European Parliament
2019-2024

Committee on Industry, Research and Energy

2023/0131(COD)

8.11.2023

DRAFT 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 regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006
(COM(2023)0193 – C9-0144/2023 – 2023/0131(COD))

Rapporteur for opinion (*): Henna Virkkunen

(*) Associated committee – Rule 57 of the Rules of Procedure

PA_Legam

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.

Transferable exclusivity vouchers

Antimicrobial resistance (AMR) is a pressing global health crisis that requires immediate EU intervention before it becomes a more severe issue. The current market for developing new medicines to combat AMR is inadequate. These products must be used carefully to maintain their effectiveness, making them less profitable for companies to invest in research and development.

The Commission has proposed Transferable Exclusivity Vouchers (TEV) to stimulate the creation of new antimicrobial drugs. The Rapporteur supports TEV as a positive development. However, the strict conditions outlined for TEV could reduce its effectiveness, particularly considering it extends only Regulatory Data Protection (RDP) and not Supplementary Protection Certificates (SPC) or patent protection. The conditions for TEV should be reconsidered, as recommended by the Rapporteur.

Unmet medical needs

Medical progress aims to address Unmet Medical Needs (UMN), which can vary and change rapidly. Classifying some UMN as "high" can be ethically problematic because it may diminish the importance of other UMN. A comprehensive understanding of UMN is needed since it can take many forms.

Debates about UMN or High Unmet Medical Needs (HUMN) are part of broader challenges related to the availability, accessibility, affordability of new medicines, and the sustainability of healthcare systems. The patient's viewpoint is often overlooked, and the potential for transforming patients' lives with new treatments is not fully acknowledged.

Restricting incentives to treatments that fit a narrow definition of UMN or HUMN today could hinder the development of vital therapies for future patients. This might decrease predictability for companies and discourage them from investing in research and development in the EU to

address UMN.

The Regulatory Sandbox

In recent years, scientific progress has rapidly increased, leading to new medicines, devices, diagnostics, and combinations of these beyond what current regulations anticipated. To ensure high-quality, safe, and effective products reach patients, regulators need flexibility and collaboration with developers. A regulatory sandbox can achieve this goal.

However, the Commission's sandbox proposal only covers pharmaceuticals. Many modern products include medical devices, diagnostics, and digital tools, each with separate regulations. The Rapporteur believes it's essential to expand the sandbox's scope to accommodate future developments in these areas.

Addressing medicine shortages

Medicine shortages are a serious issue, often caused by unexpected surges in demand. The Commission proposes extending the notification period for temporary shortages from two to six months and making shortage prevention plans mandatory for all medicines in the proposed Regulation.

To improve medicine availability, it's crucial to create an efficient system without imposing excessive administrative burdens on regulators and marketing authorization holders (MAHs). Instead of requiring shortage plans for all medicines, it would be better to focus on critical ones after assessing their necessity and specific risks.

Extending the notification period too much might lead to unnecessary "just in case" notifications. In Rapporteur's opinion It's wiser to concentrate on making demand transparent across Europe and using data and digital tools to identify and prevent shortages.

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 regulation
Article 40 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Following a request by the applicant ***when applying*** for a marketing authorisation, the Commission may, by means of implementing acts, grant a transferable data exclusivity voucher to a 'priority antimicrobial' referred to in paragraph 3, under the conditions referred to in paragraph 4 based on a scientific assessment by the Agency.	1. Following a request by the applicant for a marketing authorisation***, made before that marketing authorisation is granted***, the Commission may, by means of implementing acts, grant a transferable data exclusivity voucher to a 'priority antimicrobial' referred to in paragraph 3, under the conditions referred to in paragraph 4 based on a scientific assessment by the Agency.

Or. en

Justification

The proposed amendment aims to clarify the timing of TEV requests to the Commission, suggesting flexibility rather than strict alignment with marketing authorization submissions to EMA. EMA's scientific assessment for TEV requests focuses on determining priority antimicrobials, distinct from the marketing authorization assessment.

