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Committee on Industry, Research and Energy

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OPINION

of the Committee on Industry, Research and Energy

for the Committee on the Environment, Public Health and Food Safety

on the proposal for a directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC
(COM(2023)0192 – C9-0143/2023 – 2023/0132(COD))

Rapporteur for opinion: Henna Virkkunen

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SHORT JUSTIFICATION

The "Pharmaceutical Package" consists of the new Regulation and Directive, representing a long-awaited overhaul of pharmaceutical legislation, an integral part of building the European Health Union. As multiple legislative reforms impact the pharmaceutical sector at the same time, assessing their collective impact on the EU's global competitiveness, innovation, and medicine availability is crucial.

The Rapporteur supports the Pharmaceutical reform's objectives, aiming to foster a competitive and innovation-friendly R&D environment in Europe, enhance strategic autonomy, address antimicrobial resistance, and improve medicine accessibility. Nonetheless, some methodologies require refinement.

A significant concern is the potential migration of the pharmaceutical industry from Europe. To remain globally competitive, Europe must maintain an innovation-friendly regulatory framework. The Rapporteur emphasizes the need for legislation that is predictable, transparent, stable, and clear to enhance the attractiveness of the EU for research, development, and production of medicines.

Regulatory data protection (RDP)

Medical research and development (R&D) usually takes a long time, costs a lot, and has many uncertainties. To encourage R&D, we need strong rules for intellectual property (IP) and good incentives. The proposed Directive recommends reducing the protection period for regulatory data, which could be extended under certain conditions. In line with the European Council's conclusions in March 2023, the Rapporteur agrees that it's important to strengthen, not weaken, the protection of regulatory data and other incentives in Europe.

Unmet medical needs

The goal of medical advancements is to address Unmet Medical Needs (UMN), which can take various forms and change quickly. Since the UMN concept is important in the pharmaceutical field, having a clear definition is crucial. The Rapporteur is worried that the proposed UMN definition might hinder progress in preventing, treating, and caring for patients. UMN assessment should consider a wide range of patient outcomes and the benefits for society as a whole.

Bolar exemption

The Bolar exemption currently allows third parties to conduct necessary studies and trials on patented inventions to promote the introduction of generic medicines and biosimilars. The Commission suggests expanding this exemption to include activities like generating data for health assessments and the pricing and reimbursement process. However, this could weaken the protection of intellectual property (IP) rights for pharmaceuticals in the EU, leading to less confidence in the European IP framework and potential harm to EU competitiveness. The Rapporteur recommends limiting the Bolar exemption to activities solely related to obtaining marketing authorization.

Environmental effects

Evaluating and mitigating the environmental footprint is crucial. While environmental considerations are vital, patients' needs and swift access to innovative therapies should remain the primary focus.

Conclusion

The Rapporteur supports "The Pharmaceutical Package" and agrees with many of the Commission's proposed priorities. It is essential for this reform to protect the competitiveness of the European Union and the security of its pharmaceutical supply chain.

Given the constraints of time in preparing this initial draft report, the Rapporteur retains the prerogative to make further amendments, enhancements, and elucidations to this draft report. For a comprehensive list of entities or individuals with whom the Rapporteur has interacted or from whom input has been received during the process, please refer to the Annex at the conclusion of this draft report.

AMENDMENTS

The Committee on Industry, Research and Energy calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to take the following into account:

Amendment 1
Proposal for a directive
Recital 3

Text proposed by the Commission	*Amendment*
(3) This revision is part of the implementation of the Pharmaceutical strategy for Europe and aims to promote innovation, in particular for unmet medical needs, while reducing regulatory burden and the environmental impact of medicines; ensure access to innovative and established medicines for patients, with special attention to enhancing security of supply and addressing risks of shortages, taking into account the challenges of the smaller markets of the Union; and create a balanced and competitive system that keeps medicines affordable for health systems while rewarding innovation.	(3) This revision is part of the implementation of the Pharmaceutical strategy for Europe and aims to promote innovation, in particular for unmet medical needs, ***and establishes a conducive environment for the research, development, and manufacturing of pharmaceuticals within the Union*** while reducing regulatory burden and ***administrative burden as well as*** the environmental impact of medicines; ensure access to innovative and established medicines for patients, with special attention to enhancing security of supply and addressing risks of shortages, taking into account the challenges of the smaller markets of the Union; and create a balanced and competitive system that keeps medicines affordable for health systems while rewarding innovation.

Amendment 2
Proposal for a directive
Recital 4 a (new)

Text proposed by the Commission	*Amendment*
	(4 a) The pharmaceutical framework should be consistent with overarching EU industrial policy, including the Council Conclusions from 23 March 2023 which stressed the importance of strengthening incentives for investment in innovation and the 2016 Council Conclusions which stress any revision, including to the incentive framework, should not discourage the development of medicinal products needed for the treatment of rare diseases; increased innovation will further support patient outcomes and public health.

