European Parliament
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Committee on Public Health
Committee on Industry, Research and Energy

2025/0406(COD)

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AMENDMENTS
2048 - 2330

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 2048
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Chapter IV

Text proposed by the Commission	*Amendment*
IV EXTENSION OF THE SUPPLEMENTARY PROTECTION CERTIFICATE	***deleted***
27 Extension of the supplementary protection certificate concerning best-in-class biotechnology medicines developed in the Union	
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:	
(a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union;	
(b) the medicinal product has a mechanism of action distinctly different and shows a level of safety and efficacy	

which is at least equivalent to that of any authorised medicinal product in the Union for the same disease;

(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than two Member States;

(d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.

2. The European Medicines Agency ('the Agency') shall assess compliance with the conditions referred to in paragraph 1 as part of the marketing authorisation procedure concerned.

3. Where compliance is confirmed, the Agency shall issue a statement to that effect.

4. A copy of the statement referred to in paragraph 3 of this Article shall be included in the application for a certificate lodged under article 7 of Regulation (EC) No 469/2009.

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[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Amendment 2049
Christine Anderson

Proposal for a regulation
Chapter IV

Text proposed by the Commission	*Amendment*

IV EXTENSION OF THE SUPPLEMENTARY PROTECTION CERTIFICATE

deleted

27 Extension of the supplementary protection certificate concerning best-in-class biotechnology medicines developed in the Union

1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:

(a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union;

(b) the medicinal product has a mechanism of action distinctly different and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same disease;

(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation

were conducted in more than two Member States;

(d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.

2. The European Medicines Agency ('the Agency') shall assess compliance with the conditions referred to in paragraph 1 as part of the marketing authorisation procedure concerned.

3. Where compliance is confirmed, the Agency shall issue a statement to that effect.

4. A copy of the statement referred to in paragraph 3 of this Article shall be included in the application for a certificate lodged under article 7 of Regulation (EC) No 469/2009.

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[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Amendment 2050
Dimitris Tsiodras

Proposal for a regulation
Chapter IV

Text proposed by the Commission	*Amendment*
IV EXTENSION OF THE SUPPLEMENTARY PROTECTION CERTIFICATE	***deleted***
27 Extension of the supplementary protection certificate concerning best-in-class biotechnology medicines developed in the Union	

1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:

(a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union;

(b) the medicinal product has a mechanism of action distinctly different and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same disease;

(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than two Member States;

(d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.

2. The European Medicines Agency ('the Agency') shall assess compliance with the conditions referred to in paragraph 1 as

part of the marketing authorisation procedure concerned.

3. Where compliance is confirmed, the Agency shall issue a statement to that effect.

4. A copy of the statement referred to in paragraph 3 of this Article shall be included in the application for a certificate lodged under article 7 of Regulation (EC) No 469/2009.

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[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Justification

Deletion of Article 27. Historically, all studies, including EC studies have assessed a lack of correlation between IPR extension and investment, competitiveness. Other levers, such as financial incentives, funding, streamlining of administrative and regulatory processes. Other global Biotech hubs (China, US) have successfully increased their competitiveness without extending IPRs.

Amendment 2051
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Chapter IV

Text proposed by the Commission	*Amendment*
IV EXTENSION OF THE SUPPLEMENTARY PROTECTION CERTIFICATE	***deleted***
27 Extension of the supplementary protection certificate concerning best-in-class biotechnology medicines developed in the Union	
1. Where a marketing authorisation is granted by the Union to a medicinal	

product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:

(a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union;

(b) the medicinal product has a mechanism of action distinctly different and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same disease;

(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than two Member States;

(d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.

2. The European Medicines Agency ('the Agency') shall assess compliance with the conditions referred to in paragraph 1 as part of the marketing authorisation procedure concerned.

3. Where compliance is confirmed, the Agency shall issue a statement to that effect.

4. A copy of the statement referred to in paragraph 3 of this Article shall be included in the application for a certificate lodged under article 7 of Regulation (EC) No 469/2009.

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[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Amendment 2052
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Chapter IV – title

Text proposed by the Commission	*Amendment*
IV ***EXTENSION*** OF THE SUPPLEMENTARY PROTECTION CERTIFICATE	IV ***WAIVER*** OF THE SUPPLEMENTARY PROTECTION CERTIFICATE

Or. en

Amendment 2053
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 27

Text proposed by the Commission	*Amendment*
Article 27	***deleted***

Extension of the supplementary protection certificate concerning best-in-class biotechnology medicines developed in the Union

1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:

(a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union;

(b) the medicinal product has a mechanism of action distinctly different and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same disease;

(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than two Member States;

(d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.

2. The European Medicines Agency ('the Agency') shall assess compliance with the conditions referred to in paragraph 1 as part of the marketing authorisation procedure concerned.

3. Where compliance is confirmed, the Agency shall issue a statement to that effect.

4. A copy of the statement referred to in paragraph 3 of this Article shall be included in the application for a certificate lodged under article 7 of Regulation (EC) No 469/2009.

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[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Amendment 2054
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 27

Text proposed by the Commission	*Amendment*
Article 27	***deleted***
Extension of the supplementary protection certificate concerning best-in-class biotechnology medicines developed in the Union	
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to	

Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:

(a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union;

(b) the medicinal product has a mechanism of action distinctly different and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same disease;

(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than two Member States;

(d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.

2. The European Medicines Agency ('the Agency') shall assess compliance with the conditions referred to in paragraph 1 as part of the marketing authorisation procedure concerned.

3. Where compliance is confirmed, the Agency shall issue a statement to that effect.

4. A copy of the statement referred to in paragraph 3 of this Article shall be included in the application for a certificate lodged under article 7 of Regulation (EC) No 469/2009.

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[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Amendment 2055
Viktória Ferenc, András Gyürk

Proposal for a regulation
Article 27

Text proposed by the Commission	*Amendment*
Article 27	***deleted***
Extension of the supplementary protection certificate concerning best-in-class biotechnology medicines developed in the Union	
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a	

patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:

(a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union;

(b) the medicinal product has a mechanism of action distinctly different and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same disease;

(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than two Member States;

(d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.

2. The European Medicines Agency ('the Agency') shall assess compliance with the conditions referred to in paragraph 1 as part of the marketing authorisation procedure concerned.

3. Where compliance is confirmed, the Agency shall issue a statement to that effect.

4. A copy of the statement referred to in paragraph 3 of this Article shall be included in the application for a certificate lodged under article 7 of Regulation (EC) No 469/2009.

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[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for

medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Amendment 2056
Kateřina Konečná

Proposal for a regulation
Article 27

Text proposed by the Commission	*Amendment*
Article 27	***deleted***
Extension of the supplementary protection certificate concerning best-in-class biotechnology medicines developed in the Union	
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:	
(a) the medicinal product contains a new active substance distinctly different from	

that of any authorised medicinal product in the Union;

(b) the medicinal product has a mechanism of action distinctly different and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same disease;

(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than two Member States;

(d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.

2. The European Medicines Agency ('the Agency') shall assess compliance with the conditions referred to in paragraph 1 as part of the marketing authorisation procedure concerned.

3. Where compliance is confirmed, the Agency shall issue a statement to that effect.

4. A copy of the statement referred to in paragraph 3 of this Article shall be included in the application for a certificate lodged under article 7 of Regulation (EC) No 469/2009.

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[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Amendment 2057
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Victor Negrescu, Dario Nardella

Proposal for a regulation
Article 27 – title

Text proposed by the Commission	*Amendment*
Extension of the supplementary protection certificate concerning best-in-class biotechnology ***medicines*** developed in the Union	Extension of the supplementary protection certificate concerning best-in-class biotechnology ***medicinal products*** developed in the Union

Or. en

Amendment 2058
Michele Picaro

Proposal for a regulation
Article 27 – title

Text proposed by the Commission	*Amendment*
Extension of the supplementary protection certificate concerning best-in-class ***biotechnology*** medicines developed in the Union	Extension of the supplementary protection certificate concerning best-in-class medicines developed in the Union

Or. en

Amendment 2059
Peter Agius

Proposal for a regulation
Article 27 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is	***deleted***

protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:

(a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union;

(b) the medicinal product has a mechanism of action distinctly different and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same disease;

(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than two Member States;

(d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.

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[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Amendment 2060

Ruggero Razza

Proposal for a regulation
Article 27 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69], or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:	1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69], or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009 ***with a view to bridging the competitiveness gap vis-à-vis the protection regimes associated with biotechnology innovation in third countries and bringing the effective duration of patent protections and supplementary protection certificates into line with practice in China and the United States, not least given the lengthy nature of development cycles***, ***and*** provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:
[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1	[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1

Or. it

Amendment 2061
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 27 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use ***developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and*** that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a ***12***-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:	1. Where a marketing authorisation is granted by the Union to a medicinal product for human use that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a ***24***-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:
[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.	[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Amendment 2062
Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 27 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of ***biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex***, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that ***all of*** the following conditions are met:	1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of ***health biotechnology***, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that the following conditions are met:
[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.	[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Amendment 2063
Letizia Moratti, Fulvio Martusciello, Massimiliano Salini

Proposal for a regulation
Article 27 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*

1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of ***biotechnological processes referred to in paragraph 1 of Annex I to*** Regulation ***(EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy*** medicinal product ***referred to in paragraph 2 of that Annex***, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a ***12***-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:	1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of ***health biotechnology as defined in article 2.1(2) of this*** Regulation ***or by means of chemical synthesis, for which the clinical trials evaluating the efficacy of the*** medicinal product ***and supporting its marketing authorisation were conducted in one Member States and at least a manufacturing step***, ***excluding packaging, quality testing and certification is performed in the Union, and*** and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a ***24***-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:
[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.	[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Justification

The proposal provides for a wider extension of the (SPC) benefit up to 24 months; the conditions set out under points (c) and (d) are integrated into the operative provisions of this Regulation and are therefore mandatory, while those set out under points (a) and (b) are alternative. To address the decline in the availability of innovative medicinal products on the Union market, estimated at up to 35%, an additional six-month extension of the SPC is provided where the medicinal product is first launched worldwide in at least one Member State.

Amendment 2064
Kristoffer Storm

Proposal for a regulation
Article 27 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of ***biotechnological processes*** referred to in ***paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex,*** and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council***[69]*** , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing ***authorisation*** applicant demonstrates that ***all*** of the following conditions are met:	1. Where a marketing authorisation is granted by the Union to a medicinal product for human use ***at least partially*** developed ***or manufactured*** by means of ***biotechnology*** referred to in ***Article 2 of this Act*** and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council, or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing ***authorization*** applicant demonstrates that ***at least two*** of the following ***four*** conditions are met:
[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.	

Or. en

Amendment 2065
Morten Løkkegaard, Katri Kulmuni, Sophie Wilmès

Proposal for a regulation
Article 27 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that ***all*** of the following conditions are met:	1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that ***both of the conditions set out in points (c) and (d) and that one of the two conditions set out in points (a) and (b)*** of the following conditions are met:
[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.	[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Amendment 2066
Paulo Cunha, Sérgio Humberto

Proposal for a regulation
Article 27 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*

1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes ***referred to in paragraph 1 of Annex I to*** Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] ***or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex***, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:	1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes ***in accordance with*** Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final], and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:
[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.	[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Justification

Arbitrary considerations as to which products are encompassed by this protection is not in line with the purpose of technologic neutrality and consequently excludes several products that are also born out of innovative biotech processes. Innovative therapies and medical products that are disregarded by such legislation will lead to its research and development being disincentivized, thus hindering the development and appearance of innovative therapies and products solely due to an arbitrary selection of which products are patent-protected and which are not

Amendment 2067
Margarita de la Pisa Carrión, Laurent Castillo, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 27 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a ***12***-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates ***that all*** of the following conditions are met:	1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a ***24***-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates ***at least one of point (a) or (b), as well as at least one of point (c) or (d)*** of the following conditions are met:
[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.	[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Amendment 2068
Sophie Wilmès, Olivier Chastel, Morten Løkkegaard

Proposal for a regulation
Article 27 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that ***all of the*** following conditions are met:	1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that following conditions ***a or b as well as conditions c and d*** are met:
[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.	[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Amendment 2069
Ondřej Krutílek

Proposal for a regulation
Article 27 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed ***by***	1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed ***in***

means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] ***or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex***, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that ***all of*** the following conditions are met:

accordance with Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final], and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council ***[1]***, or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that the following conditions are met: ***[1] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.***

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[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Amendment 2070
Kristoffer Storm

Proposal for a regulation
Article 27 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of ***biotechnological processes*** referred to in ***paragraph 1 of Annex I to*** Regulation ***(EU) …/… [reference to be added after***	1. Where a marketing authorisation is granted by the Union to a medicinal product for human use ***at least partially*** developed ***or manufactured*** by means of ***biotechnology*** referred to in ***Article 2 of this*** Regulation and that is protected either

adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that ***all*** of the following conditions are met:

by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that ***at least two*** of the following ***four*** conditions are met:

[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Amendment 2071
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu

Proposal for a regulation
Article 27 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No	1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or ***via chemical synthesis or*** to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No

469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a ***12***-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:

469/2009 of the European Parliament and of the Council[5], or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a ***6***-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:

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[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Justification

The amendment introduces a proportionate model. A general six-month SPC extension may be granted where the core eligibility conditions are met, while a further extension is reserved under paragraph 3c for medicinal products addressing high unmet medical need of major public health relevance. This ensures that the strongest incentive is targeted to the most urgent public health. The addition of "or via chemical synthesis" ensures that best-in-class innovation developed in the Union can be covered irrespective of the specific production or development technology used.

Amendment 2072
Katri Kulmuni, Stine Bosse, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 27 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological ***processes*** referred to ***in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final]*** or to	1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of ***of biotechnology or biomanufacturing*** biotechnological referred to ***the definitions in Article 2*** or to an advanced therapy medicinal product referred to in

an advanced therapy medicinal product referred to in ***paragraph 2 of that Annex,*** and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:

Regulation (EC) No 1394/2007 and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:

[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Amendment 2073
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel

Proposal for a regulation
Article 27 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of ***biotechnological processes*** referred to in ***paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final]*** or to an advanced therapy medicinal product referred to in ***paragraph 2 of that Annex***, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and	1. Where a marketing authorisation is granted by the Union to a medicinal product for human use ***at least partically*** developed ***or manufactured*** by means of ***biotechnology or biomanufacturing*** referred to in ***article 2*** or to an advanced therapy medicinal product referred to in ***Regulation (EC) No 1394/2007***, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the

of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:

granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a 12-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:

[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Amendment 2074
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 27 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and ***that is protected either by*** a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council***[69]***, or by ***a patent which qualifies for the granting of*** such ***supplementary protection*** certificate, the holder of a patent or of such certificate ***shall be entitled to a 12-month*** extension of the periods referred to in Article 13,	1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and ***where this product is protected by a basic patent which qualifies for the granting of*** a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council, or ***is covered*** by such ***a*** certificate, the holder of a ***basic*** patent or of such certificate ***may apply for an*** extension of the periods referred to in Article 13, paragraphs (1)

paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:

and (2), of Regulation (EC) No 469/2009, provided that ***the extension does not exceed six months and*** the marketing authorisation applicant demonstrates that all of the following conditions are met:

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[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. pl

Amendment 2075
Laurent Castillo, Aleksandar Nikolic, Valérie Deloge, Julie Rechagneux, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 27 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69], or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to ***a 12***-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing	1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69], or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to ***an 18***-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing

authorisation applicant demonstrates that all of the following conditions are met:	authorisation applicant demonstrates that all of the following conditions are met:
[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1	[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1

Or. fr

Amendment 2076
Wouter Beke, Angelika Niebler, Angelika Winzig, Aura Salla, Jessica Polfjärd, Andrea Wechsler, Oliver Schenk, Niels Flemming Hansen, Christian Ehler

Proposal for a regulation
Article 27 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a ***12***-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that ***all*** of the following conditions ***are*** met:	1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a ***24***-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that ***one*** of the following conditions ***is*** met:

[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Amendment 2077
Aura Salla

Proposal for a regulation
Article 27 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to ***a 12***-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:	1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to ***24***-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that all of the following conditions are met:

[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Amendment 2078
Jessica Polfjärd

Proposal for a regulation
Article 27 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a ***12***-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that ***all of*** the following conditions are met:	1. Where a marketing authorisation is granted by the Union to a medicinal product for human use developed by means of biotechnological processes referred to in paragraph 1 of Annex I to Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] or to an advanced therapy medicinal product referred to in paragraph 2 of that Annex, and that is protected either by a supplementary protection certificate in accordance with Regulation (EC) No 469/2009 of the European Parliament and of the Council[69] , or by a patent which qualifies for the granting of such supplementary protection certificate, the holder of a patent or of such certificate shall be entitled to a ***24***-month extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009, provided that the marketing authorisation applicant demonstrates that the following conditions are met:
[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.	[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152, 16.6.2009, pp. 1.

Or. en

Amendment 2079

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

Proposal for a regulation
Article 27 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union;	(a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union ***and does not merely constitute a new formulation, strength, route of administration, presentation or line extension of an active substance already authorised in the Union, unless the applicant demonstrates a clinically meaningful therapeutic advantage***;

Or. en

Justification

This condition ensures that the incentive is reserved for genuinely new active substances and avoids rewarding minor modifications, line extensions or incremental changes to already authorised active substances, unless a clinically meaningful therapeutic advantage is demonstrated.

Amendment 2080
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel

Proposal for a regulation
Article 27 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union;	(a) the medicinal product contains a new active substance***, as assessed at the time of filing of the initial application for marketing authorisation, which is*** distinctly different from that of any authorised medicinal product in the Union;

Or. en

Amendment 2081
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 27 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the medicinal product contains a new active substance ***distinctly different from that of any*** authorised medicinal ***product*** in the Union;	(a) the medicinal product contains a new active substance ***whose status as such has been assessed by the Agency and which is substantially different in scientific terms from the active substances contained in other*** authorised medicinal ***products*** in the Union;

Or. pl

Amendment 2082
Letizia Moratti, Fulvio Martusciello, Massimiliano Salini

Proposal for a regulation
Article 27 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the medicinal product contains a new active substance ***distinctly different from that of any authorised medicinal product in the Union;***	(a) the medicinal product contains a new active substance***; or***

Or. en

Amendment 2083
Jessica Polfjärd

Proposal for a regulation
Article 27 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the medicinal product contains a new active substance ***distinctly different from that of any authorised medicinal product in the Union***;	(a) the medicinal product contains a new active substance ***or***;

Or. en

Amendment 2084
Kristoffer Storm, Aurelijus Veryga

Proposal for a regulation
Article 27 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the medicinal product contains a new active substance ***distinctly different from that of any authorised medicinal product in the Union***;	(a) the medicinal product contains a new active substance***, as assessed at the time of filing of the initial application for a marketing authorisation***;
	or

Or. en

Amendment 2085
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 27 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the medicinal product contains a new active substance ***distinctly different from that of any authorised medicinal product in the Union;***	(a) the medicinal product contains a new active substance***, as assessed at the time of filing of the initial application for a marketing authorisation or***

Or. en

Amendment 2086
Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 27 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*

(a) the medicinal product contains a new active substance ***distinctly different from that of any authorised medicinal product in the Union***;	(a) the medicinal product contains a new active substance ***as assessed at the time of filing of the initial application for a marketing authorisation***; ***or***

Or. en

Amendment 2087
Ondřej Krutílek

Proposal for a regulation
Article 27 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the medicinal product contains a new active substance ***distinctly different from that of any authorised medicinal product in the Union***;	(a) the medicinal product contains a new active substance***, as assessed at the time of filing of the initial application for a marketing authorisation***;

Or. en

Amendment 2088
Kristoffer Storm

Proposal for a regulation
Article 27 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the medicinal product contains a new active substance ***distinctly different from that of any authorised medicinal product in the Union;***	(a) the medicinal product contains a new active substance***, as assessed at the time of filing of the initial application for a marketing authorisation***

Or. en

Amendment 2089
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 27 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the medicinal product contains a new active substance ***distinctly different from that of any authorised medicinal product in the Union;***	(a) the medicinal product contains a new active substance ***as assessed at the time of submission of the initial marketing authorisation application***

Or. en

Amendment 2090
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 27 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the medicinal product contains a new active substance ***distinctly*** different from that of any authorised medicinal product in the Union;	(a) the medicinal product contains a new active substance different from that of any authorised medicinal product in the Union;

Or. en

Amendment 2091
Wouter Beke, Angelika Niebler, Angelika Winzig, Aura Salla, Jessica Polfjärd, Andrea Wechsler, Oliver Schenk, Niels Flemming Hansen, Christian Ehler

Proposal for a regulation
Article 27 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the medicinal product contains a new active substance ***distinctly different from that of*** any authorised medicinal product in the Union;	(a) the medicinal product contains a new active substance ***compared to*** any authorised medicinal product in the Union; ***or***

Or. en

Amendment 2092

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

Proposal for a regulation
Article 27 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the medicinal product has a mechanism of action distinctly different and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same disease;	(b) the medicinal product has a ***novel or clearly differentiated*** mechanism of action distinctly different and shows a level of safety and efficacy which is at least equivalent to ***clinically meaningfully superior, or otherwise demonstrates a clearly substantiated therapeutic advantage compared with*** that of any authorised medicinal product in the Union for the same disease ***indication. Therapeutic advantage shall be demonstrated on the basis of evidence assessed by the competent Union bodies, including where relevant clinical expertise, HTA expertise, patient input and ERN evidence for rare disease products***;

Or. en

Justification

his condition strengthens the best-in-class requirement by linking the incentive to a clinically meaningful therapeutic advantage, taking into account unmet medical need, patient-relevant outcomes, quality of life, safety and effectiveness. It also ensures that relevant evidence, including HTA expertise, patient input, ERN evidence and scientifically robust non-clinical, translational or other innovative evidence sources, where appropriate.

Amendment 2093
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 27 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the medicinal product has a mechanism of action ***distinctly different*** and shows a level of safety and efficacy	(b) the medicinal product has a ***new*** mechanism of action and ***has not previously been authorised in the Union***

which is at least equivalent to that of ***any*** authorised medicinal ***product*** in the Union for the same disease;	***for the same disease, and the difference in the mechanism of action has been demonstrated on the basis of appropriate comparative data; the product*** shows a level of safety and efficacy which is at least equivalent to that of ***other*** authorised medicinal ***products*** in the Union for the same disease***, and shows a demonstrable therapeutic advantage***;

Or. pl

Amendment 2094
Kateřina Konečná

Proposal for a regulation
Article 27 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the medicinal product has a mechanism of action distinctly different and ***shows a level of safety and efficacy which is at least equivalent to that of*** any authorised medicinal product in the Union for the same disease;	(b) the medicinal product has a mechanism of action distinctly different and***; offers a meaningful improvement in clinical outcomes and patient-relevant clinical benefit within the meaning of Article 2(1), point (26), compared to*** any authorised medicinal product in the Union for the same disease***, on the basis of a comparative assessment carried out, where applicable, in accordance with Regulation (EU) 2021/2282***;

Or. en

Amendment 2095
Ingeborg Ter Laak, Willemien Koning, Dolors Montserrat, Elena Nevado del Campo

Proposal for a regulation
Article 27 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the medicinal product has a mechanism of action distinctly different	(b) the medicinal product has a mechanism of action distinctly different

and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same disease;	and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same disease***, provided that it addresses unmet medical needs or significantly improves existing treatment options for patients***;

Or. en

Justification

This amendment maintains the Commission's proportionate 12-month incentive for genuine therapeutic innovation. It ensures that the extension is reserved for products addressing an unmet medical need or significantly improving existing treatment options, thereby promoting meaningful patient benefit and access to innovation. It also preserves the Commission's broad approach, avoiding complex therapy-specific classifications and ensuring a balanced, proportionate and workable framework.