Amendment 2

Proposal for a regulation
Article 40 – paragraph 3 – subparagraph 1 – introductory part

Text proposed by the Commission	*Amendment*
An antimicrobial shall be considered 'priority antimicrobial' if preclinical and clinical data underpin a significant clinical benefit with respect to antimicrobial resistance ***and it has at least one of the following characteristics:***	An antimicrobial shall be considered 'priority antimicrobial' if preclinical and clinical data underpin a significant clinical benefit with respect to antimicrobial resistance***.***

Or. en

Justification

To assess antimicrobial priority, emphasis should center on clinical benefit and effectiveness against resistance. Establishing a dedicated expert group and fostering early dialogues with

developers ensure a thorough, science-based evaluation with a primary focus on clinical utility.

Amendment 3

Proposal for a regulation
Article 40 – paragraph 3 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) it represents a new class of antimicrobials;	***deleted***

Or. en

Amendment 4

Proposal for a regulation
Article 40 – paragraph 3 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) its mechanism of action is distinctly different from that of any authorised antimicrobial in the Union;	***deleted***

Or. en

Amendment 5

Proposal for a regulation
Article 40 – paragraph 3 – subparagraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) it contains an active substance not previously authorised in a medicinal product in the Union that addresses a multi-drug resistant organism and serious or life threatening infection.	***deleted***

Or. en

Amendment 6

Proposal for a regulation
Article 40 – paragraph 3 – subparagraph 2

Text proposed by the Commission	*Amendment*
In ***the*** scientific assessment ***of the criteria referred to in the first subparagraph***, and in the case of antibiotics, the Agency shall take into account the 'WHO priority pathogens list for R&D of new antibiotics', or an equivalent list established at Union level.	In ***its*** scientific assessment, and in the case of antibiotics, the Agency shall take into account the 'WHO priority pathogens list for R&D of new antibiotics', or an equivalent list established at Union level.

Or. en

Justification

To assess antimicrobial priority, emphasis should center on clinical benefit and effectiveness against resistance. Establishing a dedicated expert group and fostering early dialogues with developers ensure a thorough, science-based evaluation with a primary focus on clinical utility.

Amendment 7

Proposal for a regulation
Article 40 – paragraph 4 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) provide information on all direct financial support received for research related to the development of the priority antimicrobial.	(b) provide information on all direct financial support received ***from any public authority of publicly funded body based in the European Union*** for research related to the development of the priority antimicrobial.

Or. en

Justification

The R&D funding disclosure requirement indirectly addresses medicine affordability in Europe and should apply only to EU funding, excluding external sources. EU member states regulate their funding independently within their healthcare systems and budgets.

Amendment 8

Proposal for a regulation
Article 41 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
A voucher shall only be used once and in relation to a single centrally authorised medicinal product and only if that product ***is within its first four*** years of regulatory data protection.	A voucher shall only be used once and in relation to a single centrally authorised medicinal product and only if that product ***has at least two*** years of regulatory data protection ***remaining***.

Or. en

Justification

The proposed alteration broadens the scope of eligible products for TEV association by extending it to those with a minimum of two years of protection. This expansion augments the opportunity for generic manufacturers while retaining predictability. It widens the spectrum of eligible products, amplifying the potential effectiveness and attractiveness of the incentive program.

Amendment 9

Proposal for a regulation
Article 70

Text proposed by the Commission	*Amendment*
Article 70	***deleted***
Orphan medicinal products addressing a high unmet medical need	
1. An orphan medicinal product shall be considered as addressing a high unmet medical need where it fulfils the following requirements:	
(a) there is no medicinal product authorised in the Union for such condition orwhere, despite medicinal products being authorised for such condition in the Union, the applicant demonstrates that the orphan medicinal product, in addition to having a	

significant benefit, will bring exceptional therapeutic advancement;

(b) the use of the orphan medicinal product results in a meaningful reduction in disease morbidity or mortality for the relevant patient population.

2. A medicinal product for which an application has been submitted in accordance with Article 13 of [revised Directive 2001/83/EC] shall not be considered as addressing a high unmet medical need.

