**European Parliament**
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*Committee on Industry, Research and Energy*

**2023/0132(COD)**

7.11.2023

# 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 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**
**Article 47 – paragraph 1 – point d**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (d) the ***environmental risk assessment is incomplete or insufficiently substantiated by the applicant or if the risks identified in the*** environmental risk assessment ***have not been sufficiently addressed by the applicant;*** | (d) The ***content or timelines of post-authorisation studies to further clarify*** environmental risk assessment***, as required under Article 44 (h), cannot be agreed.*** |

Or. en

*Justification*

*Rejecting initial marketing authorization solely on the basis of environmental risk assessment is not appropriate, especially in cases where the necessary data can only be gathered post-marketing or when there's no established scientific consensus (e.g., antimicrobial resistance) or overly conservative assumptions are utilized. A more suitable approach would involve promoting the collection of high-quality post-approval data, accompanied by binding and time-constrained commitments as outlined in Article 44 and 87.*

**Amendment 2**

**Proposal for a directive**
**Article 58 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Article 58a*** |
| | ***Obligation to submit an application for pricing and reimbursement in all Member States*** |
| | ***1. The marketing authorisation holder shall, upon request by a Member State in which the marketing authorisation is valid, submit in good faith an application for pricing and reimbursement no later than two years from the date when the Member State made its request, or within four years from that date for any of the following entities:*** |
| | ***(i) SMEs;*** |
| | ***(ii) entities not engaged in an economic activity ('not-for-profit entity'); and*** |
| | ***(iii) undertakings that, by the time of granting the marketing authorisation, have received not more than seven centralised marketing authorisations for the undertaking concerned or, in the case of an undertaking belonging to a group, for the group of which it is part, since the establishment of the undertaking or the group, whichever is earliest. For the purposes of this Directive and [revised Regulation (EC) No 726/2004], the Commission shall by ... [18 months after the date of entry into force of this Directive] adopt delegated acts in accordance with Article 215 to supplement this Directive by laying down the criteria to qualify as a micro, small and medium-sized enterprise, taking into account the specificities of enterprises of this sector within the Union. The marketing authorisation holder shall notify that it fulfilled the obligations set out in the first subparagraph through the EU Access to Medicines Notification*** |

***System provided for in Article 58b.***

***2. For the purposes of paragraph 1 of this Article, Member States shall make their request within two years of the granting of a marketing authorisation. Following the filing for pricing and reimbursement by the marketing authorisation holder, Directive 89/105/EEC shall apply. Where a Member State has not complied with the timelines laid down in Directive 89/105/EEC, the obligation on the marketing authorisation holder set out in this Article shall be considered to be fulfilled in that Member State.***

***3. By way of derogation from paragraph 1, the marketing authorisation holder for a designated orphan medicinal product or for an advanced therapy medicinal product may choose instead: (a) to make a medicinal product directly available to patients and the prescribing doctors who requested it; or (b) to submit an application for pricing and reimbursement only in the Member States where the relevant patient population has been identified.***

***4. Following agreement between a Member State and a marketing authorisation holder, timelines that are different from those set out in paragraphs 1 and 2 may apply. A Member State may choose, after making a request in accordance with paragraph 1, to issue a product-specific waiver after which the obligation to submit an application shall cease.***

***5. The Commission shall, after consultation of the Agency, adopt by means of implementing acts a list of products to be exempted from the obligations set out in this Article. Inclusion of a medicinal product in that list may be based on criteria such as the administration of a medicinal product in most Member States being impracticable. Those implementing acts shall be adopted in accordance with the examination***

***procedure referred to in Article 214(2).***

***6. Where a marketing authorisation is transferred to a different legal entity before the end of the period referred to in paragraph 1, the obligations shall be transferred to the new marketing authorisation holder.***

***7. The Commission shall by means of implementing acts establish a conciliation mechanism to facilitate discussions between applicants and Member States to resolve potential disputes related to the submission of applications for pricing and reimbursement and Directive 89/105/EEC. In the event of continued disagreement between an applicant and a Member State regarding the fulfilment of the obligations set out in this Article, the Commission shall be empowered to issue a legally binding Commission decision following an opinion of the Agency.***