Amendment 3
Proposal for a directive
Recital 4 b (new)

Text proposed by the Commission	*Amendment*
	(4 b) This Directive acknowledges that fostering a competitive pharmaceutical industry within the EU, bolstering EU-based clinical trials, and localizing the manufacture of active pharmaceutical ingredients are complementary objectives that enhance the Union's strategic health autonomy while increasing the affordability, accessibility, and availability of medicinal products, thereby supporting a more resilient and sustainable European health ecosystem.

Amendment 4
Proposal for a directive
Recital 11

Text proposed by the Commission	*Amendment*
(11) The Directive should work in synergy with the Regulation to enable innovation and promote competitiveness of the ***Union*** pharmaceutical industry, in particular ***SMEs***. In this respect a balanced system of incentives is proposed that rewards innovation especially in areas of unmet medical need and innovation that reaches patients and improves access across the Union. To make the regulatory system more efficient and innovation-friendly the Directive also aims at reducing administrative burden and simplifying procedures for undertakings.	(11) The Directive should work in synergy with the Regulation to enable innovation and promote competitiveness of the ***EU's*** pharmaceutical industry, in particular ***of SMEs. Furthermore, it aims to prioritize the expansion of EU-based clinical trials and the local production of active pharmaceutical ingredients, thereby reinforcing the strategic autonomy of the European health ecosystem***. In this respect a balanced system of incentives is proposed that rewards innovation especially in areas of unmet medical need***, EU-based innovation*** and innovation that reaches patients and improves access across the Union. To make the regulatory system more efficient and innovation-friendly the Directive also aims at reducing administrative burden and simplifying procedures for undertakings.

Amendment 5
Proposal for a directive
Recital 11 a (new)

Text proposed by the Commission	*Amendment*
	(11 a) This Directive should be in line with the EU's industrial, digital and trade aspirations. The European life sciences sector, and the pharmaceutical industry in particular, are essential in ensuring EU's competitiveness. Maintaining and strengthening robust R&D sectors are key pillars of the shared European sovereignty in an increasingly competitive geopolitical context.

Amendment 6
Proposal for a directive
Recital 11 b (new)

Text proposed by the Commission	*Amendment*

	(11 b) However, to improve research and development in the pharmaceutical sphere stemming from the Union, as well as contributing to open EU strategic autonomy, it could be beneficial to establish a direct link between preclinical studies conducted in the Union and an incentive prolonging data protection for a medicinal product. Therefore, an incentive to extend the data protection period is proposed where a company can demonstrate this.

Amendment 7
Proposal for a directive
Recital 26

Text proposed by the Commission	*Amendment*
(26) In order to reward the compliance with all the measures included in the agreed paediatric investigation plan, for products covered by a supplementary protection certificate, if relevant information on the results of the studies conducted is included in the product information, a reward should be granted in the form of ***a six month*** extension of the supplementary protection certificate created by [Regulation (EC) No 469/2009 of the European Parliament and of the Council[42] - OP please replace reference by new instrument when adopted].	(26) In order to reward the compliance with all the measures included in the agreed paediatric investigation plan, for products covered by a supplementary protection certificate, if relevant information on the results of the studies conducted is included in the product information, a reward should be granted in the form of ***an*** extension of the supplementary protection certificate created by [Regulation (EC) No 469/2009 of the European Parliament and of the Council[42] - OP please replace reference by new instrument when adopted].
[42] 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, p. 10).	[42] 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, p. 10).

Amendment 8
Proposal for a directive
Recital 31

Text proposed by the Commission	*Amendment*

(31) Directive 2010/63/EU of the European Parliament and of the Council[43] lays down provisions on the protection of animals used for scientific purposes based on the principles of replacement, reduction and refinement. Any study involving the use of animals, which provides essential information on the quality, safety and efficacy of a medicinal product, should take into account those principles of replacement, reduction and refinement, where they concern the care and use of live animals for scientific purposes, and should be optimised in order to provide the most satisfactory results whilst using the minimum number of animals. The procedures of such testing should be designed to avoid causing pain, suffering, distress or lasting harm to animals and should follow the available EMA and ICH guidelines. In particular, the marketing authorisation applicant and the marketing authorisation holder should take into account the principles laid down in Directive 2010/63/EU, including, where possible, use new approach methodologies in place of animal testing. These can include but are not limited to: in vitro models, such as microphysiological systems including organ-on-chips, (2D and 3D-) cell culture models, organoids and human stem cells-based models; in silico tools or read-across models.

[43] Directive 2010/63/EU of the European

(31) Directive 2010/63/EU of the European Parliament and of the Council[43] lays down provisions on the protection of animals used for scientific purposes based on the principles of replacement, reduction and refinement. Any study involving the use of animals, which provides essential information on the quality, safety and efficacy of a medicinal product, should take into account those principles of replacement, reduction and refinement, where they concern the care and use of live animals for scientific purposes, and should be ***undertaken as a last resort and be*** optimised in order to provide the most satisfactory results whilst using the minimum number of animals***. The marketing authorisation applicant should not carry out animal tests in case scientifically satisfactory non-animal testing methods are available. Where scientifically satisfactory non-animal testing methods are not available, applicants that use animal testing should ensure that the principle of replacement, reduction and refinement of animal testing for scientific purposes has been with regard to any animal study conducted for the purpose of supporting the application***. The procedures of such testing should be designed to avoid causing pain, suffering, distress or lasting harm to animals and should follow the available EMA and ICH guidelines. In particular, the marketing authorisation applicant and the marketing authorisation holder should take into account the principles laid down in Directive 2010/63/EU, including, where possible, use new approach methodologies in place of animal testing. These can include but are not limited to: in vitro models, such as microphysiological systems including organ-on-chips, (2D and 3D-) cell culture models, organoids and human stem cells-based models; in silico tools or read-across models.