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.

Or. en

Justification

When assessing Unmet Medical Need (UMN), the viewpoint, context, and inclusivity are vital. Patients dealing with a disease may have distinct needs compared to a broader societal perspective. Creating a separate category of High Unmet Medical Need in orphan medicines compared to UMN presents challenges, including ethical concerns, as it might suggest that some UMN are of lesser importance. The proposed criteria substantially overlap with those of UMN, except for the "exceptional therapeutic advancement" factor.

Amendment 10

Proposal for a regulation
Article 71 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) ***nine*** years for orphan medicinal products other than those referred to in points (b) and (c);	(a) ***ten*** years for orphan medicinal products other than those referred to in points (b) and (c);

Or. en

Justification

Strengthened incentives are crucial to bridging the competitive divide with other regions and positioning the EU as a leading center for pioneering research and development of innovative

medicines in underserved areas. Therefore, it is recommended to tie enhanced baseline protection to objective criteria. This approach would provide sponsors with the necessary certainty to invest in particularly demanding and high-risk conditions, all while avoiding the establishment of a hierarchical scale for different levels of Unmet Medical Need (UMN).

Amendment 11

Proposal for a regulation
Article 71 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) ***ten*** years for orphan medicinal products ***addressing a high unmet medical need as referred to in Article 70;***	(b) ***eleven*** years for orphan medicinal products ***which fulfil one of the following requirements***

Or. en

Justification

Strengthened incentives are crucial to bridging the competitive divide with other regions and positioning the EU as a leading center for pioneering research and development of innovative medicines in underserved areas. Therefore, it is recommended to tie enhanced baseline protection to objective criteria. This approach would provide sponsors with the necessary certainty to invest in particularly demanding and high-risk conditions, all while avoiding the establishment of a hierarchical scale for different levels of Unmet Medical Need (UMN).

Amendment 12

Proposal for a regulation
Article 71 – paragraph 2 – point b – point i (new)

Text proposed by the Commission	*Amendment*
	i) there is no medicinal product authorised in the Union for such condition or where

Or. en

Justification

Strengthened incentives are crucial to bridging the competitive divide with other regions and positioning the EU as a leading center for pioneering research and development of innovative medicines in underserved areas. Therefore, it is recommended to tie enhanced baseline protection to objective criteria. This approach would provide sponsors with the necessary

certainty to invest in particularly demanding and high-risk conditions, all while avoiding the establishment of a hierarchical scale for different levels of Unmet Medical Need (UMN).

Amendment 13

Proposal for a regulation
Article 71 – paragraph 2 – point b – point ii (new)

Text proposed by the Commission	*Amendment*
	ii) despite medicinal products being authorised for such condition in the Union, the applicant demonstrates that the orphan medicinal product, in addition to having a significant benefit, will bring exceptional therapeutic advancement, or

Or. en

Justification

Strengthened incentives are crucial to bridging the competitive divide with other regions and positioning the EU as a leading center for pioneering research and development of innovative medicines in underserved areas. Therefore, it is recommended to tie enhanced baseline protection to objective criteria. This approach would provide sponsors with the necessary certainty to invest in particularly demanding and high-risk conditions, all while avoiding the establishment of a hierarchical scale for different levels of Unmet Medical Need (UMN).

Amendment 14

Proposal for a regulation
Article 71 – paragraph 2 – point b – point iii (new)

Text proposed by the Commission	*Amendment*
	iii) the condition affects not more than 0,5 in 10,000 persons in the Union when the application for an orphan designation is submitted.

Or. en

Justification

Strengthened incentives are crucial to bridging the competitive divide with other regions and positioning the EU as a leading center for pioneering research and development of innovative

medicines in underserved areas. Therefore, it is recommended to tie enhanced baseline protection to objective criteria. This approach would provide sponsors with the necessary certainty to invest in particularly demanding and high-risk conditions, all while avoiding the establishment of a hierarchical scale for different levels of Unmet Medical Need (UMN).