Or. en

**Amendment 3**

**Proposal for a directive**
**Article 58 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Article 58b*** |
| | ***EU Access to Medicines Notification System*** |
| | ***1. The Commission shall, in collaboration with the Member States, set up and maintain an electronic notification system (the "EU Access to Medicines Notification System") as a single-entry point for the notification of compliance with the obligations set out in Article 58a. The EU Access to Medicines Notification System shall be interoperable with the other Union-wide data repositories for medicinal products.*** |
| | ***2. The marketing authorisation holder*** |

***shall use the EU Access to Medicines Notification System to notify their compliance with the obligations set out in Article 58a. In the Member States where the marketing authorisation is valid, the national competent authority shall use the EU Access to Medicines Notification System to indicate that the marketing authorisation holder has fulfilled its obligations set out in Article 58a.***

***3. By ... [3 years following the date of entry into force of this Directive], the Commission shall adopt implementing acts to establish technical and organisational requirements, including on security aspects and data governance, which are necessary for the practical implementation of the EU Access to Medicines Notification System. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).***

***4. By ... [5 years after the date of entry into force of this Directive] and every 3 years thereafter, the Commission shall present a report to the European Parliament and the Council on the use and functioning of the EU Access to Medicines Notification System.***

***5. By ... [5 years after the date of entry into force of this Directive], the Commission shall assess the feasibility of extending the EU Access to Medicines Notification System to other areas of the process for pricing of medicinal products as set out in Directive 89/105/EEC and, if appropriate, adopt implementing acts to establish this extended system. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2)***

Or. en

**Amendment 4**

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

Or. en

*Justification*

*To compete effectively on a global scale, it's essential, among other measures, to extend EU Regulatory Data Protection (RDP) to at least 9 years to maintain attractiveness for investments.*

**Amendment 5**

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

| *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:*** | ***deleted*** |
| ***(i) SMEs within the meaning of Commission Recommendation 2003/361/EC;*** | |
| ***(ii) entities not engaged in an economic activity ('not-for-profit entity'); and*** | |
| ***(iii) undertakings that, by the time of*** | |

***granting of a marketing authorisation, have received not more than five centralised marketing authorisations for the undertaking concerned or, in the case of an undertaking belonging to a group, for the group of which it is part, since the establishment of the undertaking or the group, whichever is earliest.***

Or. en

*Justification*

*Tying the recovery of the 2-year lost RDP period to the release and continuous supply of a medicinal product fails to account for factors outside the control of marketing authorization holders. This proposal inadequately considers the intricacies of the regulatory landscape, national market access schemes, and healthcare expenditure choices. As a result, it disproportionately penalizes the industry for factors largely beyond its control, without improving patient access to innovative medicines.*

**Amendment 6**

**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) ***one year***, 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; |

Or. en

*Justification*

*Recognizing and appropriately rewarding substantial efforts in conducting comparative trials, when warranted, is important. Increasing the length of RDP by one year serves this purpose.*

**Amendment 7**

**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) ***one year***, 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; |

Or. en

*Justification*

*Recognizing and appropriately rewarding substantial efforts in conducting comparative trials, when warranted, is important. Increasing the length of RDP by one year serves this purpose.*

**Amendment 8**

**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).*** |

Or. en

**Amendment 9**

**Proposal for a directive**
**Article 83 – paragraph 1 – introductory part**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 1. A medicinal product shall be considered as addressing an unmet medical need if at least one of its therapeutic indications relates to a life threatening ***or*** severely debilitating disease and the following conditions are met: | 1. A medicinal product shall be considered as addressing an unmet medical need if at least one of its therapeutic indications relates to a ***progressive,*** life threatening**,** severely debilitating ***or chronic*** disease and the following conditions are met: |

