



2023/0131(COD)

20.10.2023

*****I**

DRAFT REPORT

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))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Tiemo Wölken

Rapporteur for the opinion of the associated committee pursuant to Rule 57 of the Rules of Procedure:

Henna Virkkunen, Committee on Industry, Research and Energy

Symbols for procedures

- * Consultation procedure
- *** Consent procedure
- ***I Ordinary legislative procedure (first reading)
- ***II Ordinary legislative procedure (second reading)
- ***III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act**Amendments by Parliament set out in two columns**

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ***■*** symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.

By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

**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))**

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2023)0193),
 - having regard to Article 294(2) and Article 114 and Article 168(4), point (c), of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0144/2023),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of ...¹,
 - having regard to the opinion of the Committee of the Regions of ...²,
 - having regard to Rule 59 of its Rules of Procedure,
 - having regard to the opinion of the Committee on Industry, Research and Energy,
 - having regard to the letters from the Committee on Budgets and the Committee on Agriculture and Rural Development,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety (A9-0000/2023),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

¹ OJ C 0, 0.0.0000, p. 0. / Not yet published in the Official Journal.

² OJ C 0, 0.0.0000, p. 0. / Not yet published in the Official Journal.

Amendment 1

Proposal for a regulation Recital 9

Text proposed by the Commission

(9) As to the scope of this Regulation, the authorisation of antimicrobials is, ***in principle***, in the interest of patients' health at Union level and therefore it should be made possible to authorise them at Union level.

Amendment

(9) As to the scope of this Regulation, the authorisation of antimicrobials is in the interest of patients' health at Union level and therefore it should be made possible to authorise them at Union level.

Or. en

Amendment 2

Proposal for a regulation Recital 30

Text proposed by the Commission

(30) The Agency should be empowered to give scientific recommendations on whether a product under development, which could potentially fall under the mandatory scope of the centralised procedure, meets the scientific criteria to be a medicinal product. Such an advisory mechanism would address, as early as possible, questions related to borderline cases with other areas such as substances of human origin, cosmetics or medical devices, which may arise as science develops. To ensure that recommendations given by the Agency take into account the views of equivalent advisory mechanisms in other legal frameworks, the Agency should consult the relevant advisory or regulatory bodies.

Amendment

(30) The Agency should be empowered to give scientific recommendations on whether a product under development, which could potentially fall under the mandatory scope of the centralised procedure, meets the scientific criteria to be a medicinal product. Such an advisory mechanism would address, as early as possible, questions related to borderline cases with other areas such as ***in particular*** substances of human origin, cosmetics or medical devices, which may arise as science develops. To ensure that recommendations given by the Agency take into account the views of equivalent advisory mechanisms in other legal frameworks, the Agency should consult the relevant advisory or regulatory bodies.

Or. en

Amendment 3

Proposal for a regulation

Recital 36

Text proposed by the Commission

(36) The expertise of the Committee for Advanced Therapies (CAT), the Committee for Orphan Medicinal Products (COMP), the Paediatric Committee (PDCO) and Committee for Herbal Medicinal Products (HMPC) is retained through working groups, working parties and a pool of experts who are organised based on different domains and who are giving input to the CHMP and PRAC. The CHMP and PRAC consists of experts from all Member States while working parties consist in majority of experts appointed by the Member States, based on their expertise, and of external experts. The model of rapporteurs remains unchanged. Representation of patients and health care professionals, with expertise in all areas, including rare and paediatric diseases, is increased at the CHMP and PRAC, in addition to the dedicated working groups representing patients and health care professionals.

Amendment

(36) The expertise of the Committee for Advanced Therapies (CAT), the Committee for Orphan Medicinal Products (COMP), the Paediatric Committee (PDCO) and Committee for Herbal Medicinal Products (HMPC) is retained through working groups, ***ad-hoc working groups***, working parties and a pool of experts who are organised based on different domains and who are giving input to the CHMP and PRAC. The CHMP and PRAC consists of experts from all Member States while working parties consist in majority of experts appointed by the Member States, based on their expertise, and of external experts. The model of rapporteurs remains unchanged. Representation of patients and health care professionals, with expertise in all areas, including rare and paediatric diseases, is increased at the CHMP and PRAC, in addition to the dedicated working groups representing patients and health care professionals.

Or. en

Amendment 4

Proposal for a regulation

Recital 39

Text proposed by the Commission

(39) To allow for a more informative decision making and for exchange of information and pooling of knowledge on general issues of scientific or technical nature related to the tasks of the Agency regarding medicinal products for human

Amendment

(39) To allow for a more informative decision making and for exchange of information and pooling of knowledge on general issues of scientific or technical nature related to the tasks of the Agency regarding medicinal products for human

use, in particular to scientific guidelines on unmet medical needs and the design of clinical trials, or other studies and the generation of evidence along the life cycle of medicinal product, the Agency should be able to have recourse to a consultation process of authorities or bodies active along the life cycle of medicinal products. These authorities could be, as appropriate, representatives from Heads of Medicines Agencies, the Clinical Trial Coordination and Advisory Group, the SoHO Coordination Board, the Coordination Group on Health Technology Assessment, Medical Devices Coordination Group, medical devices national competent authorities, national competent authorities for pricing and reimbursement of medicines, national insurance funds or healthcare payers. The Agency should also be able to extend the consultation mechanism to consumers, patients, healthcare professionals, industry, associations representing payers, or other stakeholders, as relevant.