Amendment 2096
Letizia Moratti, Fulvio Martusciello, Massimiliano Salini

Proposal for a regulation
Article 27 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the medicinal product has a mechanism of action ***distinctly*** different ***and shows a level of safety and efficacy which is at least equivalent*** to that of any authorised medicinal product in the Union for the same ***disease***;	(b) the medicinal product has a mechanism of action different to that of any authorised medicinal product in the Union for the same ***indication***;

Or. en

Amendment 2097
Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 27 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*

(b) the medicinal product has a mechanism of action ***distinctly different and*** shows a level of safety ***and*** efficacy ***which is at least equivalent*** to that of any authorised medicinal product in the Union for the same ***disease***;	(b) the medicinal product has a ***different*** mechanism of action ***or*** shows a ***superior*** level of safety ***or*** efficacy to that of any authorised medicinal product in the Union for the same ***indication, as assessed at the time of filing in the initial application***; ***and***

Or. en

Amendment 2098
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel, Morten Løkkegaard

Proposal for a regulation
Article 27 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the medicinal product has a mechanism of action ***distinctly*** different and ***shows a level of*** safety and efficacy ***which is at least equivalent to that of any authorised medicinal product in the Union*** for the same ***disease***;	(b) the medicinal product has a mechanism of action ***which is*** different and ***meets the Agency's*** safety and efficacy ***requirements*** for the same ***indication, as assessed at the time of filing of the initial application for marketing authorisation***;

Or. en

Justification

It is not clear, including to the Agency itself, how EMA can establish what a "distinctly different" mechanism of action is. The proposed "safety and efficacy equivalence" requirement does not correspond to any established regulatory standard. Therefore, these are not considered to be workable requirements.

Amendment 2099
Kristoffer Storm, Aurelijus Veryga

Proposal for a regulation
Article 27 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the medicinal product has a mechanism of action ***distinctly*** different and ***shows a level of safety and efficacy***	(b) the medicinal product has a mechanism of action different and to that of any authorised medicinal product in the

which is at least equivalent to that of any authorised medicinal product in the Union for the same ***disease***;	Union for the same ***indication, as assessed at the time of filing of the initial application***; ***and***

Or. en

Amendment 2100
Kristoffer Storm

Proposal for a regulation
Article 27 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the medicinal product has a mechanism of action ***distinctly*** different and ***shows a level of safety and efficacy which is at least equivalent*** to that of any authorised medicinal product in the Union for the same disease;	(b) the medicinal product has a mechanism of action different and to that of any authorised medicinal product in the Union for the same disease ***indication, as assessed at the time of filing of the initial application***;

Or. en

Amendment 2101
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 27 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the medicinal product has a mechanism of action ***distinctly*** different and ***shows a level of safety and efficacy which is at least equivalent*** to that of any authorised medicinal product in the Union for the same ***disease***;	(b) the medicinal product has a mechanism of action different and to that of any authorised medicinal product in the Union for the same ***indication, as assessed at the time of filing of the initial application***; ***and***

Or. en

Amendment 2102

Wouter Beke, Angelika Niebler, Angelika Winzig, Aura Salla, Jessica Polfjärd, Andrea Wechsler, Oliver Schenk, Niels Flemming Hansen, Christian Ehler

Proposal for a regulation
Article 27 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the medicinal product has a mechanism of action ***distinctly different*** and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same ***disease***;	(b) the medicinal product has a mechanism of action and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same ***indication***; ***and***

Or. en

Amendment 2103
Jessica Polfjärd

Proposal for a regulation
Article 27 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the medicinal product has a mechanism of action ***distinctly different*** and shows a level of safety and efficacy which is ***at least*** equivalent to that of any authorised medicinal product in the Union for the same disease;	(b) the medicinal product has a ***different*** mechanism of action and shows a level of safety and efficacy which is equivalent to that of any authorised medicinal product in the Union for the same disease***, and***;

Or. en

Amendment 2104
Ondřej Krutílek

Proposal for a regulation
Article 27 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the medicinal product has a mechanism of action ***distinctly*** different ***and shows a level of safety and efficacy***	(b) the medicinal product has a mechanism of action different to that of any authorised medicinal product in the

which is at least equivalent to that of any authorised medicinal product in the Union for the same ***disease***;	Union for the same ***indication, as assessed at the time of filing of the initial application***;

Or. en

Amendment 2105
Letizia Moratti, Fulvio Martusciello, Massimiliano Salini

Proposal for a regulation
Article 27 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than two Member States;	***deleted***

Or. en

Amendment 2106
Tomislav Sokol

Proposal for a regulation
Article 27 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than ***two*** Member States;	(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than ***three*** Member States***, including at least one Member State accounting for less than 3 % of all clinical trials authorised under Regulation (EU) No 536/2014 during the five calendar years preceding the application for the marketing authorisation, provided that at least 10 % of the subjects enrolled in those clinical trials were recruited in that Member State***;

Or. en

Amendment 2107
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 27 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in ***more than two*** Member States;	(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in ***at least three*** Member States***, including at least one Member State whose per capita gross domestic product measured in purchasing power parities is lower than the Union average based on the latest Eurostat data available at the time when the trial commences***;

Or. pl

Amendment 2108
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Victor Negrescu, Dario Nardella

Proposal for a regulation
Article 27 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than ***two*** Member States;	(c) the clinical trials evaluating the ***safety and*** efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than ***five*** Member States ***and included patient populations that are sufficiently representative of the patients expected to use the medicinal product in the Union***;

Or. en

Justification

The amendment strengthens the Union dimension of the incentive by requiring clinical trials in more than five Member States and sufficiently representative patient populations. This supports broader clinical evidence generation across the Union and helps ensure that the product is relevant for the patients expected to use it in different Member States.

Amendment 2109
Peter Liese

Proposal for a regulation
Article 27 – paragraph 1 – point c
Article 27
Paragraph 1, point (c)

Text proposed by the Commission	*Amendment*
(c) the clinical trials evaluating the efficacy of the medicinal product and ***supporting its marketing authorisation were*** conducted in more ***than two*** Member States***;***	(c) the clinical trials evaluating the efficacy of the medicinal product and ***include at least one pivotal multinational trial*** conducted in ***two or*** more Member States ***with a demographically diverse EU population***

Or. en

Justification

Ensures that the 12-month SPC extension is linked to genuine EU-relevant data.

Amendment 2110
Kristoffer Storm, Aurelijus Veryga

Proposal for a regulation
Article 27 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than two Member States;	(c) ***at least one of*** the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than two Member States; ***or***

Or. en

Amendment 2111
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 27 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than two Member States;	(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than two Member States ***or in EEA/EFTA countries***;

Or. en

Amendment 2112
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 27 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation ***were*** conducted in more than two Member States;	(c) ***at least one of*** the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation ***was*** conducted in more than two Member States; ***or***

Or. en

Amendment 2113
Ondřej Krutílek

Proposal for a regulation
Article 27 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*

(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than two Member States;	(c) ***at least one of*** the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than two Member States;

Or. en

Amendment 2114
Kristoffer Storm

Proposal for a regulation
Article 27 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than two Member States;	(c) ***at least one of*** the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than two Member States; ***or***

Or. en

Amendment 2115
Wouter Beke, Angelika Niebler, Angelika Winzig, Aura Salla, Jessica Polfjärd, Andrea Wechsler, Oliver Schenk, Niels Flemming Hansen, Christian Ehler

Proposal for a regulation
Article 27 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than ***two*** Member States;	(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than ***one*** Member States; ***or***

Or. en

Amendment 2116
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 27 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than ***two*** Member States;	(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more than ***five*** Member States;

Or. en

Amendment 2117
Jessica Polfjärd

Proposal for a regulation
Article 27 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted ***in more than two Member States***;	(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted ***within the Union, or***;

Or. en

Amendment 2118
Letizia Moratti, Fulvio Martusciello, Massimiliano Salini

Proposal for a regulation
Article 27 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.	***deleted***

Or. en

Amendment 2119
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu, Dario Nardella

Proposal for a regulation
Article 27 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) at least ***a*** manufacturing ***step, excluding*** packaging, quality testing and certification ***is performed*** in the Union***.***	(d) at least ***substantial*** manufacturing ***steps are carried out within the Union other than import, repackaging,*** packaging ***other than immediate packaging, labelling***, quality testing and***, where applicable,*** certification***, and a substantial part of the development of the medicinal product, including clinical development or process development, was carried out*** in the Union ***and contributed to strengthening the Union's scientific, clinical or regulatory knowledge base;***

Or. en

Justification

This condition ensures that the SPC extension is linked to a substantial contribution to the Union's development, manufacturing, scientific, clinical or regulatory capacity. It avoids rewarding products with only marginal or formal links to the Union, such as packaging or quality testing alone.

Amendment 2120
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 27 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) at least ***a*** manufacturing ***step***, excluding packaging, quality testing and certification ***is*** performed in the Union***.***	(d) at least ***two significant*** manufacturing ***steps, including the manufacture of the active substance or an intermediate product of critical importance for manufacturing the medicinal product***, excluding packaging, ***batch release,*** quality testing and certification ***are*** performed in the Union***;***

Or. pl

Amendment 2121
Ruggero Razza

Proposal for a regulation
Article 27 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.	(d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union***, a provision designed to help step up European production capacities and bolster the resilience of supply chains for biotechnology medicinal products***.

Or. it

Amendment 2122
Peter Liese

Proposal for a regulation
Article 27 – paragraph 1 – point d
Article 27
Paragraph 1, Point (d)

Text proposed by the Commission	*Amendment*
(d) ***at least a*** manufacturing ***step, excluding packaging, quality testing and certification is performed in the Union***.	(d) ***The clinical development and*** manufacturing ***processes comply with the ethical limitations laid down in Directive 98/44/EC, Article 6; applicants shall provide a declaration of conformity***.

Or. en

Justification

Requiring a declaration of conformity provides legal certainty that applicants benefiting from the SPC extension comply with Union ethical requirements.

Amendment 2123

Wouter Beke, Angelika Niebler, Angelika Winzig, Aura Salla, Jessica Polfjärd, Andrea Wechsler, Oliver Schenk, Niels Flemming Hansen, Christian Ehler

Proposal for a regulation
Article 27 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.	(d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union ***, at least for the duration of the supplementary protection certificate***.

Or. en

Amendment 2124
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 27 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.	(d) at least a manufacturing step, excluding ***secondary*** packaging, quality testing and certification is performed in the Union ***or in EEA/EFTA countries***.

Or. en

Amendment 2125
Ondřej Krutílek

Proposal for a regulation
Article 27 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.	(d) at least a manufacturing step, excluding ***secondary*** packaging, quality testing and certification is performed in the Union.

Or. en

Amendment 2126
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 27 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.	(d) at least a manufacturing step, excluding ***secondary*** packaging, quality testing and certification is performed in the Union.

Or. en

Amendment 2127
Margarita de la Pisa Carrión

Proposal for a regulation
Article 27 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.	(d) at least a manufacturing step, excluding ***secondary*** packaging, quality testing and certification is performed in the Union.

Or. en

Amendment 2128
Aurelijus Veryga, Kristoffer Storm

Proposal for a regulation
Article 27 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union.	(d) at least a manufacturing step, excluding ***secondary*** packaging, quality

testing and certification is performed in the Union.

Or. en

Amendment 2129
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Article 27 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union**.**	(d) at least a manufacturing step, excluding packaging, quality testing and certification is performed in the Union***;***

Or. en

Amendment 2130
Kateřina Konečná

Proposal for a regulation
Article 27 – paragraph 1 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) (e) the marketing authorisation applicant has submitted to the Commission a binding access undertaking, signed by the holder of the patent or supplementary protection certificate concerned, by which it commits, for the duration of the extension granted under this Article, to:
	(i) submit, in each Member State which has requested the placing of the medicinal product on its market, a complete pricing and reimbursement application no later than 24 months following the marketing authorisation, and pursue that application in good faith;
	(ii) participate in joint clinical assessments and joint scientific

consultations conducted under Regulation (EU) 2021/2282 where the medicinal product falls within the scope of those procedures;

(iii) report annually to the Commission on the implementation of points (i) and (ii).

The Commission shall publish the access undertaking and the annual reports, and shall transmit them to the Agency for the purposes of the Agency's scientific tasks under Union pharmaceutical legislation. Where the Commission, on the basis of a recommendation from the Agency on scientific aspects, and after hearing the holder of the patent or supplementary protection certificate, concludes that the undertaking has been materially breached, it shall, by means of an implementing decision, inform the competent national industrial-property authority, which shall be empowered, in accordance with Article 14 of Regulation (EC) No 469/2009, to revoke the extension granted under this Article.

Or. en

Amendment 2131
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Victor Negrescu, Dario Nardella

Proposal for a regulation
Article 27 – paragraph 1 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) the marketing authorisation applicant submits an access and supply plan demonstrating how the medicinal product will be placed on the market and made available in all Member States in a timely and equitable manner, and how its availability, affordability and accessibility across the Union will be ensured. That plan shall include, at least, information on expected supply capacity, launch

timelines for each Member State, measures to prevent and address shortages, expected budgetary implications for health systems, cooperation with national competent authorities, payers and health technology assessment bodies, and a transparent declaration of direct public financial support received for the development of the medicinal product, without prejudice to the protection of commercially confidential information.

Or. en

Justification

The access and supply plan ensures that a product benefitting from additional market protection contributes to timely, equitable availability, affordability and accessibility across the Union. It links the incentive to concrete commitments on launch timelines, supply capacity, shortage prevention, cooperation with national authorities and transparency on direct public financial support.

Amendment 2132
Ondřej Knotek, Viktória Ferenc

Proposal for a regulation
Article 27 – paragraph 1 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) Where a clinical trial conducted in more than two Member States includes one or more Member States identified by the Commission as being persistently underrepresented in clinical trials conducted in more than two Member States, the marketing authorisation applicant shall be exempt from demonstrating that the medicinal product containing a new active substance is distinctively different or that the medicinal product has a mechanism of action that is distinctively different. The Commission shall, by means of an implementing act and on the basis of objective and transparent criteria

developed with the scientific support of the European Medicines Agency, identify the Member States that are persistently underrepresented in clinical trials conducted in more than two Member States

Or. en

Amendment 2133
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 27 – paragraph 1 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) the applicant has made significant and verifiable investments into research and development carried out in the Union, and discloses to the Agency details of the amount, nature, location and duration of these investments, including the share co-financed by the Union or the Member States;

Or. pl

Amendment 2134
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 27 – paragraph 1 – point d b (new)

Text proposed by the Commission	*Amendment*
	(db) the applicant submits a multi-annual cooperation plan covering the period of the extension and outlining its plans for Union-based cooperation with research organisations, universities and teaching or university hospitals, including the goals of the cooperation, measurable phases, the anticipated scientific or

clinical contribution, indicative financing and reporting rules.

Or. pl

Amendment 2135
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Victor Negrescu, Dario Nardella

Proposal for a regulation
Article 27 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. For the timely placing on the market, Member States shall, within their respective competences, facilitate the effective availability of medicinal products benefitting from the extension referred to in paragraph 1 in all Member States, including by ensuring timely national procedures related to pricing, reimbursement, procurement and supply, and by cooperating with the marketing authorisation holder, the Agency and the Commission to prevent unjustified delays or fragmentation of access across the Union.

Or. en

Justification

This paragraph clarifies that timely and equitable availability across the Union also requires action by Member States within their respective competences. It avoids placing the entire responsibility on the marketing authorisation applicant alone and addresses possible delays linked to national pricing, reimbursement, procurement and supply procedures.

Amendment 2136
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 27 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Notwithstanding paragraph 1, where the duration of a supplementary protection certificate is extended, Member States shall ensure the continued application of the SPC Manufacturing Waiver in accordance with Regulation (EU) 2019/933 and shall guarantee legal certainty for manufacturers of biosimilar medicinal products to enable their market entry from the first day following the expiry of the relevant patent and supplementary protection.

Or. en

Amendment 2137
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel

Proposal for a regulation
Article 27 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. By way of derogation from paragraph 1, the holder shall also be entitled to the extension where the marketing authorisation applicant demonstrates that both of the conditions set out in points (c) and (d) of paragraph 1 are met, that one of the two conditions set out in points (a) and (b) of paragraph 1 is met, and that the medicinal product is aligned with the list of Biotechnologies of Common European Interest established under Article 37.

Or. en

Justification

Alignment with the list of strategic technologies provides direction, both in terms of unmet medical need and in terms of industrial policy, to the application of the SPC extension. This helps ensure that at least some of the products that are granted an SPC extension are in fact

complementary to Union industrial policy strengths and/or help address unmet medical needs that are not being addressed otherwise.

Amendment 2138
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 27 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The disclosure referred to in paragraph 1, point (e), shall contain sufficient information to allow the Agency to verify whether this condition has been fulfilled. The Agency shall protect commercially confidential information in accordance with Union law and shall publish a non-confidential summary of the disclosed investments, sources of public funding and key features of the cooperation plan referred to in paragraph 1, point (f).

Or. pl

Amendment 2139
Katri Kulmuni, Stine Bosse, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 27 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The European Medicines Agency, together with the national and regional branches of the EU Health Biotechnology Support Network, may provide strategic, scientific, and regulatory guidance based on preliminary evidence submitted by the developer in order to assess whether the medicinal product could be eligible for the SPC extension.

Or. en

Justification

Structured regulatory support is essential to improve the development, scale-up and deployment of health biotechnology products in the Union, in particular for small and medium-sized enterprises. For this reason, a more structured involvement of the European Medicines Agency and the national antennas of the EU Health Biotechnology Support Network is necessary to ensure consistent and effective support across companies of different sizes.

Amendment 2140
Kateřina Konečná

Proposal for a regulation
Article 27 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The Commission shall, by means of delegated acts, specify the form, content and verification methodology of the access undertaking, including measurable criteria for assessing material breach.

Or. en

Amendment 2141
Margarita de la Pisa Carrión

Proposal for a regulation
Article 27 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. the medicinal product contains a new active substance different from that of any authorised medicinal product in the Union;

Or. en

Amendment 2142

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 27 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. The Agency and the relevant regional and national authorities may provide advice, based on the preliminary evidence submitted by the developer, on whether the medicinal product may be eligible for the SPC extension, in particular where the developer is an SME, SMC, or start-up.

Or. en

Amendment 2143
Margarita de la Pisa Carrión, Laurent Castillo, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 27 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. the medicinal product has a mechanism of action different and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same disease;

Or. en

Amendment 2144
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel, Morten Løkkegaard

Proposal for a regulation
Article 27 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. By way of derogation from paragraph 1, the extension period shall be 24 months where the medicinal product has been granted an orphan designation in accordance with Regulation (EC) No 141/2000.

Or. en

Amendment 2145
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 27 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The European Medicines Agency ('the Agency') shall assess compliance with the conditions referred to in paragraph 1 as part of the marketing authorisation procedure concerned.	2. The European Medicines Agency ('the Agency') shall assess compliance with the conditions referred to in paragraph 1 as part of the marketing authorisation procedure concerned. ***The assessment shall contain a separate and reasoned opinion on each of the conditions outlined in paragraph 1, points (a) to (f).***

Or. pl

Amendment 2146
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 27 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The European Medicines Agency ('the Agency') shall assess compliance with the conditions referred to in paragraph 1 as part of the marketing authorisation procedure concerned.	2. The European Medicines Agency ('the Agency') shall assess compliance with the conditions referred to in paragraph 1 as part of the marketing authorisation procedure concerned ***or at the request of the marketing authorization holder***.

Or. en

Amendment 2147
Aurelijus Veryga, Kristoffer Storm

Proposal for a regulation
Article 27 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The European Medicines Agency ('the Agency') shall assess compliance with the conditions referred to in paragraph 1 as part of the marketing authorisation procedure concerned.	2. The European Medicines Agency ('the Agency') shall assess compliance with the conditions referred to in paragraph 1 as part of the marketing authorisation procedure concerned ***or at the request of the marketing authorisation holder***.

Or. en

Amendment 2148
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu, Dario Nardella

Proposal for a regulation
Article 27 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The European Medicines Agency ('the Agency') shall assess compliance with the conditions referred to in paragraph 1 as part of the marketing authorisation procedure concerned.	2. The European Medicines Agency ('the Agency') shall assess compliance with the conditions referred to in paragraph 1***, and, where applicable, paragraph 3c,*** as part of the marketing authorisation procedure concerned.

Or. en

Justification

The amendment gives the Agency a clear role in assessing compliance with the relevant conditions, including therapeutic advantage, access and supply commitments and eligibility for the additional extension under paragraph 3c

Amendment 2149

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 27 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The European Medicines Agency ('the Agency') shall assess compliance with the conditions referred to in paragraph 1 ***as part of the marketing authorisation procedure concerned***.	2. The European Medicines Agency ('the Agency') shall assess compliance with the conditions referred to in paragraph 1.

Or. en

Amendment 2150
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 27 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. By way of derogation from paragraph 2, where the condition set out in paragraph 1(d) is not fulfilled at the time of the granting of the marketing authorisation, the holder may defer compliance with that condition and fulfil it after the granting of the marketing authorisation, including by means of a variation to the marketing authorisation, [provided that such deferral does not adversely affect the timely market entry of biosimilar medicinal products upon the expiry of the basic patent or supplementary protection certificate]. In such cases, the holder shall notify the Agency of the fulfilment of that condition and provide supporting evidence no later than two years before the expiry of the basic patent or supplementary protection certificate, whichever expires first. The

Agency shall assess compliance and, where confirmed, issue a supplementary statement to that effect within 90 days of receipt of the notification. The supplementary statement shall be appended to the statement referred to in paragraph 3 for the purposes of the application for the certificate extension.

Or. en

Amendment 2151
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel

Proposal for a regulation
Article 27 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Upon request by the developer, the Agency may, before the start of confirmatory Phase IIb or Phase III clinical trials, issue a preliminary, non-binding scientific opinion on whether the conditions referred to in points (a) and (b) of paragraph 1 are likely to be met, based on clinical data available at the time of the request. The opinion shall be confined to the novelty of the active substance, the distinctness of the mechanism of action. Such preliminary opinion shall:
	(i) be without prejudice to the final assessment carried out by the Agency pursuant to paragraph 2;
	(ii) not prejudge the rights of third parties; and
	(iii) not give rise to any liability on the part of the Agency.

Or. en

Amendment 2152
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel

Proposal for a regulation
Article 27 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. Based on the opinion, and upon receipt of a statement of intent from the developer to locate at least one manufacturing step in the Union, the Agency will assign the medicinal product 'SPC Candidate Status' where, on the basis of the data available at that stage, the product is considered likely to fulfil the conditions for the extension under points (a) and (b) under paragraph 1, and as relevant, the derogations outlined in paragraphs 1a and 1b.
	The assignment of SPC Candidate Status shall be without prejudice to the assessment carried out under paragraph 2 and shall not give rise to any liability on the part of the Agency.
	Medicinal products assigned SPC Candidate Status under paragraph 2b shall have immediate access to the support measures available under the Agency's existing scheme for priority medicines, namely the PRIME scheme, including early scientific advice, accelerated assessment, and continuous development support, irrespective of whether the extension is ultimately granted.
	At the final stage of the marketing authorisation procedure, the Agency will communicate to the developer the date by which the SPC Candidate product must meet the conditions set out in point (d) in order to be granted the extension.
	The opinion shall be without prejudice to the assessment carried out under paragraph 2, shall not prejudge its outcome, and shall be without prejudice to the rights of third parties. The issuing of an opinion under this paragraph shall not give rise to any liability on the part of the Agency. The competence of national

authorities to grant the certificate and its extension shall remain unaffected.