[43] Directive 2010/63/EU of the European

Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).	Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

Amendment 9
Proposal for a directive
Recital 39

Text proposed by the Commission	*Amendment*
(39) In the interest of as broad as possible access to medicinal products, a Member State that has an interest in receiving access to a particular medicinal product undergoing authorisation through the decentralised and mutual recognition procedures should be able to opt-into that procedure.	(39) In the interest of as broad as possible access to medicinal products, a Member State that has an interest in receiving access to a particular medicinal product undergoing authorisation through the decentralised and mutual recognition procedures should be able to opt-into that procedure. ***A Member State who did not join the initial application for the decentralised procedure within 30 days of the submission of the application should still have a second opportunity to opt into the procedure at a later point, in this case they should immediately inform the applicant and the competent authority of the reference Member State for the decentralised procedure.***

Amendment 10
Proposal for a directive
Recital 49 a (new)

Text proposed by the Commission	*Amendment*
	(49 a) Practices in procurement procedures for medicines differ between Member States and long-term availability is rarely a primary consideration. The 2014 Procurement Directive encourages a more strategic approach through award criteria, including criteria beyond price. Using the lowest price as the main selection criterion may reduce incentives for the industry to build for long-term supply in the EU. At the same time, vulnerability may be increased when

	public procurement procedures award contracts to a single company. Where challenges with access to a critical medicine and related affordability may be an issue, Member States can work together to increase buying power. Joint procurement between Member States can act as a powerful tool to improve access, affordability and security of supply, of particular benefit in smaller EU markets. This can improve the negotiating position of Member States to incentivise production capacities, as well as diversifying supply chains.

Amendment 11
Proposal for a directive
Recital 53

Text proposed by the Commission	*Amendment*
(53) A marketing authorisation holder should ensure the appropriate and continuous supply of a medicinal product throughout its lifetime irrespective of whether that medicinal product is covered by a supply incentive or not.	(53) A marketing authorisation holder should***, within its responsibilities,*** ensure the appropriate and continuous supply of a medicinal product throughout its lifetime irrespective of whether that medicinal product is covered by a supply incentive or not.

Amendment 12
Proposal for a directive
Recital 59 a (new)

Text proposed by the Commission	*Amendment*
	(59 a) If negotiations between Member States and developers are conducted sincerely but fail to result in an agreement on the distribution and ongoing supply of a therapy, the introduction of a mediation process is warranted. This mechanism, overseen by the Commission, should safeguard developers from unfairly missing out on incentives due to factors beyond their influence.

Amendment 13
Proposal for a directive
Article 18 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
For integral combinations of a medicinal product and a medical device the marketing authorisation applicant shall submit data establishing the safe and effective use of the integral combination of the medicinal product and the medical device.	For integral combinations of a medicinal product and a medical device the marketing authorisation applicant shall submit data establishing the safe and effective use of the integral combination of the medicinal product and the medical device***, particularly for pediatric patients, encompassing aspects such as storage, assembly, cleanliness, and the technique required for application or intake***.

Amendment 14
Proposal for a directive
Article 18 – paragraph 1 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	In case of combined products intended for paediatric use, a risk/benefit analysis should be taken into account following the opinion of the Paediatric Working Party of the Agency, established in accordance with Article 142 of the Regulation.

Amendment 15
Proposal for a directive
Article 18 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The application for a marketing authorisation for an integral combination of a medicinal product with a medical device shall include the ***documentation*** supporting the compliance of the medical device part with the general safety and performance requirements as referred to in paragraph 2 in accordance with Annex II, including, where relevant, the conformity	3. The application for a marketing authorisation for an integral combination of a medicinal product with a medical device shall include the ***evidence*** supporting the compliance of the medical device part with the general safety and performance requirements as referred to in paragraph 2 in accordance with Annex II, including, where relevant, the conformity assessment

assessment report by a notified body.	report by a notified body.

Amendment 16
Proposal for a directive
Article 24 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The setting-up of the system of ERA monographs shall be based on a risk-based prioritisation of active substances.	2. The setting-up of the system of ERA monographs shall be based on a risk-based prioritisation of active substances ***and data requested***.

Amendment 17
Proposal for a directive
Article 24 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Agency in cooperation with the competent authorities of the Member States shall conduct a proof-of-concept pilot of ERA monographs to be completed within three years after entering into force of this Directive.	4. The Agency in cooperation with the competent authorities of the Member States shall conduct a proof-of-concept pilot of ERA monographs to be completed within three years after entering into force of this Directive ***while taking into account outcomes from relevant Union initiatives, such as with regard to animal testing***.

