph and taking into account the views of the Steering Group referred to in Article 20.	2. Where the designated authority concludes that the project fulfils the conditions of Article 4, the Commission shall***, within 3 months***, by means of implementing acts, adopt a decision approving or rejecting the application for recognition referred to in paragraph 1 of this Article, based on the assessment referred to in that paragraph and taking into account the views of the Steering Group

referred to in Article 20.

Or. en

Amendment 1624
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 10 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Where a project is identified as a high-impact health biotechnology strategic project under a Union programme call for proposals, such recognition shall be treated as equivalent to recognition via the standard application route for access to support measures under this Regulation.

Or. en

Amendment 1625
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 10 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
By way of derogation from Article 8 and to paragraphs 1 and 2 of this Article, a project may also be recognised as a high impact health biotechnology strategic project in the framework of calls for proposals launched under Union programmes for the purpose of identifying, selecting and funding such projects, in line with the basic acts setting up those programmes.	By way of derogation from Article 8 and to paragraphs 1 and 2 of this Article, a project may also be recognised as a high impact health biotechnology strategic project in the framework of calls for proposals launched under Union programmes for the purpose of identifying, selecting and funding such projects, in line with the basic acts setting up those programmes. ***An ex-ante evaluation is conducted by the Commission before any recognition.***

Or. en

Amendment 1626
Ruggero Razza

Proposal for a regulation
Article 10 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission shall adopt implementing acts laying down the format of the assessment report referred to in paragraph 1 of this Article and the procedural rules for the recognition of high impact health biotechnology strategic projects. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).	4. The Commission shall adopt implementing acts laying down the format of the assessment report referred to in paragraph 1 of this Article and the procedural rules for the recognition of high impact health biotechnology strategic projects. ***To that end, the Commission shall ensure that the procedures are harmonised, transparent and proportionate and provide equal conditions for project assessment across all Member States.*** These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 65(2).

Or. it

Amendment 1627
Wouter Beke

Proposal for a regulation
Article 10 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The assessment referred to in paragraph 1 shall be conducted solely on the basis of the substantive conditions and criteria laid down in this Regulation. The geographical location of a project within the Union shall not be taken into account as a selection or prioritisation criterion. The Commission shall not apply any geographical quota or target in the recognition of high-impact biotechnology strategic projects or pan-European high-

impact biotechnology strategic projects.

Or. en

Amendment 1628
Ruggero Razza

Proposal for a regulation
Article 10 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. When assessing high impact strategic projects, the Commission shall take into account the extent to which the project successfully reduces the Union's strategic dependencies, enhances European intellectual property, bolsters domestic production capacities and fosters innovation across the Union market.

Or. it

Amendment 1629
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 10 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The Commission shall publish the decision referred to in paragraph 2 in the EU level public register to ensure transparency and facilitate consistent implementation across the Union.

Or. en

Justification

Amendment drafted by the BEUC (The European consumer organisation)

Amendment 1630
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 10 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The Commission shall publish the decision referred to in paragraph 2 in the EU-level public register to ensure transparency and facilitate consistent implementation across the Union.

Or. en

Justification

Publishing assessment outcomes in a central EU register would enhance transparency, provide stakeholders with clear information on recognition decisions, and improve legal certainty across the Union.

Amendment 1631
Christine Anderson

Proposal for a regulation
Article 10 a (new)

Text proposed by the Commission	*Amendment*
	Article 10a
	No automatic public-interest presumption
	Health biotechnology projects shall not be deemed to be of public interest, overriding public interest or highest national significance solely by virtue of falling within the scope of this Regulation. Any such designation shall be made only on the basis of a case-by-case assessment under applicable Union and national law and shall not prejudge environmental, ethical, health, safety, spatial-planning or judicial assessments.

Or. en

Amendment 1632
Christine Anderson

Proposal for a regulation
Article 11 – title

Text proposed by the Commission	*Amendment*
Single points of contact	Single points of contact ***for health biotechnology***

Or. en

Amendment 1633
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 11 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Each Member State shall designate one or more authorities as single points of contact at the relevant administrative level to facilitate and coordinate the permit-granting process for health biotechnology strategic projects and high impact health biotechnology strategic projects and shall provide information on the general administrative support and the technical and financial support set out in this [Section] through a dedicated webpage.	1. Each Member State shall designate one or more authorities as single points of contact at the relevant administrative level to facilitate and coordinate the permit-granting process for health biotechnology strategic projects and high impact health biotechnology strategic projects and shall provide information on the general administrative support and the technical and financial support set out in this [Section] through a dedicated webpage. ***The single point of contact shall ensure effective and coherent coordination between all authorities and agencies involved in the procedures related to the recognised project, including authorities operating at different administrative levels, in accordance with national administrative arrangements.***

Or. en

Amendment 1634
Ruggero Razza

Proposal for a regulation
Article 11 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Each Member State shall designate one or more authorities as single points of contact at the relevant administrative level to facilitate and coordinate the permit-granting process for health biotechnology strategic projects and high impact health biotechnology strategic projects and shall provide information on the general administrative support and the technical and financial support set out in this [Section] through a dedicated webpage.	1. Each Member State shall designate one or more authorities as single points of contact at the relevant administrative level to facilitate and coordinate the permit-granting process for health biotechnology strategic projects and high impact health biotechnology strategic projects and shall provide information on the general administrative support and the technical and financial support set out in this [Section]***, including support for intellectual property and patents,*** through a dedicated webpage.

Or. it

Amendment 1635
Christine Anderson

Proposal for a regulation
Article 11 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Each Member State shall designate one or more authorities as single points of contact at the relevant administrative level to facilitate and coordinate the permit-granting process for health biotechnology ***strategic*** projects ***and high impact health biotechnology strategic projects and*** shall ***provide information on the general administrative support and the technical and financial support set out in this [Section] through a dedicated webpage***.	1. Each Member State shall designate one or more authorities as single points of contact at the relevant administrative level to facilitate and coordinate the permit-granting process ***and other administrative procedures*** for health biotechnology projects ***falling within the scope of this Regulation. The single point of contact*** shall ***be available to all project promoters, in particular SMEs, start-ups, scale-ups, non-commercial research organisations and university spin-offs***.

Or. en

Amendment 1636
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 11 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Each Member State shall designate one ***or more authorities*** as single ***points*** of contact at the relevant administrative level to facilitate and coordinate the permit-granting process for health biotechnology strategic projects and high impact health biotechnology strategic projects and shall provide information on the general administrative support and the technical and financial support set out in this [Section] through a dedicated webpage.	1. Each Member State shall designate one ***single authority*** as single ***point*** of contact at the relevant administrative level to facilitate and coordinate the permit-granting process for health biotechnology strategic projects and high impact health biotechnology strategic projects and shall provide information on the general administrative support and the technical and financial support set out in this [Section] through a dedicated webpage.

Or. en

Amendment 1637
Christine Anderson

Proposal for a regulation
Article 11 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The single point of contact shall be the sole point of contact for the project promoter during the permit-granting process and shall assist the project promoter in handling any administrative matter relevant to the permit-granting process.	3. The single point of contact shall be the sole point of contact for the project promoter during the permit-granting process and shall assist the project promoter in handling any administrative matter relevant to the permit-granting process ***without prejudice to the competences of the authorities responsible for safety, ethics, environmental protection, biosecurity and data protection***.

Or. en

Amendment 1638
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 11 – paragraph 4

Text proposed by the Commission	*Amendment*
4. It shall coordinate the exchange of documents and information between the project promoters and the competent authorities and shall notify the promoter of the outcome of the decision-making process related to permit-granting, in accordance with national administrative arrangements. The authorities involved in the permit-granting process and other authorities concerned shall specify and make available to the single point of contact concerned the requirements and the scope of information requested of a project promoter.	4. It shall coordinate the exchange of documents and information between the project promoters and the competent authorities and shall notify the promoter of the outcome of the decision-making process related to permit-granting, in accordance with national administrative arrangements. The authorities involved in the permit-granting process and other authorities concerned shall specify and make available to the single point of contact concerned the requirements and the scope of information requested of a project promoter. ***The single point of contact shall furthermore ensure that all relevant documents are made available upon request by the project promoter.***

Or. en

Amendment 1639
Ruggero Razza

Proposal for a regulation
Article 11 – paragraph 4

Text proposed by the Commission	*Amendment*
4. It shall coordinate the exchange of documents and information between the project promoters and the competent authorities and shall notify the promoter of the outcome of the decision-making process related to permit-granting, in accordance with national administrative arrangements. The authorities involved in the permit-granting process and other authorities concerned shall specify and	4. It shall coordinate the exchange of documents and information between the project promoters and the competent authorities ***in an interoperable format*** and shall notify the promoter of the outcome of the decision-making process related to permit-granting, in accordance with national administrative arrangements. The authorities involved in the permit-granting process and other authorities concerned

make available to the single point of contact concerned the requirements and the scope of information requested of a project promoter.	shall specify and make available to the single point of contact concerned the requirements and the scope of information requested of a project promoter.