Or. en

Justification

The purpose of the SPC Candidate Status mechanism is to create additional commercial value for those developers interested in innovating and manufacturing novel biopharmaceutical products in the Union in alignment with the political intention behind Aricle 27, thus making such investments as well as subsequent medical product launches more attractive to developers established in the Union as well as those established in third countries.

As a result, the SPC Candidate Status mechanism should strengthen investment in the Union, boost patient access to clinical trials and to innovative biopharmaceuticals in the Member States, as well as help send strong investment signals to capital markets at the earliest possible development stage of the relevant medicinal products.

Amendment 2153
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel

Proposal for a regulation
Article 27 – paragraph 2 c (new)

Text proposed by the Commission	*Amendment*
	2c. Where the conditions referred to in points (a) and (b) of paragraph 1 are satisfied by more than one medicinal product having the same mechanism of action for the same indication, the extension referred to in paragraph 1 shall be granted only to the first such medicinal product to receive a marketing authorisation from the Union, and to any other such medicinal product that receives a marketing authorisation from the Union within 12 months of that first authorisation.

Or. en

Justification

Innovative biopharmaceuticals typically have very long development lifecycles. Therefore, a grace period of at least 12 months is necessary to ensure that investments made in such

biopharmaceutical products be adequately assessed and rewarded under the mechanisms foreseen under Article 27.

Amendment 2154
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu, Dario Nardella

Proposal for a regulation
Article 27 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where compliance is confirmed, the Agency shall issue a statement to that effect.	3. Where compliance is confirmed, the Agency shall issue a statement to that effect***, including, where applicable, whether the biotechnology medicinal product fulfils the criteria for the further extension referred to in paragraph 3c***.

Or. en

Justification

This amendment ensures that the Agency's statement provides legal clarity not only on compliance with the basic conditions for the six-month extension, but also, where applicable, on whether the medicinal product fulfils the criteria for the further six-month extension under paragraph 3a.

Amendment 2155
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 27 – paragraph 3

Text proposed by the Commission	*Amendment*
3. ***Where*** compliance ***is confirmed***, the Agency shall issue a statement ***to that effect***.	3. ***After assessing*** compliance, the Agency shall issue a statement ***confirming compliance or non-compliance***. ***In both cases, the statement shall be published together with a non-confidential summary of the reasoning.***

Or. pl

Amendment 2156
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu, Dario Nardella

Proposal for a regulation
Article 27 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. After the Agency issues its assessment of compliance, the authority issuing the certificate shall consult a panel comprising representatives of patient organisations and of public payers, including public health insurance providers and other relevant public payer bodies of the Member State where the SPC is issued. The panel shall provide an opinion on the public health relevance, the anticipated impact on patient access, and the budgetary implications for health systems of granting the extension. That opinion shall be annexed to the Agency's assessment.

Or. en

Justification

This amendment strengthens transparency and accountability in the granting of SPC extensions by ensuring that patient organisations and public payers are consulted before the certificate-issuing authority takes its decision. It allows patient access, public health relevance and budgetary implications for health systems to be duly considered alongside the Agency's scientific assessment

Amendment 2157
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 27 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. An entity affected directly and individually by a statement as referred to in paragraph 3 may challenge this statement before the General Court of the

European Union no later than two months after its publication. The option of pleading the invalidity or ineffectiveness of a statement in proceedings before the competent national court or the Unified Patent Court shall be without prejudice to Union law.

Or. pl

Amendment 2158
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu, Dario Nardella

Proposal for a regulation
Article 27 – paragraph 3 b (new)

Text proposed by the Commission	*Amendment*
	3b. Where the authority issuing the certificate grants the extension referred to in this article, it shall, without undue delay, inform the competent authorities of the other Member States and the Commission thereof, including the identity of the biotechnology medicinal product concerned, the duration of the extension granted, and the area referred to in paragraph 3c new, points (a), (b), (c) or (d) under which the extension was granted.

Or. en

Amendment 2159
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Victor Negrescu

Proposal for a regulation
Article 27 – paragraph 3 c (new)

Text proposed by the Commission	*Amendment*
	3c. In addition to the extension referred to in paragraph 1, the periods

referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009 may be considered for a further extension, of a duration to be determined by the authority issuing the certificate, but no longer than the period stated in Paragraph 1 of this Article, where the Agency has assessed that the biotechnology medicinal product addresses a high unmet medical need of major public health relevance, in particular in one or more of the following areas:

(a) orphan medicinal products, in accordance with Article 69 and breakthrough orphan medicinal products in accordance with Article 70 of Regulation 2023/0131;

(b) priority antimicrobials in line with the One Health approach and in accordance with Article 40 (3) of Regulation 2023/0131;

(c) serious infectious diseases, in particular infectious diseases caused by multi-drug resistant pathogens, including multi-drug resistant tuberculosis.

(d) products that qualify as Technology of Common European Interest on the list established under Article 37 6 (b)

Where the Agency's assessment confirms that the criteria are met, the authority issuing the certificate may take this into account in deciding whether, and for what duration, to grant the further extension.

The Commission shall adopt implementing acts laying down the detailed criteria and evidence requirements for the Agency's assessment, and the procedure for its transmission to the authority issuing the certificate, including guidance on the assessment of high unmet medical need, major therapeutic advantage, public health relevance, access and supply considerations, and budgetary implications for health systems. Those

implementing acts shall be prepared in consultation with Member States and relevant stakeholders, including patient organisations, the Agency, health technology assessment bodies, public health insurance providers and other relevant public payers, clinical experts and public health experts.

Or. en

Justification

This amendment provides a targeted and evidence-based possibility for an additional SPC extension where a medicinal product addresses a high unmet medical need of major public health relevance, in particular for rare and ultra-rare diseases, antimicrobial resistance and serious infectious diseases. It ensures that any further incentive is not automatic, but subject to an Agency assessment and a decision by the certificate-issuing authority, taking into account therapeutic value, access and supply considerations, and budgetary implications for health systems

Amendment 2160
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 27 – paragraph 4

Text proposed by the Commission	*Amendment*
4. A copy of the statement referred to in paragraph 3 of this Article shall be included in the application for a certificate lodged under article 7 of Regulation (EC) No 469/2009.	4. A copy of the statement referred to in paragraph 3 of this Article shall be included in the application for a certificate ***or the application for an extension of the duration of a certificate*** lodged under Article 7 of Regulation (EC) No 469/2009.

Or. pl

Amendment 2161
Michele Picaro, Aurelijus Veryga, Kristoffer Storm

Proposal for a regulation
Article 27 – paragraph 4

Text proposed by the Commission	*Amendment*
4. A copy of the statement referred to in paragraph 3 ***of this Article*** shall be included in the application for a certificate lodged under article 7 of Regulation (EC) No 469/2009.	4. A copy of the statement referred to in paragraph 3 shall be included in the application for ***a certificate or extension of*** a certificate lodged under article 7 of Regulation (EC) No 469/2009.

Or. en

Amendment 2162
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 27 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. With a view to facilitating patient access to the medicinal product referred to in paragraph 1, the Member State may request the holder of the marketing authorisation to place this product on the market of that Member State and to supply it in a volume corresponding to justified patient needs as determined by this Member State.

Or. pl

Amendment 2163
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 27 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Upon the expiry of the Supplementary Protection Certificate (SPC), the Agency shall adopt the transparency lists providing for the interchangeability of the reference biologic medicinal product with the

corresponding biosimilar medicinal product.

Or. en

Justification

The proposed amendment is intended to promote the use of biosimilar medicinal products once they are manufactured by companies producing so-called "generic medicines." In particular, the simultaneous adoption of the transparency lists facilitates the immediate interchangeability of the reference (originator) medicinal product with its generic or biosimilar equivalent, while reducing administrative requirements.In this way, the medicines agencies of the individual Member States could also rely on the guidance provided by the European Medicines Agency (EMA) by implementing the interchangeability recommendations reflected in the transparency lists.

Amendment 2164
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 27 – paragraph 4 b (new)

Text proposed by the Commission	*Amendment*
	4b. The holder of the marketing authorisation shall fulfil the obligation referred to in paragraph 5 unless it can demonstrate objective, exceptional and unforeseeable circumstances preventing supply. If, three years after a Member State has made a request under paragraph 5, the holder of the authorisation has not ensured the accessibility and continuity of supply of the product in that Member State, the Agency, after allowing the holder of the authorisation to submit observations, shall amend or revoke the statement referred to in paragraph 3 in relation to the possibility of obtaining an extension in this Member State. If the non-fulfilment of the obligation affects at least three Member States, the Agency may revoke the statement with effect throughout the Union. The Member State shall publish information on the request and its outcome without undue delay.

Or. pl

Amendment 2165
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 27 – paragraph 4 c (new)

Text proposed by the Commission	*Amendment*
	4c. The Commission shall assess the functioning of this Article no later than five years after the date of its application and every five years thereafter. The assessment shall encompass in particular the impact of the extension on investments into research and development and manufacturing in the Union, the availability of products in the Member States, competition from biosimilars, expenditure of health systems and time to market of competing products. The Commission shall present to the European Parliament, the Council and the European Economic and Social Committee a report with its main findings and, where appropriate, a legislative proposal amending or repealing this Article.

Or. pl

Amendment 2166
Anja Hazekamp, Anthony Smith, Sebastian Everding, Lynn Boylan

Proposal for a regulation
Article 27 a (new)
Amendments to Directive 98/44/EC
Article 4, Article 8, Article 9

Text proposed by the Commission	*Amendment*
	Article27a
	Amendments to Directive 98/44/EC1

1. Article 4 of Directive 98/44/EC on the legal protection of biotechnological inventions is amended as follows:

(a) In paragraph 1, the following points are added:

‘(ba) NGT plants, plant material, parts thereof, genetic information and process features they contain, as defined in Regulation (EU) .../... [O.J. please insert the number of this Regulation]; (bb) plants, plant material, parts thereof, genetic information and process features they contain that can be yielded by techniques excluded from the scope of Directive 2001/18/EC as listed in Annex I B to that directive.’

(b) the following paragraph 3 a is added:‘3a. Paragraphs 2 and 3 shall be without prejudice to the exclusions from patentability covered in paragraph 1.’

2. In Article 8, the following paragraph is added:

‘2a. By way of derogation from paragraphs 1 and 2, the protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall not extend to biological material possessing the same characteristics that is obtained independently of the patented biological material and from essentially biological processes, or to biological material obtained from such material through propagation or multiplication.’

3. In Article 9, the following paragraphs are added:

1a. By way of derogation from paragraph1, a plant product containing or consisting of genetic information obtained by a patentable technical process shall not be patentable if it is not distinguishable from plant products containing or consisting of the same genetic information obtained by an essentially biological process.

1b. By way of derogation from paragraph 1, the protection conferred by a patent on a product containing or consisting of genetic information shall not extend to plant material in which the product is incorporated and in which the genetic information is contained and performs its function but which is not distinguishable from plant material obtained or which can be obtained by an essentially biological process.

1c. The protection conferred by a patent on a technical process that enables the production of a product containing or consisting of genetic information shall not extend to plant material in which the product is incorporated and in which the genetic information is contained and performs its function but which is not distinguishable from plant material obtained or which can be obtained by an essentially biological process.'

Or. en

Justification

The EuropeanParliament has repeatedly voiced its concerns regarding patentability of plantsand genetic traits. The patent framework does not provide sufficient clarityand safeguards on the patentability of genetic traits that may also occurnaturally or be achieved through conventional breeding. Concerns relate inparticular to access to genetic resources, freedom to operate and possiblemarket concentration in the seed sector. This amendment reflects the position of the European Parliament on the issue of patents, adopted in the mandate on the new genomic techniques regulation on 7 February 2024

Amendment 2167
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 27 a (new)

Text proposed by the Commission	*Amendment*
	Article27a
	Article 61a

Amendments to Regulation (EC) No 469/2009 : Regulation (EC) No 469/2009 is amended as follows:

1) (a) Article 5 is amended as follows:

Paragraph (2) is replaced by the following: '2. By way of derogation from paragraph 1, the certificate referred to in paragraph 1 shall not confer protection against certain acts which would otherwise require the consent of the holder of the certificate ('the certificate holder'), if the following conditions are met:

(a) the acts comprise:

(i) the making of a product, or a medicinal product containing that product, for the purpose of export to third countries; or

(ii) any related act that is necessary for the making, in the Union, referred to in point (i), or for the actual export; or

(iii) the making of a product, or a medicinal product containing that product, for the purpose of storing it in the Member State of making, in order to place that product, or a medicinal product containing that product, on the market of Member States after the expiry of the corresponding certificate; or

(iv) any related act that is necessary for the making, in the Union, referred to in point (iii), for the actual storing, supplying or placing on the Union market after the expiry of the corresponding certificate or expiry of the basic patent, where no SPC exists.

(b) in the case of products, or medicinal products containing those products, made for the purpose of export to third countries, the maker ensures that a logo, in the form set out in Annex -I, is affixed to the outer packaging of the product, or the medicinal product containing that product, referred to in point (a)(i) of this

paragraph, and, where feasible, to its immediate packaging;

(c) the maker complies with paragraph 9 of this Article and, if applicable, with Article 12(2).

(d) Paragraphs (4), (5), (6) and (7) are deleted.

Or. en

Amendment 2168
Letizia Moratti, Fulvio Martusciello, Massimiliano Salini, Tomislav Sokol

Proposal for a regulation
Article 27 a (new)

Text proposed by the Commission	*Amendment*
	Article27a
	Choose Europe - incentive for medicinal products submitted first in the Union - extension of the supplementary protection certificate
	1. This Article applies to a medicinal product for human use in accordance in respect of which the applicant:
	(a) submits the application for marketing authorisation to the Agency before the corresponding application for authorisation is submitted to any regulatory authority of a third country ('first-in-the-Union filing'); and
	(b) undertakes to submit, for the first time, the applications required for pricing and reimbursement in at least 3 Member States no later than 6 months after the granting of the marketing authorisation ('Union availability undertaking').
	2. Where the conditions set out in paragraph 1 are fulfilled, the holder of a patent or of a supplementary protection certificate shall be entitled to a 6-month extension of the periods referred to in

Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009.

3. The applicant shall include, in the application for marketing authorisation, a declaration confirming the first-in-the-Union filing and containing the Union availability undertaking, together with a commitment to comply with the procedures and timelines set out in paragraph 1. The Agency shall verify that declaration and undertaking as part of the marketing authorisation procedure concerned and shall record their fulfilment.

4. Where the Union availability undertaking is not honoured, the extension granted under paragraph 2 shall not take effect or, if already granted, shall lapse.

5. The extension provided for in this Article shall be cumulative with the extension provided for in Article 27. The total extension of the periods referred to in Article 13, paragraphs (1) and (2), of Regulation (EC) No 469/2009 under Article 27 and this Article shall not exceed 24 months.

Or. en

Amendment 2169
Letizia Moratti, Fulvio Martusciello, Massimiliano Salini

Proposal for a regulation
Article 27 b (new)

Text proposed by the Commission	*Amendment*
	Article27b
	Choose Europe - incentive for medicinal products submitted first in the Union - the accelerated assessment and priority treatment

1. This Article applies to a medicinal product for human use in accordance in respect of which the applicant:

(a) submits the application for marketing authorisation to the Agency before the corresponding application for authorisation is submitted to any regulatory authority of a third country ('first-in-the-Union filing'); and

(b) undertakes to submit, for the first time, the applications required for pricing and reimbursement in at least 3 Member States no later than 6 months after the granting of the marketing authorisation ('Union availability undertaking').

2. Where, during the development of the medicinal product, the applicant declares its intention to make a first-in-the-Union filing and gives the Union availability undertaking, the medicinal product shall be eligible for:

(a) the accelerated assessment procedure referred to in Article 6 paragraphs (7) of Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final]; and

(b) priority treatment under the joint clinical assessment provided for in Regulation (EU) 2021/2282 on Health Technology Assessment (HTA); provided that the medicinal product meets the scientific eligibility criteria applicable to each of those procedures.

3. The applicant shall include, in the application for marketing authorisation, a declaration confirming the first-in-the-Union filing and containing the Union availability undertaking, together with a commitment to comply with the procedures and timelines set out in paragraph 1. The Agency shall verify that declaration and undertaking as part of the marketing authorisation procedure concerned and shall record their fulfilment.

4. Where the declaration concerning the first-in-the-Union filing is found to be incorrect, the medicinal product shall be deemed never to have been eligible for the incentives provided for in this Article.

Or. en

Amendment 2170
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Chapter V – title

Text proposed by the Commission	*Amendment*
V ENHANCING COMPETITIVENESS IN BIOSIMILARS	V ENHANCING COMPETITIVENESS IN BIOSIMILARS***, BIOHYBRIDS AND ACADEMICAL RESEARCH ON ADVANCED THERAPY MEDICINAL PRODUCTS***

Or. en

Amendment 2171
Christine Anderson

Proposal for a regulation
Chapter V – title

Text proposed by the Commission	*Amendment*
V ENHANCING COMPETITIVENESS IN BIOSIMILARS	V ENHANCING COMPETITIVENESS IN BIOSIMILARS ***AND IMPROVING AVAILABILITY OF CRITICAL ESTABLISHED MEDICINAL PRODUCTS***

Or. en

Amendment 2172
Dimitris Tsiodras

Proposal for a regulation
Article 28 – title

Text proposed by the Commission	*Amendment*
Guidance ***by the Agency*** on biosimilars	Guidance on biosimilars

Or. en

Amendment 2173
Wouter Beke, Ingeborg Ter Laak, Angelika Niebler, Adam Jarubas, Angelika Winzig, Aura Salla, Liesbet Sommen, Paulo Cunha, Sérgio Humberto, Sirpa Pietikäinen, Willemien Koning, Andrea Wechsler, Dolors Montserrat, Oliver Schenk, Elena Nevado del Campo, András Tivadar Kulja, Niels Flemming Hansen

Proposal for a regulation
Article 28 – title

Text proposed by the Commission	*Amendment*
Guidance ***by the Agency*** on biosimilars	Guidance on biosimilars

Or. en

Amendment 2174
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 28 – paragraph 1

Text proposed by the Commission	*Amendment*
The Agency, in consultation with the Commission, shall develop and update non-binding guidance on a tailored regulatory approach for the development of biosimilars, reflecting advances in manufacturing and analytical testing. The guidance shall consider a potential reduction of the clinical data required for the development and approval of biosimilars, without affecting their quality, safety and efficacy.	***deleted***

Or. en

Amendment 2175
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 28 – paragraph 1

Text proposed by the Commission	*Amendment*
The Agency, in consultation with the Commission, shall develop and update non-binding guidance on ***a tailored*** regulatory ***approach for*** the development of biosimilars, reflecting advances in manufacturing and analytical testing***.*** The guidance shall consider a potential reduction of the clinical data required for the development and approval of biosimilars, without affecting their quality, safety and efficacy.	The Agency, in consultation with the Commission, shall develop and update non-binding guidance on ***the development of biosimilars to ensure that*** regulatory ***requirements remain fit for purpose and facilitate*** the development of biosimilars ***across a broad range of biological medicinal products***, ***including ATMPs.*** Reflecting advances in manufacturing and analytical testing***,*** the guidance shall consider a ***streamlining of*** potential reduction of the clinical data required for the development and approval of biosimilars ***as scientifically justified***, without affecting their quality, safety and efficacy***, and acceptance of global comparator product without PK-bridging studies***. ***The Agency shall, where relevant, promote the acceptance of global comparator products and, in cooperation with international regulatory partners, support the reciprocal recognition of such comparators within international regulatory cooperation frameworks. The Agency shall organise early dialogue on follow-on multi-source biotechnologies, including ATMPs. This may be complemented by national biosimilar plans covering demand-side policies, including patient and HCP education, measures to support biosimilar uptake and patient access monitoring.***

Or. en

Amendment 2176
Dimitris Tsiodras

Proposal for a regulation
Article 28 – paragraph 1

Text proposed by the Commission	*Amendment*
The Agency, in consultation with the Commission, shall develop and update ***non-binding*** guidance ***on a tailored regulatory approach for the*** development ***of biosimilars***, reflecting advances in manufacturing and analytical testing***.*** The guidance shall consider ***a potential reduction*** of the clinical data required for the development and approval of biosimilars, without affecting their quality, safety and efficacy.	The Agency, in consultation with the Commission, shall develop and update ***biosimilar*** guidance ***documents to ensure fit-for-purpose*** development ***requirements and to encourage biosimilar development for a broad range of biological products***, ***including ATMPs.*** Reflecting advances in manufacturing and analytical testing***,*** the guidance shall consider ***streamlining*** of the clinical data required for the development and approval of biosimilars ***(e.g. CES, PK studies) as scientifically justified***, without affecting their quality, safety and efficacy***,*** ***acceptance of global comparator product without PK-bridging studies***. ***The acceptance of a global comparator (foreign sourced reference product) should be reconfirmed and reciprocally included in international regulatory cooperation frameworks. The European Medicines Agency should organise early dialogue on follow-on multi-source biotechnologies incl. ATMPs. This shall be complemented by national biosimilar strategies and strategic plans covering patient and HCP education, measures to support biosimilar uptake, active market participation of multiple suppliers, biologic market competition and patient access monitoring.***

Or. en

Justification

While EMA and the international regulators community are moving to implementation of CES-waivers for most biosimilar medicine developments, following several years of regulatory-science discussions; it is important that the Biotech Act encourages further streamlining of regulatory requirements to ensure those are fit-for-purpose and as such supportive of Europe's competitiveness and attractivity for biotech R&D.In addition, the European regulatory network should lead the global regulatory conversation ahead of new

biotechnology platforms opening up to multi-source, follow-on biologic competition. Early dialogue and requirements considerations for biosimilar candidate applications for eg ATMPs, ADCs are key to de-risk investment by industry and to attract and retain capability and capacity in Europe. Complementary to EMA guidance, it is critical that this is supported at national level with strategic biosimilar plans. This way the work done at European level and through the AUGMENT project can be leveraged to its fullest extent.

Amendment 2177
Borys Budka, Kamila Gasiuk-Pihowicz

Proposal for a regulation
Article 28 – paragraph 1

Text proposed by the Commission	*Amendment*
The Agency, in consultation with the Commission, shall develop and update non-binding guidance on a tailored regulatory approach for the development of biosimilars, reflecting advances in manufacturing and analytical testing. The guidance shall consider a potential reduction of the clinical data required for the development and approval of biosimilars, without affecting their quality, safety and efficacy.	The Agency, in consultation with the Commission, shall develop and update non-binding guidance on a tailored regulatory approach for the development of biosimilars, reflecting advances in manufacturing and analytical testing. The guidance shall consider a potential reduction of the clinical data required for the development and approval of biosimilars, without affecting their quality, safety and efficacy. ***It shall also address, for critical biological medicinal products with well-established medicinal use in the Union and authorised in one or more Member States before they became subject to mandatory Union authorisation, the use of bibliographic data and real-world evidence, including criteria for establishing a scientific bridge to the medicinal product concerned, quality comparability and immunogenicity assessment.***

Or. en

Amendment 2178
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation

Article 28 – paragraph 1

Text proposed by the Commission	*Amendment*
The Agency, in consultation with the Commission, shall develop and update non-binding guidance on a tailored regulatory approach for the development of biosimilars, reflecting advances in manufacturing and analytical testing. The guidance shall ***consider*** a potential reduction of the clinical data required for the development and approval of biosimilars, without affecting their quality, safety and efficacy.	The Agency, in consultation with the Commission, shall develop and update non-binding guidance on a tailored regulatory approach for the development of biosimilars, reflecting advances in manufacturing and analytical testing. The guidance shall ***set up conditions for considering on a case-by-case basis and where scientifically justified (e.g. in weight of evidence approaches) for the waiving of preclinical data requirements, prioritising where possible non-animal approaches, as well as*** a potential reduction of the clinical data required for the development and approval of biosimilars, without affecting their quality, safety and efficacy.