Amendment 18
Proposal for a directive
Article 24 – paragraph 5 – point e a (new)

Text proposed by the Commission	*Amendment*
	(e a) the risk-based prioritisation of data requirements for active substances, including to avoid unnecessary animal testing.

Amendment 19
Proposal for a directive
Article 34 – paragraph 3

Text proposed by the Commission	*Amendment*

3. The applicant shall inform all the competent authorities of all Member States of its application at the time of submission. The competent authority of a Member State ***may request for justified public health reasons*** to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the decentralised procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay.	3. The applicant shall inform all the competent authorities of all Member States of its application at the time of submission. The competent authority of a Member State ***shall have the possibility*** to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the decentralised procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay.

Amendment 20
Proposal for a directive
Article 34 – paragraph 4 – subparagraph 2

Text proposed by the Commission	*Amendment*
The competent authority of the reference Member State for the decentralised procedure shall summarise the deficiencies in writing. On this basis, the competent authority of the reference Member State for the decentralised procedure shall inform the applicant and the competent authorities of the Member States concerned accordingly and set a time limit to address the deficiencies. The application shall be suspended until the applicant addresses the deficiencies. If the applicant fails to address those deficiencies within the time limit set by the competent authority of the reference Member State for the decentralised procedure, the application shall be considered as withdrawn.	The competent authority of the reference Member State for the decentralised procedure shall summarise the deficiencies in writing. On this basis, the competent authority of the reference Member State for the decentralised procedure shall inform the applicant and the competent authorities of the Member States concerned accordingly and set a time limit ***of minimum 14 days*** to address the deficiencies. The application shall be suspended until the applicant addresses the deficiencies. If the applicant fails to address those deficiencies within the time limit set by the competent authority of the reference Member State for the decentralised procedure, the application shall be considered as withdrawn.

Amendment 21
Proposal for a directive
Article 34 – paragraph 5

Text proposed by the Commission	*Amendment*

5. Within 120 days after validation of the application, the competent authority of the reference Member State for the decentralised procedure shall prepare an assessment report, a summary of product characteristics, the labelling and the package leaflet and shall send them to the Member States concerned and to the applicant.	5. Within 120 days after validation of the application, the competent authority of the reference Member State for the decentralised procedure shall prepare an assessment report, a summary of product characteristics, the labelling and the package leaflet and shall send them to the Member States concerned and to the applicant. ***During this period, a competent authority of a Member State may request to enter the procedure after validation and shall inform the applicant and the competent authority of the reference Member State for the decentralised procedure.***

Amendment 22
Proposal for a directive
Article 36 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The applicant shall inform the competent authorities of all Member States of its application at the time of submission. The competent authority of a Member State ***may request for justified public health reasons*** to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the mutual recognition procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay.	4. The applicant shall inform the competent authorities of all Member States of its application at the time of submission. The competent authority of a Member State ***shall have the possibility*** to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the mutual recognition procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay.

Amendment 23
Proposal for a directive
Article 36 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4 a. In order to examine an application submitted in accordance with Articles 6 and 9 to 14, the competent authorities of

	the Member States shall verify within 20 days whether the particulars and documentations submitted in support of the application comply with Articles 6 and 9 to 14 ('validation'), and examine whether the conditions for issuing a marketing authorization set out in Articles 43 to 45 are complied with.

Amendment 24
Proposal for a directive
Article 43 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The competent authorities of the Member States shall, without undue delay, make publicly available the national marketing authorisation together with the summary of product characteristics, the package leaflet as well as any conditions established in accordance with Articles 44, 45 and any obligations imposed subsequently in accordance with Article 87, together with any deadlines for the fulfilment of those conditions and obligations for each medicinal product that they have authorised.	3. The competent authorities of the Member States shall, without undue delay, make publicly available the national marketing authorisation together with the summary of product characteristics, the package leaflet***, the antimicrobial stewardship plan and special information requirements referred to in Article 17 (1) and Annex I*** as well as any conditions established in accordance with Articles 44, 45 and any obligations imposed subsequently in accordance with ***Article 17 (2) and*** Article 87, together with any deadlines for the fulfilment of those conditions and obligations for each medicinal product that they have authorised.

Amendment 25
Proposal for a directive
Article 81 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The regulatory data protection period shall be ***six*** years from the date when the marketing authorisation for that medicinal product was granted in accordance with Article 6(2). For marketing authorisations that belong to the same global marketing authorisation the period of data protection shall start from	1. The regulatory data protection period shall be ***nine*** years from the date when the marketing authorisation for that medicinal product was granted in accordance with Article 6(2). For marketing authorisations that belong to the same global marketing authorisation the period of data protection shall start from

the date when the initial marketing authorisation was granted in the Union.	the date when the initial marketing authorisation was granted in the Union.