use, in particular to scientific guidelines on unmet medical needs and the design of clinical trials, or other studies and the generation of evidence along the life cycle of medicinal product, the Agency should be able to have recourse to a consultation process of authorities or bodies active along the life cycle of medicinal products. These authorities could be, as appropriate, representatives from Heads of Medicines Agencies, the Clinical Trial Coordination and Advisory Group, the SoHO Coordination Board, the Coordination Group on Health Technology Assessment, Medical Devices Coordination Group, medical devices national competent authorities, national competent authorities for pricing and reimbursement of medicines, national insurance funds or healthcare payers. The Agency should also be able to extend the consultation mechanism to consumers, patients, healthcare professionals, industry, associations representing payers, *academia* or other stakeholders, as relevant.

Or. en

Amendment 5

Proposal for a regulation Recital 43

Text proposed by the Commission

(43) In the interest of public health, marketing authorisation decisions under the centralised procedure should be taken on the basis of the objective scientific criteria of quality, safety and efficacy of the medicinal product concerned, to the exclusion of economic and other considerations. However, Member States should be able, exceptionally, to prohibit the use in their territory of medicinal products for human use.

Amendment

(43) In the interest of public health, marketing authorisation decisions under the centralised procedure should be taken on the basis of the objective scientific criteria of quality, safety and efficacy of the medicinal product concerned, to the exclusion of economic and other considerations. However, Member States should be able, exceptionally, to prohibit the use in their territory of medicinal products for human use. ***Member States should provide due justification for such***

prohibition to the Agency.

Or. en

Amendment 6

Proposal for a regulation Recital 60

Text proposed by the Commission

(60) Regulatory decision-making on the development, authorisation and supervision of medicinal products may be supported by access and analysis of health data, including real world data, where appropriate, i.e. health data generated outside of clinical studies. The Agency should be able to use such data, including via the Data Analysis and Real World Interrogation Network (DARWIN) and the European Health Data Space interoperable infrastructure. Through these capabilities the Agency may take advantage of all the potential of supercomputing, artificial intelligence and big data science to fulfil its mandate, without compromising privacy rights. Where necessary the Agency may cooperate with the competent authorities of the Member States towards this objective.

Amendment

(60) Regulatory decision-making on the development, authorisation and supervision of medicinal products may be supported by access and analysis of health data, including real world data, where appropriate, i.e. health data generated outside of clinical studies. The Agency should be able to use such data, including via the Data Analysis and Real World Interrogation Network (DARWIN) and the European Health Data Space interoperable infrastructure. Through these capabilities the Agency may take advantage of all the potential of supercomputing, artificial intelligence and big data science to fulfil its mandate, without compromising privacy rights. ***In this regard, the Agency should also engage in a systematic early and continuous dialogue on the collection of real-world-data with the Member State Coordination Group on Health Technology Assessment in accordance with Regulation (EU) 2021/2282, payers, healthcare professionals, patient and consumer organisations and developers.*** Where necessary the Agency may cooperate with the competent authorities of the Member States towards this objective.

Or. en

Amendment 7

Proposal for a regulation Recital 67

Text proposed by the Commission

(67) The Agency, in consultation with the Member States and the Commission, should set the scientific selection criteria for medicinal products that receive pre-authorisation support with priority to be given to the most promising developments in therapies. In the case of medicinal products for unmet medical needs, based on the scientific selection criteria set by the Agency, any interested developer can submit preliminary evidence to demonstrate that the medicinal product has the potential to provide a major therapeutic advancement with respect to the identified unmet medical need.

Amendment

(67) The Agency, in consultation with the Member States and the Commission, should set the scientific selection criteria for medicinal products that receive pre-authorisation support with priority to be given to the most promising developments in therapies. In the case of medicinal products for unmet medical needs, based on the scientific selection criteria set by the Agency, any interested developer can submit preliminary evidence to demonstrate that the medicinal product has the potential to provide a major therapeutic advancement with respect to the identified unmet medical need. ***Information on the advice given in relation to the enhanced scientific and regulatory support for priority medicinal products should be included in a dedicated specific section within the European public assessment report.***

Or. en

Amendment 8

Proposal for a regulation Recital 68

Text proposed by the Commission

(68) Before a medicinal product for human use is authorised for placing on the market of one or more Member States, it generally has to undergo extensive studies to ensure that it is safe, of high quality and effective for use in the target population. However, in the case of certain categories of medicinal products for human use, in order to meet unmet medical needs of

Amendment

(68) Before a medicinal product for human use is authorised for placing on the market of one or more Member States, it generally has to undergo extensive studies to ensure that it is safe, of high quality and effective for use in the target population. However, in the case of certain categories of medicinal products for human use, in order to meet unmet medical needs of

patients and in the interest of public health, it may be necessary to grant marketing authorisation on the basis of less complete data than is normally the case. Such marketing authorisation should be granted subject to specific obligations. The categories of medicinal products for human use concerned should be the medicinal products, including orphan medicinal products, that aim at the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases, or that are intended to be used in emergency situations in response to public health threats.

patients and in the interest of public health, it may be necessary to grant **a conditional** marketing authorisation on the basis of less complete data than is normally the case. Such marketing authorisation should be granted subject to specific obligations. The categories of medicinal products for human use concerned should be the medicinal products, including orphan medicinal products, that aim at the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases, or that are intended to be used in emergency situations in response to public health threats.