Or. en

Justification

Advances in analytical methods and non-animal approaches, including NAMs, increasingly enable robust non-clinical evidence for biosimilars without reliance on animal studies. Clarifying that animal data requirements may be waived, where scientifically justified, and that non-animal approaches should be prioritised supports more efficient, human-relevant development pathways while maintaining high standards of quality, safety and efficacy, in line with evolving scientific and regulatory practices.

Amendment 2179
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 28 – paragraph 1

Text proposed by the Commission	*Amendment*
The Agency, in consultation with the Commission, shall develop and update non-binding guidance on a tailored regulatory approach for the development of biosimilars, reflecting advances in	The Agency, in consultation with the Commission, shall develop and update non-binding guidance on a tailored regulatory approach for the development of biosimilars, reflecting advances in

manufacturing and analytical testing. The guidance shall consider a potential reduction of the clinical data required for the development and approval of biosimilars, without affecting their quality, safety and efficacy.	manufacturing and analytical testing. The guidance shall consider a potential reduction of the clinical data required for the development and approval of biosimilars, without affecting their quality, safety and efficacy***, and with a view to facilitating timely availability of biosimilars, supporting competition and contributing to more accessible and affordable biological therapies for patients and health systems across the Union***.

Or. en

Amendment 2180
Anja Hazekamp, Anthony Smith, Sebastian Everding, Lynn Boylan

Proposal for a regulation
Article 28 – paragraph 1

Text proposed by the Commission	*Amendment*
The Agency, in consultation with the Commission, shall develop and update non-binding guidance on a tailored regulatory approach for the development of biosimilars, reflecting advances in manufacturing and analytical testing. The guidance shall consider a potential reduction of the clinical data required for the development and approval of biosimilars, without affecting their quality, safety and efficacy.	The Agency, in consultation with the Commission, shall develop and update non-binding guidance on a tailored regulatory approach for the development of biosimilars, reflecting advances in manufacturing and analytical testing. The guidance shall consider ***where scientifically justified, e.g. in weight of evidence approaches, the waiving of preclinical animal data requirements and prioritising the use of non-animal approaches and*** a potential reduction of the clinical data required for the development and approval of biosimilars, without affecting their quality, safety and efficacy.

Or. en

Amendment 2181
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 28 – paragraph 1

Text proposed by the Commission	*Amendment*
The Agency, in consultation with the Commission, shall develop and update non-binding guidance on a tailored regulatory approach for the development of biosimilars, reflecting advances in manufacturing and analytical testing. The guidance shall consider a potential reduction of the clinical data required for the development and approval of biosimilars, without affecting their quality, safety and efficacy.	The Agency, in consultation with the Commission ***and following consultation with relevant scientific experts, healthcare professionals, patient organisations and industry***, shall develop and update non-binding guidance on a tailored regulatory approach for the development of biosimilars, reflecting advances in manufacturing and analytical testing. The guidance shall consider a potential reduction of the clinical data required for the development and approval of biosimilars, without affecting their quality, safety and efficacy.

Or. en

Amendment 2182
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 28 – paragraph 1

Text proposed by the Commission	*Amendment*
The Agency, in consultation with the Commission, shall develop and update non-binding guidance on a tailored regulatory approach for the development of biosimilars, reflecting advances in manufacturing and analytical testing. The guidance shall ***consider*** a potential reduction of the clinical data required for the development and approval of biosimilars, without affecting their quality, safety and efficacy.	The Agency, in consultation with the Commission, shall develop and update non-binding guidance on a tailored regulatory approach for the development of biosimilars, reflecting advances in manufacturing and analytical testing. The guidance shall ***set-up conditions for considering on a case-by-case basis*** a potential reduction of the clinical data required for the development and approval of biosimilars, without affecting their quality, safety and efficacy.

Or. en

Amendment 2183
Aurelijus Veryga

Proposal for a regulation
Article 28 – paragraph 1

Text proposed by the Commission	*Amendment*
The Agency, in consultation with the Commission, shall develop and update non-binding guidance on a tailored regulatory approach for the development of biosimilars, reflecting advances in manufacturing and analytical testing. The guidance shall consider a potential reduction of the clinical data required for the development and approval of biosimilars, without affecting their quality, safety and efficacy.	The Agency, in consultation with the Commission, shall develop and update non-binding guidance on a tailored***,*** ***science based*** regulatory approach for the development of biosimilars, reflecting advances in manufacturing and analytical testing. The guidance shall consider a potential reduction of the clinical data required for the development and approval of biosimilars, without affecting their quality, safety and efficacy.

Or. en

Amendment 2184
András Tivadar Kulja

Proposal for a regulation
Article 28 – paragraph 1

Text proposed by the Commission	*Amendment*
The Agency, in consultation with the Commission, shall develop and update non-binding guidance on a tailored regulatory approach for the development of biosimilars, reflecting advances in manufacturing and analytical testing. The guidance shall consider a potential reduction of the clinical data required for the development and approval of biosimilars, without affecting their quality, safety and efficacy.	The Agency, in consultation with the Commission, shall develop and update non-binding guidance on a tailored ***science based*** regulatory approach for the development of biosimilars, reflecting advances in manufacturing and analytical testing. The guidance shall consider a potential reduction of the clinical data required for the development and approval of biosimilars, without affecting their quality, safety and efficacy.

Or. en

Amendment 2185

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

Proposal for a regulation
Article 28 – paragraph 1

Text proposed by the Commission	*Amendment*
The Agency, in consultation with the Commission, shall develop and update non-binding guidance on a tailored regulatory approach for the development of biosimilars, reflecting advances in manufacturing and analytical testing. The guidance shall ***consider a potential reduction of the*** clinical data required for the development and approval of biosimilars, ***without affecting*** their quality, safety and efficacy.	The Agency, in consultation with the Commission, shall develop and update non-binding guidance on a tailored regulatory approach for the development of biosimilars, reflecting advances in manufacturing and analytical testing. The guidance shall ***ensure robust*** clinical data required for the development and approval of biosimilars, ***in order to preserve*** their quality, safety and efficacy.

Or. en

Amendment 2186
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 28 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1. The Agency, in consultation with the Commission, shall develop and update non-binding guidance on a tailored regulatory approach for the development of biosimilars, with a view to ensuring fit-for-purpose development requirements and encouraging the development of biosimilars for a broad range of biological medicinal products, including advanced therapy medicinal products. Reflecting advances in manufacturing and analytical testing, the guidance shall consider, where scientifically justified, a streamlining of the clinical data required for the development and approval of biosimilars, including comparative efficacy studies and comparative

pharmacokinetic studies, without affecting their quality, safety and efficacy. The guidance shall also consider the acceptance of a global comparator product, without requiring comparative pharmacokinetic bridging studies where scientifically justified.

2.For the purposes of demonstrating biosimilarity, the clinical data requirements shall, as a general rule, be limited to comparative pharmacokinetic studies establishing pharmacokinetic equivalence between the biosimilar medicinal product and the reference medicinal product. Comparative clinical efficacy studies shall not be required where biosimilarity has been adequately demonstrated through comprehensive comparative analytical and quality studies using state-of-the-art methodologies. Where comparative clinical efficacy studies are submitted, the applicant shall justify their inclusion and demonstrate the contribution of those studies to the overall evidence supporting biosimilarity.

3. The Agency and the Commission shall, in the context of international regulatory cooperation, promote the reciprocal acceptance of global comparator products, where scientifically justified.

4. The Agency shall organise early scientific dialogue on the development of follow-on biotechnology medicinal products, including advanced therapy medicinal products, in accordance with Articles 11 and 12 of Directive 2023/0132.

Or. en

Amendment 2187
Wouter Beke, Ingeborg Ter Laak, Angelika Niebler, Adam Jarubas, Angelika Winzig, Aura Salla, Liesbet Sommen, Paulo Cunha, Sérgio Humberto, Sirpa Pietikäinen, Willemien Koning, Andrea Wechsler, Dolors Montserrat, Oliver Schenk, Elena Nevado del Campo, András Tivadar Kulja, Niels Flemming Hansen

Proposal for a regulation
Article 28 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	The Agency shall streamline the approval of biosimilars in line with low-intervention clinical trials as referred to in article 2, (a), (3) of Regulation (EU) No 536/2014.

Or. en

Amendment 2188
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 28 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	The Agency shall periodically review and update the guidance referred to in paragraph 1 to reflect scientific and technological developments and accumulated regulatory experience.

Or. en

Amendment 2189
Wouter Beke, Ingeborg Ter Laak, Angelika Niebler, Adam Jarubas, Angelika Winzig, Aura Salla, Liesbet Sommen, Paulo Cunha, Sérgio Humberto, Sirpa Pietikäinen, Willemien Koning, Andrea Wechsler, Dolors Montserrat, Oliver Schenk, Elena Nevado del Campo, András Tivadar Kulja, Niels Flemming Hansen

Proposal for a regulation
Article 28 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	The Commission, assisted by the Agency, will monitor and incentivize the unified application of the Bolar exemption as well as the uptake of biosimilars in the market across the Member States.

Or. en

Amendment 2190
Wouter Beke, Ingeborg Ter Laak, Angelika Niebler, Adam Jarubas, Aura Salla, Liesbet Sommen, Paulo Cunha, Sérgio Humberto, Sirpa Pietikäinen, Willemien Koning, Andrea Wechsler, Dolors Montserrat, Oliver Schenk, Elena Nevado del Campo, András Tivadar Kulja, Niels Flemming Hansen

Proposal for a regulation
Article 28 – paragraph 1 c (new)

Text proposed by the Commission	*Amendment*
	The EU Biotechnology Support Network shall develop specific support programmes for the biosimilar industry within their mission as referred to in article 19.

Or. en

Amendment 2191
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 28 a (new)

Text proposed by the Commission	*Amendment*
	Article28a
	Guidance by the Agency on academical translational research
	1. The Agency, in cooperation with the competent authorities of the Member States and, where appropriate, in consultation with the Commission, shall support the collaborative development of medicinal products by academic research clusters through the use of open platforms and platform technology master files. For the purposes of this Article, academic research clusters may include academic institutions, healthcare establishments, research organisations and, where applicable, commercial partners

collaborating in the development of medicinal products.

2. Open platforms and platform technology master files shall provide a common scientific and technical framework enabling the joint development, maintenance and subsequent regulatory use of shared manufacturing, quality, non-clinical and, where appropriate, clinical data and procedures. Following acceptance by the Agency or the relevant competent authority, such platforms and master files may be referenced by multiple medicinal product developers, where appropriate, in support of regulatory submissions.

3. The use of open platforms and platform technology master files shall aim to: (a) facilitate regulatory assessment and scientific evaluation; (b) promote harmonised scientific and manufacturing standards and good regulatory practices; (c) reduce unnecessary duplication of studies and testing; (d) accelerate the development and availability of medicinal products; (e) optimise the use of public and private research resources; and (f) contribute to the long-term quality, safety and sustainability of medicinal product development.

4. The Agency, in consultation with the Commission and the competent authorities of the Member States, shall develop and regularly update non-binding scientific and regulatory guidance on the establishment, maintenance and regulatory use of open platforms and platform technology master files. Such guidance shall reflect scientific and technological progress, including advances in multi-centre clinical trials, analytical methodologies, manufacturing technologies and data generation.

5. The guidance referred to in paragraph 5 may provide for a tailored regulatory approach for academic research clusters developing advanced therapy medicinal

products, including, where scientifically justified, recommendations on the adaptation of the clinical data requirements applicable to such products. Any such adaptation shall be based on a risk-proportionate approach and shall not compromise the demonstration of the quality, safety or efficacy of the medicinal product.

6. The Commission shall adopt an implementing act establishing the procedural and technical requirements for the submission, assessment and maintenance of open platform technology master files, with particular regard to their use in the development of advanced therapy medicinal products, including those targeting rare diseases. The Commission can apply as holder an open platform of public interest for the development of both commercial and academical research in advanced-therapy medicinal products. That implementing act shall be adopted in accordance with the procedure referred to in Article 64.

7. Where a technology platform is intended to serve the general interest of the development of medicinal products within a given product class or therapeutic area, an open platform may be established and maintained by a not-for-profit entity or by the Commission.

8. Where a technology platform is established for the development of medicinal products within an academic or collaborative development cluster, appropriate measures for the protection of intellectual property rights and confidential information shall be ensured to safeguard the commercial viability of the resulting medicinal products and technologies, without prejudice to the application of the conditions laid down in Article 14.

9. The protection referred to in paragraph 2 shall not prevent the sharing of scientific, technical or regulatory data

within the development cluster to the extent necessary for the operation of the platform, nor the regulatory use of platform technology master files in accordance with this Regulation.

Or. en

Amendment 2192
Aurelijus Veryga

Proposal for a regulation
Article 28 a (new)

Text proposed by the Commission	*Amendment*
	Article 28a
	Resilient and sustainable biosimilar supply in the Union
	1. In order to strengthen the resilience, sustainability and competitiveness of the Union's biosimilar market, the Commission shall, in cooperation with the Member States and the European Health Biotechnology Steering Group, assess structural factors affecting the long-term viability of biosimilar manufacturing and supply in the Union.
	2. The assessment referred to in paragraph 1 shall analyse, in particular:
	a. the impact of procurement design on diversified supplier participation and long-term market sustainability;
	b. the relationship between pricing dynamics, volume predictability and continued market participation;
	c. structural supply risks arising from market concentration, single-winner mechanisms or abrupt volume reallocations;
	d. the interaction between industrial capacity, investment conditions and biosimilar pipeline development.

3. On the basis of that assessment, the Commission shall, where appropriate, issue non-binding guidance identifying best practices to support sustainable competition, diversified supply and security of supply in biosimilars, in full respect of Member States' competences in pricing, reimbursement and procurement decisions.

4. The guidance referred to in paragraph 3 may include recommendations on:

a. the use of procurement criteria promoting supply reliability and long-term market participation;

b. mechanisms supporting multi-supplier frameworks where appropriate;

c. approaches to improve volume predictability and reduce avoidable supply disruptions;

d. data transparency and monitoring of biosimilar market sustainability indicators.

5. The Commission shall periodically report to the European Parliament and the Council on the evolution of biosimilar competition and supply resilience in the Union, including any identified risks to the sustainable functioning of the internal market.

Or. en

Amendment 2193
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 28 a (new)

Text proposed by the Commission	*Amendment*
	Article28a
	Resilient and sustainable biosimilar supply in the Union

1. In order to strengthen the resilience, sustainability and competitiveness of the Union's biosimilar market, the Commission shall, in cooperation with the Member States and the European Health Biotechnology Steering Group, assess structural factors affecting the long-term viability of biosimilar manufacturing and supply in the Union.

2. The assessment referred to in paragraph 1 shall analyse, in particular: a. the impact of procurement design on diversified supplier participation and long-term market sustainability; b. the relationship between pricing dynamics, volume predictability and continued market participation; c. structural supply risks arising from market concentration, single-winner mechanisms or abrupt volume reallocations; d. the interaction between industrial capacity, investment conditions and biosimilar pipeline development.

3. On the basis of that assessment, the Commission shall, where appropriate, issue non-binding guidance identifying best practices to support sustainable competition, diversified supply and security of supply in biosimilars, in full respect of Member States' competences in pricing, reimbursement and procurement decisions.

4. The guidance referred to in paragraph 3 may include recommendations on: a. the use of procurement criteria promoting supply reliability and long-term market participation; b. mechanisms supporting multi-supplier frameworks where appropriate; c. approaches to improve volume predictability and reduce avoidable supply disruptions; d. data transparency and monitoring of biosimilar market sustainability indicators.

5. The Commission shall periodically report to the European Parliament and the Council on the evolution of biosimilar

competition and supply resilience in the Union, including any identified risks to the sustainable functioning of the internal market.

Or. en

Amendment 2194
Peter Agius

Proposal for a regulation
Article 28 a (new)

Text proposed by the Commission	*Amendment*
	Article 28a
	Application of Article 85 of [the revised Directive on the Union code relating to medicinal products for human use] during the period of the supplementary protection certificate extension1. For the avoidance of doubt, the exemption laid down in Article 85 of [the revised Directive on the Union code relating to medicinal products for human use] shall apply, in full, to studies, trials and other activities conducted by manufacturers of generic, biosimilar, hybrid or bio-hybrid medicinal products, and by their suppliers, during the 12-month extension granted under Article 27 of this Regulation.2. The activities referred to in paragraph 1 shall include, in particular, those necessary for an application for a marketing authorisation, for a health technology assessment under Regulation (EU) 2021/2282, for a pricing and reimbursement decision, or for the submission of an application in a procurement procedure, in accordance with Article 85 of [the revised Directive on the Union code relating to medicinal products for human use]. Decisions taken by competent national authorities or by the Commission concerning such activities shall not be refused, revoked or

suspended on grounds of the patent or supplementary protection certificate status of the reference medicinal product, in accordance with Article 85(2) of that Directive.3. Article 9 of Regulation (EC) No 469/2009 and Article 27d of the Agreement on a Unified Patent Court shall apply, accordingly, to the period of the extension referred to in paragraph 1.

Or. en

Amendment 2195
Christine Anderson

Proposal for a regulation
Article 28 a (new)

Text proposed by the Commission	*Amendment*
	Article 28a
	Guidance on critical established biological medicinal products
	1. The Agency, in consultation with the Commission and the competent authorities of the Member States, shall develop non-binding scientific guidance on evidence requirements that may support applications concerning critical established biological medicinal products.
	2. For the purposes of this Article, critical established biological medicinal products shall mean biological medicinal products which:
	(a) have been in well-established medicinal use in the Union for the same therapeutic use and route of administration for at least ten years;
	(b) are included in the Union list of critical medicinal products or are otherwise demonstrated to be essential for public health and security of supply; and
	(c) are subject to full quality, manufacturing, GMP and

pharmacovigilance requirements under Union law.

3. The guidance shall identify the circumstances in which reliance on bibliographic data, historical clinical experience, pharmacovigilance data, real-world evidence and scientific bridging may be appropriate, without lowering requirements relating to quality, safety, efficacy, GMP, pharmacovigilance or benefit-risk assessment.

4. This Article shall not confer strategic-project status, financial support, market exclusivity or any derogation from applicable safety and quality requirements.

Or. en

Amendment 2196
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka, Kamila Gasiuk-Pihowicz

Proposal for a regulation
Article 28 a (new)

Text proposed by the Commission	*Amendment*
	Article28a
	Guidance by the Agency on critical established biological medicinal products
	1. The Agency, in consultation with the Commission, shall develop non-binding scientific guidance on the evidence that may support applications concerning critical established biological medicinal products.
	2. For the purposes of this Article, critical established biological medicinal products shall mean biological medicinal products which:
	(a) have been in well-established medicinal use in the Union for the same therapeutic use and route of administration for at least ten years;

(b) are included in the Union list of critical medicinal products or are otherwise demonstrated to be essential for public health and security of supply; and

(c) are manufactured as part of a strategic project under Regulation (EU) …/… [Critical Medicines Act; reference to be added after adoption, cf. COM(2025) 102 final], or at least one key manufacturing step relating to the production of the active substance or the finished biological medicinal product is carried out in the Union at commercial scale, excluding packaging, quality testing and certification alone;

3. The guidance shall identify the circumstances in which reliance on bibliographic data, historical clinical experience and scientific bridging may be appropriate.

Or. en

Justification

A dedicated guidance provision is necessary because critical established biological medicinal products are neither new innovative products nor biosimilars. They may have extensive clinical experience and well-documented therapeutic use, but their broader Union availability may be limited due to historical national authorisations or the absence of a proportionate centralised route. The proposed guidance would support a predictable and scientifically robust evidentiary approach for such products, while preserving the full quality, manufacturing and pharmacovigilance standards applicable to biological medicines. This would contribute to wider availability of critical biological medicines and support Union-based manufacturing capacity.

Amendment 2197
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 28 b (new)

Text proposed by the Commission	*Amendment*
	Article28b

Cost Recovery and Compensation for Open Technology Platforms

1. The holder of an open technology platform may receive fair and proportionate compensation for the maintenance, updating and regulatory upkeep of the platform, including its interaction with regulatory authorities.

2. Such compensation may be structured as a fee or contribution levied on the use of the platform technology, provided that it is transparent, proportionate to the actual costs incurred, and does not create barriers to access or disincentivise the use of the platform by developers or other stakeholders. The level of any fee referred to in paragraph 2 shall be limited to the recovery of reasonable costs associated with: (a) the maintenance and continuous updating of the platform; (b) the preparation, maintenance and regulatory interaction of platform documentation with competent authorities; (c) the provision of technical and regulatory support to developers using the platform; and (d) other activities necessary to ensure the continued operability, compliance and scientific validity of the platform.

3. Fees shall not exceed what is necessary to ensure the sustainability of the platform and shall not be designed or applied in a manner that restricts fair competition, innovation, or access to the platform by potential users

Or. en

Amendment 2198
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 28 c (new)

Text proposed by the Commission	*Amendment*

Article28c

Guidance by the Agency on biohybrid advanced therapy medicinal products

The Agency, in consultation with the Commission, shall develop and regularly update non-binding guidance on the scientific and regulatory requirements applicable to biohybrid advanced therapy medicinal products. The guidance shall establish a tailored, case-by-case framework for determining the evidence required for marketing authorisation, taking into account:

(a) the nature and extent of the modifications introduced in comparison with the reference advanced therapy medicinal product;

(b) advances in manufacturing technologies, analytical methods and platform technologies;

(c) the appropriate use of prior knowledge, published scientific evidence and regulatory experience;

(d) the application of fit-for-purpose evidence and the totality-of-evidence approach; and

(e) the reduction or adaptation of non-clinical and clinical studies where justified by the residual scientific uncertainty, while ensuring that the quality, safety and efficacy of the medicinal product are demonstrated.

Or. en

Amendment 2199
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 28 d (new)

Text proposed by the Commission	*Amendment*

Article28d

Cross-border access to hospital exemption advanced therapy medicinal products

1. Cross-border exchange of hospital exemption medicinal products may be authorised when patient mobility is not feasible due to medical condition, treatment duration, or when the expected patient population in the receiving Member State so requires.

2. The receiving hospital may apply for a hospital exemption authorisation in its own Member State, provided that it demonstrates its capacity to replicate the treatment in accordance with the same quality, safety, and process standards as those applied in the originating Member State.

3. In the circumstances referred to in paragraph 1, the competent national regulatory authority of the receiving Member State may allow the cross-border transfer of the hospital exemption-advanced therapy medicinal product under the hospital exemption framework and designate a treating reference centre in the receiving Member State, subject to the authorisation of the competent national regulatory authorities of the originating Member State for the production and export of the product.