Amendment 15

Proposal for a regulation
Article 71 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) ***five*** years for orphan medicinal products which have been authorised in accordance with Article 13 of [revised Directive 2001/83/EC].	(c) ***six*** years for orphan medicinal products which have been authorised in accordance with Article 13 of [revised Directive 2001/83/EC].

Or. en

Justification

Strengthened incentives are crucial to bridging the competitive divide with other regions and positioning the EU as a leading center for pioneering research and development of innovative medicines in underserved areas. Therefore, it is recommended to tie enhanced baseline protection to objective criteria. This approach would provide sponsors with the necessary certainty to invest in particularly demanding and high-risk conditions, all while avoiding the establishment of a hierarchical scale for different levels of Unmet Medical Need (UMN).

Amendment 16

Proposal for a regulation
Article 72 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The periods of market exclusivity referred to in Article 71, paragraph 2, points (a) and (b), shall be prolonged by 12 months, where the orphan marketing authorisation holder can demonstrate that the conditions referred to in Article 81(2), point (a), and Article 82(1) [of revised Directive 2001/83/EC] are fulfilled. ***The procedures set out in Articles 82(2) to (5) [of revised Directive 2001/83/EC] shall***	***deleted***

accordingly apply to the prolongation of market exclusivity.

Or. en

Justification

OME periods should not be tied to access conditions in Member States. Linking them to "release and continuous supply" in all 27 Member States makes R&D incentives dependent on factors mostly beyond the control of medicine developers. Even under the best circumstances, concluding pricing and reimbursement negotiations with 27 Member States within two years is an almost insurmountable challenge for most companies, especially for SMEs, even with a three-year extension. This undermines the industry's existing levels of OME protection and fails to serve as a genuine incentive.

Amendment 17

Proposal for a regulation
Article 72 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
The period of market exclusivity shall be prolonged by an additional ***12*** months for orphan medicinal products referred to in Article 71(2), points (a) and (b), if at least two years before the end of the exclusivity period, the orphan marketing authorisation holder obtains a marketing authorisation for one or more new therapeutic indications for a different orphan condition.	The period of market exclusivity shall be prolonged by an additional ***24*** months for orphan medicinal products referred to in Article 71(2), points (a) and (b), if at least two years before the end of the exclusivity period, the orphan marketing authorisation holder obtains a marketing authorisation for one or more new therapeutic indications for a different orphan condition.

Or. en

Amendment 18

Proposal for a regulation
Article 72 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	If the newly approved therapeutic indication meets one of the requirements listed in Article 71(2) point (b), and when

	the first orphan marketing authorisation was not granted a period of market exclusivity as referred to in Article 71(2) point (b), the period of market exclusivity shall be prolonged by 36 months in total.

Or. en

Justification

Encouraging the development and approval of additional therapeutic indications is more beneficial than penalizing it. These can offer valuable treatment opportunities to more patients with rare conditions, requiring substantial additional development, particularly in various orphan conditions. Therefore, there should be no limitation on the number of OME extensions, as long as each pertains to a different orphan condition.

Amendment 19

Proposal for a regulation
Article 72 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
Such a prolongation may be granted twice, if the new therapeutic indications are each time for different orphan conditions.	***deleted***

Or. en

Amendment 20

Proposal for a regulation
Article 72 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2 a. The holder of an orphan marketing authorisation shall be entitled to a total maximum period of [15] years of orphan marketing exclusivity from the time the orphan medicinal product in question first obtains an authorization as defined in Article 69.

Or. en

Justification

Introducing a maximum exclusivity period is proposed to provide certainty to other stakeholders, aligning with the maximum protection offered by Supplementary Protection Certificates (SPC).

Amendment 21

Proposal for a regulation
Article 72 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2 b. As an alternative to the reward foreseen under Article 86 [of revised Directive 2001/83/EC] and upon request from the applicant, the period of market exclusivity for orphan medicinal products referred to in Article 71(2), points (a) and (b) shall be prolonged by an additional 24 months where an application for orphan marketing authorisation is submitted in respect of a designated orphan medicinal product pursuant to this Regulation and that the application includes the results of all studies conducted in compliance with an agreed paediatric investigation plan.
	The first sub-paragraph shall also apply when completion of the agreed paedriatic investigation plan fails to lead to the authorisation of a paedriatic indication, but the results of the studies conducted are reflected in the summary of the product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned. The 24 month extension of the period of market exclusivity shall be reflected in the marketing authorisation.