Amendment 26
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 1 – point a – introductory part

Text proposed by the Commission	*Amendment*
(a) 24 months, where the marketing authorisation holder demonstrates that the conditions referred to in Article 82(1) are fulfilled within two years, from the date when the marketing authorisation was granted or, within ***three*** years from that date for any of the following entities:	(a) 24 months, where the marketing authorisation holder demonstrates that the conditions referred to in Article 82(1) are fulfilled within two years, from the date when the marketing authorisation was granted or, within ***four*** years from that date for any of the following entities:

Amendment 27
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(a a) 12 months, where the marketing authorisation holder demonstrates that significant preclinical development of the medicinal product has been done within the Union as referred to in Article 82a;

Amendment 28
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) ***six*** months, where the marketing authorisation applicant demonstrates at the time of the initial marketing authorisation application that the medicinal product addresses an unmet medical need as referred to in Article 83;	(b) ***12*** months, where the marketing authorisation applicant demonstrates at the time of the initial marketing authorisation application ***or subsequent variation*** that the medicinal product addresses an unmet medical need ***at least in one of its indications*** as referred to in Article 83;

Amendment 29

Proposal for a directive
Article 81 – paragraph 2 – subparagraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) ***six*** months, for medicinal products containing a new active substance, where the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency;	(c) ***12*** months, for medicinal products containing a new active substance, where the clinical trials supporting the initial marketing authorisation application ***or subsequent variation*** use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency ***in consultation with health technology assessment authorities, set out in a delegated act in accordance with article 215***;

Amendment 30
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 1 – point d a (new)

Text proposed by the Commission	*Amendment*
	(d a) 12 months, where the marketing authorisation applicant has submitted a clinical trial application for a new medicinal product within the territory of the EU;

Amendment 31
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 1 – point d b (new)

Text proposed by the Commission	*Amendment*
	(d b) 12 months, where the marketing authorisation applicant supports the establishment of public-private partnerships, University Hospital Institutes, centres of excellence and bioclusters to accelerate research and development of a new medicinal product;

Amendment 32
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 1 – point d c (new)

Text proposed by the Commission	*Amendment*
	(d c) 12 months, for medicinal products containing a majority, as defined by the Agency, of critical active pharmaceutical ingredients produced within the EU.

Amendment 33
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
In the case of a conditional marketing authorisation granted in accordance with Article 19 of [revised Regulation (EC) No 726/2004] the prolongation referred to in the first subparagraph, point (b), shall only apply if, ***within four years of the granting of the conditional marketing authorisation,*** the medicinal product has been granted a marketing authorisation in accordance with Article 19(7) of [revised Regulation (EC) No 726/2004.	In the case of a conditional marketing authorisation granted in accordance with Article 19 of [revised Regulation (EC) No 726/2004] the prolongation referred to in the first subparagraph, point (b), shall only apply if, ***during the regulatory data protection period*** the medicinal product has been granted a marketing authorisation in accordance with Article 19(7) of [revised Regulation (EC) No 726/2004. ***The prolongations referred to in the first subparagraph, points (b), (c) and (d), may each only be granted once and may only be granted during the period of regulatory data protection referred to in paragraph (1).***

Amendment 34
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 3

Text proposed by the Commission	*Amendment*
The prolongation referred to in the first subparagraph, point (d), may only be granted once.	***deleted***

Amendment 35
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 3 a (new)

Text proposed by the Commission	*Amendment*
	The above incentives may be combined up to a maximum of 13 years.

Amendment 36
Proposal for a directive
Article 82 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
The prolongation of the data protection period referred to in Article 81(2), first subparagraph, point (a), shall only be granted to medicinal products if they are ***released and continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the*** patients in the Member States in which the marketing authorisation is valid.	The prolongation of the data protection period referred to in Article 81(2), first subparagraph, point (a), shall only be granted to medicinal products if they are ***made available to*** patients ***or prescribing doctors who requested the medicinal product,*** in the Member States in which the marketing authorisation is valid.

Amendment 37
Proposal for a directive
Article 82 – paragraph 2 – subparagraph 3 – introductory part

Text proposed by the Commission	*Amendment*
The application for a variation shall contain documentation from the Member States in which the marketing authorisation is valid. Such documentation shall:	The application for a variation shall contain documentation from the Member States ***competent authority*** in which the marketing authorisation is valid. Such documentation shall:

Amendment 38
Proposal for a directive
Article 82 – paragraph 2 – subparagraph 4 a (new)

Text proposed by the Commission	*Amendment*
	Where the conditions set out in paragraph 1 have not been fully satisfied within the time set out in Article 81(2), first subparagraph, point (a), due to duly justified circumstances out of the control of the marketing authorisation holder, the

	Member State shall confirm the conditions in paragraph 1 have been satisfied in their territory, subject to guarantee that these conditions will be fulfilled in an acceptable period of time agreed between the marketing authorisation holder and the Member State. Where the conditions set out in paragraph 1 cannot be fully satisfied due to circumstances fully within the control of the Member State, the Member State shall confirm the conditions in paragraph 1 have been satisfied in their territory.