Or. it

Amendment 1640
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 11 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The single point of contact shall direct project promoters to the relevant national and regional antennas of the EU Health Biotechnology Support Network referred to in Article 19.	5. The single point of contact shall direct project promoters to the relevant national and regional antennas of the EU Health Biotechnology Support Network referred to in Article 19. ***where appropriate, and shall ensure that such engagement does not undermine the coordination role of the single point of contact during the permit-granting process.***

Or. en

Amendment 1641
Ruggero Razza

Proposal for a regulation
Article 11 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The single point of contact shall direct project promoters to the relevant national and regional antennas of the EU Health Biotechnology Support Network referred to in Article 19.	5. The single point of contact shall direct project promoters to the relevant national and regional antennas of the EU Health Biotechnology Support Network referred to in Article 19***, while ensuring coordination with existing national and regional support instruments***.

Or. it

Amendment 1642
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 11 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. The project promoter shall appoint one coordinator responsible for the project application and as a contact body to the single point of contact of the Member State. Any changes in the setting should be communicated without any delay.

Or. en

Amendment 1643
Christine Anderson

Proposal for a regulation
Article 11 – paragraph 7

Text proposed by the Commission	*Amendment*
7. Member States shall promote ***the*** reuse of existing data, studies ***and*** authorisations in order to avoid duplication of procedures, reduce administrative burden and ensure consistency of decision-making. For that purpose, they shall ensure that, when assessing an application, competent authorities ***duly take into account*** all relevant studies, assessments and valid permits or authorisations already carried out or issued for the same project ***or its components***, provided that they remain applicable and up to date.	7. Member States shall promote ***mutual recognition and*** reuse of existing data, studies***, assessments, inspections, permits,*** authorisations***, certificates and opinions*** in order to avoid duplication of procedures, reduce administrative burden and ensure consistency of decision-making. For that purpose, they shall ensure that, when assessing an application, competent authorities ***recognise, or where appropriate rely on,*** all relevant ***data,*** studies, assessments***, inspections*** and valid permits or authorisations already carried out or issued ***by a competent authority in another Member State*** for the same project***, product, process, facility, activity or component***, provided that they remain ***valid,*** applicable and up to date. ***Where the***

competent authority refuses to recognise or rely on such data, studies, assessments, inspections, permits, authorisations, certificates or opinions, it shall provide a written, reasoned explanation in accordance with Article 7a(4).

Or. en

Amendment 1644
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 11 – paragraph 7

Text proposed by the Commission	*Amendment*
7. Member States shall promote the reuse of existing data, studies and authorisations in order to avoid duplication of procedures, reduce administrative burden and ensure consistency of decision-making. For that purpose, they shall ensure that, when assessing an application, competent authorities duly take into account all relevant studies, assessments and valid permits or authorisations already carried out or issued for the same project or its components, provided that they remain applicable and up to date.	7. Member States shall promote the reuse of existing data, studies and authorisations in order to avoid duplication of procedures, reduce administrative burden and ensure consistency of decision-making. For that purpose, they shall ensure that, when assessing an application, competent authorities duly take into account all relevant studies, assessments and valid permits or authorisations already carried out or issued for the same project or its components, provided that they remain applicable and up to date. ***Member States shall apply the once-only principle where possible and shall not require project promoters, in particular SMEs, start-ups and scale-ups, to resubmit information already available to the competent authority, unless such resubmission is necessary and duly justified for the assessment concerned.***

Or. en

Amendment 1645
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation

Article 11 – paragraph 7

Text proposed by the Commission	*Amendment*
7. Member States shall promote the reuse of existing data, studies and authorisations in order to avoid duplication of procedures, reduce administrative burden and ensure consistency of decision-making. For that purpose, they shall ensure that, when assessing an application, competent authorities duly take into account all relevant studies, assessments and valid permits or authorisations already carried out or issued for the same project or its components, provided that they remain applicable and up to date.	7. Member States shall ***ensure and*** promote the reuse of existing data, studies and authorisations in order to avoid duplication of procedures, reduce administrative burden and ensure consistency of decision-making. For that purpose, they shall ensure that, when assessing an application, competent authorities ***systematically and without delay*** duly take into account all relevant studies, assessments and valid permits or authorisations already carried out or issued for the same project or its components, provided that they remain applicable and up to date.

Or. en

Amendment 1646
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 11 – paragraph 7

Text proposed by the Commission	*Amendment*
7. Member States shall promote the reuse of existing data, studies and authorisations in order to avoid duplication of procedures, reduce administrative burden and ensure consistency of decision-making. For that purpose, they shall ensure that, when assessing an application, competent authorities duly take into account all relevant studies, assessments and valid permits or authorisations already carried out or issued for the same project or its components, provided that they remain applicable and up to date.	7. Member States shall promote the reuse of existing data, studies and authorisations in order to avoid duplication of procedures, reduce administrative burden and ensure consistency of decision-making. For that purpose, they shall ensure that, when assessing an application, competent authorities duly take into account all relevant studies, assessments and valid permits or authorisations already ***available to them or previously*** carried out or issued for the same project or its components, provided that they remain applicable and up to date.

Or. en

Amendment 1647
Ruggero Razza

Proposal for a regulation
Article 11 – paragraph 7

Text proposed by the Commission	*Amendment*
7. Member States shall promote the reuse of existing data, studies and authorisations in order to avoid duplication of procedures, reduce administrative ***burden*** and ensure consistency of decision-making. For that purpose, they shall ensure that, when assessing an application, competent authorities duly take into account all relevant studies, assessments and valid permits or authorisations already carried out or issued for the same project or its components, provided that they remain applicable and up to date.	7. Member States shall promote the reuse of existing data, studies and authorisations in order to avoid duplication of procedures, reduce administrative ***and regulatory burdens*** and ensure consistency of decision-making. For that purpose, they shall ensure that, when assessing an application, competent authorities duly take into account all relevant studies, assessments and valid permits or authorisations already carried out or issued for the same project or its components, provided that they remain applicable and up to date.

Or. it

Amendment 1648
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 11 – paragraph 8

Text proposed by the Commission	*Amendment*
8. Member States shall ensure that the single points of contact and all authorities involved in the permit-granting process have a sufficient number of qualified staff and adequate resources.	8. Member States shall ensure that the single points of contact and all authorities involved in the permit-granting process have a sufficient number of qualified staff and adequate resources ***and are provided with a clear mandate enabling them to effectively fulfil their responsibilities under this Chapter, in accordance with national administrative arrangements***.

Or. en

Amendment 1649
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 11 – paragraph 8

Text proposed by the Commission	*Amendment*
8. Member States shall ensure that the single points of contact and all authorities involved in the permit-granting process have a sufficient number of qualified staff and adequate resources.	8. Member States shall ensure that the single points of contact and all authorities involved in the permit-granting process have a sufficient number of qualified staff ***to assess all relevant selection criterions, including those referring to ethical, environmental and social aspects of strategic projects*** and adequate resources.

Or. en

Amendment 1650
Ruggero Razza

Proposal for a regulation
Article 11 – paragraph 8

Text proposed by the Commission	*Amendment*
8. Member States shall ensure that the single points of contact and all authorities involved in the permit-granting process have a sufficient number of qualified staff and adequate resources.	8. Member States shall ensure that the single points of contact and all authorities involved in the permit-granting process have a sufficient number of qualified staff ***with scientific, regulatory and industrial expertise*** and adequate resources.

Or. it

Amendment 1651
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 11 – paragraph 9 a (new)

Text proposed by the Commission	*Amendment*

9a. Member States shall ensure that each single point of contact meets the following minimum criteria before becoming operational:

(a) a dedicated organisational unit or team has been established with clearly defined responsibilities for the permit-granting coordination function, with qualified staff assigned to this function;

(b) internal procedures for the coordination of the permit-granting process have been adopted and published, including indicative timelines for each procedural step;

(c) a dedicated digital platform or webpage has been established providing, at minimum: contact details, a description of the permit-granting process, a list of all competent authorities involved, templates and checklists for project promoters, and information on dispute resolution mechanisms referred to in paragraph 9;

(d) interoperability arrangements with all relevant competent authorities involved in the permit-granting process have been formalised, including protocols for information exchange and document management.

Or. en

Amendment 1652
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Article 11 – paragraph 9 a (new)

Text proposed by the Commission	*Amendment*
	9a. Member States shall ensure that each single point of contact meets the following minimum criteria before becoming operational:
	(a) a dedicated organisational unit or team has been established with clearly

defined responsibilities for the permit-granting coordination function, with qualified staff assigned to this function;

(b) internal procedures for the coordination of the permit-granting process have been adopted and published, including indicative timelines for each procedural step;

(c) a dedicated digital platform or webpage has been established providing, at minimum: contact details, a description of the permit-granting process, a list of all competent authorities involved, templates and checklists for project promoters, and information on dispute resolution mechanisms referred to in paragraph 9;

(d) interoperability arrangements with all relevant competent authorities involved in the permit-granting process have been formalised, including protocols for information exchange and document management.