Or. en

Justification

While not frequently employed to date, the +2-year extension of OME as a reward for

Pediatric Investigation Plan (PIP) completion is a crucial option, potentially the only means of gaining an effective exclusivity extension, for some orphan products that may not benefit from SPC. As long as this possibility remains mutually exclusive with the SPC extension reward, it is fair and suitable to retain it in the revised legislation.

Amendment 22

Proposal for a regulation
Article 72 – paragraph 2 c (new)

Text proposed by the Commission	*Amendment*
	2 c. An orphan medicinal product which benefits from the prolongation of market exclusivity as referred to in paragraph 4, shall not benefit from the rewards referred to in Article 86 [of revised Directive 2001/83/EC].

Or. en

Amendment 23

Proposal for a regulation
Article 72 – paragraph 2 d (new)

Text proposed by the Commission	*Amendment*
	2 d. The limitation referred to in paragraph 3 shall not apply where the period of orphan marketing exclusivity is extended in accordance with paragraph 4 in relation to such extension.

Or. en

Amendment 24

Proposal for a regulation
Article 113 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) it is not possible to develop the	(a) it is not possible to ***adequately***

medicinal product or category of products in compliance with the requirements applicable to medicinal products due to scientific or regulatory challenges arising from characteristics or methods related to the product;	develop the medicinal product or category of products in compliance with the requirements applicable to ***such*** medicinal products due to scientific or regulatory challenges arising from characteristics or methods related to the product;

Or. en

Justification

Medicines regulators must have the flexibility to transcend legislative requirements and collaborate with developers to establish the necessary evidence criteria for ensuring high-quality, safe, and effective products for patients. The regulatory sandbox provision offers a solution for this. However, the Commission's proposals for a regulatory sandbox are confined to pharmaceuticals. As innovative products increasingly blend with medical devices, diagnostics, and digital tools, each governed by distinct frameworks, it is imperative to broaden the sandbox's scope.

Amendment 25

Proposal for a regulation
Article 113 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
The regulatory sandbox shall set out a regulatory framework, including scientific requirements, for the development and, where appropriate clinical trials and placing on the market of a product referred to in paragraph 1 under the conditions set out in this Chapter. The regulatory sandbox may allow targeted derogations to this Regulation, [revised Directive 2001/83/EC] or Regulation (EC) 1394/2007 under the conditions set out in Article 114.	The regulatory sandbox shall set out a regulatory framework, including scientific requirements, for the development and, where appropriate clinical trials and placing on the market of a product referred to in paragraph 1 under the conditions set out in this Chapter. The regulatory sandbox may allow targeted derogations to this Regulation, [revised Directive 2001/83/EC] or Regulation (EC) 1394/2007 ***and other applicable Union legislation*** under the conditions set out in Article 114.

Or. en

Justification

Medicines regulators must have the flexibility to transcend legislative requirements and collaborate with developers to establish the necessary evidence criteria for ensuring high-quality, safe, and effective products for patients. The regulatory sandbox provision offers a

solution for this. However, the Commission's proposals for a regulatory sandbox are confined to pharmaceuticals. As innovative products increasingly blend with medical devices, diagnostics, and digital tools, each governed by distinct frameworks, it is imperative to broaden the sandbox's scope.