Or. en

Amendment 9

Proposal for a regulation Recital 76

Text proposed by the Commission

(76) It is considered appropriate to also have the possibility for the Commission to grant temporary emergency marketing authorisations to address public health emergencies. Temporary emergency marketing authorisations may be granted provided that, having regard to the circumstances of the public health emergency, the benefit of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent to the fact that additional comprehensive quality, non-clinical, clinical data may still be required. A temporary emergency marketing authorisation should be valid only during the public health emergency. The Commission should be given the possibility to vary, suspend or revoke such marketing authorisations in order to protect public health or when the marketing authorisation holder has not complied with

Amendment

(76) It is considered appropriate to also have the possibility for the Commission to grant temporary emergency marketing authorisations to address public health emergencies. Temporary emergency marketing authorisations may be granted provided that, having regard to the circumstances of the public health emergency, the benefit of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent to the fact that additional comprehensive quality, non-clinical, clinical data may still be required. A temporary emergency marketing authorisation should be valid only during the public health emergency. The Commission should be given the possibility to vary, suspend or revoke such marketing authorisations in order to protect public health or when the marketing authorisation holder has not complied with

the conditions and obligations set out in the temporary emergency marketing authorisation.

the conditions and obligations set out in the temporary emergency marketing authorisation ***or when the marketing authorisation holder has been granted a standard or conditional marketing authorisation for the relevant indication.***

Or. en

Amendment 10

Proposal for a regulation Recital 76 a (new)

Text proposed by the Commission

Amendment

(76a) It is imperative to have in place robust transparency measures and standards regarding the Agency's regulatory activities in relation to medicinal products that receive a temporary emergency marketing authorisation. Those measures should include the timely publication of all relevant information on approved medicinal products and medical devices and of clinical data, including clinical trial protocols. The public information regarding clinical trials and marketing authorisation decisions should be in accordance with Regulation (EU) 2022/123 of the European Parliament and of the Council^{1a}.

^{1a} Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1).

Or. en

Amendment 11

Proposal for a regulation Recital 77

Text proposed by the Commission

(77) The development of antimicrobial resistance is a growing concern and the pipeline of effective antimicrobials is obstructed due to a market failure; it is therefore necessary to consider new measures to promote the development of priority antimicrobials that are effective against antimicrobial resistance and to support undertakings, often SMEs, which choose to invest in this area.

Amendment

(77) The development of antimicrobial resistance is a growing concern and the pipeline of effective antimicrobials is obstructed due to a market failure ***whereby pharmaceutical companies neglect investment in research and development (R&D) concerning novel antibiotics due to profitability considerations***; it is therefore necessary to consider new measures to promote the development of priority antimicrobials that are effective against antimicrobial resistance and to support undertakings, often SMEs, which choose to invest in this area.

Or. en

Amendment 12

Proposal for a regulation Recital 78 a (new)

Text proposed by the Commission

Amendment

(78a) In addition to the growing threat of antimicrobial resistance, there are other market failures present in the pharmaceutical sector for which further action at Union level is required to meet the public health needs of Union citizens. In particular, there is a stark misalignment between the R&D priorities of the pharmaceutical industry and the public health needs of Union citizens. The market failures in the Union have, in certain instances, also resulted in excessive prices for medicinal products and have led to shortages of medicinal products. This Regulation should therefore address those market failures to

better deliver on the objectives of affordability, accessibility and availability of medicinal products in the Union.

Or. en

Amendment 13

Proposal for a regulation Recital 78 b (new)

Text proposed by the Commission

Amendment

(78b) Member States, the Union, third countries, international organisations and agencies have identified the key areas of priority pharmaceutical research, including novel antibiotics and antivirals, improved diagnostics and treatments for emerging infectious diseases, affordable and efficacious medicinal products in the areas oncology, neurodegenerative diseases and other areas of unmet medical need for which the development of orphan medicinal products is needed. However, while Member States and the Union offer generous corporate R&D subsidies as well as R&D tax incentives to stimulate pharmaceutical research, there is little evidence to suggest, and no obligation to ensure, that the composition of R&D portfolios of pharmaceutical companies is determined by such direct or indirect subsidies. It is therefore increasingly evident that effective public health policy is undermined by shortcomings in transparency and accountability in public expenditure directed towards health.

Or. en

Amendment 14

Proposal for a regulation Recital 78 c (new)

(78c) Those market failures highlight the need for a paradigm shift in both the Member States' and the Union's approach to generating pharmaceutical R&D in key areas of priority and in public expenditure directed towards health. The establishment of a mission oriented R&D facility at Union level which acts in the public interest could alleviate those market failures. The European Medicines Facility ('EMF') should therefore be established as an independent agency under this Regulation. The EMF should be tasked with conducting research and developing novel antimicrobials as well as with regard to other areas of unmet medical need, to support the Union to overcome market failures.