Amendment 39
Proposal for a directive
Article 82 – paragraph 3

Text proposed by the Commission	*Amendment*
3. To receive the documentation referred to in paragraph 2, third subparagraph, the marketing authorisation holder shall make a request to the relevant Member State. Within 60 days from the request of the marketing authorisation holder, the ***Member State*** shall issue a confirmation of compliance or, a reasoned statement of non-compliance or alternatively provide a statement of non-objection to prolong the period of regulatory data protection pursuant to this Article.	3. To receive the documentation referred to in paragraph 2, third subparagraph, the marketing authorisation holder shall make a request to the relevant Member State ***competent authority***. Within 60 days from the request of the marketing authorisation holder, the ***competent authority*** shall issue a confirmation of compliance or, a reasoned statement of non-compliance ***based on objective and verifiable criteria,*** or alternatively provide a statement of non-objection to prolong the period of regulatory data protection pursuant to this Article. ***When a competent authority issues a justified statement of non-fulfilment, it must detail the requisite actions that would allow the conditions to be met and enable the resubmission of a request for confirmation of fulfilment within a reasonable time frame. The authority shall subsequently provide a confirmation of fulfilment or a reasoned statement of non-fulfilment within two months from the date of the resubmission request.***
	The Commission is tasked with creating a mediation mechanism via implementing

	acts. This mechanism will support dialogue between developers and Member States to address disputes arising from a declaration of non-compliance by a Member State after earnest negotiations, or due to negotiation delays. Within this framework, there will be an option for a Commission decision that can supersede the documents referred to in paragraph 2.

Amendment 40
Proposal for a directive
Article 82 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
In cases where a Member State has not replied to the application of the marketing authorisation holder within the deadline referred to in paragraph 3, it shall be considered that a statement of non-objection has been provided.	In cases where a Member State has not replied to the application of the marketing authorisation holder within the deadline referred to in paragraph 3, it shall be considered that a statement of non-objection has been provided. ***Should a Member State fail to adhere to the deadlines specified in Articles 2 and 6 of Directive 89/105/EEC, the conditions outlined in paragraph 1 will cease to be applicable within that Member State's jurisdiction with regard to the extension period.***

Amendment 41
Proposal for a directive
Article 82 – paragraph 4 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Time limits other than those set out in paragraphs 1 to 3 may apply if a Member State and a marketing authorization holder reach an agreement to that effect.

Amendment 42
Proposal for a directive
Article 82 – paragraph 4 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	The Commission shall ensure that Marketing Authorisation Holders are not unduly prevented from receiving the incentives for actions beyond their control.

Amendment 43
Proposal for a directive
Article 82 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The Commission shall check the application referred to in paragraph 2, subparagraph 2, and grant approval or rejection to the prolongation referred to in Article 81(2). In those cases in which one or more Member States have issued a reasoned statement for refusal of the prolongation, the Commission shall ensure that the reasons described are justified and substantiated. The Commission shall ensure that Marketing Authorisation Holders are not unduly prevented from receiving the incentives for actions beyond their control.

Amendment 44
Proposal for a directive
Article 82 – paragraph 4 b (new)

Text proposed by the Commission	*Amendment*
	4b. The Commission shall make publicly available any information related to the decision taken on the grant or refusal of the prolongation of the data exclusivity period after deletion of information of a commercially confidential nature.

Amendment 45
Proposal for a directive

Article 82 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Commission, based on the experience of Member States and relevant stakeholders, may adopt ***implementing*** measures relating to the procedural aspects outlined in this Article and regarding the conditions mentioned in paragraph 1. Those ***implementing*** acts shall be adopted in accordance with the procedure referred to in Article ***214(2)***.	6. The Commission, based on the experience of Member States and relevant stakeholders, may adopt ***delegated*** measures relating to the procedural aspects outlined in this Article and regarding the conditions mentioned in paragraph 1. Those ***delegated*** acts shall be adopted in accordance with the procedure referred to in Article ***215***.

Amendment 46
Proposal for a directive
Article 82 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6 a. The Commission, via implementing acts, shall compile a list of products that, either due to their nature or other duly justified and accredited limiting factors or technical specificities, shall be exempt from the stipulations outlined in Article 81(2), point (a), and within this same Article 81, paragraphs 1 to 7. These specified products will be granted an automatic extension of the data protection period for 12 months, as detailed in Article 81(2), point (a). The adoption of these implementing acts shall proceed in line with the examination procedure described in Article 214(2) and (3).

Amendment 47
Proposal for a directive
Article 82 a (new)

Text proposed by the Commission	*Amendment*
	Article 82a
	Prolongation of the data protection period for medicinal products developed

primarily within the Union

1. A regulatory data protection period of one year shall be granted for a medicinal product if the marketing authorisation holder can demonstrate that the majority of its preclinical development was performed in the Union, even if another independent legal entity performed those studies, in initial stages of development, before the marketing authorisation holder acquired it.

2. By [OP please insert the date =12 months after the date of entering into force of this Directive] the Commission shall adopt a delegated act setting out the procedural aspects regarding the conditions mentioned in paragraph 1. Those delegated acts shall be adopted in accordance with the procedure referred to in Article 215. Before the adoption of the delegated act, the Commission shall publish a study on the most adequate indicators to evaluate that the provision in paragraph 1 is met. with a particular focus on those indicators that could most effectively promote research and development within the Union, particularly for SMEs.