Amendment 26

Proposal for a regulation
Article 113 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency shall monitor the field of emerging medicinal products and ***may*** request information and data from marketing authorisation holders, developers, independent experts and researchers, and representatives of healthcare professionals and of patients and ***may*** engage with them in preliminary discussions**.**	3. The Agency shall monitor the field of emerging medicinal products and ***shall*** request information and data from marketing authorisation holders, developers, independent experts and researchers, and representatives of healthcare professionals and of patients and ***shall*** engage with them in preliminary discussions***, where relevant by invoking the mechanism of consultation of Article 162***

Or. en

Justification

Medicines regulators must have the flexibility to transcend legislative requirements and collaborate with developers to establish the necessary evidence criteria for ensuring high-quality, safe, and effective products for patients. The regulatory sandbox provision offers a solution for this. However, the Commission's proposals for a regulatory sandbox are confined to pharmaceuticals. As innovative products increasingly blend with medical devices, diagnostics, and digital tools, each governed by distinct frameworks, it is imperative to broaden the sandbox's scope.

Amendment 27

Proposal for a regulation
Article 113 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
Where the Agency considers it appropriate to set up a regulatory sandbox for medicinal products ***which are likely to fall***	Where the Agency considers it appropriate to set up a regulatory sandbox for ***products which might be regulated as*** medicinal

under the scope of this Regulation, it shall provide a recommendation to the Commission. The Agency shall list eligible products or category of products in that recommendation and shall include the sandbox plan referred to in paragraph 1.	products ***(including advanced therapy medicinal products), medical devices, in-vitro diagnostics, substances of human origin***, it shall provide a recommendation to the Commission***, where relevant after invoking the mechanism of consultation of Article 162***. The Agency shall list eligible products or category of products in that recommendation and shall include the sandbox plan referred to in paragraph 1.

Or. en

Justification

Medicines regulators must have the flexibility to transcend legislative requirements and collaborate with developers to establish the necessary evidence criteria for ensuring high-quality, safe, and effective products for patients. The regulatory sandbox provision offers a solution for this. However, the Commission's proposals for a regulatory sandbox are confined to pharmaceuticals. As innovative products increasingly blend with medical devices, diagnostics, and digital tools, each governed by distinct frameworks, it is imperative to broaden the sandbox's scope.

Amendment 28

Proposal for a regulation
Article 113 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Agency shall be responsible for developing a sandbox plan based on data submitted by developers of eligible products and following appropriate consultations. The plan shall set out clinical, scientific and regulatory justification for a sandbox, including the identification of the requirements of this Regulation, [revised Directive 2001/83/EC] ***and*** Regulation (EC) 1394/2007 that cannot be complied with and a proposal for alternative or mitigation measures, where appropriate. The plan shall also include a proposed timeline for the duration of the sandbox. Where appropriate, the Agency shall also propose measures in order to mitigate any possible	5. The Agency shall be responsible for developing a sandbox plan based on data submitted by developers of eligible products and following appropriate consultations. The plan shall set out clinical, scientific and regulatory justification for a sandbox, including the identification of the requirements of this Regulation, [revised Directive 2001/83/EC]**,** Regulation (EC) 1394/2007 ***and other applicable Union legislation*** that cannot be complied with and a proposal for alternative or mitigation measures, where appropriate. The plan shall also include a proposed timeline for the duration of the sandbox. Where appropriate, the Agency shall also propose

distortion of market conditions as a consequence of establishing a regulatory.	measures in order to mitigate any possible distortion of market conditions as a consequence of establishing a regulatory.

Or. en

Justification

Medicines regulators must have the flexibility to transcend legislative requirements and collaborate with developers to establish the necessary evidence criteria for ensuring high-quality, safe, and effective products for patients. The regulatory sandbox provision offers a solution for this. However, the Commission's proposals for a regulatory sandbox are confined to pharmaceuticals. As innovative products increasingly blend with medical devices, diagnostics, and digital tools, each governed by distinct frameworks, it is imperative to broaden the sandbox's scope.

Amendment 29

Proposal for a regulation
Article 113 – paragraph 7 – point c

Text proposed by the Commission	*Amendment*
(c) include as part of the sandbox plan the requirements of this Regulation ***and*** of [revised Directive 2001/83/EC] that cannot be complied with and shall include appropriate measures to mitigate potential risks to health and to the environment.	(c) include as part of the sandbox plan the requirements of this Regulation of [revised Directive 2001/83/EC]***, of Regulation (EC) 1394/2007 and of other applicable Union legislation*** that cannot be complied with and shall include appropriate measures to mitigate potential risks to health and to the environment.