Or. en

Amendment 15

Proposal for a regulation Recital 79

(79) The creation of a voucher rewarding the development of priority antimicrobials through an additional year of regulatory data protection has the capacity to provide the needed financial support to developers of priority antimicrobials. However, in order to ensure that the financial reward which is ultimately borne by health systems is mostly absorbed by the developer of the priority antimicrobial and not the buyer of the voucher, the number of available vouchers on the market should be kept to a minimum. It is therefore necessary to establish strict conditions of granting, transfer and use of the voucher and to

deleted

further give the possibility to the Commission to revoke the voucher under certain circumstances.

Or. en

Amendment 16

Proposal for a regulation Recital 80

Text proposed by the Commission

Amendment

(80) *A transferable data exclusivity voucher should only be available to those antimicrobial products that bring a significant clinical benefit with respect to antimicrobial resistance, and which have the characteristics described in this Regulation. It is also necessary to ensure that an undertaking which receives this incentive is in turn capable to supply the medicinal product to patients across the Union in sufficient quantities and to provide information on all funding received for research related to its development in order to provide a full account of the direct financial support given to the medicinal product.* **deleted**

Or. en

Amendment 17

Proposal for a regulation Recital 81

Text proposed by the Commission

Amendment

(81) *To ensure a high level of transparency and complete information on the economic effect of the transferable data exclusivity voucher, notably as regards the risk of overcompensation of investment, a developer of a priority* **deleted**

antimicrobial is required to provide information on all direct financial support received for research related to the development of the priority antimicrobial. The declaration should include direct financial support received from any source worldwide.

Or. en

Amendment 18

Proposal for a regulation Recital 82

Text proposed by the Commission

Amendment

(82) A transfer of a voucher for a priority antimicrobial may be conducted by sale. The value of the transaction which may be monetary or otherwise agreed between the buyer and the seller, shall be made public so as to inform regulators and the public. The identity of the holder of a voucher that has been granted and not yet used should be publicly known at all times so as to ensure a maximum level of transparency and trust.

deleted

Or. en

Amendment 19

Proposal for a regulation Recital 83

Text proposed by the Commission

Amendment

(83) The provisions related to transferable data exclusivity vouchers shall be applicable for a specified period from the entry into force of this Regulation or until a maximum number of vouchers are granted by the

deleted

Commission in order to limit the total cost of the measure to Member State health systems. The limited application of the measure will also provide the possibility to assess the effect of the measure in addressing the market failure in the development of new antimicrobials addressing antimicrobial resistance and assess the cost on national health systems. Such assessment will provide the necessary knowledge to decide whether to extend the application of the measure.

Or. en

Amendment 20

Proposal for a regulation Recital 84

Text proposed by the Commission

Amendment

(84) *The period of application of the provisions on transferable exclusivity vouchers for priority antimicrobials and the total number of vouchers may be extended by the Parliament and the Council upon proposal by the Commission on the basis of the experience acquired.*

deleted

Or. en

Amendment 21

Proposal for a regulation Recital 90

Text proposed by the Commission

Amendment

(90) Objective criteria for the orphan designation based on the prevalence of the life-threatening or chronically debilitating condition for which diagnosis, prevention or treatment is sought and the existence of

(90) Objective criteria for the orphan designation based on the prevalence of the life-threatening or chronically debilitating condition for which diagnosis, prevention or treatment is sought and the existence of

no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in the Union should be maintained; a prevalence of not more than five affected persons per 10 000 is generally regarded as the appropriate threshold. The orphan designation criterion on the basis of return on investment *has been abolished, since it has never been used.*

no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in the Union should be maintained; a prevalence of not more than five affected persons per 10 000 is generally regarded as the appropriate threshold. The orphan designation criterion on the basis of return on investment *should be mandatory during the review and, where necessary, the marketing exclusivity should be reduced where it is shown on the basis of available evidence that the product is sufficiently profitable, and that therefore the maintenance of market exclusivity regarding the product is no longer justified.*

Or. en

Amendment 22

Proposal for a regulation Recital 102

Text proposed by the Commission

(102) In order to incentivise research and development of orphan medicinal products addressing high unmet needs, to ensure market predictability and to ensure a fair distribution of incentives, a modulation of market exclusivity has been introduced; orphan medicinal products addressing high unmet medical needs benefit from the longest market exclusivity, while market exclusivity for well-established use orphan medicinal products, requiring less investment, is the shortest. *In order to ensure increased predictability for developers, the possibility to review the eligibility criteria for market exclusivity after six years after the marketing authorisation has been abolished.*

Amendment

(102) In order to incentivise research and development of orphan medicinal products addressing high unmet needs, to ensure market predictability and to ensure a fair distribution of incentives, a modulation of market exclusivity has been introduced; orphan medicinal products addressing high unmet medical needs benefit from the longest market exclusivity, while market exclusivity for well-established use orphan medicinal products, requiring less investment, is the shortest.

Or. en

Amendment 23

Proposal for a regulation Recital 123

Text proposed by the Commission

(123) The summary of the results of all the paediatric clinical trials included in the European clinical trial database created by Regulation (EU) No 536/2014 should be made publicly available within 6 months after the end of the clinical trials unless this is not possible for justified scientific reasons.