Or. en

*Justification*

*An overly restrictive definition of unmet medical need poses the risk of excluding vital therapeutic developments for patients. This approach inadvertently discourages companies from investing in R&D that could have addressed significant unmet medical needs, reducing overall predictability. Additionally, patients often assign different values to the impact of new treatments compared to society. Society may prioritize incremental improvements for diseases with substantial societal burdens or those that aid in preventing future pandemics.*

**Amendment 10**

**Proposal for a directive**
**Article 83 – paragraph 1 – point a**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (a) there is no medicinal product authorised in the Union for such disease, or, where despite medicinal products being authorised for such disease in the Union, the disease is associated with a remaining ***high*** morbidity ***or*** mortality; | (a) there is no medicinal product authorised in the Union for such disease, or, where despite medicinal products being authorised for such disease in the Union, the disease is associated with a remaining morbidity**,** mortality ***or impact on quality of life***; |

Or. en

*Justification*

*An overly restrictive definition of unmet medical need poses the risk of excluding vital therapeutic developments for patients. This approach inadvertently discourages companies from investing in R&D that could have addressed significant unmet medical needs, reducing overall predictability. Additionally, patients often assign different values to the impact of new*

*treatments compared to society. Society may prioritize incremental improvements for diseases with substantial societal burdens or those that aid in preventing future pandemics.*

**Amendment 11**

**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 in<br><br>***(i)*** a meaningful reduction in disease morbidity***,*** mortality***, severity or side effects*** for the relevant patient population***; or***<br><br>***(ii) a meaningful positive impact on quality of life; or***<br><br>***(iii) a meaningful prevention, delay of the onset, or delay of progression of the disease or its complications***. |

Or. en

*Justification*

*An overly restrictive definition of unmet medical need poses the risk of excluding vital therapeutic developments for patients. This approach inadvertently discourages companies from investing in R&D that could have addressed significant unmet medical needs, reducing overall predictability. Additionally, patients often assign different values to the impact of new treatments compared to society. Society may prioritize incremental improvements for diseases with substantial societal burdens or those that aid in preventing future pandemics.*

**Amendment 12**

**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 | 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]. | 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 and other relevant stakeholders***. |

Or. en

*Justification*

*It is of critical importance that the appropriate stakeholders are involved in identifying unmet medical needs from different perspectives. Collaborations need to be established to get an aligned understanding of UMN.*

**Amendment 13**

**Proposal for a directive**
**Article 85 – paragraph 1 – introductory part**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Patent rights, or supplementary protection certificates under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted] shall not be regarded as infringed when a ***reference*** medicinal product is used for the ***purposes*** of: | Patent rights, or supplementary protection certificates under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted] shall not be regarded as infringed when a medicinal product is used for the ***exclusive purpose*** of: |

Or. en

*Justification*

*A well-defined Bolar exemption that streamlines the regulatory approval process is crucial. It should cover strictly necessary activities, even when conducted by third parties in a reactive manner, while maintaining a precise scope to prevent misuse. Yet, extending the Bolar exemption to cover commercial or pre-commercial actions at the national level, such as pricing and reimbursement applications, is unwarranted. Such an extension would only facilitate risk-driven launches, jeopardizing patent rights' effectiveness in Europe and undermining their reliability.*

**Amendment 14**

**Proposal for a directive**
**Article 85 – paragraph 1 – point a – introductory part**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (a) studies***,*** trials ***and other activities*** conducted to generate data for an application***, for:*** | (a) ***Necessary*** studies ***and*** trials conducted to generate data for an application ***for a marketing authorisation.*** |

Or. en

*Justification*

*A well-defined Bolar exemption that streamlines the regulatory approval process is crucial. It should cover strictly necessary activities, even when conducted by third parties in a reactive manner, while maintaining a precise scope to prevent misuse. Yet, extending the Bolar exemption to cover commercial or pre-commercial actions at the national level, such as pricing and reimbursement applications, is unwarranted. Such an extension would only facilitate risk-driven launches, jeopardizing patent rights' effectiveness in Europe and undermining their reliability.*

**Amendment 15**

**Proposal for a directive**
**Article 85 – paragraph 1 – point a – point i**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| ***(i) a marketing authorisation of generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent variations;*** | ***deleted*** |