3. The Commission shall adopt delegated measures relating to the procedural aspects outlined in this Article and regarding the conditions mentioned in paragraph 1. Those delegated acts shall be adopted in accordance with the procedure referred to in Article 215. When setting up the conditions mentioned in paragraph 1, the Commission shall take into account the conclusions drawn from the study mentioned in paragraph 2.

Amendment 48
Proposal for a directive
Article 83 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*

(b) the use of the medicinal product results in a meaningful reduction in disease morbidity or mortality for the relevant patient population.	(b) the use of the medicinal product results***:***
	(i) in a meaningful reduction in disease morbidity or mortality***,*** for the relevant patient population ***or***
	(ii) a meaningful prevention, delay of the onset, or delay of progression of the disease or its complications.

Amendment 49
Proposal for a directive
Article 83 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the Agency adopts scientific guidelines for the application of this Article it shall consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004].	3. Where the Agency adopts scientific guidelines for the application of this Article it shall consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004]***, representatives of patients' organisations in the relevant disease areas, healthcare professionals, representatives of pharmaceutical industry, members from patient organizations related to the pertinent disease areas, and other relevant stakeholders***.

Amendment 50
Proposal for a directive
Article 86 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Where an application for marketing authorisation, includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a six-month extension of the period referred to in Article 13, paragraphs 1 and 2 of [Regulation (EC) No 469/2009 - OP please	Where an application for marketing authorisation, includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a six-month extension of the period referred to in Article 13, paragraphs 1 and 2 of [Regulation (EC) No 469/2009 - OP please

replace reference by new instrument when adopted].	replace reference by new instrument when adopted]. ***Where the agreed paediatric investigation plan is conducted in relation to a disease that is different from the one for which the medicinal product is intended in the adult population, the holder of the patent or supplementary protection certificate shall be entitled to a 12-month extension of the period.***

Amendment 51
Proposal for a directive
Article 147 – paragraph 1 – subparagraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(a a) maintain the market adequately supplied with the registered products, in an adequate and continuous manner, so that the needs of patients are covered;

Amendment 52
Proposal for a directive
Article 147 – paragraph 1 – subparagraph 1 – point g

Text proposed by the Commission	*Amendment*
(g) use only active substances that have been manufactured in accordance with good manufacturing practice for active substances and distributed in accordance with good distribution practices for active substances;	(g) use only active substances that have been manufactured in accordance with good manufacturing practice for active substances and distributed in accordance with good distribution practices for active substances***, which include reliable, constant and timely delivery of the active substances to the manufacturing authorization holders***;

Amendment 53
Proposal for a directive
Article 147 – paragraph 1 – subparagraph 1 – point j a (new)

Text proposed by the Commission	*Amendment*
	(j a) comply with the risk mitigating measures in accordance with Article 22(4). In this regard, they shall comply

	and permit representatives of competent authorities of Member States to access their manufacturing premises, sites, and any outdoor facilities and effluents at any time. This obligation shall also apply where decentralised manufacturing or testing takes place.

Amendment 54
Proposal for a directive
Article 147 – paragraph 1 – subparagraph 3 a (new)

Text proposed by the Commission	*Amendment*
	Manufacturing authorisation holders may diversify their contracts with manufacturer or distributors of active substances if needed to ensure an adequate, constant and timely provision to comply with their public service obligations for supply.

Amendment 55
Proposal for a directive
Article 195 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission may suspend***, revoke*** or vary a marketing authorisation if a serious risk to the environment ***or*** public health has been identified and not sufficiently addressed by the marketing authorisation holder.	2. The competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission may suspend or vary a marketing authorisation if a serious risk to the environment***, including*** public health***,*** has been identified and not sufficiently addressed by the marketing authorisation holder***, with the exception of medicinal products authorised before 30 October 2005 to avoid restricting patients' access to existing treatments***. ***Should the environmental risks, which also encompass public health dangers, surpass the therapeutic benefits for the intended patients and if these risks are not adequately reducible, the relevant Member State authorities or the Commission may revoke the marketing***

authorization of the holder.

Amendment 56
Proposal for a directive
Article 196 – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
(f) a serious risk to ***the environment or to public health via*** the environment has been identified and not sufficiently addressed by the marketing authorisation holder.	(f) a serious risk to the environment has been identified and not sufficiently addressed by the marketing authorisation holder ***via conditions laid out in Articles 44(h) or 87(c)***.

Amendment 57
Proposal for a directive
Article 208 a (new)

Text proposed by the Commission	*Amendment*
	Article 208a
	Fostering research, innovation and production of medicinal products in the Union
	1. The Commission shall establish a strategy on research, innovation and production of medicinal products in the Union, based on the results published in the report defined in paragraph 2. Member States shall be encouraged to participate in this strategy.
	2. By... [two years after the date of entry into force of this Directive] the Commission shall present an impact assessment evaluating potential measures to be implemented at Union level, and at a Member State level to foster research, innovation and production of critical medicinal products in the Union. This report shall evaluate the effect of measures such as:
	(a) funding and push and pull incentives directed to foster research and innovation in the Union, including public and private funding for preclinical and clinical

research and innovation;

(b) public-private partnerships in research and innovation;

(c) regulatory support for public research and innovation entities;

(d) incentives for production of critical medicinal products inside the Union. Proposed measures shall be in line with developing a strategic autonomy for the Union regarding medicinal products.