4. This shall not require that all manufacturing activities be carried out within a single Member State, provided that the originating site serves as the reference model for quality, manufacturing, and process standards.

5. Manufacturing activities may be outsourced to the originating Member State. Regulatory responsibility shall remain with the medical practitioner and the hospital requesting the hospital exemption in the receiving Member State, in cooperation with its competent national regulatory authority.

	6. The implementation of this Article shall be subject to: (a) the conduct of appropriate comparability studies, when appropriate and feasible, taking into account the prevalence of the condition to be treated; (b) the use of harmonised clinical and quality protocols; and (c) the capacity to aggregate and analyse clinical data jointly with the data generated by the hospital holding the original hospital exemption authorisation, in compliance with Union data protection rules.
	7. Member States shall ensure that the implementation of this Article does not undermine patient safety, data integrity, or the non-commercial nature of the hospital exemption framework.

Or. en

Amendment 2200
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 29 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
To enable access to the support measures laid down in Section II of Chapter II, Member States shall recognise projects located in the Union as biotechnology health strategic projects in the form of biotechnology health strategic projects for biosimilars only where they make a substantial contribution to at least one the specific objectives referred to in Article [3][(1)] and fulfil ***either*** of the following conditions:	To enable access to the support measures laid down in Section II of Chapter II, Member States shall recognise projects located in the Union as biotechnology health strategic projects in the form of biotechnology health strategic projects for biosimilars only where they ***support the timely availability and affordability of biosimilar medicinal products in the Union and*** make a substantial contribution to at least one the specific objectives referred to in Article [3][(1)] and fulfil ***one*** of the following conditions:

Or. en

Amendment 2201
Viktória Ferenc, András Gyürk

Proposal for a regulation
Article 29 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
To enable access to the support measures laid down in Section II of Chapter II, Member States shall recognise projects located in the Union as biotechnology health strategic projects in the form of biotechnology health strategic projects for biosimilars ***only*** where they make a substantial contribution to at least one the specific objectives referred to in Article [3][(1)] ***and fulfil either of the following conditions:***	To enable access to the support measures laid down in Section II of Chapter II, Member States shall recognise projects located in the Union as biotechnology health strategic projects in the form of biotechnology health strategic projects for biosimilars where they make a substantial contribution to at least one the specific objectives referred to in Article [3][(1)]

Or. en

Amendment 2202
Dimitris Tsiodras

Proposal for a regulation
Article 29 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
To enable access to the support measures laid down in Section II of Chapter II, Member States shall recognise projects located in the Union as biotechnology health strategic projects in the form of biotechnology health strategic projects for biosimilars ***only*** where they make a substantial contribution to at least one the specific objectives referred to in Article [3][(1)] ***and fulfil either of the following conditions:***	To enable access to the support measures laid down in Section II of Chapter II, Member States shall recognise projects located in the Union as biotechnology health strategic projects in the form of biotechnology health strategic projects for biosimilars where they make a substantial contribution to at least one the specific objectives referred to in Article [3][(1)]

Or. en

Justification

As an integral part of the EU biotech ecosystem, biosimilar projects should be recognised as strategic wherever they make a substantial contribution to at least one specific objective referred to in Article 3 (1).Contribution to analytical testing or innovative manufacturing extension is unduly restrictive and discriminatory whereas the ecosystem resilience is built on flexible interplay.

Amendment 2203
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 29 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
To enable access to the support measures laid down in Section II of Chapter II, Member States shall recognise projects located in the Union as biotechnology health strategic projects in the form of biotechnology health strategic projects for biosimilars ***only*** where they make a substantial contribution to at least one the specific objectives referred to in Article [3][(1)] ***and fulfil either of the following conditions:***	To enable access to the support measures laid down in Section II of Chapter II, Member States shall recognise projects located in the Union as biotechnology health strategic projects in the form of biotechnology health strategic projects for biosimilars where they make a substantial contribution to at least one the specific objectives referred to in Article [3][(1)]**.**

Or. en

Amendment 2204
Dimitris Tsiodras

Proposal for a regulation
Article 29 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) they contribute to the setting up and extension of innovative biomanufacturing capacity, and infrastructures for analytical testing procedures;	***deleted***

Or. en

Amendment 2205
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 29 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) they contribute to the setting up and extension of innovative biomanufacturing capacity, and infrastructures for analytical testing procedures;	***deleted***

Or. en

Amendment 2206
Viktória Ferenc, András Gyürk

Proposal for a regulation
Article 29 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) they contribute to the setting up and extension of innovative biomanufacturing capacity, and infrastructures for analytical testing procedures;	***deleted***

Or. en

Amendment 2207
Ruggero Razza

Proposal for a regulation
Article 29 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) they contribute to the setting up and extension of innovative biomanufacturing	(a) they contribute to the setting up and extension of innovative biomanufacturing capacity, and infrastructures for analytical testing procedures ***with a view to***

capacity, and infrastructures for analytical testing procedures;	***promoting the uptake of advanced production technologies and the modernisation of existing facilities***;

Or. it

Amendment 2208
Dimitris Tsiodras

Proposal for a regulation
Article 29 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) they contribute to the research, development and marketing authorisation of biosimilars, and where appropriate to strengthening the use of platform technologies; this includes analytical methodologies that would reduce the need for clinical data for biosimilars, without affecting their quality, safety and efficacy.	***deleted***

Or. en

Amendment 2209
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 29 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) they contribute to the research, development and marketing authorisation of biosimilars, and where appropriate to strengthening the use of platform technologies; this includes analytical methodologies that would reduce the need for clinical data for biosimilars, without affecting their quality, safety and efficacy.	***deleted***

Or. en

Amendment 2210
Viktória Ferenc, András Gyürk

Proposal for a regulation
Article 29 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) they contribute to the research, development and marketing authorisation of biosimilars, and where appropriate to strengthening the use of platform technologies; this includes analytical methodologies that would reduce the need for clinical data for biosimilars, without affecting their quality, safety and efficacy.	***deleted***

Or. en

Amendment 2211
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 29 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) they contribute to the prevention or mitigation of shortages of biological medicines, including through diversified manufacturing capacity, supply-chain resilience, stockpiling where appropriate or contingency planning in cooperation with relevant authorities;

Or. en

Amendment 2212
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 29 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) they facilitate technology transfer and scale-up of biosimilar production processes within the Union, including through collaboration between research organisations, contract development and manufacturing organisations, and industrial producers.

Or. en

Amendment 2213
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 29 a (new)

Text proposed by the Commission	*Amendment*
	Article29a
	Biosimilars and Biomanufacturing Support Scheme
	A Biosimilars and Biomanufacturing Support Scheme is hereby established in order to strengthen the resilience, competitiveness, and strategic autonomy of the Union pharmaceutical and biotechnology sector as well as the long-term financial sustainability of Union public health systems through the development, manufacture and market uptake of biosimilar medicinal products within the Union.
	The Scheme shall support activities contributing to:
	(i) the development and clinical validation of biosimilar medicinal products;
	(ii) the establishment, expansion or modernisation of Union-based biomanufacturing capacity;
	(iii) the reduction of market barriers and investment risks associated with biosimilar development; and

(iv) the diversification of API manufacturing and strengthening the security of supply of critical biologic medicinal products.

Financial support under the Scheme may be granted for:

(i) analytical comparability and biosimilarity studies;

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

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

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

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

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

(vii) workforce development and specialised biotechnology training programmes;

(viii) strategic manufacturing reserve capacity for critical biologic medicinal products.

Priority shall be given to projects contributing to:

(i) supply chain resilience within the Union;

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

(iii) environmentally sustainable manufacturing processes;

(iv) cross-border industrial cooperation between Member States; and

(v) the participation of small and medium-sized enterprises (SMEs), scale-ups and emerging biotechnology undertakings.

Recognising the contribution that regional and cohesion investment can make to a resilient and geographically distributed Union biomanufacturing base, the Commission shall actively encourage and support the programming of relevant Union shared-management funds towards the objectives of the Scheme. In its dialogue with Member States on the National and Regional Partnership Plans, and in the relevant investment guidance addressed to Member States, the Commission shall draw attention to the strategic importance of biosimilar and biomanufacturing investment, including in less-developed and transition regions and in regions affected by industrial transition, and shall promote the use for these purposes of the European Regional Development Fund, the Cohesion Fund, the European Social Fund Plus and, for cross-border projects, European Territorial Cooperation (Interreg), as well as collaborate with Member States in identifying relevant state aid mechanisms.

The European Investment Bank Group shall be encouraged to support projects falling within the scope of this Article through loans, guarantees, venture debt, risk-sharing mechanisms, blended finance instruments or public-private investment platforms. It may also cooperate with national promotional banks and institutions in order to mobilise additional public and private investment towards strengthening Union leadership in innovation, manufacturing and commercialisation of biosimilars.

Or. en

Amendment 2214
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka, Kamila Gasiuk-Pihowicz

Proposal for a regulation
Article 29 a (new)

Text proposed by the Commission	*Amendment*
	Article29a
	Biotechnology health strategic projects for critical established biological medicinal products
	To enable access to the support measures laid down in Section II of Chapter II, Member States may recognise projects located in the Union as biotechnology health strategic projects in the form of biotechnology health strategic projects for critical established biological medicinal products where they:
	(a) concern a critical established biological medicinal product within the meaning of Article 28a;
	(b) contribute to the maintenance, modernisation, upgrading, expansion or long-term sustainability of Union-based manufacturing capacity;
	(c) contribute to the security, continuity or resilience of supply of biological medicinal products in the Union.

Or. en

Justification

The proposed provision creates a dedicated strategic project route for critical established biological medicinal products. This is important for products with long-standing clinical use and public health relevance whose availability across the Union may remain limited despite their critical importance. The provision would allow support measures to cover investments in existing Union-based manufacturing capacity, including modernisation, regulatory compliance, capacity expansion and long-term sustainability. It is therefore directly aligned with the objectives of security of supply, strategic autonomy and resilience, while maintaining the regulatory standards applicable to biological medicines.

Amendment 2215
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka, Kamila Gasiuk-Pihowicz

Proposal for a regulation
Article 29 b (new)

Text proposed by the Commission	*Amendment*
	Article29b
	Authorisation pathway for critical established biological medicinal products
	1. The Commission shall ensure that a proportionate centralised authorisation pathway is available for critical established biological medicinal products, in particular where such products have been authorised in one or more Member States but are not effectively available across the Union, through the amendment to Regulation (EU) …/… provided for in Article 61a.
	2. That pathway shall allow, where scientifically justified, reliance upon bibliographic data, historical clinical experience and scientific bridging in support of the non-clinical and clinical parts of the application, provided that the applicant demonstrates that:
	(a) the product has been in well-established medicinal use in the Union for the same therapeutic use and route of administration for at least ten years;
	(b) the product is included in the Union list of critical medicinal products or is otherwise essential for public health and security of supply;
	(c) the product is manufactured as part of a strategic project referred to in Article 5(1)(a) of Regulation (EU) …/… [reference to be added after adoption, cf. COM(2025) 102 final] or at least one key manufacturing step relating to the production of the active substance or the finished biological medicinal product is carried out in the Union at commercial scale, excluding packaging, quality testing and certification alone;

(d) the totality of evidence supports a positive benefit-risk balance.

3. The simplified pathway shall be without prejudice to the applicant's obligation to submit a complete quality dossier and data necessary to demonstrate the quality, safety and efficacy of the medicinal product.

4. A marketing authorisation granted under this Article shall be valid throughout the Union.

Or. en

Justification

This provision establishes the policy objective of creating a proportionate centralised authorisation pathway for critical established biological medicinal products, while leaving the detailed legal mechanism to the amendment of the pharmaceutical framework in Article 61a.By allowing, where scientifically justified, reliance on bibliographic data, historical clinical experience and scientific bridging, the amendment avoids unnecessary duplication of studies for products with long-standing and well-documented use, while fully preserving quality, safety and efficacy requirements. The absence of such a pathway in practice limits patient access to medicinal products of critical importance across the entire EU.The targeted scope ensures that this simplified pathway applies only to products recognised as critical and manufactured as part of strategic projects contributing to Union-based manufacturing capacity. This approach enhances regulatory efficiency, supports continuity of supply, and strengthens incentives for maintaining and upgrading biological manufacturing in the Union, without lowering regulatory standards or granting automatic authorisation.

Amendment 2216
Katri Kulmuni, Stine Bosse, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 30 – paragraph 1

Text proposed by the Commission	*Amendment*
Where appropriate, promoters of projects related to biosimilars and other companies working in this area, shall explore opportunities to establish or strengthen cooperation with international biotechnology clusters, including with a view to fulfilling the conditions referred to in Article [29] for the recognition of	Where appropriate, promoters of projects related to biosimilars and other companies working in this area, shall explore opportunities to establish or strengthen cooperation with international biotechnology clusters ***located in countries with which the Union has concluded a mutual recognition agreement that***

biotechnology health strategic projects for biosimilars.	***encourages the uptake of health biotechnology products developed in the Union,*** , including with a view to fulfilling the conditions referred to in Article [29] for the recognition of biotechnology health strategic projects for biosimilars.

Or. en

Amendment 2217
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 30 – paragraph 1

Text proposed by the Commission	*Amendment*
Where appropriate, promoters of projects related to biosimilars and other companies working in this area, shall explore opportunities to establish or strengthen cooperation with international biotechnology clusters, including with a view to fulfilling the conditions referred to in Article [29] for the recognition of biotechnology health strategic projects for biosimilars.	Where appropriate, promoters of projects related to biosimilars and other companies working in this area, shall explore opportunities to establish or strengthen cooperation with international biotechnology clusters, including with a view to fulfilling the conditions referred to in Article [29] for the recognition of biotechnology health strategic projects for biosimilars. ***International cooperation under this Article shall contribute to strengthening the resilience and strategic autonomy of the Union's biotechnology manufacturing capacity.***

Or. en

Amendment 2218
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Article 30 – paragraph 1

Text proposed by the Commission	*Amendment*
Where appropriate, promoters of projects related to biosimilars and other companies working in this area, shall explore	Where appropriate, promoters of projects related to biosimilars and other companies working in this area, shall explore

opportunities to establish or strengthen cooperation with international biotechnology clusters, including with a view to fulfilling the conditions referred to in Article [29] for the recognition of biotechnology health strategic projects for biosimilars.	opportunities to establish or strengthen cooperation with international biotechnology clusters ***located in countries with which the Union has concluded a mutual recognition agreement that promotes the use of health biotechnology produced in the Union***, including with a view to fulfilling the conditions referred to in Article [29] for the recognition of biotechnology health strategic projects for biosimilars.

Or. en

Justification

Amending this Article would help reduce structural trade asymmetries with third countries with whom the Union has concluded a mutual recognition agreement. By aligning trade conditions more closely with EU strategic objectives, the amendment would support a more balanced and resilient trade framework that strengthens the Union's industrial and economic position.

Amendment 2219
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Chapter V a (new)

Text proposed by the Commission	*Amendment*
	Va CHAPTER Va ENHANCING COMPETITIVENESS AND DEPLOYMENT OF BACTERIOPHAGE TECHNOLOGIES
	Article 30a - Guidance by the Agency on bacteriophages
	1. The Agency, in consultation with the Commission and the relevant competent authorities, shall develop and regularly update non-binding guidance on a tailored regulatory approach for the development of bacteriophage products and therapies, with a view to facilitating their development and ensuring a fit-for-purpose regulatory framework reflecting scientific and technological advances.

The guidance shall, where appropriate, address the classification of bacteriophage products and therapies, quality requirements, manufacturing standards, analytical testing, susceptibility testing, adaptive and platform-based clinical development, lifecycle management and comparability-based modifications. It shall also consider scientifically justified approaches to the use of curated phage libraries, bacterial host collections, AI-enabled matching systems and other innovative technologies supporting the development and deployment of bacteriophage therapies, without affecting their quality, safety and efficacy.

Article 30b - Biotechnology health strategic projects for bacteriophages

Member States shall recognise projects located in the Union as biotechnology health strategic projects for bacteriophage products and therapies where they make a substantial contribution to the objectives referred to in Article 3 and fulfil at least one of the following conditions:

(a) they contribute to the establishment, expansion or modernisation of innovative biomanufacturing capacity, analytical testing infrastructure, quality control infrastructure or susceptibility-testing infrastructure for bacteriophage products and therapies;

(b) they contribute to the research, development, clinical validation, marketing authorisation or deployment of bacteriophage products and therapies, including, where appropriate, through the development of platform technologies, curated phage libraries, bacterial host collections or AI-enabled matching systems.

Article 30c - International partnerships

The Agency and the Commission shall, in the context of international regulatory cooperation and where appropriate,

	promote collaboration with international biotechnology clusters, antimicrobial resistance initiatives and One Health networks, with a view to supporting the development, regulatory convergence and deployment of bacteriophage products and therapies. Project promoters shall, where appropriate, explore opportunities to establish or strengthen such cooperation in order to facilitate recognition as biotechnology health strategic projects.

Or. en

Amendment 2220
Michele Picaro

Proposal for a regulation
Article 31 – title

Text proposed by the Commission	*Amendment*
Guidance on the deployment and use of systems based on advanced technologies, including AI, in the lifecycle of medicinal products	Guidance on the deployment and use of systems based on advanced technologies, including AI ***models and systems***, in the lifecycle of medicinal products

Or. en

Amendment 2221
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 31 – title

Text proposed by the Commission	*Amendment*
Guidance on the deployment and use of systems based on advanced technologies, including AI, in the lifecycle of medicinal products	Guidance on the deployment and use of systems based on advanced technologies, including AI ***models and systems***, in the lifecycle of medicinal products

Or. en

Amendment 2222
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 31 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency shall publish and regularly update, as appropriate, non-binding guidance on the deployment and use of systems based on advanced technologies, including AI, in the lifecycle of medicinal products development, including during pre-clinical research, clinical development and trials, manufacturing and post-authorisation monitoring.	The Agency shall publish and regularly update, as appropriate, non-binding guidance on the deployment and use of systems based on advanced technologies, including AI ***and its ethical use,*** , in the lifecycle of medicinal products development, including during pre-clinical research, clinical development and trials, manufacturing and post-authorisation monitoring***, with a view to facilitating innovation, accelerating the ethical, safe and responsible uptake of advanced technologies, and providing regulatory clarity and predictability for developers, in particular SMEs, start-ups, scale-ups and spin-offs. Such guidance shall, where appropriate, support the use of trustworthy, interoperable, secure and auditable AI tools available to Union researchers, developers and competent authorities, while taking into account risks linked to overdependence on tools controlled exclusively under third-country jurisdictions.***

Or. en

Amendment 2223
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 31 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*

The Agency shall publish and regularly update, as appropriate, non-binding guidance on the deployment and use of systems based on advanced technologies, including ***AI***, in the lifecycle of medicinal products development, including during pre-clinical research, clinical development and trials, manufacturing and post-authorisation monitoring.	The Agency***, following consultation with stakeholders,*** shall publish and regularly update, as appropriate, non-binding guidance on the deployment and use of systems based on advanced technologies, including ***complex in vitro models, organ on chip and general-purpose AI models or AI systems***, in the lifecycle of medicinal products development, including during pre-clinical research, clinical development and trials, manufacturing and post-authorisation monitoring ***and aligned with domain specific guidance on AI listed in EMA/HMA workplans***. ***Such guidance shall ensure full coherence with the requirements laid down in this Regulation and Regulation (EU) 2024/1689 and with any guidance issued under those regulations, including regarding general-purpose AI models or AI systems.***

Or. en

Justification

AI has been highlighted in the proposal, but advanced technologies should include fabricated devices using human relevant tissues and cells too. These technologies require guidance in their use in biomedical research and for regulatory application.

Amendment 2224
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Sophie Wilmès

Proposal for a regulation
Article 31 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency shall publish and ***regularly*** update, as appropriate, non-binding guidance on the deployment and use of systems based on advanced technologies, including AI, in the lifecycle of medicinal products development, including during pre-clinical research, clinical development and trials, manufacturing and post-authorisation monitoring.	The Agency***, following stakeholder consultation*** shall publish and update, as appropriate, non-binding guidance on the deployment and use of systems based on advanced technologies, including AI ***models and systems***, in the lifecycle of medicinal products development, including during pre-clinical research, clinical development and trials, manufacturing and post-authorisation monitoring.

Or. en

Amendment 2225
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 31 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency shall publish and regularly update, as appropriate, non-binding guidance on the deployment and use of systems based on advanced technologies, including AI, in the lifecycle of medicinal products development, including during pre-clinical research, clinical development and trials, manufacturing and post-authorisation monitoring.	The Agency***, following stakeholder consulatition,*** shall publish and regularly update, as appropriate, non-binding guidance on the deployment and use of systems based on advanced technologies, including AI, in the lifecycle of medicinal products development, including during pre-clinical research, clinical development and trials, manufacturing and post-authorisation monitoring.

Or. en

Amendment 2226
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 31 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency shall publish and regularly update, as appropriate, non-binding guidance on the deployment and use of systems based on advanced technologies, including AI, in the lifecycle of medicinal products development, including during pre-clinical research, clinical development and trials, manufacturing and post-authorisation monitoring.	The Agency shall publish and regularly update, as appropriate, non-binding guidance on the deployment and use of systems based on advanced technologies, including AI ***and its ethical use***, in the lifecycle of medicinal products development, including during pre-clinical research, clinical development and trials, manufacturing and post-authorisation monitoring.

Or. en

Amendment 2227
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 31 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency shall publish and regularly update, as appropriate, ***non-binding*** guidance on the deployment and use of systems based on advanced technologies, including AI, in the lifecycle of medicinal products development, including during pre-clinical research, clinical development and trials, manufacturing and post-authorisation monitoring.	The Agency shall publish and regularly update, as appropriate, guidance on the deployment and use of systems based on advanced technologies, including AI ***and its ethical use***, in the lifecycle of medicinal products development, including during pre-clinical research, clinical development and trials, manufacturing and post-authorisation monitoring.

Or. en

Amendment 2228
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 31 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency shall publish and regularly update, as appropriate, non-binding guidance on the deployment and use of systems based on advanced technologies, ***including*** AI, in the lifecycle of medicinal products development, including during pre-clinical research, clinical development and trials, manufacturing and post-authorisation monitoring.	The Agency shall publish and regularly update, as appropriate, non-binding guidance on the deployment and use of systems based on advanced technologies, ***includingNAMs and*** AI, in the lifecycle of medicinal products development, including during pre-clinical research, clinical development and trials, manufacturing and post-authorisation monitoring.

Or. en

Amendment 2229
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 31 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
Such guidance shall be developed, updated and published in agreement with the Commission, including with the AI Office.	Such guidance shall be developed, updated and published in agreement with the Commission, including with the AI Office ***and aligned with domain-specific guidance on AI listed in EMA and HMA multi-annual AI workplans***.

Or. en

Amendment 2230
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Sophie Wilmès

Proposal for a regulation
Article 31 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
Such guidance shall be developed, updated and published in agreement with the Commission, including with the AI Office.	Such guidance shall be developed, updated and published in agreement with the Commission, including with the AI Office ***and aligned with domain-specific guidance on AI set out in the EMA and HMA workplans***.

Or. en

Amendment 2231
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 31 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
Such guidance shall be developed, updated and published in agreement with the Commission, including with the AI Office.	Such guidance shall be developed, updated and published in agreement with the Commission, including with the AI Office ***and aligned with domain specific guidance on AI listed in EMA/HMA workplans***.