Or. en

*Justification*

*A well-defined Bolar exemption that streamlines the regulatory approval process is crucial. It should cover strictly necessary activities, even when conducted by third parties in a reactive manner, while maintaining a precise scope to prevent misuse. Yet, extending the Bolar exemption to cover commercial or pre-commercial actions at the national level, such as pricing and reimbursement applications, is unwarranted. Such an extension would only facilitate risk-driven launches, jeopardizing patent rights' effectiveness in Europe and undermining their reliability.*

**Amendment 16**

**Proposal for a directive**
**Article 85 – paragraph 1 – point a – point ii**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| ***(ii) health technology assessment as defined in Regulation (EU) 2021/2282;*** | ***deleted*** |

Or. en

*Justification*

*A well-defined Bolar exemption that streamlines the regulatory approval process is crucial. It should cover strictly necessary activities, even when conducted by third parties in a reactive manner, while maintaining a precise scope to prevent misuse. Yet, extending the Bolar exemption to cover commercial or pre-commercial actions at the national level, such as pricing and reimbursement applications, is unwarranted. Such an extension would only facilitate risk-driven launches, jeopardizing patent rights' effectiveness in Europe and undermining their reliability.*

**Amendment 17**

**Proposal for a directive**
**Article 85 – paragraph 1 – point b**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (b) ***the activities conducted exclusively for the purposes*** set out in point (a), ***may cover the submission of the application for a marketing authorisation and the offer,*** manufacture, sale, supply, storage, import, use and purchase of patented medicinal products or processes, including by third party suppliers and service providers. | (b) ***any necessary activity*** set out in point (a), ***which may include the*** manufacture, sale, supply, storage, import, use and purchase of patented medicinal products or processes, including by third party suppliers and service providers. |

Or. en

*Justification*

*A well-defined Bolar exemption that streamlines the regulatory approval process is crucial. It should cover strictly necessary activities, even when conducted by third parties in a reactive manner, while maintaining a precise scope to prevent misuse. Yet, extending the Bolar exemption to cover commercial or pre-commercial actions at the national level, such as pricing and reimbursement applications, is unwarranted. Such an extension would only facilitate risk-driven launches, jeopardizing patent rights' effectiveness in Europe and undermining their reliability.*

**Amendment 18**

**Proposal for a directive**
**Article 85 – paragraph 2**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| This exception shall not cover the placing on the market of the medicinal products resulting from such activities. | This exception ***shall cover the submission of the application for marketing authorisation. It*** shall not cover the placing on the market of the medicinal products resulting from such activities. |

Or. en

*Justification*

*A well-defined Bolar exemption that streamlines the regulatory approval process is crucial. It should cover strictly necessary activities, even when conducted by third parties in a reactive manner, while maintaining a precise scope to prevent misuse. Yet, extending the Bolar exemption to cover commercial or pre-commercial actions at the national level, such as pricing and reimbursement applications, is unwarranted. Such an extension would only facilitate risk-driven launches, jeopardizing patent rights' effectiveness in Europe and undermining their reliability.*

**Amendment 19**

**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 or public health has been identified and not sufficiently addressed by the marketing authorisation holder ***via conditions laid out in Articles 44(h) or 87(c)***. |

Or. en

*Justification*

*The significance of conducting an ERA as part of the marketing authorization process for medicinal products is undisputed. However, the idea of suspending, revoking or altering a*

*marketing authorization for environmental reasons seems unwarranted and could affect patient access to medicines if not associated with the conditions of marketing authorization. A more suitable approach involves implementing binding, time-limited post-authorization commitments to grant market authorization holders the chance to address data indicating potential serious environmental risks.*

**Amendment 20**

**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)***. |

Or. en

*Justification*

*The prospect of restricting the supply or withdrawing a medicinal product based on environmental concerns may be unwarranted and could adversely affect patient access to essential medications. A more suitable approach entails the utilization of binding, time-limited post-authorization commitments or similar measures, providing market authorization holders with the opportunity to address data that indicate potential serious environmental risks.*

## 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 |