Or. en

Amendment 1653
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 11 – paragraph 9 b (new)

Text proposed by the Commission	*Amendment*
	9b. Member States shall notify the Commission of the designation of each single point of contact and shall provide information on the measures taken to comply with the criteria set out in paragraph 10 no later than 6 months after the entry into force of this Regulation. The Commission may request additional information where the notification does not demonstrate that the single point of contact is operational.

Or. en

Amendment 1654
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Article 11 – paragraph 9 b (new)

Text proposed by the Commission	*Amendment*
	9b. Member States shall notify the Commission of the designation of each single point of contact and shall provide information on the measures taken to comply with the criteria set out in paragraph 10 no later than 6 months after the entry into force of this Regulation. The Commission may request additional information where the notification does not demonstrate that the single point of contact is operational..

Or. en

Justification

The proposed amendment is intended to ensure that single points of contact become effective operational tools for project promoters rather than merely formal designations. In order to provide real administrative support, single points of contact should have a clearly defined organisational structure, qualified staff, published procedures, accessible digital information and formalised arrangements with the competent authorities involved in the permit-granting process. Introducing minimum operational criteria would support more consistent implementation across Member States and reduce the risk of fragmentation. At the same time, the amendment leaves Member States flexibility as to the internal organisation of their administrations, while ensuring that the single point of contact is capable of coordinating the permitting process in practice.

Amendment 1655
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 12

Text proposed by the Commission	*Amendment*

[...]	deleted

Or. en

Amendment 1656
Christine Anderson

Proposal for a regulation
Article 12

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

Or. en

Amendment 1657
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 12 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Health biotechnology strategic projects shall be considered as contributing to the strengthening of the biomanufacturing capacity and to the supply resilience of biotechnology products in the Union ***and***, therefore***, shall*** be considered to be of public interest.	Health biotechnology strategic projects shall be considered as contributing to the strengthening of the biomanufacturing capacity and to the supply resilience of biotechnology products in the Union***, the promotion of research and development of products that provide meaningful added value to patient care***, ***and the overall improvement of global public health. Such projects shall also contribute to improving equitable access to innovative healthcare across Member States and may*** therefore be considered to be of public interest.

Or. en

Amendment 1658

Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 12 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Health biotechnology strategic projects shall be considered as contributing to the strengthening of the biomanufacturing capacity and to the supply resilience of biotechnology products in the Union ***and***, therefore, shall be considered to be of public interest.	Health biotechnology strategic projects shall be considered as contributing to the strengthening of the biomanufacturing capacity and to the supply resilience of biotechnology products in the Union ***as well as to the promotion of research and development of products that truly bring added value to patients' care and ultimately improve equitable access across Member States***, ***and*** therefore, shall be considered to be of public interest.

Or. en

Justification

Strategic health biotechnology projects have the potential to contribute positively to strengthening the Union's health biotechnology ecosystem. However, it is essential to ensure that robust scrutiny and accountability mechanisms are in place. To that end, clear, transparent and measurable criteria for the designation and evaluation of such projects should be established and consistently applied across all Member States. Those criteria should aim to ensure that supported initiatives effectively address unmet medical needs and deliver tangible added value for patients, including by promoting the development of products that improve patient care and contribute to equitable access across the Union. In order to reinforce transparency and accountability, relevant stakeholders, in particular patient organisations, should be appropriately consulted in the development of such criteria or related guidance.

Amendment 1659
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 12 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Health biotechnology strategic projects shall be considered as contributing to the strengthening of the biomanufacturing capacity and to the supply resilience of	Health biotechnology strategic projects shall be considered as contributing to the strengthening of the biomanufacturing capacity and to the supply resilience of

biotechnology products in the Union and, therefore, shall be considered to be of public interest.	biotechnology products in the Union ***as well as to research and development, including clinical research and development, of medicinal products that bring about public health benefits*** and, therefore, shall be considered to be of public interest.

Or. en

Amendment 1660
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 12 – paragraph 3

Text proposed by the Commission	*Amendment*
3. High impact health biotechnology strategic projects shall be considered to be of public interest and may be considered to have an overriding public interest with specific consideration given to the high impact strategic nature of such projects in accordance with Article 14 of Regulation [Regulation on speeding-up environmental impact assessments – permitting regulation] and point I of the Annex to that Regulation.	***deleted***

Or. en

Amendment 1661
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 12 – paragraph 3

Text proposed by the Commission	*Amendment*
3. High impact health biotechnology strategic projects shall be considered to be of public interest and may be considered to	3. High impact health biotechnology strategic projects shall be considered to be of public interest and may be considered to

have an overriding public interest with specific consideration given to the high impact strategic nature of such projects in accordance with Article 14 of Regulation [Regulation on speeding-up environmental impact assessments – permitting regulation] and point I of the Annex to that Regulation.	have an overriding public interest with specific consideration given to the high impact strategic nature of such projects in accordance with Article 14 of Regulation [Regulation on speeding-up environmental impact assessments – permitting regulation] and point I of the Annex to that Regulation. ***Such overriding public interest may be recognised only on the basis of a case-by-case assessment by the competent permitting authority and provided that all relevant conditions set out in Directives 2000/60/EC, 2009/147/EC and 92/43/EEC, as applicable, and in Union legislative acts on nature restoration, are met. This paragraph shall apply without prejudice to those Directives and to that legislation.***

Or. en

Amendment 1662
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 12 – paragraph 3

Text proposed by the Commission	*Amendment*
3. High impact health biotechnology strategic projects ***shall*** be considered to be of public interest and may be considered to have an overriding public interest with specific consideration given to the high impact strategic nature of such projects in accordance with Article 14 of Regulation [Regulation on speeding-up environmental impact assessments – permitting regulation] and point I of the Annex to that Regulation.	3. High impact health biotechnology strategic projects ***may*** be considered to be of public interest and may***, in dully justified cases,*** be considered to have an overriding public interest with specific consideration given to the high impact strategic nature of such projects in accordance with Article 14 of Regulation [Regulation on speeding-up environmental impact assessments – permitting regulation] and point I of the Annex to that Regulation.

Or. en

Amendment 1663

Wouter Beke

Proposal for a regulation
Article 12 – paragraph 3

Text proposed by the Commission	*Amendment*
3. High impact health biotechnology strategic projects shall be considered to be of public interest and ***may*** be considered to have an overriding public interest with specific consideration given to the high impact strategic nature of such projects in accordance with Article 14 of Regulation [Regulation on speeding-up environmental impact assessments – permitting regulation] and point I of the Annex to that Regulation.	3. High impact health biotechnology strategic projects shall be considered to be of public interest and ***are presumed to*** be considered to have an overriding public interest with specific consideration given to the high impact strategic nature of such projects in accordance with Article 14 of Regulation [Regulation on speeding-up environmental impact assessments – permitting regulation] and point I of the Annex to that Regulation.

Or. en

Amendment 1664
Ruggero Razza

Proposal for a regulation
Article 12 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Where a project is recognised as a health biotechnology strategic project, Member States shall grant that project the status of project with the highest national significance possible, where such a status exists in national law and shall ensure that the relevant process for permit-granting and the licensing procedures, including environmental assessments and spatial planning, are treated in the most rapid way possible in accordance with Union and national law and shall benefit from any accelerated procedures provided for in applicable Union and national law.	4. Where a project is recognised as a health biotechnology strategic project, Member States shall grant that project the status of project with the highest national significance possible ***and with due regard for the competences of the Member States***, where such a status exists in national law and shall ensure that the relevant process for permit-granting and the licensing procedures, including environmental assessments and spatial planning, are treated in the most rapid way possible in accordance with Union and national law and shall benefit from any accelerated procedures provided for in applicable Union and national law.

Or. it

Amendment 1665
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 12 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Where a project is recognised as a health biotechnology strategic project, Member States ***shall*** grant that project the status of project with the highest national significance possible, where such a status exists in national law and shall ensure that the relevant process for permit-granting and the licensing procedures, ***including environmental assessments and spatial planning,*** are treated in the most rapid way possible in accordance with Union and national law and ***shall*** benefit from any accelerated procedures provided for in applicable Union and national law.	4. Where a project is recognised as a health biotechnology strategic project, Member States ***may*** grant that project the status of project with the highest national significance possible, where such a status exists in national law and shall ensure that the relevant process for permit-granting and the licensing procedures, are treated in the most rapid way possible in accordance with Union and national law and ***may*** benefit from any accelerated procedures provided for in applicable Union and national law.

Or. en

Amendment 1666
Laurent Castillo, Aleksandar Nikolic, Valérie Deloge, Julie Rechagneux, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 12 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Where a project is recognised as a health biotechnology strategic project, Member States shall grant that project the status of project with the highest national significance possible***, where such a status exists in national law*** and shall ensure that the relevant process for permit-granting and the licensing procedures, including environmental assessments and spatial planning, are treated in the most rapid way	4. Where a project is recognised as a health biotechnology strategic project, Member States shall grant that project the status of project with the highest national significance possible and shall ensure that the relevant process for permit-granting and the licensing procedures, including environmental assessments and spatial planning, are treated in the most rapid way possible in accordance with Union and

possible in accordance with Union and national law and shall benefit from any accelerated procedures provided for in applicable Union and national law.

national law and shall benefit from any accelerated procedures provided for in applicable Union and national law.