Or. en

Amendment 2232
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 31 – paragraph 1 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	Such guidance shall ensure that the processing of personal data, in particular health and genetic data, must comply strictly with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725, ensuring in particular the principles of data minimisation, purpose limitation and security of processing.

Or. en

Amendment 2233
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Sophie Wilmès

Proposal for a regulation
Article 31 – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
Such guidance shall ensure full coherence with the requirements laid down in Regulation (EU) 2024/1689 and with any guidance issued under ***that Regulation*** regarding general-purpose AI models or AI systems.	Such guidance shall ensure full coherence with the requirements laid down in ***this Regulation and*** Regulation (EU) 2024/1689 and with any guidance issued under ***those regulations, including*** regarding general-purpose AI models or AI systems.

Or. en

Amendment 2234
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation

Article 31 – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
Such guidance shall ensure full coherence with the requirements laid down in Regulation (EU) 2024/1689 and with any guidance issued under ***that Regulation*** regarding general-purpose AI models or AI systems.	Such guidance shall ensure full coherence with the requirements laid down in ***this Regulation and*** Regulation (EU) 2024/1689 and with any guidance issued under ***those Regulations, including*** regarding general-purpose AI models or AI systems.

Or. en

Amendment 2235
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 31 – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
Such guidance shall ensure full coherence with the requirements laid down in Regulation (EU) 2024/1689 and with any guidance issued under that Regulation regarding general-purpose AI models or AI systems.	Such guidance shall ensure full coherence with the requirements laid down in ***in this Regulation and*** Regulation (EU) 2024/1689 and with any guidance issued under that Regulation regarding general-purpose AI models or AI systems.

Or. en

Justification

The amendment better aligns the proposed Article on non-binding guidance on AI with existing workstreams in the EMA as well as clearly requires stakeholder consultation as part of the process. Furthermore, it better aligns the terminology with that of the AI Act (e.g. General-purpose AI models and AI systems)

Amendment 2236
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 31 – paragraph 1 – subparagraph 3 – point 1 (new)

Text proposed by the Commission	*Amendment*

(1) Such guidance shall address, where appropriate, the use of registries, real-world data and patient-reported outcomes in rare diseases and advanced therapies, with safeguards against bias and unequal outcomes.

Or. en

Amendment 2237
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 31 – paragraph 1 – subparagraph 3 a (new)

Text proposed by the Commission	*Amendment*
	Guidance created under the EU Biotech Act should not only cover AI use in primary research, but also AI use for secondary research activities.

Or. en

Justification

This added provision aims to ensure greater harmonisation amongst research practices across different research organisations and shall facilitate the use and interoperability of data generated through the use of AI.

Amendment 2238
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 31 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
In developing and updating the guidance referred to in paragraph 1, the Agency shall consult the relevant authorities, at national ***and*** European level, and stakeholders ***as appropriate***.	In developing and updating the guidance referred to in paragraph 1, the Agency shall consult the relevant authorities, at national***,*** European***, and international*** level, ***including regulatory agencies in third countries*** and stakeholders***, including providers and deployers of AI***.

Or. en

Amendment 2239
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 31 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
In developing and updating the guidance referred to in paragraph 1, the Agency shall consult the relevant authorities, at national and European level, and stakeholders as appropriate.	In developing and updating the guidance referred to in paragraph 1, the Agency shall consult the relevant authorities, at national and European level, and stakeholders***, including developers, patient and healthcare organisations,*** as appropriate.

Or. en

Amendment 2240
Michele Picaro

Proposal for a regulation
Article 31 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
In developing and updating the guidance referred to in paragraph 1, the Agency shall consult the relevant authorities, at national and European level, and stakeholders ***as appropriate***.	In developing and updating the guidance referred to in paragraph 1, the Agency shall consult the relevant authorities, at national and European level, and stakeholders***, including developers and users of AI***.

Or. en

Amendment 2241
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Sophie Wilmès

Proposal for a regulation
Article 31 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*

In developing and updating the guidance referred to in paragraph 1, the Agency shall consult the relevant authorities, at national and European level, and stakeholders ***as appropriate***.	In developing and updating the guidance referred to in paragraph 1, the Agency shall consult the relevant authorities, at national and European level, and stakeholders***, including developers and users of AI***.

Or. en

Amendment 2242
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 31 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
To the extent that the guidance concerns the deployment and use of systems based on advanced technologies, including AI, across the clinical trials lifecycle, the Agency shall further cooperate with the Clinical Trials Coordination [and Advisory] Group ('CTAG') referred to in Article [85] of Regulation (EU) No 536/2014, with the Medical Device Coordination Group ('MDCG') referred to in Article 103 of Regulation (EU) 2017/745 and with the Artificial Intelligence Board referred to in Article 65 of Regulation (EU) 2024/1689, as appropriate and shall publish that guidance in agreement with the consulted entities referred to in this subparagraph.	To the extent that the guidance concerns the deployment and use of systems based on advanced technologies, including ***NAMs and*** AI, across the clinical trials lifecycle, the Agency shall further cooperate with the Clinical Trials Coordination [and Advisory] Group ('CTAG') referred to in Article [85] of Regulation (EU) No 536/2014, with the Medical Device Coordination Group ('MDCG') referred to in Article 103 of Regulation (EU) 2017/745 and with the Artificial Intelligence Board referred to in Article 65 of Regulation (EU) 2024/1689, as appropriate and shall publish that guidance in agreement with the consulted entities referred to in this subparagraph.

Or. en

Amendment 2243
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 31 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*

To the extent that the guidance concerns the deployment and use of systems based on ***advanced technologies, including AI***, across the clinical trials lifecycle, the Agency shall further cooperate with the Clinical Trials Coordination [and Advisory] Group ('CTAG') referred to in Article [85] of Regulation (EU) No 536/2014, with the Medical Device Coordination Group ('MDCG') referred to in Article 103 of Regulation (EU) 2017/745 and with the Artificial Intelligence Board referred to in Article 65 of Regulation (EU) 2024/1689, as appropriate and shall publish that guidance in agreement with the consulted entities referred to in this subparagraph.	To the extent that the guidance concerns the deployment and use of systems based on ***general-purpose AI models and AI systems***, across the clinical trials lifecycle, the Agency shall further cooperate with the Clinical Trials Coordination [and Advisory] Group ('CTAG') referred to in Article [85] of Regulation (EU) No 536/2014, with the Medical Device Coordination Group ('MDCG') referred to in Article 103 of Regulation (EU) 2017/745 and with the Artificial Intelligence Board referred to in Article 65 of Regulation (EU) 2024/1689, as appropriate and shall publish that guidance in agreement with the consulted entities referred to in this subparagraph.

Or. en

Amendment 2244
Michele Picaro

Proposal for a regulation
Article 31 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
To the extent that the guidance concerns the deployment and use of systems based on ***advanced technologies, including*** AI, across the clinical trials lifecycle, the Agency shall further cooperate with the Clinical Trials Coordination [and Advisory] Group ('CTAG') referred to in Article [85] of Regulation (EU) No 536/2014, with the Medical Device Coordination Group ('MDCG') referred to in Article 103 of Regulation (EU) 2017/745 and with the Artificial Intelligence Board referred to in Article 65 of Regulation (EU) 2024/1689, as appropriate and shall publish that guidance in agreement with the consulted entities referred to in this subparagraph.	To the extent that the guidance concerns the deployment and use of systems based on AI ***models and systems***, across the clinical trials lifecycle, the Agency shall further cooperate with the Clinical Trials Coordination [and Advisory] Group ('CTAG') referred to in Article [85] of Regulation (EU) No 536/2014, with the Medical Device Coordination Group ('MDCG') referred to in Article 103 of Regulation (EU) 2017/745 and with the Artificial Intelligence Board referred to in Article 65 of Regulation (EU) 2024/1689, as appropriate and shall publish that guidance in agreement with the consulted entities referred to in this subparagraph.

Or. en

Amendment 2245
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Sophie Wilmès

Proposal for a regulation
Article 31 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Agency, national competent authorities and other Union regulatory bodies shall conduct their regulatory assessments on the basis of the latest available scientific evidence, duly considering relevant advances in science and technology as well as, where appropriate, scientific consensus recognised at international level.

Or. en

Amendment 2246
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 31 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency shall develop and publish in agreement with the Commission, including the AI Office where appropriate, and in cooperation with the national competent authorities, non-binding guidance on the deployment and use of advanced technologies, including AI, in the procedures for the authorisation of medicinal products.	3. The Agency shall develop and publish in agreement with the Commission, including the AI Office where appropriate, and in cooperation with the national competent authorities, non-binding guidance on the deployment and use of advanced technologies, including AI, in the procedures for the authorisation of medicinal products. ***Guidance shall promote auditability, traceability and appropriate post-deployment monitoring of high-risk AI systems used in biotechnology.***

Or. en

Amendment 2247
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Sophie Wilmès

Proposal for a regulation
Article 31 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency shall develop and publish in agreement with the Commission, including the AI Office where appropriate, and in cooperation with the national competent authorities, non-binding guidance on the deployment and use of advanced technologies, including AI, in the procedures for the authorisation of medicinal products.	3. The Agency shall develop and***, following stakeholder consultation,*** publish in agreement with the Commission, including the AI Office where appropriate, and in cooperation with the national competent authorities, non-binding guidance on the deployment and use of advanced technologies, including AI ***models and systems***, in the procedures for the authorisation of medicinal products ***by the Agency and national competent authorities***.

Or. en

Amendment 2248
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 31 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency shall develop and publish in agreement with the Commission, including the AI Office where appropriate, and in cooperation with the national competent authorities, non-binding guidance on the deployment and use of ***advanced technologies, including AI***, in the procedures for the authorisation of medicinal products.	3. The Agency shall develop and***, following stakeholder consultation,*** publish in agreement with the Commission, including the AI Office where appropriate, and in cooperation with the national competent authorities, non-binding guidance on the deployment and use of ***general-purpose AI models and AI systems***, in the procedures for the authorisation of medicinal products ***by the Agency and national competent authorities***.

Or. en

Justification

The amendments better align the proposed Articles on non-binding guidance on AI with existing workstreams in the EMA and the AI Office, as well as clearly require stakeholder consultation as part of the process. Furthermore, they better aligns the terminology with that of the AI Act (e.g. general-purpose AI models and AI systems)

Amendment 2249
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 31 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency shall develop and publish in agreement with the Commission, including the AI Office where appropriate, and in cooperation with the national competent authorities, non-binding guidance on the deployment and use of ***advanced technologies, including*** AI, in the procedures for the authorisation of medicinal products.	3. The Agency shall develop and***, following stakeholder consultation,*** publish in agreement with the Commission, including the AI Office where appropriate, and in cooperation with the national competent authorities, non-binding guidance on the deployment and use of AI ***models and systems***, in the procedures for the authorisation of medicinal products ***by the Agency and national competent authorities***.

Or. en

Amendment 2250
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 31 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency shall develop and publish in agreement with the Commission, including the AI Office where appropriate, and in cooperation with the national competent authorities, non-binding guidance on the deployment and use of advanced technologies, including AI, in the	3. The Agency shall develop and publish in agreement with the Commission, including the AI Office where appropriate, and in cooperation with the national competent authorities, non-binding guidance on the deployment and use of advanced technologies, including AI ***and***

procedures for the authorisation of medicinal products.

its ethical use, in the procedures for the authorisation of medicinal products.

Or. en

Amendment 2251
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 31 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The guidance referred to in paragraphs 1 to 3 shall ensure that systems based on advanced technologies, including artificial intelligence, are deployed and used in a manner that guarantees appropriate and effective human oversight, transparency, accountability, data security, traceability and scientific reliability throughout the lifecycle of medicinal products.

Or. en

Amendment 2252
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 31 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The guidance shall encourage the use of representative datasets reflecting population diversity, including women, older persons and underrepresented groups.

Or. en

Amendment 2253
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 31 – paragraph 3 b (new)

Text proposed by the Commission	*Amendment*
	3b. The guidance shall promote a governance framework that safeguards patient safety, fundamental rights and public trust, including by ensuring the meaningful involvement of healthcare professionals and patients, preserving the contextual integrity of data and analyses, and preventing inaccurate, misleading or clinically unsafe outputs.

Or. en

Amendment 2254
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 32 – 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 trusted testing environments for advanced health biotechnology innovations, where such innovations are enabled, enhanced or significantly supported by AI or advanced computational methods, only where they comply with the criteria laid down in Article 4(1) and substantially strengthens the Union's capacity for responsible experimentation, development, testing and validation of such innovations and they fulfils all 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 trusted testing environments for advanced health biotechnology innovations, where such innovations are ***NAMs or*** enabled, enhanced or significantly supported by AI or advanced computational methods, only where they comply with the criteria laid down in Article 4(1) and substantially strengthens the Union's capacity for responsible experimentation, development, testing and validation of such innovations and they fulfils all of the following conditions:

Or. en

Amendment 2255
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 32 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) operate under trusted conditions ensuring compliance and alignment with relevant Union and national legislation and complements where appropriate testing and experimentation facilities ***and AI regulatory sandboxes established in accordance with Regulation (EU) 2024/1689***, while ensuring consistency and synergies in their implementation;	(a) operate under trusted conditions ensuring compliance and alignment with relevant Union and national legislation and complements where appropriate testing and experimentation facilities, while ensuring consistency and synergies in their implementation;

Or. en

Amendment 2256
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 32 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) operate under trusted conditions ensuring compliance and alignment with relevant Union and national legislation and complements where appropriate testing and experimentation facilities and AI regulatory sandboxes established in accordance with Regulation (EU) 2024/1689, while ensuring consistency and synergies in their implementation;	(a) operate under trusted ***and ethical*** conditions ensuring compliance and alignment with relevant Union and national legislation and complements where appropriate testing and experimentation facilities and AI regulatory sandboxes established in accordance with Regulation (EU) 2024/1689, while ensuring consistency and synergies in their implementation;

Or. en

Amendment 2257
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 32 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) operate under trusted conditions ensuring compliance and alignment with relevant Union and national legislation and complements where appropriate testing and experimentation facilities ***and AI regulatory sandboxes*** established in accordance with Regulation (EU) 2024/1689, while ensuring consistency and synergies in their implementation;	(a) operate under trusted conditions ensuring compliance and alignment with relevant Union and national legislation and complements where appropriate testing and experimentation facilities established in accordance with Regulation (EU) 2024/1689, while ensuring consistency and synergies in their implementation;

Or. en

Amendment 2258
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 32 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) seek, where appropriate, to leverage AI systems or other advanced computational tools, alongside advanced technologies and analytics, to optimise workflows and increase efficiency;	(b) seek, where appropriate, to leverage AI systems or other advanced computational tools, alongside advanced technologies and analytics, to optimise workflows and increase efficiency ***without prejudice to the ethical use of artificial intelligence, the implementation of the FAIR principles (Findable, Accessible, Interoperable and Reusable), the safeguarding of patients' rights and confidentiality, and the avoidance of discriminatory bias***;

Or. en

Amendment 2259
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 32 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) seek, where appropriate, to leverage AI systems or other advanced computational tools, alongside advanced technologies and analytics, to optimise workflows and increase efficiency;	(b) seek, where appropriate, to leverage AI systems or other advanced computational tools, alongside advanced technologies and analytics, to optimise workflows and increase efficiency***, while ensuring rigorous data quality control standards***;

Or. en

Amendment 2260
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 32 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) aim to enable innovation in biotechnology areas where the use of AI-enabled or computationally enhanced methods can be particularly impactful, such as enhancing efficacy and safety of immunology treatments and of ATMP gene therapies, ***or*** developing ***NAMs*** that combine advanced experimental and computational approaches***;***	(c) aim to enable innovation in biotechnology areas where the use of AI-enabled or computationally enhanced methods can be particularly impactful, such as enhancing efficacy and safety of immunology treatments and of ATMP gene therapies, developing ***new approach methodologies*** that combine advanced experimental and computational approaches***, and supporting innovation in brain and mental health, including for stratification, trial optimisation, patient selection, outcome modelling and implementation planning.***

Or. en

Amendment 2261
Aurelijus Veryga

Proposal for a regulation
Article 32 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) aim to enable innovation in biotechnology areas where the use of AI-enabled or computationally enhanced methods can be particularly impactful, such as enhancing efficacy and safety of immunology treatments and of ATMP gene therapies, or developing NAMs that combine advanced experimental and computational approaches;	(c) aim to enable innovation in biotechnology areas where the use of AI-enabled or computationally enhanced methods can be particularly impactful, such as enhancing efficacy and safety of immunology treatments and of ATMP gene therapies, or developing NAMs that combine advanced experimental and computational approaches ***and supporting innovation in brain and mental health, including for stratification, trial optimisation, patient selection, outcome modelling and implementation planning***;

Or. en

Amendment 2262
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 32 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) aim to enable innovation in biotechnology areas where the use of AI-enabled or computationally enhanced methods can be particularly impactful***, such as enhancing efficacy and safety of immunology treatments and of ATMP gene therapies, or developing NAMs that combine advanced experimental and computational approaches***;	(c) aim to enable innovation in biotechnology areas where the use of AI-enabled or computationally enhanced methods can be particularly impactful;

Or. en

Amendment 2263
Sirpa Pietikäinen

Proposal for a regulation
Article 32 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) aim to enable innovation in biotechnology areas where the use of AI-enabled or computationally enhanced methods can be particularly impactful, such as enhancing efficacy and safety of ***immunology treatments*** and of ATMP gene therapies, or developing NAMs that combine advanced experimental and computational approaches;	(c) aim to enable innovation in biotechnology areas where the use of AI-enabled or computationally enhanced methods can be particularly impactful, such as enhancing efficacy and safety of ***immunotherapies, immunodiagnostics and immune monitoring*** and of ATMP gene therapies, or developing NAMs that combine advanced experimental and computational approaches;

Or. en

Justification

This is a direct clarification placing immunodiagnostics and immune monitoring alongside the therapeutic and ATMP examples already in the text.

Amendment 2264
Wouter Beke, Ingeborg Ter Laak, Angelika Niebler, Adam Jarubas, Aura Salla, Jessica Polfjärd, Liesbet Sommen, Paulo Cunha, Sérgio Humberto, Sirpa Pietikäinen, Willemien Koning, Andrea Wechsler, Dolors Montserrat, Oliver Schenk, Elena Nevado del Campo, András Tivadar Kulja, Niels Flemming Hansen

Proposal for a regulation
Article 32 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) aim to enable innovation in biotechnology areas where the use of AI-enabled or computationally enhanced methods can be particularly impactful, such as enhancing efficacy and safety of immunology treatments and of ATMP gene therapies, or developing NAMs that combine advanced experimental and computational approaches;	(c) aim to enable innovation in biotechnology areas where the use of AI-enabled or computationally enhanced methods can be particularly impactful, such as ***drug design using AI,*** enhancing efficacy and safety of immunology treatments and of ATMP gene therapies, or developing NAMs that combine advanced experimental and computational approaches;

Or. en

Amendment 2265
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 32 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) make available, under fair and transparent conditions, evidence, results and lessons learned generated within such testing environments, to inform Union guidance, standardisation and best-practice frameworks***, and, where appropriate, the design or implementation of regulatory sandboxes in accordance with Union or national law***.	(d) make available, under fair and transparent conditions, evidence, results and lessons learned generated within such testing environments, to inform Union guidance, standardisation and best-practice frameworks.

Or. en

Amendment 2266
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 32 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) make available, under fair and transparent conditions, evidence, results and lessons learned generated within such testing environments, to inform Union guidance, standardisation and best-practice frameworks***, and, where appropriate, the design or implementation of regulatory sandboxes*** in accordance with Union or national law.	(d) make available, under fair and transparent conditions, evidence, results and lessons learned generated within such testing environments, to inform Union guidance, standardisation and best-practice frameworks in accordance with Union or national law.

Or. en

Amendment 2267

Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 32 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) make available, under fair and transparent conditions, evidence, results and lessons learned generated within such testing environments, to inform Union guidance, standardisation and best-practice frameworks, and, where appropriate, the design or implementation of regulatory sandboxes in accordance with Union or national law.	(d) make available, under fair and transparent conditions, evidence, results and lessons learned***, including on the ethical use of AI,*** generated within such testing environments, to inform Union guidance, standardisation and best-practice frameworks, and, where appropriate, the design or implementation of regulatory sandboxes in accordance with Union or national law.

Or. en

Amendment 2268
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 32 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) make available, under fair and transparent conditions, evidence, results and lessons learned generated within such testing environments, to inform Union guidance, standardisation and best-practice frameworks, and, where appropriate, the design or implementation of regulatory sandboxes in accordance with Union or national law.	(d) make available, under fair and transparent conditions, evidence, results and lessons learned***, including on the ethical use of AI,*** generated within such testing environments, to inform Union guidance, standardisation and best-practice frameworks, and, where appropriate, the design or implementation of regulatory sandboxes in accordance with Union or national law.

Or. en

Amendment 2269
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 32 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) make available, under ***fair and transparent*** conditions, evidence, results and lessons learned generated within such testing environments, to inform Union guidance, standardisation and best-practice frameworks, and, where appropriate, the design or implementation of regulatory sandboxes in accordance with Union or national law.	(d) make available, under ***the*** conditions ***referred to in Article 16 of this Regulation***, evidence, results and lessons learned generated within such testing environments, to inform Union guidance, standardisation and best-practice frameworks, and, where appropriate, the design or implementation of regulatory sandboxes in accordance with Union or national law.

Or. en

Amendment 2270
Monika Beňová

Proposal for a regulation
Article 32 – paragraph 1 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) ensure appropriate technical, organisational and contractual safeguards to prevent electronic health data, confidential biotechnology data, trade secrets, intellectual property or biotechnology know-how processed in such environments from being used to train, fine-tune or improve third party AI systems or models, unless expressly authorised under Union law, the applicable data permit and contractual arrangements.

Or. en

Justification

It is important to highlight that AI developed systems and corresponding biotechnology infrastructure inside the EU include safeguards against the unauthorized use or exporting of sensitive data, annotations, prompts, outputs, derived insights, intellectual property and biotechnology know-how for the training, fine-tuning or development of third party, extra

European AI systems or models. This is particularly important where frontier AI providers are established in third countries or are active in competing biotechnology markets. The objective is to ensure that Union health data, proprietary datasets and especially specialised biotechnology AI models trained on such data remain under the effective control of the relevant data holder or project promoter, unless further use is expressly authorised under Union law, the applicable data permit and contractual arrangements.

Amendment 2271
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 33 – 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 biotechnology data quality accelerators, only where they comply with the criteria laid down in Article 4(1) and fulfil the conditions laid down in paragraph 2 of this Article and they make a significant contribution to the curation, maintenance and responsible use of high-quality, appropriately annotated and provenance-verified datasets that are essential for the training, validation and testing of AI systems and models used in health biotechnology applications.	1. To enable access to the support measures laid down in Section 2 of Chapter II, the Commission shall recognise projects located in the Union as high impact health biotechnology strategic projects in the form of biotechnology data quality accelerators, only where they comply with ***EU regulations on data protection and use of personnal data as well as*** the criteria laid down in Article 4(1) and fulfil the conditions laid down in paragraph 2 of this Article and they make a significant contribution to the curation, maintenance and responsible use of high-quality, appropriately annotated and provenance-verified datasets that are essential for the training, validation and testing of AI systems and models used in health biotechnology applications***, including, where applicable, the correction of sex and gender data gaps in datasets that underpin or facilitate the development and deployment of biotechnologies***.