Or. en

Justification

Medicines regulators must have the flexibility to transcend legislative requirements and collaborate with developers to establish the necessary evidence criteria for ensuring high-quality, safe, and effective products for patients. The regulatory sandbox provision offers a solution for this. However, the Commission's proposals for a regulatory sandbox are confined to pharmaceuticals. As innovative products increasingly blend with medical devices, diagnostics, and digital tools, each governed by distinct frameworks, it is imperative to broaden the sandbox's scope.

Amendment 30

Proposal for a regulation
Article 113 – paragraph 9

Text proposed by the Commission	*Amendment*
9. Where after the Decision to establish the regulatory sandbox in accordance with paragraph 6, risks to health are identified but these risks can be fully mitigated by ***the adoption of supplementary*** conditions, the Commission may, after consultation of the Agency, amend its decision by means of implementing acts. The Commission may also prolong the duration of a regulatory sandbox by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 173(2).	9. Where after the Decision to establish the regulatory sandbox in accordance with paragraph 6, risks to health are identified but these risks can be fully mitigated by ***adapting the applicable requirements and*** conditions ***laid down in paragraphs 6 and 7***, the Commission may, after consultation of the Agency, amend its decision by means of implementing acts. The Commission may also prolong the duration of a regulatory sandbox by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 173(2).

Or. en

Justification

Medicines regulators must have the flexibility to transcend legislative requirements and collaborate with developers to establish the necessary evidence criteria for ensuring high-quality, safe, and effective products for patients. The regulatory sandbox provision offers a solution for this. However, the Commission's proposals for a regulatory sandbox are confined to pharmaceuticals. As innovative products increasingly blend with medical devices, diagnostics, and digital tools, each governed by distinct frameworks, it is imperative to broaden the sandbox's scope.

Amendment 31

Proposal for a regulation
Article 114 – paragraph 3

Text proposed by the Commission	*Amendment*
3. In duly justified cases, the marketing authorisation of a medicinal product developed under the regulatory sandbox may include derogations from the requirements set out in this Regulation ***and***	3. In duly justified cases, the marketing authorisation of a medicinal product developed under the regulatory sandbox may include derogations from the requirements set out in this Regulation**,**

[revised Directive 2001/83/EC]. Those derogations may entail adapted, enhanced, waived or deferred requirements. Each derogation shall be limited to what is apt and strictly necessary to attain the objectives pursued, duly justified and specified in the conditions to the marketing authorisation.	[revised Directive 2001/83/EC]***, Regulation (EC) 1394/2007 and of other applicable Union legislation***. Those derogations may entail adapted, enhanced, waived or deferred requirements. Each derogation shall be limited to what is apt and strictly necessary to attain the objectives pursued, duly justified and specified in the conditions to the marketing authorisation.

Or. en

Justification

The proposed amendment is proposed for consistency of the terms used across provisions.

Amendment 32

Proposal for a regulation
Article 115 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
The regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. In case of identification of risks to public health or safety concerns associated with the use of products covered by a sandbox, competent authorities shall take immediate and adequate temporary measures in order to ***suspend*** or restrict their use and inform the Commission in accordance with Article 113(2).	The regulatory sandboxes shall not affect the supervisory and corrective powers of the competent authorities. In case of identification of risks to public health or safety concerns associated with the use of products covered by a sandbox, competent authorities shall take immediate and adequate temporary measures in order to ***stop*** or restrict their use and inform the Commission in accordance with Article 113(2).

Or. en

Justification

The proposed amendment is proposed for consistency of the terms used across provisions.

Amendment 33

Proposal for a regulation
Article 115 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
Where such mitigation is not possible or proves to be ineffective, the development and testing process shall be suspended without delay until an effective mitigation takes place.	Where such mitigation is not possible or proves to be ineffective, the development and testing process shall be suspended without ***any*** delay until an effective mitigation takes place.