Or. fr

Amendment 1667
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 12 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Health biotechnology strategic projects shall also benefit, where applicable, from the tacit-approval in accordance with Article 14 and point II of the Annex to [COM Proposal 2025(984) for a Regulation on speeding-up environmental impact assessments – permitting regulation].	***deleted***

Or. en

Amendment 1668
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 12 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Health biotechnology strategic projects shall also benefit, where applicable, from the tacit-approval in accordance with Article 14 and point II of the Annex to [COM Proposal 2025(984) for a Regulation on speeding-up environmental impact assessments – permitting regulation].	5. Health biotechnology strategic projects shall also benefit, where applicable***, for under applicable Union or national law***, from the tacit-approval in accordance with Article 14 and point II of the Annex to [COM Proposal 2025(984) for a Regulation on speeding-up environmental impact assessments – permitting regulation].

Or. en

Amendment 1669
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 12 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. Permit-granting applications, covering all permits and licences required for the implementation of the recognised project, shall be submitted to the single point of contact in accordance with Article 11. Submission through the single point of contact shall not replace the substantive requirements under applicable Union or national law but shall serve as the coordinated entry point for all competent authorities involved in the permit-granting process.

Or. en

Amendment 1670
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 12 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The permit-granting process shall not exceed ten months for health biotechnology strategic projects, and eight months for high impact health biotechnology strategic projects, from the date of acknowledgement of the completeness of the permit application. In duly justified cases requiring complex procedures under Union or national legislation, such as in the case of multi-site or multi-purpose projects, the competent authority may extend the period by up to	6. The permit-granting process shall not exceed ten months for health biotechnology strategic projects, and eight months for high impact health biotechnology strategic projects, from the date of acknowledgement of the completeness of the permit application***. All procedures, including consultations and opinions required from other public authorities as well as public participation procedures, shall be carried out within this period***. In duly justified cases

three additional months, provided that the reasons for such extension are communicated in writing to the project promoter.	requiring complex procedures under Union or national legislation, such as in the case of multi-site or multi-purpose projects, the competent authority may extend the period by up to three additional months, provided that the reasons for such extension are communicated in writing to the project promoter.

Or. en

Amendment 1671
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 12 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The permit-granting process shall not exceed ten months for health biotechnology strategic projects, and eight months for high impact health biotechnology strategic projects, from the date of acknowledgement of the completeness of the permit application**.** In duly justified cases requiring complex procedures under Union or national legislation, such as in the case of multi-site or multi-purpose projects, the competent authority may extend the period by up to three additional months, provided that the reasons for such extension are communicated in writing to the project promoter.	6. The permit-granting process shall not exceed ten months for health biotechnology strategic projects, and eight months for high impact health biotechnology strategic projects, from the date of acknowledgement of the completeness of the permit application***, the deadline may be extended in the event of any uncertainty or where relevant information or evidence is missing*** In duly justified cases requiring complex procedures under Union or national legislation, such as in the case of multi-site or multi-purpose projects, the competent authority may extend the period by up to ***further*** three additional months, provided that the reasons for such extension are communicated in writing to the project promoter.

Or. en

Amendment 1672
Morten Løkkegaard, Katri Kulmuni, Stine Bosse, Sophie Wilmès

Proposal for a regulation
Article 12 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The permit-granting process shall not exceed ten months for health biotechnology strategic projects, and eight months for high impact health biotechnology strategic projects, from the date of acknowledgement of the completeness of the permit application. In duly justified cases requiring complex procedures under Union or national legislation, such as in the case of multi-site or multi-purpose projects, the competent authority may extend the period by up to ***three*** additional ***months***, provided that the reasons for such extension are communicated in writing to the project promoter.	6. The permit-granting process***, including all associated procedures such as consultations and opinions required from other public authorities,*** shall not exceed ten months for health biotechnology strategic projects, and eight months for high impact health biotechnology strategic projects, from the date of acknowledgement of the completeness of the permit application. In duly justified cases requiring complex procedures under Union or national legislation, such as in the case of multi-site or multi-purpose projects, the competent authority may extend the period by up to ***one*** additional ***month***, provided that the reasons for such extension are communicated in writing to the project promoter.

Or. en

Amendment 1673
Kristoffer Storm

Proposal for a regulation
Article 12 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The permit-granting process shall not exceed ***ten*** months for health biotechnology strategic projects, and ***eight*** months for high impact health biotechnology strategic projects, from the date of acknowledgement of the completeness of the permit application. In duly justified cases requiring complex procedures under Union or national legislation, such as in the case of multi-site or multi-purpose projects, the competent authority may extend the period by up to	6. The permit-granting process shall not exceed ***six*** months for health biotechnology strategic projects, and ***four*** months for high impact health biotechnology strategic projects, from the date of acknowledgement of the completeness of the permit application. In duly justified cases requiring complex procedures under Union or national legislation, such as in the case of multi-site or multi-purpose projects, the competent authority may extend the period by up to

three additional ***months, provided that the reasons for such extension are communicated in writing to the project promoter***.	***one*** additional ***month***.

Or. en

Amendment 1674
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 12 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The permit-granting process shall not exceed ***ten*** months for health biotechnology strategic projects, and ***eight*** months for high impact health biotechnology strategic projects, from the date of acknowledgement of the completeness of the permit application. In duly justified cases requiring complex procedures under Union or national legislation, such as in the case of multi-site or multi-purpose projects, the competent authority may extend the period by up to three additional months, provided that the reasons for such extension are communicated in writing to the project promoter.	6. The permit-granting process shall not exceed ***six*** months for health biotechnology strategic projects, and ***four*** months for high impact health biotechnology strategic projects, from the date of acknowledgement of the completeness of the permit application. In duly justified cases requiring complex procedures under Union or national legislation, such as in the case of multi-site or multi-purpose projects, the competent authority may extend the period by up to three additional months, provided that the reasons for such extension are communicated in writing to the project promoter.

Or. en

Amendment 1675
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 12 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The permit-granting process shall not exceed ***ten*** months for health biotechnology strategic projects, and ***eight***	6. The permit-granting process shall not exceed ***six*** months for health biotechnology strategic projects, and ***three***

months for high impact health biotechnology strategic projects, from the date of acknowledgement of the completeness of the permit application. In duly justified cases requiring complex procedures under Union or national legislation, such as in the case of multi-site or multi-purpose projects, the competent authority may extend the period by up to ***three*** additional months, provided that the reasons for such extension are communicated in writing to the project promoter.	months for high impact health biotechnology strategic projects, from the date of acknowledgement of the completeness of the permit application. In duly justified cases requiring complex procedures under Union or national legislation, such as in the case of multi-site or multi-purpose projects, the competent authority may extend the period by up to ***one*** additional months, provided that the reasons for such extension are communicated in writing to the project promoter.

Or. en

Amendment 1676
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 12 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The permit-granting process shall not exceed ***ten*** months for health biotechnology strategic projects, and ***eight*** months for high impact health biotechnology strategic projects, from the date of acknowledgement of the completeness of the permit application. In duly justified cases requiring complex procedures under Union or national legislation, such as in the case of multi-site or multi-purpose projects, the competent authority may extend the period by up to ***three*** additional ***months***, provided that the reasons for such extension are communicated in writing to the project promoter.	6. The permit-granting process shall not exceed ***six*** months for health biotechnology strategic projects, and ***four*** months for high impact health biotechnology strategic projects, from the date of acknowledgement of the completeness of the permit application. In duly justified cases requiring complex procedures under Union or national legislation, such as in the case of multi-site or multi-purpose projects, the competent authority may extend the period by up to ***one*** additional ***month***, provided that the reasons for such extension are communicated in writing to the project promoter.

Or. en

Amendment 1677
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 12 – paragraph 7

Text proposed by the Commission	*Amendment*
7. Where an environmental impact assessment is required pursuant to Directive 2011/92/EU, the step of the preparation of the environmental impact assessment report referred to in Article 1(2), point (g)(i), of that Directive shall not be included in the maximum duration of the permit-granting process referred to in paragraph [5] of this Article.	7. Where an environmental impact assessment is required pursuant to Directive 2011/92/EU, the step of the preparation of the environmental impact assessment report referred to in Article 1(2), point (g)(i), of that Directive shall not be included in the maximum duration of the permit-granting process referred to in paragraph [5] of this Article. ***All subsequent assessments, consultations and decision-making phases carried out by competent authorities shall be included within the maximum duration set out in this Article.***

Or. en

Amendment 1678
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 12 – paragraph 8

Text proposed by the Commission	*Amendment*
8. No later than ***45*** days from the receipt of the permit-granting application, the single point of contact shall acknowledge that the application is complete or, if the project promoter has not sent all the information required to process the application, request the project promoter to submit a complete application without undue delay, specifying which information is missing. In the event that the submitted application is deemed to be incomplete for a second time, the single point of contact may, within 30 days of the second submission, make a second request for information. The single point of contact shall not request information in areas not	8. No later than ***30*** days from the receipt of the permit-granting application, the single point of contact shall acknowledge that the application is complete or, if the project promoter has not sent all the information required to process the application, request the project promoter to submit a complete application without undue delay, specifying which information is missing. In the event that the submitted application is deemed to be incomplete for a second time, the single point of contact may, within 30 days of the second submission, make a second request for information. The single point of contact shall not request information in areas not

covered in the first request for additional information and shall be entitled only to request further evidence to complete the identified missing information. The date of the acknowledgement of the completeness of the application from the single point of contact shall serve as the start of the permit-granting process for that particular application.	covered in the first request for additional information and shall be entitled only to request further evidence to complete the identified missing information. The date of the acknowledgement of the completeness of the application from the single point of contact shall serve as the start of the permit-granting process for that particular application.