Amendment

(123) The summary of the results of all the paediatric clinical trials included in the European clinical trial database created by Regulation (EU) No 536/2014 should be made publicly available within 6 months after the end of the clinical trials unless this is not possible for justified scientific reasons. ***Non-compliance with Regulation (EU) No 536/2014 should be subject to penalties.***

Or. en

Amendment 24

Proposal for a regulation Recital 129

Text proposed by the Commission

(129) Scientific and technological progresses in data analytics and data infrastructure are essential for the development, authorisation and supervision of medicinal products. The digital transformation has affected regulatory decision-making, making it more data-driven and multiplying the possibilities to access evidence, across the life cycle of a medicinal product. This Regulation recognises the Agency's experience and capacity to access and analyse data submitted independently from the marketing authorisation applicant or marketing authorisation holder. On this basis, the Agency should take initiative to update the summary of product characteristics in case new efficacy or

Amendment

(129) Scientific and technological progresses in data analytics and data infrastructure are essential for the development, authorisation and supervision of medicinal products. The digital transformation has affected regulatory decision-making, making it more data-driven and multiplying the possibilities to access evidence, across the life cycle of a medicinal product. This Regulation recognises the Agency's experience and capacity to access and analyse data submitted independently from the marketing authorisation applicant or marketing authorisation holder. On this basis, the Agency should, ***after consulting with the affected marketing authorisation holder***, take initiative to update the

safety data has an impact on the benefit-risk balance of a medicinal product.

summary of product characteristics in case new efficacy or safety data has an impact on the benefit-risk balance of a medicinal product.

Or. en

Amendment 25

Proposal for a regulation Recital 133

Text proposed by the Commission

Amendment

(133) Regulatory sandboxes can provide the opportunity for advancing regulation through proactive regulatory learning, enabling regulators to gain better regulatory knowledge and to find the best means to regulate innovations based on real-world evidence, especially at a very early stage of development of a medicinal product, which can be particularly important in the face of high uncertainty and disruptive challenges, as well as when preparing new policies. Regulatory sandboxes provide a structured context for experimentation, enable where appropriate in a real-world environment the testing of innovative technologies, products, services or approaches – at the moment especially in the context of digitalisation or the use of artificial intelligence and machine learning in the life cycle of medicinal products from drug discovery, development to the administration of medicinal products – for a limited time and in a limited part of a sector or area under regulatory supervision ensuring that appropriate safeguards are in place. In its conclusions of 23 December 2020 the Council has encouraged the Commission to consider the use of regulatory sandboxes on a case-by-case basis when drafting and reviewing legislation.

deleted

Amendment 26

Proposal for a regulation Recital 134

Text proposed by the Commission

Amendment

(134) In the area of medicinal products, a high level of protection of inter alia citizens, consumers, health, as well as legal certainty, a level playing field and fair competition always need to be ensured and existing levels of protection need to be respected. **deleted**

Or. en

Amendment 27

Proposal for a regulation Recital 135

Text proposed by the Commission

Amendment

(135) The establishment of a regulatory sandbox should be based on a Commission Decision following a recommendation of the Agency. Such decision should be based on a detailed plan outlining the particularities of the sandbox as well as describing the products to be covered. A regulatory sandbox should be limited in duration and may be terminated at any time based on public health considerations. The learning stemming from a regulatory sandbox should inform future changes to the legal framework to fully integrate the particular innovative aspects into the medicinal product regulation. Where appropriate, adapted frameworks may be developed by the Commission on the basis of the results of a regulatory sandbox. **deleted**

Amendment 28**Proposal for a regulation****Recital 137***Text proposed by the Commission*

(137) To achieve a better security of supply for medicinal products in the internal market and to contribute thereby to a high level of public health protection, it is appropriate to approximate the rules on monitoring and reporting of actual or potential shortages of medicinal products, including the procedures and the respective roles and obligations of concerned entities in this Regulation. It is important to ensure continued supply of medicinal products, which is often taken for granted across Europe. This is especially true for the most critical medicinal products which are essential to ensure the continuity of care, the provision of quality healthcare and guarantee a high level of public health protection in Europe.

Amendment

(137) To achieve a better security of supply for medicinal products in the internal market and to contribute thereby to a high level of public health protection, it is appropriate to approximate the rules on monitoring and reporting of actual or potential shortages of medicinal products, including the procedures and the respective roles and obligations of concerned entities in this Regulation. It is important to ensure continued supply of medicinal products, which is often taken for granted across Europe. This is especially true for the most critical medicinal products which are essential to ensure the continuity of care, the provision of quality healthcare and guarantee a high level of public health protection in Europe. ***Member States should be able to introduce or maintain more robust measures to achieve security of supply for medicines than the safeguards provided for in this Regulation.***

Amendment 29**Proposal for a regulation****Recital 141***Text proposed by the Commission*

(141) To ensure the enforcement of certain obligations relating to the marketing authorisation for medicinal

Amendment

(141) To ensure the enforcement of certain obligations relating to the marketing authorisation for medicinal

products for human use granted in accordance with this Regulation, the Commission should be able to impose financial penalties. When assessing the responsibility for failures to comply with those obligations and imposing such penalties, it is important that means exist to address the fact that marketing authorisation holders could be part of a wider economic entity. Otherwise, there is a clear and identifiable risk that the responsibility for a failure to comply with those obligations could be evaded, which might have an impact on the ability to impose effective, proportional and dissuasive penalties. The penalties imposed should be effective, proportionate and dissuasive, having regard to the circumstances of the specific case. For the purposes of ensuring legal certainty in the conduct of the infringement procedure, it is necessary to set maximum amounts for penalties. Those maximum amounts should not be linked to the turnover of a particular medicinal product but the economic entity involved.