Or. en

Justification

The proposed amendment is proposed for consistency of the terms used across provisions.

Amendment 34

Proposal for a regulation
Article 116 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) a temporary disruption in supply of a medicinal product in a given Member State, of an expected duration of in excess of two weeks or, based on the demand forecast of the marketing authorisation holder no less than ***six*** months before the start of such temporary disruption of supply or, if this is not possible and where duly justified, as soon as they become aware of such temporary disruption, to allow the Member State to monitor any potential or actual shortage in accordance with Article 118(1).	(d) a temporary disruption in supply of a medicinal product in a given Member State, of an expected duration of in excess of two weeks or, based on the demand forecast of the marketing authorisation holder no less than ***three*** months before the start of such temporary disruption of supply or, if this is not possible and where duly justified, as soon as they become aware of such temporary disruption, to allow the Member State to monitor any potential or actual shortage in accordance with Article 118(1).

Or. en

Justification

Efficient and harmonized shortage reporting should not unduly prolong the notification period for temporary shortages. Extending the notification period is likely to result in a surge of notifications for potential temporary supply disruptions that may not translate into actual shortages, thereby complicating the detection of real shortages. Rather than extending the notification period too much, it is crucial to standardize the reporting of supply interruptions and define shortages and supply interruptions uniformly across the EU.

Amendment 35

Proposal for a regulation
Article 117 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The marketing authorisation holder as defined in Article 116(1) shall have in place and keep up to date a shortage prevention plan, for any medicinal product placed on the ***market***. To put in place the shortage prevention plan, the marketing authorisation holder shall include the minimum set of information set out in Part V of Annex IV and take into account the guidance drawn up by the Agency according to paragraph 2.	1. The marketing authorisation holder as defined in Article 116(1) shall have in place and keep up to date a shortage prevention plan, for any medicinal product placed on the ***Union list of critical medicinal products referred to in Article 131***. To put in place the shortage prevention plan, the marketing authorisation holder shall include the minimum set of information set out in Part V of Annex IV and take into account the guidance drawn up by the Agency according to paragraph 2.

Or. en

Justification

Current shortages prevention plans prove to be an effective method for averting shortages. However, mandating this requirement for non-critical medicines imposes a significant burden on both manufacturers and competent authorities, potentially becoming disproportionate. To ensure the security of medicine supply in Europe, a more effective strategy involves a risk-based approach that concentrates on critical products. This approach leads to the development of tailored shortage prevention plans for vital products through a collaborative process in a standardized format.

Amendment 36

Proposal for a regulation
Article 122 – paragraph 6

Text proposed by the Commission	*Amendment*
6. For the purposes of implementing this Regulation, the Agency shall expand the scope of the ESMP. The Agency shall ensure that***, where relevant,*** data is interoperable between the ESMP, Member States' IT systems and other relevant IT	6. For the purposes of implementing this Regulation, the Agency shall expand the scope of the ESMP. The Agency shall ensure that data is interoperable between the ESMP, Member States' IT ***regulatory and shortages reporting*** systems and other

systems and databases, without duplication of reporting.	relevant IT systems and databases, ***including the repositories system containing information on safety features referred to in Article 67, paragraph 2, second subparagraph, point (e) of Directive 2023/0132 (COD)*** without duplication of reporting ***for Marketing Authorisation Holders and National Competent Authorities***.

Or. en

Justification

Europe should strive for the establishment of a streamlined interoperable system for regulatory medicinal product data and shortages reporting, avoiding redundant reporting by marketing authorization holders and national competent authorities. This approach minimizes data disparities between the European Medicines Agency and National Medicines Agencies and reduces unnecessary administrative burdens for authorities and marketing authorization holders, who often face resource constraints.

ANNEX: LIST OF ENTITIES OR PERSONS FROM WHOM THE RAPPORTEUR HAS RECEIVED INPUT

The following list is drawn up under the exclusive responsibility of the rapporteur. The rapporteur has received input from the following entities or persons in the preparation of the draft opinion:

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