Or. en

Justification

Amendment drafted by the Deutsche Stiftung Weltbevölkerung (DSW)

Amendment 2272
Sirpa Pietikäinen

Proposal for a regulation
Article 33 – 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 biotechnology data quality accelerators, only where they comply with the criteria laid down in Article 4(1) and fulfil the conditions laid down in paragraph 2 of this Article and they make a significant contribution to the curation, maintenance and responsible use of high-quality, appropriately annotated and provenance-verified datasets that are essential for the training, validation and testing of AI systems and models used in health biotechnology applications.	1. To enable access to the support measures laid down in Section 2 of Chapter II, the Commission shall recognise projects located in the Union as high impact health biotechnology strategic projects in the form of biotechnology data quality accelerators, only where they comply with the criteria laid down in Article 4(1) and fulfil the conditions laid down in paragraph 2 of this Article and they make a significant contribution to the curation, maintenance and responsible use of high-quality, appropriately annotated and provenance-verified datasets that are essential for the training, validation and testing of AI systems and models used in health biotechnology applications***, including, where applicable, the correction of sex and gender data gaps in datasets that underpin or facilitate the development and deployment of biotechnologies***.

Or. en

Amendment 2273
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 33 – 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 biotechnology data quality 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 data quality accelerators,

only where they comply with the criteria laid down in Article 4(1) and fulfil the conditions laid down in paragraph 2 of this Article and they make a significant contribution to the curation, maintenance and responsible use of high-quality, appropriately annotated and provenance-verified datasets that are essential for the training, validation and testing of AI systems and models used in health biotechnology applications.	only where they comply with the criteria laid down in Article 4(1) and fulfil the conditions laid down in paragraph 2 of this Article and they make a significant contribution to the curation, maintenance***, ethical*** and responsible use of high-quality, appropriately annotated and provenance-verified datasets that are essential for the training, validation and testing of AI systems and models used in health biotechnology applications.

Or. en

Amendment 2274
Monika Beňová

Proposal for a regulation
Article 33 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Biotechnology data quality accelerators shall include appropriate technical, organisational and contractual safeguards to prevent data, metadata, annotations, prompts, model outputs, derived insights, trade secrets, intellectual property, confidential business information or biotechnology know-how generated or processed in the context of such accelerators from being used to train, fine-tune or improve third-party AI systems or models, unless such use is expressly authorised under applicable Union law, the relevant data permit and contractual arrangements.

Or. en

Justification

It is important to highlight that AI developed systems and corresponding biotechnology infrastructure inside the EU include safeguards against the unauthorized use or exporting of sensitive data, annotations, prompts, outputs, derived insights, intellectual property and biotechnology know-how for the training, fine-tuning or development of third party, extra European AI systems or models. This is particularly important where frontier AI providers

are established in third countries or are active in competing biotechnology markets. The objective is to ensure that Union health data, proprietary datasets and especially specialised biotechnology AI models trained on such data remain under the effective control of the relevant data holder or project promoter, unless further use is expressly authorised under Union law, the applicable data permit and contractual arrangements.

Amendment 2275
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 33 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The Commission shall regularly assess barriers limiting the effective use of European Health Data Space data for research and biotechnology innovation and report on measures to improve implementation.

Or. en

Amendment 2276
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 33 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) aim to foster the development and deployment of trustworthy and competitive AI systems in health biotechnologies, including large-scale and general-purpose models relevant for biological, biomedical or biomanufacturing use cases;	(a) aim to foster the development and deployment of ***ethical,*** trustworthy and competitive AI systems ***without unfair bias*** in health biotechnologies, including large-scale and general-purpose models relevant for biological, biomedical or biomanufacturing use cases;

Or. en

Amendment 2277

Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 33 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) aim to foster the development and deployment of trustworthy and competitive AI systems in health biotechnologies, including large-scale and general-purpose models relevant for biological, biomedical or biomanufacturing use cases;	(a) aim to foster the development and deployment of ***ethical, non-biased,*** trustworthy and competitive AI systems in health biotechnologies, including large-scale and general-purpose models relevant for biological, biomedical or biomanufacturing use cases;

Or. en

Amendment 2278
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 33 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) contribute to the development of ***Union*** standards ***and quality frameworks for data representativeness, provenance,*** interoperability ***and annotation in biotechnology***;	(c) contribute to the development of ***common European data*** standards ***improving*** interoperability ***between registries, hospitals, biobanks, clinical research infrastructures and European Reference Networks***;

Or. en

Amendment 2279
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 33 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) supporting the responsible curation, interoperability and use of

exposome-relevant datasets, including environmental, occupational, dietary, biological and health-related data, where such data are lawfully processed and necessary for prevention-oriented biotechnology research and innovation

Or. en

Amendment 2280
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 33 – paragraph 2 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) support, where appropriate, the development, curation, interoperability and responsible use of datasets relevant to brain and mental health innovation, including data on patient functioning, quality of life, longitudinal outcomes, treatment adherence and implementation in real-world care settings, in compliance with applicable Union legislation on data governance, ethics and fundamental rights.

Or. en

Amendment 2281
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 33 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Data quality accelerators supported under this Article shall, where relevant, promote Union-level coordination, interoperability and secure data sharing, in particular in areas where

fragmented datasets or small patient populations require cross-border cooperation, including rare diseases, rare cancers, paediatric conditions, complex diseases and other areas of unmet medical need. Where appropriate, such accelerators shall support the linking of relevant registries, biobanks, genomic initiatives, clinical research infrastructures and European Reference Networks, in full respect of Union law on the protection of personal data, health data governance, cybersecurity and patients' rights.

Or. en

Amendment 2282
Christine Anderson

Proposal for a regulation
Article 33 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The processing of personal data by ***the*** entities that lawfully hold the relevant datasets enhanced as provided for in paragraph 2, point (b) ***of this Article***, and by ***the*** biotechnology data quality accelerator projects ***takes place in the public interest***.	4. The processing of personal data by entities that lawfully hold the relevant datasets enhanced as provided for in paragraph 2, point (b), and by biotechnology data quality accelerator projects ***shall comply with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725. The recognition of a project as a biotechnology data quality accelerator shall not in itself constitute a legal basis for the processing of personal data. For each processing operation, the controller shall identify the applicable legal basis under Article 6 of Regulation (EU) 2016/679 and, where genetic data, biometric data or data concerning health are processed, the applicable condition under Article 9(2) of that Regulation.***

Or. en

Amendment 2283
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 33 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The processing of personal data by the entities that lawfully hold the relevant datasets enhanced as provided for in paragraph 2, point (b) of this Article, and by the biotechnology data quality accelerator projects ***takes place in the public interest***.	4. The processing of personal data by the entities that lawfully hold the relevant datasets enhanced as provided for in paragraph 2, point (b) of this Article, and by the biotechnology data quality accelerator projects ***shall be done in accordance with provisions laid down in Regulation (EU) 2016/679***.

Or. en

Justification

Referencing existing legislation to ensure consistency in the application of rules around the processing of personal data. The GDPR specifically safeguards the public interest and individual's fundamental rights.

Amendment 2284
Christine Anderson

Proposal for a regulation
Article 33 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Where processing is based on the consent of the data subject, such consent shall be freely given, specific, informed and unambiguous, and, in the case of special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, explicit. Consent to participate in a clinical trial, medical procedure or research project shall not be construed as consent to unrelated further processing.

Or. en

Amendment 2285
Christine Anderson

Proposal for a regulation
Article 33 – paragraph 4 c (new)

Text proposed by the Commission	*Amendment*
	4c. Where processing of genetic data, biometric data or data concerning health is based on reasons of public interest in the area of public health or on scientific research purposes pursuant to Article 9(2), points (i) or (j), of Regulation (EU) 2016/679, such processing shall be provided for by Union or Member State law and shall be subject to specific and suitable safeguards for the rights and freedoms of the data subject, including purpose limitation, data minimisation, pseudonymisation or anonymisation where possible, access controls, logging of access, storage limitation and independent oversight.

Or. en

Amendment 2286
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 33 – paragraph 5 – subparagraph 1

Text proposed by the Commission	*Amendment*
Entities that lawfully hold relevant datasets enhanced as provided for in paragraph 2, point (b) of this Article, shall make available such datasets under fair, reasonable and non-discriminatory conditions, ensuring equitable access for users including research organisations, SMEs and public institutions, under the	Entities that lawfully hold relevant datasets enhanced as provided for in paragraph 2, point (b) of this Article, shall make available such datasets under fair, reasonable and non-discriminatory conditions, ensuring equitable access for users including research organisations, SMEs and public institutions, under the conditions referred to in Article 16 of this

conditions referred to in Article 16 of this Regulation.	Regulation. ***For datasets that do not constitute personal data or electronic health data, access conditions shall be proportionate to the risks and intended use of the data and shall not impose requirements designed for personal health data unless necessary for security, confidentiality or biosecurity reasons.***

Or. en

Justification

It is important that strict security requirements for health data, such as personal health data, do not create unnecessary barriers for the wider use of biotechnology-related data.

Amendment 2287
Christine Anderson

Proposal for a regulation
Article 33 – paragraph 5 – subparagraph 1

Text proposed by the Commission	*Amendment*
Entities that lawfully hold relevant datasets enhanced as provided for in paragraph 2, point (b) of this Article, shall make available such datasets under fair, reasonable and non-discriminatory conditions, ensuring equitable access for users including research organisations, SMEs and public institutions, under the conditions referred to in Article 16 of this Regulation.	Entities that lawfully hold relevant datasets enhanced as provided for in paragraph 2, point (b) of this Article, shall make available such datasets under fair, reasonable and non-discriminatory conditions, ensuring equitable access for users including research organisations, SMEs and public institutions, under the conditions referred to in Article 16 of this Regulation***, provided that such access complies with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725, does not undermine the rights and freedoms of data subjects, and is limited to what is necessary and proportionate for a specified, explicit and legitimate purpose***.

Or. en

Amendment 2288
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 33 – paragraph 5 – subparagraph 1

Text proposed by the Commission	*Amendment*
Entities that lawfully hold relevant datasets enhanced as provided for in paragraph 2, point (b) of this Article, shall make available such datasets under fair, reasonable and non-discriminatory conditions, ensuring equitable access for users including research organisations, SMEs and public institutions, under the conditions referred to in Article 16 of this Regulation.	Entities that lawfully hold relevant datasets enhanced as provided for in paragraph 2, point (b) of this Article, shall make available such datasets under fair, reasonable and non-discriminatory conditions, ensuring equitable access for users including research organisations, SMEs and public institutions, under the conditions referred to in Article 16 of this Regulation. ***Those conditions shall protect trade secrets, intellectual property rights, cybersecurity, personal data and commercially sensitive information, and shall be proportionate for SMEs, start-ups, scale-ups and non-profit research organisations.***

Or. en

Amendment 2289
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 33 – paragraph 5 – subparagraph 1

Text proposed by the Commission	*Amendment*
Entities that lawfully hold relevant datasets enhanced as provided for in paragraph 2, point (b) of this Article, shall make available such datasets under fair, reasonable and non-discriminatory conditions, ensuring equitable access for users including research organisations, SMEs and public institutions, under the conditions referred to in Article 16 of this Regulation.	Entities that lawfully hold relevant datasets enhanced as provided for in paragraph 2, point (b) of this Article, shall make available such datasets under fair, reasonable and non-discriminatory conditions, ensuring equitable access for users including research organisations, SMEs and public institutions, under the conditions referred to in Article 16 of this Regulation. ***Patients should receive clear information regarding the secondary use of their data under applicable Union legislation and retain confidence that***

such use serves legitimate public health and research objectives.

Or. en

Amendment 2290
Christine Anderson

Proposal for a regulation
Article 33 – paragraph 5 – subparagraph 2

Text proposed by the Commission	*Amendment*
Electronic health data referred to in Article 51 of Regulation (EU) 2025/327 shall be made available in accordance with that Regulation.	Electronic health data referred to in Article 51 of Regulation (EU) 2025/327 shall be made available in accordance with that Regulation ***and with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725***. ***No personal data, genetic data, biometric data or data concerning health shall be made available unless the controller has identified a valid legal basis and implemented appropriate safeguards against re-identification, unauthorised access, onward transfer and function creep.***

Or. en

Amendment 2291
Christine Anderson

Proposal for a regulation
Article 33 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. Data subjects shall be informed in clear and plain language whether personal data concerning them, including genetic data, biometric data or data concerning health, are processed or further processed in the context of a biotechnology data quality accelerator. Such information shall include the

purposes of processing, the categories of data concerned, the categories of recipients, the applicable legal basis, the retention period and the rights available to the data subject under Regulation (EU) 2016/679.

Or. en

Amendment 2292
Christine Anderson

Proposal for a regulation
Article 33 – paragraph 5 c (new)

Text proposed by the Commission	*Amendment*
	5c. The further processing of personal data for scientific research purposes shall be subject to Article 5(1), point (b), and Article 89 of Regulation (EU) 2016/679. Such further processing shall not be used to make decisions concerning the individual data subject, to exclude that person from services, to discriminate against that person, or to create individual risk profiles unrelated to the original research or public-health purpose.

Or. en

Amendment 2293
Christine Anderson

Proposal for a regulation
Article 33 – paragraph 5 d (new)

Text proposed by the Commission	*Amendment*
	5d. Biotechnology data quality accelerators shall keep an auditable access log for datasets containing personal data, genetic data, biometric data or data concerning health. The access log shall record the accessing entity, the

purpose of access, the categories of data accessed, the date of access and the applicable legal basis. The log shall be made available to the competent supervisory authority upon request.

Or. en

Amendment 2294
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 33 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Entities that lawfully hold relevant datasets enhanced as provided for in paragraph 2, point (b) of the Article, shall support, where appropriate, the integration of such datasets into Union infrastructures, including the European Research Area data spaces, data labs, AI factories and the infrastructures operated by high impact health biotechnology strategic projects.	6. Entities that lawfully hold relevant datasets enhanced as provided for in paragraph 2, point (b) of the Article, shall support, where appropriate, the integration of such datasets into Union infrastructures, including the European Research Area data spaces, data labs, AI factories and the infrastructures operated by high impact health biotechnology strategic projects***, under the conditions referred to in Article 16 of this Regulation provided that such Union infrastructures comply with the technical, interoperability, and security safeguards established under Regulation (EU) 2025/327 (European Health Data Space)***. ***Data holders shall not be required to integrate datasets into any Union infrastructure that does not conform to these technical and security specifications.***

Or. en

Amendment 2295
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 33 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Entities that lawfully hold relevant datasets enhanced as provided for in paragraph 2, point (b) of the Article, shall support, where appropriate, the integration of such datasets into Union infrastructures, including the European Research Area data spaces, data labs, AI factories and the infrastructures operated by high impact health biotechnology strategic projects.	6. Entities that lawfully hold relevant datasets enhanced as provided for in paragraph 2, point (b) of the Article, shall support, where appropriate, the integration of such datasets into Union infrastructures, including the European Research Area data spaces, data labs, AI factories and the infrastructures operated by high impact health biotechnology strategic projects ***under the conditions referred to in Article 16 of this Regulation provided that such Union infrastructures comply with the technical, interoperability, and security safeguards established under Regulation (EU) 2025/327 on the European Health Data Space, including legal, organisational and technical nature to protect intellectual property and trade secrets***.

Or. en

Justification

The EHDS already provides for clear mechanisms to access electronic health data, also relevant for biotech innovation, and sets out requirements protection measures, including around IP and trade secret, on how said data is to be shared. Alignment between Biotech Act and EHDS is needed to ensure trust and legal clarity for innovators and any public-private partnerships.

Amendment 2296
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 33 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Entities that lawfully hold relevant datasets enhanced as provided for in paragraph 2, point (b) of the Article, shall	6. Entities that lawfully hold relevant datasets enhanced as provided for in paragraph 2, point (b) of the Article, shall

support, where appropriate, the integration of such datasets into Union infrastructures, including the European Research Area data spaces, data labs, AI factories and the infrastructures operated by high impact health biotechnology strategic projects.	support, where appropriate, the integration of such datasets into Union infrastructures, ***while ensuring the compatibility and interoperability of those datasets from early stages of the projects,*** including the European Research Area data spaces, data labs, AI factories and the infrastructures operated by high impact health biotechnology strategic projects. ***Where Union infrastructures process electronic health data governed by Regulation (EU) 2025/327, such integration shall comply with the technical, interoperability and security requirements established under that Regulation.***

Or. en

Amendment 2297
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 33 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Entities that lawfully hold relevant datasets enhanced as provided for in paragraph 2, point (b) of the Article, shall support, where appropriate, the integration of such datasets into Union infrastructures, including the European Research Area data spaces, data labs, AI factories and the infrastructures operated by high impact health biotechnology strategic projects.	6. Entities that lawfully hold relevant datasets enhanced as provided for in paragraph 2, point (b) of the Article, shall support, where appropriate, the integration of such datasets into Union infrastructures, including the European Research Area data spaces, data labs, AI factories and the infrastructures operated by high impact health biotechnology strategic projects. ***Data generated and processed under this framework should, where appropriate and in accordance with applicable Union data protection and sectoral legislation, adhere to the principles of findability, accessibility, interoperability and reusability (FAIR principles)***

Or. en

Justification

The addition of the FAIR principles closes a gap in the original text, which mandates integration of datasets into Union infrastructures but says nothing about their quality or format. Without this standard, data could be technically present yet poorly usable (badly documented, incompatible across sources). The FAIR principles ensure data is genuinely reusable for research and AI development, in line with standards already adopted in other Union instruments (EOSC, EHDS), while still preserving data protection safeguards through the accompanying qualifying clauses.

Amendment 2298
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 33 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Entities that lawfully hold relevant datasets enhanced as provided for in paragraph 2, point (b) of the Article, shall support, where appropriate, the integration of such datasets into Union infrastructures, including the European Research Area data spaces, data labs, AI factories and the infrastructures operated by high impact health biotechnology strategic projects.	6. Entities that lawfully hold relevant datasets enhanced as provided for in paragraph 2, point (b) of the Article, shall support, where appropriate, the integration of such datasets into Union infrastructures, including the European Research Area data spaces, ***the European Health Data Space as established in Regulation (EU) 2025/327,*** data labs, AI factories ***and gigafactories,*** and the infrastructures operated by high impact health biotechnology strategic projects.

Or. en

Amendment 2299
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 33 – paragraph 8

Text proposed by the Commission	*Amendment*
8. With regard to biotechnology data quality accelerators recognised in the context of a call for proposals as provided for in Article 10(3), the Commission shall,	8. With regard to biotechnology data quality accelerators recognised in the context of a call for proposals as provided for in Article 10(3), the Commission shall,

by means of implementing acts, adopt, before the launch of the related call, a decision establishing the modalities of processing of personal data necessary to achieve the purpose of the project. That decision shall specify the categories of data to be processed, the roles of the entities participating in the project, the categories of the entities which may use the curated data and the safeguards. The selected beneficiaries shall comply with the conditions laid down in that decision.	by means of implementing acts, adopt, before the launch of the related call, a decision establishing the modalities of processing of personal data necessary to achieve the purpose of the project. That decision shall specify the categories of data to be processed, the roles of the entities participating in the project, the categories of the entities which may use the curated data and the safeguards. The selected beneficiaries shall comply with the conditions laid down in that decision. ***Any initiative taken by the Commission in this context shall be fully compliant with EU regulations on data protection and use of personnal data.***

Or. en

Amendment 2300
Wouter Beke, Ingeborg Ter Laak, Angelika Niebler, Adam Jarubas, Aura Salla, Jessica Polfjärd, Liesbet Sommen, Paulo Cunha, Sérgio Humberto, Sirpa Pietikäinen, Willemien Koning, Andrea Wechsler, Dolors Montserrat, Oliver Schenk, Elena Nevado del Campo, András Tivadar Kulja, Niels Flemming Hansen

Proposal for a regulation
Article 33 – paragraph 8 a (new)

Text proposed by the Commission	*Amendment*
	8a. The Commission may adopt implementing acts specifying technical conditions for ensuring the consistent application of this Article in relation to electronic health data made available pursuant to Regulation (EU) 2025/327, in particular regarding the timing and technical conditions for the secondary use of clinical trial data.

Or. en

Amendment 2301
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 33 a (new)

Text proposed by the Commission	*Amendment*
	Article33a
	European health biotechnology data coordination
	1. The Commission shall, in cooperation with Eurostat, the European Medicines Agency, relevant Union bodies and agencies, Member States and, where appropriate, European Reference Networks referred to in Article 40a, support Union-level coordination, interoperability, interconnectivity and availability of high-quality aggregated, statistical and, to the extent possible, reusable data relevant to biotechnology, particularly in the area of health, building on existing Union data infrastructures and governance frameworks, including the European Health Data Space established by Regulation (EU) 2025/327 and the European statistical system.
	2. That coordination shall support the mapping, standardisation, linkage and reuse of relevant datasets, metadata and indicators, including in relation to Clinical trials Information System, rare diseases, rare cancers, complex conditions, advanced therapies, newborn screening, genomic initiatives, the 1+ Million Genomes initiative, biobanks, registries, clinical research infrastructures, post-authorisation evidence generation, health technology assessment cooperation and the European Health Data Space, without duplicating existing reporting obligations or data-governance structures under Union law.
	3. Particular attention shall be given to areas where small or fragmented patient populations require Union-level cooperation, including rare diseases, rare cancers, paediatric conditions, complex

diseases and other areas of unmet medical need, in order to support responsible research, innovation, regulatory science and the development, training, validation and monitoring of artificial intelligence systems.

4. The coordination referred to in this Article shall support a One Health approach, including through interoperable data relevant to antimicrobial resistance, zoonotic diseases, emerging infectious disease threats, pathogen surveillance, vaccine-preventable diseases, human-animal-health interlinkages and environmental factors relevant to health. 5. Eurostat shall establish and maintain a Union health biotechnology data dashboard providing comparable statistical information relevant to the implementation of this Regulation. The dashboard shall include, where relevant, indicators on disease burden, clinical trial activity, patient access, availability of relevant diagnostics and therapies, advanced therapies, newborn screening, genomic initiatives, antimicrobial resistance, zoonotic diseases, vaccine-preventable diseases, development, progress of New Approach Methodologies, biomanufacturing capacity and health-system resilience.

6. The Commission shall be empowered to adopt delegated acts in accordance with Article 65b to supplement this Regulation by specifying the detailed content, structure, indicators, reporting categories, update frequency, presentation format and interoperability and interconnectivity requirements of the dashboard referred to in paragraph 5. Those delegated acts shall, in particular, specify: (a) common indicators and reporting categories necessary to ensure comparability of statistical information across Member States; (b) standardised templates, metadata requirements and reporting methodologies to be used by Member

States, including requirements on timeliness, data quality and compatibility with the European Health Data Space, the European statistical system and relevant Union data infrastructures; (c) modalities for presenting the dashboard in a user-friendly, accessible and interactive format, including public access to aggregated statistical information.

7. Member States shall provide the statistical information referred to in paragraph 6 in accordance with the standardised templates and reporting methodologies established by the Commission, drawing as far as possible on data already available and avoiding additional administrative burden, while ensuring consistency with Union law on statistics, data protection, health data governance and cybersecurity.

8. Data use under this Article shall be privacy-preserving, cybersecure and aligned with the European Health Data Space, Union data protection law, health data governance rules, patient consent where required, patients' rights and the protection of commercially confidential information.

9. The Commission shall ensure that adequate Union funding is available for the implementation of this article. The Commission shall, within five years from the date of entry into application of this Article, present to the European Parliament and the Council a report on the implementation and impact of this Article.