products for human use granted in accordance with this Regulation, the Commission should be able to impose financial penalties. When assessing the responsibility for failures to comply with those obligations and imposing such penalties, it is important that means exist to address the fact that marketing authorisation holders could be part of a wider economic entity. Otherwise, there is a clear and identifiable risk that the responsibility for a failure to comply with those obligations could be evaded, which might have an impact on the ability to impose effective, proportional and dissuasive penalties. The penalties imposed should be effective, proportionate and dissuasive, ***taking into consideration the economic power of the operator and*** having regard to the circumstances of the specific case. For the purposes of ensuring legal certainty in the conduct of the infringement procedure, it is necessary to set maximum amounts for penalties. Those maximum amounts should not be linked to the turnover of a particular medicinal product but the economic entity involved.

Or. en

Amendment 30

Proposal for a regulation

Article 2 – paragraph 2 – point 4

Text proposed by the Commission

(4) ‘orphan ***medicine*** sponsor’ means any legal or natural person, established in the Union, who submitted an application for or has been granted an orphan designation by a decision referred to in Article 64(4);

Amendment

(4) ‘orphan ***medicinal products*** sponsor’ means any legal or natural person, established in the Union, who submitted an application for or has been granted an orphan designation by a decision referred to in Article 64(4);

Or. en

Amendment 31

Proposal for a regulation

Article 2 – paragraph 2 – point 7

Text proposed by the Commission

(7) ‘significant benefit’ means a clinically relevant advantage or a major contribution to patient care of an orphan medicinal product ***if such an advantage or contribution benefits a substantial part of the target population;***

Amendment

(7) ‘significant benefit’ means a clinically relevant advantage or a major contribution to patient care of an orphan medicinal product;

Or. en

Amendment 32

Proposal for a regulation

Article 2 – paragraph 2 – point 12

Text proposed by the Commission

(12) ‘shortage’ means a situation in which the supply of a medicinal product that is authorised and placed on the market in a Member State does not meet the demand for that medicinal product in that Member State.

Amendment

deleted

Or. en

Amendment 33

Proposal for a regulation

Article 2 – paragraph 2 – point 14 a (new)

Text proposed by the Commission

Amendment

(14a) ‘supply’ means the total volume of stock of a given medicinal product that is placed on the market by a marketing authorisation holder or a manufacturer;

Or. en

Amendment 34

Proposal for a regulation

Article 2 – paragraph 2 – point 14 b (new)

Text proposed by the Commission

Amendment

(14b) ‘demand’ means the request for a medicinal product by a healthcare professional or patient in response to clinical need; the demand is satisfactorily met when the medicinal product is acquired in appropriate time and in sufficient quantity to allow continuity of provision of the best care to patients;

Or. en

Amendment 35

Proposal for a regulation

Article 5 – paragraph 2

Text proposed by the Commission

Amendment

2. An applicant shall agree with the Agency the submission date of an application for a marketing authorisation.

2. An applicant shall agree with the Agency the submission date of an application for a marketing authorisation.
The applicant shall also inform the Agency of its intention of applying for a marketing authorisation under Article 18 or 19.

Or. en

Amendment 36

Proposal for a regulation

Article 6 – paragraph 2 – subparagraph 1

Text proposed by the Commission

Amendment

For medicinal products that are likely to offer an exceptional therapeutic

For medicinal products, ***during a public health emergency***, that are likely to offer

advancement in the diagnosis, prevention or treatment of a life-threatening, ***seriously debilitating or serious and chronic*** condition in the Union, the Agency may, following the advice of the Committee for Medicinal Products for Human Use regarding the maturity of the data related to the development, offer to the applicant a phased review of complete data packages for individual modules of particulars and documentation as referred to in paragraph 1.

an exceptional therapeutic advancement in the diagnosis, prevention or treatment of a life-threatening condition in the Union, the Agency may, ***after the Commission has recognised a public health emergency at Union level in accordance with Article 23(1) of Regulation (EU) 2022/2371 and*** following the advice of the Committee for Medicinal Products for Human Use regarding the maturity of the data related to the development, offer to the applicant a phased review of complete data packages for individual modules of particulars and documentation as referred to in paragraph 1.

Or. en

Amendment 37

Proposal for a regulation

Article 6 – paragraph 2 – subparagraph 2

Text proposed by the Commission

The Agency may at any stage suspend or cancel the phased review, where the Committee for Medicinal Products for Human Use considers that the submitted data are not of sufficient maturity or where it is considered that the medicinal product no longer fulfils an exceptional therapeutic advancement. The Agency shall inform the applicant accordingly.

Amendment

The Agency may at any stage suspend or cancel the phased review, where the Committee for Medicinal Products for Human Use considers that the submitted data are not of sufficient maturity or where it is considered that the medicinal product no longer fulfils an exceptional therapeutic advancement ***or where the Commission terminates the recognition of a public health emergency in accordance with Article 23(2) of Regulation (EU) 2022/2371.*** The Agency shall inform the applicant accordingly.

Or. en

Amendment 38

Proposal for a regulation

Article 6 – paragraph 5 – subparagraph 2

Text proposed by the Commission

The marketing authorisation applicant shall not carry out animal tests in case scientifically satisfactory non-animal testing methods are available.