Or. en

Amendment 1679
Ruggero Razza

Proposal for a regulation
Article 12 – paragraph 9 a (new)

Text proposed by the Commission	*Amendment*
	9a. The Member States may devise specific administrative procedures for strategic projects with a view to facilitating coordination between the competent authorities on matters pertaining to permits, innovation, industrial property and investments, and ultimately preventing the duplication of procedures.

Or. it

Amendment 1680
Christine Anderson

Proposal for a regulation
Article 12 a (new)

Text proposed by the Commission	*Amendment*
	Article 12a
	General permit-granting simplification
	1. Member States shall ensure that permit-granting procedures for health

biotechnology projects are efficient, transparent, proportionate and time-bound.

2. Member States shall ensure that relevant authorities coordinate their assessments in order to avoid duplication, contradictory requests and unnecessary delays.

3. Member States shall ensure that permit-granting procedures make use of electronic submission, reusable studies, consolidated information requests and clear administrative deadlines.

4. Accelerated administrative procedures may be provided under Union or national law, provided that such procedures are available on the basis of objective, transparent and non-discriminatory criteria and do not favour incumbent operators or projects selected through political or administrative discretion.

5. No accelerated procedure shall reduce the quality of assessment, informed consent, ethical review, patient safety, data protection, environmental protection, public participation or judicial protection.

6. Tacit approval shall not apply to procedures involving patient safety, clinical trials, environmental assessment, deliberate release of genetically modified organisms, reproductive medicine, germline interventions, the use of human biological material, genetic data, biosecurity or other areas involving fundamental rights or significant public-interest concerns.

Or. en

Amendment 1681
Tomislav Sokol

Proposal for a regulation
Article 12 a (new)

Text proposed by the Commission	*Amendment*
	Article 12a
	Synergies with the European Health Data Space
	When implementing measures supporting Health Biotechnology Strategic Projects and High-impact Health Biotechnology Strategic Projects, the Commission and the Member States shall, where relevant, promote synergies with the European Health Data Space established by Regulation (EU) 2025/327 in order to facilitate the secure and lawful use of electronic health data for clinical research, evidence generation, regulatory decision-making and innovation throughout the lifecycle of health biotechnology products.

Or. en

Amendment 1682
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 13 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Upon request of a project promoter, Member States shall provide administrative support to biotechnology projects located on their territory, including health biotechnology strategic projects and high impact health biotechnology strategic projects and shall take all appropriate measures to facilitate their timely and effective implementation, including:	1. Upon request of a project promoter, Member States***' authorities*** shall provide administrative support to biotechnology projects located on their territory, including health biotechnology strategic projects and high impact health biotechnology strategic projects and shall take all appropriate measures to facilitate their timely and effective implementation, including:

Or. en

Amendment 1683
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 13 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) assistance to project promoters to ensure compliance with applicable administrative, regulatory, and reporting obligations;	(a) assistance to project promoters to ensure compliance with applicable administrative, regulatory, and reporting obligations***, including tailored support for non-commercial sponsors such as university hospitals, with the objective of minimising administrative complexity and avoiding disproportionate costs associated with regulatory procedures, particularly for cross-border coordination of regulatory procedures, including support for parallel or joint assessments under the Clinical Trials Regulation***;

Or. en

Justification

University hospitals are core actors in Europe's biotech ecosystem, combining clinical care, research and translational innovation, and are key to delivering investigator initiated trials and early-stage innovation. However, current regulatory frameworks are largely designed around commercial actors, resulting in disproportionate administrative burden and costs for academic sponsors.

Without targeted support, this risks reducing participation of university hospitals in multinational clinical research, diverting limited public resources away from innovation and patient care, and ultimately weakening Europe's capacity to translate scientific excellence into scalable innovation. Providing tailored administrative support is therefore necessary to ensure that non-commercial sponsors can effectively contribute to the objectives of the Biotech Act and to maximise the use of Europe's public research infrastructure.

Support for parallel or joint assessments under the Clinical Trials Regulation (CTR) is particularly important for rare ATMP indications, where clinical development necessarily relies on multinational trials to achieve sufficient patient enrolment and generate statistically meaningful evidence.

Amendment 1684
Ruggero Razza

Proposal for a regulation
Article 13 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) assistance to project promoters to ensure compliance with applicable administrative, regulatory, and reporting obligations;	(a) assistance to project promoters to ensure compliance with applicable administrative, regulatory, and reporting obligations***, including advisory services for intellectual property management, European patents, permits and the exploitation of research findings for industrial use***;

Or. it

Amendment 1685
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 13 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) assistance to inform the public and those in the vicinity of the project with the aim of increasing public acceptance of the project;	(c) assistance to inform the public and those in the vicinity of the project with the aim of increasing public acceptance of the project ***and, where relevant, facilitating the consultation of local communities, organisations and social partners***; ***;***

Or. en

Amendment 1686
Ruggero Razza

Proposal for a regulation
Article 13 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) assistance to inform the public and those in the vicinity of the project with the aim of increasing public acceptance of the project;	(c) assistance to inform the public and those in the vicinity of the project with the aim of increasing public acceptance of the project ***through transparent and well-founded scientific information***;

Or. it

Amendment 1687
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 13 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) assistance to inform the public and those in the vicinity of the project with the aim of increasing public acceptance of the project;	(c) assistance to inform ***and consult*** the public and those in the vicinity of the project with the aim of increasing ***local consultations and*** public ***relevance and*** acceptance of the project;

Or. en

Amendment 1688
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 13 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) assistance to inform the public and those in the vicinity of the project with ***the aim of increasing public acceptance of the project***;	(c) assistance to inform the public and those in the vicinity of the project with ***a view to facilitating informed participation in relevant procedures***;

Or. en

Amendment 1689
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 13 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) support to academical and clinical research developing advanced therapy medicinal products, specially in good manufacturing practices and regulatory help in the developing of hospital

exemption authorisation and its upscaling;

Or. en

Amendment 1690
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 13 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) coordination between relevant national authorities in order to reduce unnecessary administrative delays

Or. en

Amendment 1691
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 13 – paragraph 1 – point c b (new)

Text proposed by the Commission	*Amendment*
	(cb) support to the establishment of platform technology master files and the development of clusters for open platform technology masterfiles for advanced therapy medicinal products;

Or. en

Amendment 1692
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 13 – paragraph 3

Text proposed by the Commission	*Amendment*

3. The administrative support referred to in paragraphs 1 and 2 shall be provided including through the single points of contact and the national and regional antennas of the EU Health Biotechnology Support Network referred to in Article 19.	3. The administrative support referred to in paragraphs 1 and 2 shall be provided including through the single points of contact and the national and regional antennas of the EU Health Biotechnology Support Network referred to in Article 19***, with the single points of contact acting as the primary coordination interface for administrative and permit-granting matters, and the EU Health Biotechnology Support Network providing complementary information and support services in accordance with Article 19***.

Or. en

Amendment 1693
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 13 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The administrative support referred to in paragraphs 1 and 2 shall be provided including through the single ***points*** of contact and the national and regional antennas of the EU Health Biotechnology Support Network referred to in Article 19.	3. The administrative support referred to in paragraphs 1 and 2 shall be provided including through the single ***point*** of contact and the national and regional antennas of the EU Health Biotechnology Support Network referred to in Article 19.

Or. en

Amendment 1694
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Article 13 – paragraph 4 – point b

Text proposed by the Commission	*Amendment*
(b) the single ***points*** of contact referred to in Article 11;	(b) the single ***point*** of contact referred to in Article 11;

Or. en

Amendment 1695
Ruggero Razza

Proposal for a regulation
Article 13 – paragraph 4 – point d

Text proposed by the Commission	*Amendment*
(d) the permit-granting process, including information on dispute settlement;	(d) the permit-granting process, including ***the relevant procedural deadlines and*** information on dispute settlement;

Or. it

Amendment 1696
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 13 – paragraph 5

Text proposed by the Commission	*Amendment*
5. When providing the administrative support referred to in paragraph 1 of this Article, Member States shall pay particular attention to SMEs, start-ups and scale-ups. Where appropriate, Member States shall ensure that a dedicated channel for communication with SMEs, start-ups and scale-ups is available within the single points of contact to provide guidance and respond to queries related to the implementation of this Regulation.	5. When providing the administrative support referred to in paragraph 1 of this Article, Member States shall pay particular attention to SMEs, start-ups and scale-ups***, while not preventing proportionate support for established operators whose activities are essential for securing the supply of critical or essential biological medicinal products, where such contribution is demonstrated on the basis of objective criteria***. Where appropriate, Member States shall ensure that a dedicated channel for communication with SMEs, start-ups and scale-ups is available within the single points of contact to provide guidance and respond to queries related to the implementation of this Regulation.