Or. en

Amendment 2302
Laurence Trochu

Proposal for a regulation
Article 33 a (new)

Text proposed by the Commission	*Amendment*
	Article 33a.
	Exclusion of gender transition clinical trials on minors
	1. Clinical trials involving participants under 18 years of age may not be authorised, funded, promoted, conducted or carried out when their primary or secondary purpose is to develop, assess, administer or study medicines, advanced therapy medicinal products (ATMP), medical devices or any other medical intervention aimed at bringing about, facilitating or assessing a medical gender transition as part of treatment for gender dysphoria or gender incongruence.
	This shall apply in particular to:
	(a) puberty blockers;
	(b) cross-sex hormone therapy, including the use of androgens or oestrogens;
	(c) surgical interventions or any other medical intervention aimed at modifying primary or secondary sexual characteristics;
	(d) any medication, biotechnology product, advanced therapy medicinal product (ATMP) or other intervention with the same objective.
	2. The exclusion set out in paragraph 1 shall apply without exception, including to low-intervention clinical trials, early phase clinical trials, combined studies, studies conducted in the context of regulatory sandboxes or accelerated procedures, as well as any study benefiting from simplified procedures or subject to substantial modifications under this Regulation or Regulation (EU) No 536/2014.

Or. fr

Amendment 2303
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 33 a (new)

Text proposed by the Commission	*Amendment*
	Article33a
	Guidance on the use of real-world evidence and registry data in the health technology assessments
	1. The Commission, in consultation with the Member State Coordination Group on Health Technology Assessment established pursuant to Article 3 of Regulation (EU) 2021/2282 and with interested parties, shall develop, and where appropriate update, guidance on the use of real-world evidence and registry data in the health technology assessments of advanced therapy medicinal products, including in their cost and economic evaluation.

Or. en

Justification

ATMPs frequently generate evidence through registries and post-authorisation data collection due to small patient populations and ethical or practical limits on randomised trials. However, the absence of clear guidance on the use of such evidence in HTA, including economic evaluation, may lead to inconsistent assessment practices across Member States. Establishing guidance would improve predictability, support methodological convergence and facilitate more equitable patient access across the Union.

Amendment 2304
András Tivadar Kulja

Proposal for a regulation
Article 33 a (new)

Text proposed by the Commission	*Amendment*
	Article33a

Real-world evidence and registry data in the Health Technology Assessments

The Commission, in consultation with the Member State Coordination Group on Health Technology Assessment established pursuant to Article 3 of Regulation (EU) 2021/2282, shall develop, and where appropriate update, guidance on the use of real-world evidence and registry data in the health technology assessments of Advanced Therapy Medicinal Products (ATMPs).

Or. en

Amendment 2305
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 33 b (new)

Text proposed by the Commission	*Amendment*
	Article33b
	Newborn screening, early diagnosis and integration with the European Health Data Space
	1. Member States are encouraged to ensure that national newborn screening programmes record screening results in formats interoperable with the European Health Data Space,subject to a reinforced consent and governance framework, reflecting the genetic nature of such data, the fact that they relate to a minor, and the fact that they are generated in the absence of the consent of the data subject.
	2. Newborn screening data integrated with the European Health Data Space shall be subject to strict purpose limitation. Their use for insurance underwriting, for employment screening, or for any non-health commercial exploitation is prohibited.

3. The integration established shall be coupled with support, through the Open Method of Coordination, for the progressive convergence of national newborn screening panels. To that end, the Commission shall, in cooperation with the Member States, the European Reference Networks and other cross-border health networks and the relevant expert groups, support the development of Union guidelines on the conditions recommended for newborn screening and the evidence-based addition of new screening targets as treatments become available.

Or. en

Amendment 2306
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 33 b (new)

Text proposed by the Commission	*Amendment*
	Article33b
	Guidance on the joint clinical assessments for advanced therapy medicinal products
	1. The Member State Coordination Group on Health Technology Assessment established pursuant to Article 3 of Regulation (EU) 2021/2282 shall develop, and where appropriate update, methodological guidance for joint clinical assessments of advanced therapy medicinal products. The guidance shall consider the relevance and value of single-arm trials, surrogate endpoints and real-world evidence for the joint clinical assessments of advanced therapy medicinal products.

Or. en

Justification

The specific clinical characteristics of ATMPs, including reliance on single-arm trials, surrogate endpoints and real-world evidence, are not always adequately reflected in existing HTA methodologies. Dedicated methodological guidance for joint clinical assessments would help ensure that these products are assessed using approaches proportionate to their scientific and clinical context. This would support more consistent assessments, reduce uncertainty for developers and contribute to timely patient access to innovative therapies.

Amendment 2307
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 33 c (new)

Text proposed by the Commission	*Amendment*
	Article33c
	Agency reports on the use of single-arm trials, surrogate endpoints and real-world evidence
	1. Within three years after entry into force of this Regulation, the Agency shall draw up a report on its experience with the use of single-arm trials, surrogate endpoints and real-world evidence in the assessment of advanced therapy medicinal products.
	2. Based on the report, the Member State Coordination Group on Health Technology Assessment (HTACG) shall, if appropriate, update methodological guidance for performing joint clinical assessments for advanced therapy medicinal products.

Or. en

Justification

The European Medicines Agency has accumulated significant expertise in assessing advanced therapy medicinal products using evidence sources such as single-arm trials, surrogate endpoints and real-world evidence. A dedicated report would help capture and share this experience with the HTACG, supporting methodological learning and coherence between regulatory and HTA processes. This would facilitate evidence-based updates to JCA guidance while respecting the respective competences established under Union law.

Amendment 2308
Sirpa Pietikäinen

Proposal for a regulation
Article 34 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The EU Health Biotechnology Support Network referred to in Article 19 shall, upon request, assist developers, in particular SMEs, start-ups and scale-ups, with identifying and using the appropriate regulatory procedural pathway and regulatory support mechanisms with regard to innovative health biotechnology products or biotechnology services for human use that exhibit characteristics that raise questions on the application or applicability of the Regulation (EU) 2017/745, Regulation (EU) 2017/746, Regulation (EU) 2024/1938, Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] and Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 192 final] Regulation (EC) 1394/2007 and Directive 2010/45/EU.	1. The EU Health Biotechnology Support Network referred to in Article 19 shall, upon request, assist developers, in particular SMEs, start-ups and scale-ups, with identifying and using the appropriate regulatory procedural pathway and regulatory support mechanisms with regard to innovative health biotechnology products or biotechnology services for human use that exhibit characteristics that raise questions on the application or applicability of the Regulation (EU) 2017/745, Regulation (EU) 2017/746, Regulation (EU) 2024/1938, Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] and Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 192 final] Regulation (EC) 1394/2007 and Directive 2010/45/EU. ***The assistance under this paragraph shall in particular cover radiopharmaceuticals, imaging agents and combined diagnostic-therapeutic, or theranostic, products, which may engage radiation protection and good manufacturing practice requirements in addition to the frameworks listed in this paragraph.***

Or. en

Justification

This addition would provide clearer preliminary assistance across frameworks that are relevant for these products but not explicitly named in the current provision.

Amendment 2309

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

Proposal for a regulation
Article 34 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The EU Health Biotechnology Support Network referred to in Article 19 shall, upon request, assist developers, in particular SMEs, start-ups and scale-ups, with identifying and using the appropriate regulatory procedural pathway and regulatory support mechanisms with regard to innovative health biotechnology products or biotechnology services for human use that exhibit characteristics that raise questions on the application or applicability of the Regulation (EU) 2017/745, Regulation (EU) 2017/746, Regulation (EU) 2024/1938, Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] and Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 192 final] Regulation (EC) 1394/2007 and Directive 2010/45/EU.	1. The EU Health Biotechnology Support Network referred to in Article 19 shall, upon request, assist developers, in particular ***academic and research centers, nonprofits,*** SMEs, start-ups and scale-ups, with identifying and using the appropriate regulatory procedural pathway and regulatory support mechanisms with regard to innovative health biotechnology products or biotechnology services for human use that exhibit characteristics that raise questions on the application or applicability of the Regulation (EU) 2017/745, Regulation (EU) 2017/746, Regulation (EU) 2024/1938, Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] and Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 192 final] Regulation (EC) 1394/2007 and Directive 2010/45/EU.

Or. en

Amendment 2310
Romana Jerković

Proposal for a regulation
Article 34 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The EU Health Biotechnology Support Network shall provide dedicated regulatory assistance to academic and non-commercial developers, including universities, hospitals and public research organisations. Such assistance shall include support with scientific advice

procedures, regulatory strategy, clinical development planning and preparation of marketing authorisation applications.

Or. en

Amendment 2311
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 34 – paragraph 3 – point c

Text proposed by the Commission	*Amendment*
(c) regulatory sandboxes established in Article 40 and under [revised Regulation (EU) 2017/745], [revised Regulation (EU) 2017/746], Regulation (EU) 2024/1938 and in Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final].	***deleted***

Or. en

Amendment 2312
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 34 – paragraph 3 – point c

Text proposed by the Commission	*Amendment*
(c) regulatory sandboxes established in Article 40 and under [revised Regulation (EU) 2017/745], [revised Regulation (EU) 2017/746], Regulation (EU) 2024/1938 and in Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final].	***deleted***

Or. en

Amendment 2313
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 35 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The ***Commission*** shall compile, maintain, develop and make publicly available a regulatory status repository (‘regulatory status repository’).	1. The ***Agency*** shall compile, maintain, develop and make publicly available a regulatory status repository (‘regulatory status repository’).

Or. en

Amendment 2314
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 35 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The ***Commission*** shall compile, maintain, develop and make publicly available a regulatory status repository (‘regulatory status repository’).	1. The ***Agency*** shall compile, maintain, develop and make publicly available a regulatory status repository (‘regulatory status repository’).

Or. en

Amendment 2315
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 35 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The ***Commission*** shall compile, maintain, develop and make publicly available a regulatory status repository (‘regulatory status repository’).	1. The ***Agency*** shall compile, maintain, develop and make publicly available a regulatory status repository (‘regulatory status repository’).

Or. en

Justification

The Agency has already established a user-friendly database in line with its functions under the new Pharmaceutical Legislation. Assigning responsibility for the Union regulatory repository to the Agency could help prevent unnecessary duplication.

Amendment 2316
Aurelijus Veryga

Proposal for a regulation
Article 35 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The ***Commission*** shall compile, maintain, develop and make publicly available a regulatory status repository ('regulatory status repository').	1. The ***Agency*** shall compile, maintain, develop and make publicly available a regulatory status repository ('regulatory status repository').

Or. en

Amendment 2317
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 35 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States shall make publicly available, through the relevant national platforms or registries, decisions, opinions, scientific recommendations, and other outputs issued at national level concerning the regulatory status of health biotechnology products. Member States shall inform the ***Commission*** where such information is made available.	3. Member States shall make publicly available, through the relevant national platforms or registries, decisions, opinions, scientific recommendations, and other outputs issued at national level concerning the regulatory status of health biotechnology products. Member States shall inform the ***Agency*** where such information is made available.

Or. en

Amendment 2318
Aurelijus Veryga

Proposal for a regulation
Article 35 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States shall make publicly available, through the relevant national platforms or registries, decisions, opinions, scientific recommendations, and other outputs issued at national level concerning the regulatory status of health biotechnology products. Member States shall inform the ***Commission*** where such information is made available.	3. Member States shall make publicly available, through the relevant national platforms or registries, decisions, opinions, scientific recommendations, and other outputs issued at national level concerning the regulatory status of health biotechnology products. Member States shall inform the ***Agency*** where such information is made available.

Or. en

Amendment 2319
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 35 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States shall make publicly available, through the relevant national platforms or registries, decisions, opinions, scientific recommendations, and other outputs issued at national level concerning the regulatory status of health biotechnology products. Member States shall inform the ***Commission*** where such information is made available.	3. Member States shall make publicly available, through the relevant national platforms or registries, decisions, opinions, scientific recommendations, and other outputs issued at national level concerning the regulatory status of health biotechnology products. Member States shall inform the ***Agency*** where such information is made available.

Or. en

Amendment 2320
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 35 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States shall make publicly available, through the relevant national platforms or registries, decisions, opinions, scientific recommendations, and other outputs issued at national level concerning the regulatory status of health biotechnology products. Member States shall inform the ***Commission*** where such information is made available.	3. Member States shall make publicly available, through the relevant national platforms or registries, decisions, opinions, scientific recommendations, and other outputs issued at national level concerning the regulatory status of health biotechnology products. Member States shall inform the ***Agency*** where such information is made available.

Or. en

Amendment 2321
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 35 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The regulatory status repository, strategic mapping activities and support measures under this Regulation shall not require the disclosure of trade secrets or other confidential business information. In particular, they shall not require the disclosure of CMC data, process parameters, quality-control methods, supplier identities or other commercially sensitive manufacturing information where disclosure would undermine supply security, competitiveness or compliance. This shall be without prejudice to the disclosure of information required under Union law for reasons of public health, safety, transparency or regulatory oversight.

Or. en

Amendment 2322
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 35 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The information shared in the Union regulatory status repository should respect confidentiality and protection of proprietary data and designs. Prior of the publication on the repository, the sponsor should be notified and given the opportunity to assess if the information is correct and that not protected data is making public.

Or. en

Amendment 2323
Aurelijus Veryga

Proposal for a regulation
Article 35 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The information shared in the Union regulatory status repository should respect confidentiality and protection of proprietary data and designs. Prior of the publication on the repository, the sponsor should be notified and given the opportunity to assess if the information is correct and that not protected data is making public.

Or. en

Amendment 2324
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 35 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The information shared in the Union regulatory status repository should respect confidentiality and protection of proprietary data and designs. Prior of the publication on the repository, the sponsor should be notified and given the opportunity to assess if the information is correct and that not protected data is making public.

Or. en

Amendment 2325
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 35 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The information shared in the Union regulatory status repository should respect confidentiality and protection of proprietary data and designs. Prior of the publication on the repository, the sponsor should be notified and given the opportunity to assess if the information is correct and that not protected data is making public.

Or. en

Justification

As the EMA has already established a user-friendly database in line with its functions under the new pharmaceutical legislation, assigning responsibility for the Union regulatory repository to the EMA could help prevent unnecessary duplication. Moreover, respecting the confidential nature of these decisions and ensuring that confidential information is not published is essential for sponsors

Amendment 2326
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 35 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The Agency, national competent authorities and other Union regulatory bodies shall base their regulatory assessment on the most up-to-date scientific evidence, taking into account relevant scientific and technological developments and, where applicable, internationally recognised scientific consensus.

Or. en

Justification

It is important that relevant regulatory agencies base their decision the latest scientific data or emerging evidence. Regulatory systems must remain dynamic and responsive to scientific progress.

The repository should be fully transparent, ensuring trust, traceability and informed decision-making by all stakeholders.

Amendment 2327
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Article 35 a (new)

Text proposed by the Commission	*Amendment*
	Article35a
	Voluntary delegation of national authorisation functions
	1. A Member State may, on a voluntary basis, decide to rely on the European Medicines Agency or on the competent authority of another Member State for the performance of all or part of the functions relating to the authorisation and lifecycle management of medicinal products for human use that fall within national

competence, in accordance with this Article.

2. A delegation under paragraph 1 may cover, at the choosing Member State's discretion:

(a) the scientific assessment of applications for marketing authorisation;

(b) the assessment of variations, renewals and transfers;

(c) pharmacovigilance and post-authorisation safety and efficacy oversight;

(d) related scientific and administrative tasks.

3. Where a Member State relies on the Agency or on another Member State under paragraph 1, it may provide, in its national law, that a marketing authorisation shall be granted, or that an authorisation granted on the basis of that assessment shall be recognised, on its territory without a further national scientific assessment, while retaining the formal act of authorisation and any decision on grounds of public interest reserved to it under Union law.

4. A Member State shall notify the Commission and the Agency of any decision to rely on delegation under this Article, specifying its scope, the delegate, and its duration. The choosing Member State may terminate the arrangement, subject to reasonable transitional arrangements for products already authorised.

5. Where the Agency acts as delegate, it shall do so within the resources made available for that purpose. The Commission may adopt implementing acts laying down standard arrangements, including on languages, timelines, fees and the allocation of responsibilities, in order to facilitate delegation under this Article.

6. Delegation under this Article shall be without prejudice to the responsibilities of the choosing Member State regarding the pricing and reimbursement of medicinal products and the organisation and delivery of health services on its territory.

Or. en

Justification

· Companies frequently deprioritise or skiplaunches in small markets because the per-market regulatory andlifecycle-maintenance cost is disproportionate to the commercial return, andbecause some national authorities have long queues or limited capacity toassess complex biologics. If a Member State can outsource assessment to the EMAor a larger neighbour and grant on that basis automatically, the marginal costof adding that market falls sharply, and the administrative bottleneckdisappears, thus removing two of the main reasons medicines arrive late, or notat all, in smaller EU countries.· For orphan and niche products, the economics areeven more lopsided. A national authority may have to build assessment expertiseit will use only rarely, for a handful of patients. Pooling the assessment atEMA level means the expertise is marshalled once and reused, so ultra-rare andspecialised therapies become viable to authorise even where the domesticcaseload could never justify the in-house capability.· A resource-constrained authority that no longerhas to duplicate scientific assessment for every product can redirect itsspecialists toward pharmacovigilance signals, shortages management, and localclinical priorities. The measure is capacity-multiplying, and because it'svoluntary and reversible, a Member State retains full sovereignty and can pullfunctions back in as its own capacity grows.

Amendment 2328
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Article 35 b (new)

Text proposed by the Commission	*Amendment*
	Article35b
	Automatic and proactive sharing of substance assessments between Union agencies
	1. Building on the 'one substance, one assessment' approach and without prejudice to Regulation (EU) 2025/2457 and to the Regulation establishing a common data platform on chemicals, the European Medicines Agency (EMA), the

European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA) shall automatically and proactively share with one another all assessments of substances that they carry out in the exercise of their respective mandates.

2. The obligation in paragraph 1 shall apply to completed assessments and to their underlying non-confidential scientific data and conclusions, including as regards the identity, properties, hazards, exposure, risk and regulatory status of the substance concerned. Sharing shall take place as soon as an assessment is finalised, without the need for a prior request from another agency.

3. Each agency receiving an assessment under paragraph 1 shall take it into account in its own work in order to avoid duplication, promote scientific consistency across Union legislation, and enable the earlier identification of risks and benefits for patients and consumers. Where an agency's own assessment diverges materially from an assessment shared with it, it shall document the reasons for that divergence.

4. The agencies shall carry out the sharing under this Article through the common data platform on chemicals once that platform is operational for the purpose concerned, and, until then and where necessary thereafter, through direct interoperable means using common formats and controlled vocabularies. Pending full operability of the platform, the agencies shall not defer the sharing required under paragraph 1.

5. This Article shall apply subject to the protection of personal data and of confidential and commercially sensitive information under Union law. The obligation to share shall extend to such protected information only between the agencies and only to the extent necessary for the performance of their tasks, and

shall not authorise its disclosure to the public.

6. The Commission may adopt implementing acts specifying the categories of assessments covered, the timing and technical arrangements for sharing, and the interface with the common data platform on chemicals. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article [comitology].

Or. en

Justification

The core inefficiency addressed by this article is that the same substance is today assessed repeatedly, in isolation, by different Union agencies working to different mandates, and even under OSOA, the Common Data Platform that is meant to fix this will not be fully operational until around 2036. In the intervening decade, valuable scientific assessments will continue to sit siloed inside EMA, ECHA and EFSA unless there is a hard obligation to push them to one another automatically. This article closes that gap.

Amendment 2329
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Article 36 – paragraph 1

Text proposed by the Commission	*Amendment*
With a view to ensuring the timely assessment of the regulatory status of health biotechnology products, the advisory bodies and other relevant entities mandated under [revised Regulation (EU) 2017/745, [revised Regulation (EU) 2017/746], Regulation (EU) 2024/1938 Regulation], Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] and Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 192 final] to provide a recommendation or opinion, including preparatory consultations, on the regulatory status of a product***, shall act***	With a view to ensuring the timely assessment of the regulatory status of health biotechnology products, the ***Commission shall adopt implementing acts setting out time limits for*** advisory bodies and other relevant entities mandated under [revised Regulation (EU) 2017/745, [revised Regulation (EU) 2017/746], Regulation (EU) 2024/1938 Regulation], Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 193 final] and Regulation (EU) …/… [reference to be added after adoption cf. COM(2023) 192 final] to provide a recommendation or opinion, including

swiftly, without prejudice to the time limits for the forming of such recommendations or opinions established in the above legal acts.	preparatory consultations, on the regulatory status of a product***. These time limits are*** without prejudice to the time limits for the forming of such recommendations or opinions established in the above legal acts.

Or. en

Justification

Clear regulatory time frames increase predictability for developers andmake the EU regulatory environment more attractive.

Amendment 2330
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Article 36 a (new)

Text proposed by the Commission	*Amendment*
	Article36a
	Exemptions to labelling and electronic product information and support to the implementation of multi-country packs for medicinal products
	1. In order to facilitate timely availability and uptake of innovative health biotechnology products, the Commission shall support the transition to electronic product information and proportionate labelling approaches, in accordance with applicable Union pharmaceutical legislation, including Article 63 of [revised Pharmaceutical Directive].
	2. For medicinal products intended for small patient populations, including orphan medicinal products, derogations from article 72 of [revised Pharmaceutical Directive] may be provided for, where patient safety, traceability and information needs are duly ensured.
	3. Where the medicinal product is a designated orphan medicinal product, the

European Commission and Member States shall permit the particulars listed in Annex IV of [revised Pharmaceutical Directive], to appear in only one of the official languages of the Union, supporting cross-border use, facilitating multi-country packs and reducing unnecessary barriers to availability.

4. The Commission shall, in cooperation with the European Medicines Agency and the Member States, issue guidance to harmonise Member State-labelling requirements under Articles 65, 73 and 77 of [revised Pharmaceutical Directive], including with regard to symbols and pictograms, ensuring that the location of the so called 'blue box' is the same across Member States, with a view to supporting cross-border use, facilitating multi-country packs and reducing unnecessary barriers to availability.

Or. en

Justification

The implementation of multi-country packs for medicines has encountered numerous challenges, including complexities around labelling and packaging constraints in the EU.

Challenges for multi-country packs include lack of space on the packaging for multiple so called "blue boxes", a boxed area included in the labelling, with a blue border, aimed at containing information specific to each Member State. The reason for this is that some Member States require a significant amount of information in the "blue box", and there is significant lack of harmonisation between Member States.

This poses challenges in cases where a manufacturer wants to quickly move an OMP from one Member State to another in the case of unexpected demand, as non-harmonised forms of labelling would require additional time and resources, delaying much-needed access to medicines, given that current national labelling and packaging requirements mean that a product packaged and labelled for one Member State is not accepted for supply in another without relabelling, repackaging or additional steps. Multi-country packs, including clear language exemptions and full implementation of electronic package leaflets (ePL) for OMPs would stand to significantly enhance availability across the EU, especially benefiting the smaller markets and small volume products seen in rare diseases.

Directive 2001/83, as amended by Directive 2004/27, currently recognises the specificities of OMPs, by including the following provision "In the case of certain orphan medicinal products, the particulars listed in Article 54 may, on reasoned request, appear in only one of the official languages of the Community". This provision must be strengthened in the revised

legislation to a clear derogation, leveraging the potential of digitalisation for these types of products and improving access.