Amendment

The marketing authorisation applicant shall 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 shall ensure that the principle of replacement, reduction and refinement of animal testing for scientific purposes has been applied in compliance with Directive 2010/63/EU with regard to any animal study conducted for the purpose of supporting the application.***

Or. en

Amendment 39

Proposal for a regulation

Article 8 – paragraph 1 – point b

Text proposed by the Commission

(b) identification and characterisation of hazards for the environment, animals and for human health;

Amendment

(b) identification and characterisation of hazards for the environment, animals and for human health; ***for the purpose of this point, ‘hazards for human health’ includes the risks to the health of human beings other than the treated patient as the risk to the treated patient shall be assessed as part of the benefit-risk assessment of the medicinal product;***

Or. en

Amendment 40

Proposal for a regulation

Article 9 – paragraph 2

Text proposed by the Commission

2. In case of first-in-class medicinal products or when a novel question is raised during the assessment of the submitted environmental risk assessment, the Committee for Medicinal Products for Human Use, or the rapporteur, shall carry out necessary consultations with bodies Member States have set up in accordance with Directive 2001/18/EC. They **may** also consult with relevant Union bodies. Details on the consultation procedure shall be published by the Agency at the latest by [OJ:12 months after the date of entry into force of this Regulation].

Amendment

2. In case of first-in-class medicinal products or when a novel question is raised during the assessment of the submitted environmental risk assessment, the Committee for Medicinal Products for Human Use, or the rapporteur, shall carry out necessary consultations with bodies Member States have set up in accordance with Directive 2001/18/EC. They **shall** also consult with relevant Union bodies, ***inter alia the European Environment Agency***. Details on the consultation procedure shall be published by the Agency at the latest by [OJ:12 months after the date of entry into force of this Regulation].

Or. en

Amendment 41

Proposal for a regulation
Article 10 – paragraph 2

Text proposed by the Commission

2. Where within 90 days of the validation of the marketing authorisation application and during the assessment the Committee for Medicinal Products for Human Use considers that the submitted data are not of sufficient quality or maturity to complete the assessment, the assessment can be terminated. The Committee for Medicinal Products for Human Use shall summarise the deficiencies in writing. On this basis, the Agency shall inform the applicant 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 Agency, the application

Amendment

2. Where within 90 days of the validation of the marketing authorisation application and during the assessment the Committee for Medicinal Products for Human Use considers that the submitted data are not of sufficient quality or maturity to complete the assessment, the assessment can be terminated. The Committee for Medicinal Products for Human Use shall summarise the deficiencies in writing. On this basis, the Agency shall inform the applicant accordingly and set a ***reasonable*** 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 Agency, the

shall be considered as *withdrawn*.

application shall be considered as *refused*.

Or. en

Amendment 42

Proposal for a regulation

Article 12 – paragraph 4 – point f

Text proposed by the Commission

(f) where appropriate, details of any recommended obligation to conduct post-authorisation safety studies or to comply with obligations on the recording or reporting of suspected adverse reactions which are stricter than those referred to in Chapter VIII;

Amendment

(f) where appropriate, details of any recommended obligation to conduct post-authorisation safety studies or to comply with obligations on the recording or reporting of suspected adverse reactions which are stricter than those referred to in Chapter VIII ***as well as possible penalties in case of non-compliance***;

Or. en

Amendment 43

Proposal for a regulation

Article 12 – paragraph 4 – point g

Text proposed by the Commission

(g) where appropriate, details of any recommended obligation to conduct post-authorisation efficacy studies where concerns relating to some aspects of the efficacy of the medicinal product are identified and can be resolved only after the medicinal product has been marketed. Such an obligation to conduct such studies shall be based on the delegated acts adopted pursuant to Article 21 while taking into account the scientific guidance referred to in Article 123 of [revised Directive 2001/83/EC];

Amendment

(g) where appropriate, details of any recommended obligation to conduct post-authorisation efficacy studies where concerns relating to some aspects of the efficacy of the medicinal product are identified and can be resolved only after the medicinal product has been marketed. Such an obligation to conduct such studies shall be based on the delegated acts adopted pursuant to Article 21 while taking into account the scientific guidance referred to in Article 123 of [revised Directive 2001/83/EC] ***and the consultation process in accordance with Article 162 of this Regulation***;

Amendment 44

Proposal for a regulation

Article 12 – paragraph 4 – point h

Text proposed by the Commission

(h) where appropriate, details of any recommended obligation to conduct any other post-authorisation studies to improve the safe and effective use of the medicinal product;

Amendment

(h) where appropriate, details of any recommended obligation to conduct any other post-authorisation studies to improve the safe and effective use of the medicinal product ***as well as possible penalties in case of non-compliance;***

Or. en

Amendment 45

Proposal for a regulation

Article 12 – paragraph 4 – point i

Text proposed by the Commission

(i) in case of medicinal products for which there is ***substantial*** uncertainty as to the surrogate endpoint relation to the expected health outcome, where appropriate and relevant for the benefit-risk balance, a post-authorisation obligation to substantiate the clinical benefit;

Amendment

(i) in case of medicinal products for which there is ***a detailed justification as to the grounds of*** uncertainty as to the surrogate endpoint relation to the expected health outcome, where appropriate and relevant for the benefit-risk balance, ***with specific attention given to new active substances and therapeutic indications,*** a post-authorisation obligation to substantiate the clinical benefit ***as well as possible penalties in case of non-compliance;***