Or. en

Amendment 1697
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 13 – paragraph 5

Text proposed by the Commission	*Amendment*
5. When providing the administrative support referred to in paragraph 1 of this Article, Member States shall pay particular attention to SMEs, start-ups and scale-ups. Where appropriate, Member States shall ensure that a dedicated channel for communication with SMEs, start-ups and scale-ups is available within the single points of contact to provide guidance and respond to queries related to the implementation of this Regulation**.**	5. When providing the administrative support referred to in paragraph 1 of this Article, Member States shall pay particular attention to SMEs, start-ups and scale-ups**,** ***while not preventing proportionate support for established operators whose activities are essential for securing the supply of critical or essential biological medicinal products, where such contribution is demonstrated on the basis of objective criteria***. Where appropriate, Member States shall ensure that a dedicated channel for communication with SMEs, start-ups and scale-ups is available within the single points of contact to provide guidance and respond to queries related to the implementation of this Regulation

Or. en

Justification

The proposed amendment maintains the priority given to SMEs, start-ups and scale-ups, while clarifying that administrative support should also be available, where justified, to established operators whose activities are essential for the security, continuity and resilience of supply of critical or essential biological medicinal products. This approach reflects the structure of the health biotechnology sector. Stable and continuous supply of biological medicines requires not only innovative and fast-growing companies, but also mature manufacturers with validated production infrastructure, quality systems, regulatory experience and the capacity to maintain production under crisis conditions. The extension of support to established operators should be based on objective supply-security considerations and should not create an automatic preference for incumbent companies. This ensures that support remains targeted, proportionate and aligned with the public health and strategic autonomy objectives of the Regulation.

Amendment 1698
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 13 – paragraph 5

Text proposed by the Commission	*Amendment*
5. When providing the administrative support referred to in paragraph 1 of this Article, Member States shall pay particular attention to SMEs, start-ups and scale-ups. Where appropriate, Member States shall ensure that a dedicated channel for communication with ***SMEs, start-ups and scale-ups*** is available within the single points of contact to provide guidance and respond to queries related to the implementation of this Regulation.	5. When providing the administrative support referred to in paragraph 1 of this Article, Member States shall pay particular attention to SMEs, start-ups and scale-ups ***and not-for-profit entities***. Where appropriate, Member States shall ensure that a dedicated channel for communication with ***them*** is available within the single points of contact to provide guidance and respond to queries related to the implementation of this Regulation.

Or. en

Amendment 1699
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 13 – paragraph 5

Text proposed by the Commission	*Amendment*
5. When providing the administrative support referred to in paragraph 1 of this Article, Member States shall pay particular attention to SMEs, start-ups and scale-ups. ***Where appropriate,*** Member States shall ensure that a dedicated channel for communication with SMEs, start-ups and scale-ups is available within the single points of contact to provide guidance and respond to queries related to the implementation of this Regulation.	5. When providing the administrative support referred to in paragraph 1 of this Article, Member States shall pay particular attention to SMEs, start-ups and scale-ups. Member States shall ensure that a dedicated channel for communication with SMEs, start-ups and scale-ups is available within the single points of contact to provide guidance and respond to queries related to the implementation of this Regulation.

Or. en

Justification

SMEs, start-ups and scale-ups have the most to gain from administrative support and the least capacity to navigate complex regulatory systems. "Where appropriate" renders the channel discretionary. Member States can decline to establish it without justification. Removing it

converts a discretionary provision into a meaningful and baseline obligation that will be broadly useful for innovators.

Amendment 1700
Kateřina Konečná

Proposal for a regulation
Article 14 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Without prejudice to Articles 107 and 108 TFEU, Member States may make use, where applicable, of the relevant frameworks for providing public support to health biotechnology strategic projects and high impact health biotechnology strategic projects, including national promotional banks and other relevant public support instruments, as provided for in Article 24, paragraphs (4), (5) and (6). Where public support is granted, Member States shall ensure that such support is coordinated with other support measures at Union or national level and is in line with applicable State aid rules.	1. Without prejudice to Articles 107 and 108 TFEU, Member States may make use, where applicable, of the relevant frameworks for providing public support to health biotechnology strategic projects and high impact health biotechnology strategic projects, including national promotional banks and other relevant public support instruments, as provided for in Article 24, paragraphs (4), (5) and (6). Where public support is granted, Member States shall ensure that such support is coordinated with other support measures at Union or national level and is in line with applicable State aid rules.
	Where public support is granted to health biotechnology strategic projects or high impact health biotechnology strategic projects, project promoters shall ensure that the products and services they develop based on, or partly based on, the results of the supported activities are affordable, available and accessible in the Member States under fair and reasonable conditions.
	Projects receiving public funding or recognised as health biotechnology strategic projects or high impact health biotechnology strategic projects under this Regulation shall comply with appropriate transparency requirements. Such requirements shall include, as a minimum, the disclosure to the Commission of information on the total amount of public support received from

	Union and national sources, and on research and development costs fully or partially covered by public funds. Contracting authorities and national authorities responsible for pricing and reimbursement may require beneficiaries to provide audited information on research and development, production and distribution costs associated with the resulting products.

Or. en

Amendment 1701
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 14 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Without prejudice to Articles 107 and 108 TFEU, Member States may make use, where applicable, of the relevant frameworks for providing public support to health biotechnology strategic projects and high impact health biotechnology strategic projects, including national promotional banks and other relevant public support instruments, as provided for in Article 24, paragraphs (4), (5) and (6). Where public support is granted, Member States shall ensure that such support is coordinated with other support measures at Union or national level and is in line with applicable State aid rules.	1. Without prejudice to Articles 107 and 108 TFEU, Member States may make use, where applicable, of the relevant frameworks for providing public support to health biotechnology strategic projects and high impact health biotechnology strategic projects, including national promotional banks and other relevant public support instruments, as provided for in Article 24, paragraphs (4), (5) and (6). ***Member States shall ensure that information on such frameworks is made publicly available in a clear and accessible manner.*** Where public support is granted, Member States shall ensure that such support is coordinated with other support measures at Union or national level and is in line with applicable State aid rules.

Or. en

Amendment 1702
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 14 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Without prejudice to Articles 107 and 108 TFEU, Member States may make use, where applicable, of the relevant frameworks for providing public support to health biotechnology strategic projects and high impact health biotechnology strategic projects, including national promotional banks and other relevant public support instruments, as provided for in Article 24, paragraphs (4), (5) and (6). Where public support is granted, Member States shall ensure that such support is coordinated with other support measures at Union or national level and is in line with applicable State aid rules.	1. Without prejudice to Articles 107 and 108 TFEU, Member States may ***establish dedicated funding mechanisms for health biotechnology strategic projects and*** make use, where applicable, of the relevant frameworks for providing public support to health biotechnology strategic projects and high impact health biotechnology strategic projects, including national promotional banks and other relevant public support instruments, as provided for in Article 24, paragraphs (4), (5) and (6). Where public support is granted, Member States shall ensure that such support is coordinated with other support measures at Union or national level and is in line with applicable State aid rules.

Or. en

Amendment 1703
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 14 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Where public support is granted to health biotechnology strategic projects or high impact health biotechnology strategic projects, project promoters shall ensure that the products and services they develop based on, or partly based on, the results of the supported activities are affordable, available and accessible in the Member States under fair and reasonable conditions. The authority granting such public support shall set proportionate obligations, milestones and reporting

requirements, including, where relevant, on expected supply capacity, shortage-prevention measures, access conditions and the transparent declaration of direct public financial support received, without prejudice to the protection of commercially confidential information. Where serious non-compliance with those obligations is established, appropriate corrective measures may be applied in accordance with Union and national law.

Or. en

Amendment 1704
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 14 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Where public support is granted to health biotechnology strategic projects or high impact health biotechnology strategic projects, project promoters shall ensure that the products and services they develop based on, or partly based on, the results of the supported activities are affordable, available and accessible in the Member States under fair and reasonable conditions. Where the resulting products address significant public health needs in third countries in critical need, project promoters shall submit a global access plan to supply those countries, including through development partners or voluntary licensing. The minimum elements of the access plan are set out in Annex [IV].

Or. en

Amendment 1705
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 14 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Health biotechnology strategic projects and high impact health biotechnology strategic projects benefiting from Member states or Union funding must fully comply with Union and national ethical, environmental and social legislations. Project promoters shall ensure that the products and services they develop based on, or partly based on, the results of the supported activities are affordable, available and accessible in the Member States under fair and reasonable conditions.