ANNEX: ENTITIES OR PERSONS FROM WHOM THE RAPPORTEUR FOR THE OPINION HAS RECEIVED INPUT

Pursuant to Article 8 of Annex I to the Rules of Procedure, the rapporteur for the opinion declares that she has received input from the following entities or persons in the preparation of the opinion, until the adoption thereof in committee:

Entity and/or person
Bayer
The European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
The European Federation of Pharmaceutical Industries and Associations (EFPIA)
The Finnish Medicines Agency Fimea
University of Helsinki
Novartis
Orion
Permanent representation of Finland to the EU
Pharma Industry Finland
Boehringer Ingelheim
Johnson & Johnson

The list above is drawn up under the exclusive responsibility of the rapporteur for the opinion.

PROCEDURE – COMMITTEE ASKED FOR OPINION

Title	Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC
References	COM(2023)0192 – C9-0143/2023 – 2023/0132(COD)
Committee responsible Date announced in plenary	ENVI 14.9.2023
Opinion by Date announced in plenary	ITRE 14.9.2023
Rapporteur for the opinion Date appointed	Henna Virkkunen 5.10.2023
Discussed in committee	28.11.2023
Date adopted	22.2.2024
Result of final vote	+: 34 –: 26 0: 2
Members present for the final vote	Hildegard Bentele, Michael Bloss, Marc Botenga, Martin Buschmann, Cristian-Silviu Buşoi, Jerzy Buzek, Maria da Graça Carvalho, Ignazio Corrao, Beatrice Covassi, Josianne Cutajar, Nicola Danti, Marie Dauchy, Christian Ehler, Nicolás González Casares, Christophe Grudler, Henrike Hahn, Robert Hajšel, Ivo Hristov, Ivars Ijabs, Romana Jerković, Seán Kelly, Łukasz Kohut, Zdzisław Krasnodębski, Marisa Matias, Eva Maydell, Marina Mesure, Angelika Niebler, Ville Niinistö, Johan Nissinen, Mauri Pekkarinen, Tsvetelina Penkova, Morten Petersen, Manuela Ripa, Sara Skyttedal, Maria Spyraki, Riho Terras, Grzegorz Tobiszowski, Henna Virkkunen, Pernille Weiss
Substitutes present for the final vote	Pascal Arimont, Laura Ballarín Cereza, Jakop G. Dalunde, Margarita de la Pisa Carrión, Francesca Donato, Alicia Homs Ginel, Alin Mituța, Luděk Niedermayer, Susana Solís Pérez
Substitutes under Rule 209(7) present for the final vote	Alexander Bernhuber, Sara Cerdas, Ibán García Del Blanco, Mircea-Gheorghe Hava, Radan Kanev, Guy Lavocat, Javi López, Karen Melchior, Jessica Polfjärd, Bergur Løkke Rasmussen, Caroline Roose, Birgit Sippel, Dragoş Tudorache, Axel Voss

FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

34	+
ECR	Johan Nissinen, Margarita de la Pisa Carrión
ID	Marie Dauchy
PPE	Pascal Arimont, Hildegard Bentele, Alexander Bernhuber, Cristian-Silviu Buşoi, Jerzy Buzek, Maria da Graça Carvalho, Christian Ehler, Mircea-Gheorghe Hava, Radan Kanev, Seán Kelly, Eva Maydell, Angelika Niebler, Luděk Niedermayer, Jessica Polfjärd, Sara Skyttedal, Maria Spyraki, Riho Terras, Henna Virkkunen, Axel Voss, Pernille Weiss
Renew	Nicola Danti, Christophe Grudler, Ivars Ijabs, Guy Lavocat, Karen Melchior, Alin Mituța, Mauri Pekkarinen, Morten Petersen, Bergur Løkke Rasmussen, Susana Solís Pérez, Dragoş Tudorache

26	-
NI	Martin Buschmann, Francesca Donato
S&D	Laura Ballarín Cereza, Sara Cerdas, Beatrice Covassi, Josianne Cutajar, Ibán García Del Blanco, Nicolás González Casares, Robert Hajšel, Alicia Homs Ginel, Ivo Hristov, Romana Jerković, Łukasz Kohut, Javi López, Tsvetelina Penkova, Birgit Sippel
The Left	Marc Botenga, Marisa Matias, Marina Mesure
Verts/ALE	Michael Bloss, Ignazio Corrao, Jakop G. Dalunde, Henrike Hahn, Ville Niinistö, Manuela Ripa, Caroline Roose

2	0
ECR	Zdzisław Krasnodębski, Grzegorz Tobiszowski

Key to symbols:
+ : in favour
- : against
0 : abstention