Or. en

Amendment 1706
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 14 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. Projects receiving public funding or recognised as health biotechnology strategic projects or high impact health biotechnology strategic projects under this Regulation shall comply with appropriate transparency requirements. Such requirements shall include, as a minimum, the disclosure to the Commission of information on the total amount of public support received from Union and national sources, and on research and development costs fully or partially covered by public funds. Contracting authorities and national authorities responsible for pricing and reimbursement shall require beneficiaries to provide audited information on

research and development, production and distribution costs associated with the resulting products.

Or. en

Justification

Amendment drafted by Doctors without borders

Amendment 1707
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 14 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. Projects receiving public funding or recognised as health biotechnology strategic projects or high impact health biotechnology strategic projects under this Regulation shall comply with appropriate transparency requirements. Such requirements shall include, as a minimum, the disclosure to the Commission of information on the total amount of public support received from Union and national sources, and on research and development costs fully or partially covered by public funds. Contracting authorities and national authorities responsible for pricing and reimbursement may require beneficiaries to provide audited information on research and development, production and distribution costs associated with the resulting products.

Or. en

Amendment 1708
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation

Article 14 – paragraph 1 c (new)

Text proposed by the Commission	*Amendment*
	1c. Beneficiaries of health biotechnology strategic projects and high impact health biotechnology strategic projects receiving financial support pursuant to paragraphs 1 and 2 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 competent authority referred to in Article 9 and 10 and prepared in line with the guidance referred to in paragraph 3.

Or. en

Justification

Amendment drafted by the BEUC (the European consumer organisation)

Amendment 1709
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 14 – paragraph 1 c (new)

Text proposed by the Commission	*Amendment*
	1c. Non-compliance with the obligations set out in this paragraph by an undertaking that has received financial support for a health biotechnology strategic project may result in appropriate penalties, including the suspension, termination, or recovery — in full or in part — of the financial support granted, particularly in cases where the undertaking fails to ensure the availability or affordability of the resulting products in the Member States.

Or. en

Amendment 1710
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 14 – paragraph 1 d (new)

Text proposed by the Commission	*Amendment*
	1d. Non-compliance with the obligations set out in this paragraph by an undertaking and/or project promoter that has received financial support for a health biotechnology strategic project shall result in appropriate penalties, including the suspension, termination, or recovery of the financial support granted, particularly in cases where the undertaking fails to ensure the availability or affordability of the resulting products in the Member States.

Or. en

Justification

Amendment drafted by Doctors Without Borders

Amendment 1711
Ruggero Razza

Proposal for a regulation
Article 14 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) may be given particular consideration for Union financial support including in the form of blended financing, under Union programmes, funds and financial instruments and for national support as provided for in Article 25, if the basic regulations setting up such Union programmes allow it;	(a) may be given particular consideration for Union financial support including in the form of blended financing, ***with priority given to projects that generate lasting benefits for industry and employment in the Union,*** under Union programmes, funds and financial instruments and for national support as provided for in Article 25, if the basic regulations setting up such Union

programmes allow it;

Or. it

Amendment 1712
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Article 14 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) ***may*** be given particular consideration for Union financial support including in the form of blended financing, under Union programmes, funds and financial instruments and for national support as provided for in Article 25, if the basic regulations setting up such Union programmes allow it;	(a) ***shall*** be given particular consideration for Union financial support including in the form of blended financing, under Union programmes, funds and financial instruments and for national support as provided for in Article 25, if the basic regulations setting up such Union programmes allow it;

Or. en

Amendment 1713
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 14 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) ***may*** be given ***particular consideration*** for Union financial support including in the form of blended financing, under Union programmes, funds and financial instruments and for national support as provided for in Article 25, if the basic regulations setting up such Union programmes allow it;	(a) ***shall*** be given ***priority*** for Union financial support including in the form of blended financing, under Union programmes, funds and financial instruments and for national support as provided for in Article 25, if the basic regulations setting up such Union programmes allow it;

Or. en

Amendment 1714

Kristoffer Storm

Proposal for a regulation
Article 14 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) ***may be given particular consideration*** for Union financial support including in the form of blended financing, under Union programmes, funds and financial instruments and for national support as provided for in Article 25, if the basic regulations setting up such Union programmes allow it;	(a) ***shall receive priority*** for Union financial support including in the form of blended financing, under Union programmes, funds and financial instruments and for national support as provided for in Article 25, if the basic regulations setting up such Union programmes allow it;

Or. en

Amendment 1715
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 14 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) ***may be given particular consideration for*** Union financial support including in the form of blended financing, under Union programmes, funds and financial instruments and for national support as provided for in Article 25, if the basic regulations setting up such Union programmes allow it;	(a) ***shall receive priority*** Union financial support including in the form of blended financing, under Union programmes, funds and financial instruments and for national support as provided for in Article 25, if the basic regulations setting up such Union programmes allow it;

Or. en

Amendment 1716
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 14 – paragraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) shall comply with appropriate transparency requirements, including, at a minimum, the disclosure to the Commission of information on the total amount of public support received from Union and national sources, as well as on research and development costs fully or partially financed by public funds. Contracting authorities and national authorities responsible for pricing and reimbursement may require beneficiaries to provide audited information on research, development, production and distribution costs associated with the resulting products.

Or. en

Amendment 1717
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 14 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Beneficiaries of health biotechnology strategic projects and high-impact health biotechnology strategic projects receiving financial support pursuant to paragraphs 1 and 2 shall ensure that resulting products are affordable, available and accessible under fair and reasonable conditions. Where the resulting products address significant public health needs in third countries in critical need, project promoters shall submit a global access plan to supply those countries, including through development partners or voluntary licensing. These minimum elements shall be set out in an access plan submitted to the competent authority referred to in Article 9 and 10 and prepared in line with

the guidance referred to in paragraph 3.

Or. en

Justification

Public support should deliver public value. Requiring beneficiaries to include access and affordability measures in an access plan helps ensure that publicly funded health technologies improve patient access and provide a clear basis for accountability.

Amendment 1718
Aurelijus Veryga

Proposal for a regulation
Article 14 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Where public support is granted to health biotechnology strategic projects or high impact health biotechnology strategic projects, project promoters shall ensure that the products and services they develop based on, or partly based on, the results of the supported activities are affordable, available and accessible in the Member States under fair and reasonable conditions.

Or. en

Amendment 1719
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 14 – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
(a) support project promoters in identifying funding opportunities at Union level, and facilitate the liaison between project promoters and investors;	(a) support project promoters in identifying ***and accessing relevant*** funding opportunities at Union ***and national*** level***, including through the European Investment Bank Group, national promotional banks and institutions***, and

facilitate the liaison between project promoters and investors;

Or. en

Amendment 1720
Monika Beňová

Proposal for a regulation
Article 14 – paragraph 3 – point c

Text proposed by the Commission	*Amendment*
(c) facilitating access, in particular for SMEs, to relevant research and technological infrastructures, including where such infrastructures are funded through Union funding programmes, funds and financial instruments.	(c) facilitating access, in particular for SMEs***, start-ups and academic institutions***, to relevant research and technological infrastructures***, data infrastructures, testing environments, data quality accelerators and computing capacities***, including where such infrastructures are funded through Union funding programmes, funds and financial instruments***, under transparent, proportionate and affordable conditions***.

Or. en

Justification

It is important to clarify the role of start ups, academic institutions operating with little resources in small teams have access to the relevant enabling infrastructure to allow for competition with established entities. The nature of AI enabled approaches is that small teams even with a single member may compete with large entities if they have access to relevant data, compute infrastructure and resources.

Amendment 1721
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 14 – paragraph 3 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) promote equitable access to the

health biotechnology products and services resulting from supported activities, including by facilitating the uptake of access plans submitted pursuant to paragraph 1, issuing guidelines on their content and implementation, and, where relevant, supporting engagement with international partners and civil society organisations to facilitate access to such products in low- and middle-income countries.

Or. en

Amendment 1722
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 14 – paragraph 3 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) promote equitable access to the health biotechnology products and services resulting from supported activities, including by facilitating the uptake of access plans submitted pursuant to paragraph 1, issuing guidelines on their content and implementation, and, where relevant, supporting engagement with international partners and development organisations to facilitate access to such products in low- and middle-income countries.

Or. en

Amendment 1723
Kateřina Konečná

Proposal for a regulation
Article 14 – paragraph 3 – point c a (new)

Text proposed by the Commission	*Amendment*

(ca) promote equitable access to the health biotechnology products and services resulting from supported activities, including by facilitating the uptake of access plans submitted pursuant to paragraph 1, issuing guidelines on their content and implementation, and, where relevant, supporting engagement with international partners and development organisations to facilitate access to such products in low- and middle-income countries.

Or. en

Amendment 1724
Jérémy Decerle, Christophe Grudler

Proposal for a regulation
Article 14 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Where financial support is provided pursuant to this Article to health biotechnology strategic projects or high-impact health biotechnology strategic projects, project promoters shall take all appropriate measures, throughout the implementation of the supported project and for as long as the project benefits from such recognition, to maintain the project and its contribution referred to in Article 3(1) to critical capacities or technologies within the Union's health biotechnology value chain in the European Union's territory.
	The Commission is empowered to adopt delegated acts in accordance with Article 64 supplementing this Regulation by establishing a harmonised framework specifying the criteria and modalities for determining what constitutes 'appropriate measures' within the meaning of paragraph 4. Such delegated acts shall be adopted no later than 12 months after the

entry into force of this Regulation.

Or. en

Amendment 1725
Laurent Castillo, Aleksandar Nikolic, Valérie Deloge, Julie Rechagneux, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 14 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Member States that provide financial support for a strategic project shall lay down requirements for the beneficiary, including requiring them to prioritise supplies to the Union. Member States shall impose effective, proportionate and dissuasive penalties in the event that the rules are contravened. In the case of public funding for health biotechnology strategic projects or high impact health biotechnology strategic projects, the project promoters shall ensure that the products and services developed on the basis of the outcomes of the funded activities, or at least in part, are affordable, available and accessible to patients within the Union.

Or. fr

Amendment 1726
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 14 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. When Union financial support is provided, the European Commission shall set clearly defined obligations, milestones, and reporting requirements for the

beneficiary, and shall monitor and evaluate at regular intervals the use of such support and the beneficiary's compliance with those obligations. Where non-compliance is established, the European Commission shall impose effective, proportionate, and dissuasive sanctions.

Or. en

Justification

Facilitating access to funding can play an important role in strengthening the EU's industrial biomanufacturing capacity. However, improved access to funding must be accompanied by strong transparency mechanisms, robust monitoring, and clear reporting requirements when financial support is provided under Union programmes, instruments and as foreseen by the European Investment Bank Group. It is also essential to ensure that public investments deliver clear added value for patients, including a direct link to improved access, affordability, and better health outcomes.

Amendment 1727
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 14 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Clear and clearly defined obligations, milestones, and reporting requirements shall be established for beneficiaries. The Member State or the Commission providing financial support shall monitor and evaluate, at regular intervals, the use of such support and the beneficiary's compliance with those obligations.

Or. en

Amendment 1728
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 14 – paragraph 3 b (new)

Text proposed by the Commission	*Amendment*
	3b. Non-compliance by an undertaking receiving financial support for a health biotechnology strategic project shall result in appropriate corrective measures and sanctions, including the suspension, termination, or full or partial recovery of the financial support granted, in particular where the undertaking fails to ensure the availability or affordability of the resulting products across the Member States.

Or. en

Amendment 1729
Letizia Moratti, Fulvio Martusciello, Massimiliano Salini

Proposal for a regulation
Article 14 a (new)

Text proposed by the Commission	*Amendment*
	Article14a
	Accelerated assessment of clinical trials
	1. At the request of the sponsor of an investigational medicinal product, a clinical trial conducted in more than one Member State may be assessed in accordance with the accelerated procedure set out in this Article.
	2. The reporting Member State shall validate Part I of the application dossier, and each Member State concerned shall validate Part II of the application dossier for its territory, within five days from the date of submission.
	Where no notification is made within that period, the relevant part of the application dossier shall be deemed valid upon expiry

of that period.

Where the reporting Member State or a Member State concerned considers that the relevant part of the application dossier is not complete, it shall notify the sponsor via the EU portal and set a deadline not exceeding five days for completion of the application dossier. Upon submission of the completed application dossier, the reporting Member State and the Member States concerned shall confirm compliance with the requirements referred to in paragraph 2 within five days.

3. The reporting Member State shall assess Part I of the application dossier and prepare the Part I assessment report, and each Member State concerned shall assess Part II of the application dossier for its territory, within 26 days from the date of submission.

The conclusion of the reporting Member State as regards Part I of the assessment report shall be deemed to be accepted by the Member States concerned, unless a Member State concerned raises duly substantiated considerations on one of the grounds referred to in Article 8(2).

Within 21 days from the date of submission, each Member State concerned shall notify, via the EU portal, for the purposes of Part II of the assessment report, whether it intends to rely on the assessment of the reporting Member State for common elements of the application dossier or to provide comments on aspects specific to its territory.

4. Where no additional information is requested from the sponsor, the reporting Member State shall submit the final Part I assessment report and each Member State concerned shall complete Part II of the assessment report within 33 days from the submission date.

Where additional information is requested

from the sponsor in relation to Part I or Part II, the sponsor shall submit the requested information within the period set by the reporting Member State or the Member State concerned, as applicable. That period shall not exceed seven days from receipt of the request.

The reporting Member State shall finalise Part I of the assessment report, as part of the consolidation phase referred to in Article 6, and each Member State concerned shall complete Part II of the assessment report within seven days following completion of such review.

Upon receipt of the additional information, the reporting Member State and the Member States concerned shall review the information within seven days.

The reporting Member State shall finalise Part I of the assessment report, as part of the consolidation phase referred to in Article 6, and each Member State concerned shall complete Part II of the assessment report within seven days following completion of such review.

5. Each Member State concerned shall notify the sponsor through the EU portal, by way of one single decision, as to whether the clinical trial is authorised, authorised subject to conditions, or whether authorisation is refused, within five days from the reporting date or from the completion of the Part II assessment, whichever is later.

6. The application of this Article shall not affect the requirements for the protection of subjects, the assessment criteria set out in Articles 6 and 7, or the grounds for refusal or disagreement set out in Article 8.

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, and Clinical Trials Coordination and Advisory Group on the application of this Article.

This report shall be based, among others, on the information provided by the RMSs and sponsors regarding the impact of the accelerated procedure on the initiation of clinical trials.

The Commission shall, if appropriate, present legislative proposals based on that evaluation to expand, amend, or delete this Article.

Or. en

Amendment 1730
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 14 a (new)

Text proposed by the Commission	*Amendment*
	Article14a
	Joint procurement and innovative payment arrangements for medical countermeasures
	1. In support of the objectives of this Regulation, the Commission shall, in cooperation with Member States, develop guidelines on joint procurement, subscription-based payment arrangements and other innovative payment models for biotechnology products of strategic importance to the Union's health security, including vaccines, priority antimicrobials and other medical countermeasures against biological threats.
	2. The guidelines referred to in paragraph 1 may, in particular:
	(a) facilitate regional cooperation between groups of Member States with comparable health systems, health technology assessment frameworks and reimbursement environments, in order to aggregate demand and stabilise revenue streams for products affected by

recognised structural market failures;

(b) support the design of subscription-based or other delinked payment arrangements that decouple revenue from sales volume, in accordance with the principles set out 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;

(c) ensure complementarity with Joint Procurement Agreements concluded under Decision No 1082/2013/EU, or any successor instrument, on serious cross-border threats to health, and with the procurement-related provisions of Union legislation establishing measures to ensure the supply of critical medicinal products.

3. Member States are encouraged to make use of the guidelines referred to in paragraph 1 in the design of their national procurement and reimbursement procedures for products falling within the scope of this Regulation.

Or. en

Justification

Predictable procurement, including innovation procurement as demonstrated by DG HERA, is as decisive as upstream incentives in determining whether priority vaccines and antimicrobials reach patients. Subscription-based and delinked payment arrangements piloted in the United Kingdom and several Member States have demonstrated their feasibility and public-health value, but their broader deployment is constrained by the fragmentation of national procurement systems. The proposed Article 14a does not impose harmonisation: it tasks the Commission, in cooperation with Member States, with developing guidelines facilitating regional cooperation between Member States with comparable health-system characteristics. The provision complements the Critical Medicines Act and the Joint Procurement framework under Decision No 1082/2013/EU.

Amendment 1731
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 14 a (new)

Text proposed by the Commission	*Amendment*
	Article14a
	One Health priority product designation
	1. A medicinal product for human use, a veterinary medicinal product, or a medicinal product intended for both human and veterinary use, that is designed for the prevention, treatment or control of a zoonotic disease of significant public health relevance may, upon application by the developer or on the initiative of the Commission, be designated as a One Health Priority Product, in accordance with the criteria laid down in this Regulation.
	2. A medicinal product designated as a One Health Priority Product shall be eligible to benefit from the following support measures (a) priority scientific advice and enhanced regulatory support from the competent Union authorities; (b) accelerated assessment procedures, where the conditions established under the applicable Union pharmaceutical legislation are fulfilled; (c) a reduction or waiver of regulatory fees, in accordance with the applicable Union legal framework; (d) priority consideration for designation as a Strategic Project and eligibility for the financial and administrative support measures provided for under this Regulation; and (e) priority consideration in Union procurement, advance purchasing, stockpiling and other demand-side support mechanisms, including those established under the Critical Medicines Act and the instruments managed by the Health Emergency Preparedness and Response Authority (HERA).
	3. The designation of a medicinal product as a One Health Priority Product shall not affect the requirements relating to its quality, safety and efficacy under applicable Union pharmaceutical

legislation, nor shall it confer any exclusive rights beyond those expressly provided for in this Regulation.

Or. en