Or. en

Amendment 46

Proposal for a regulation

Article 12 – paragraph 4 – point j

Text proposed by the Commission

(j) where appropriate, details of any recommended obligation to conduct additional post-authorisation environmental risk assessment studies, collection of monitoring data or information on use, where concerns about risks to the environment or public health, including antimicrobial resistance need to be further investigated after the medicinal product has been marketed;

Amendment

(j) where appropriate, details of any recommended obligation to conduct additional post-authorisation environmental risk assessment studies, collection of monitoring data or information on use, where concerns about risks to the environment or public health, including antimicrobial resistance need to be further investigated after the medicinal product has been marketed, ***as well as possible penalties in case of non-compliance***;

Or. en

Amendment 47

Proposal for a regulation

Article 12 – paragraph 4 – point m a (new)

Text proposed by the Commission

Amendment

(ma) a stewardship plan in accordance with Article 17 of [revised Directive 2001/83/EC] and special information requirements in accordance with Article 69 of that Directive for any antimicrobials, as well as any other obligations imposed on the marketing authorisation holder;

Or. en

Amendment 48

Proposal for a regulation

Article 12 – paragraph 4 – point m b (new)

Text proposed by the Commission

Amendment

(mb) where applicable, a confirmation as to whether the medicinal product

satisfies the criteria of Article 83 of [revised Directive 2001/83/EC] regarding medicinal products addressing an unmet medical need;

Or. en

Amendment 49

Proposal for a regulation

Article 13 – paragraph 1 – subparagraph 5

Text proposed by the Commission

Where the draft decision differs from the opinion of the Agency, the Commission shall provide a detailed explanation of the reasons for the differences.

Amendment

Where the draft decision differs from the opinion of the Agency, the Commission shall provide a detailed explanation of the reasons for the differences ***and make that information publicly available at the same time as the decision.***

Or. en

Amendment 50

Proposal for a regulation

Article 13 – paragraph 1 – subparagraph 6

Text proposed by the Commission

The Commission shall send the draft decision to the Member States and the applicant.

Amendment

The Commission shall send the draft decision ***and the accompanying reasoning referred to in the fifth subparagraph*** to the Member States and the applicant.

Or. en

Amendment 51

Proposal for a regulation

Article 13 – paragraph 4

Text proposed by the Commission

4. The Agency shall disseminate the documents referred to in Article 12(4), points (a) to (e), together with any deadlines laid down pursuant to paragraph 1, first subparagraph.

Amendment

4. The Agency shall disseminate the documents referred to in Article 12(4), points (a) to (e), ***and, where relevant, the documents referred to in Article 12(4), points (f) to (mb)***, together with any deadlines laid down pursuant to paragraph 1, first subparagraph.

Or. en

Amendment 52

Proposal for a regulation

Article 15 – paragraph 1 – point d

Text proposed by the Commission

(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;

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 ***risk mitigation measures proposed by the applicant in accordance with Article 22(3) of [revised Directive 2001/83/EC]***;

Or. en

Amendment 53

Proposal for a regulation

Article 16 – paragraph 3 – subparagraph 1

Text proposed by the Commission

The Agency shall immediately publish the assessment report on the medicinal product for human use and the reasons for its opinion in favour of granting marketing authorisation, after deletion of any information of a commercially confidential

Amendment

The Agency shall immediately publish the assessment report on the medicinal product for human use and the reasons for its opinion in favour of granting marketing authorisation, after deletion of any information of a commercially confidential

nature.

nature *and following a consultation of relevant patient organisations with regard to the readability, clarity and comprehensibility of European public assessment report summaries.*

Or. en

Amendment 54

Proposal for a regulation

Article 16 – paragraph 3 – subparagraph 2 – indent 2

Text proposed by the Commission

– a summary of environmental risk assessment studies and their results as submitted by the marketing authorisation holder and the assessment of the environmental risk assessment and the information referred to in Article 22(5) of [revised Directive 2001/83/EC] by the Agency.

Amendment

– *the complete environmental risk assessment submitted to the Agency by the marketing authorisation applicant as well as* a summary of environmental risk assessment studies and their results as submitted by the marketing authorisation holder and the assessment of the environmental risk assessment and the information referred to in Article 22(5) of [revised Directive 2001/83/EC] by the Agency.

Or. en

Amendment 55

Proposal for a regulation

Article 16 – paragraph 3 – subparagraph 2 – indent 2 a (new)

Text proposed by the Commission

Amendment

– *for antimicrobials, all information referred to in Article 17 of and Annex I to [revised Directive 2001/83/EC] as well as any other obligations imposed on the marketing authorisation holder.*

Or. en

Amendment 56

Proposal for a regulation Article 17 – paragraph 1

Text proposed by the Commission

1. ***Without prejudice to paragraph 2,*** a marketing authorisation for a medicinal product shall be valid for ***an unlimited period.***

Amendment

1. A marketing authorisation for a medicinal product shall be valid for ***five years.***

Or. en

Amendment 57

Proposal for a regulation Article 17 – paragraph 2 – subparagraph 1

Text proposed by the Commission

By way of derogation from paragraph 1, the Commission may decide when granting an authorisation, on the basis of a scientific opinion by the Agency concerning the safety of the medicinal product, to limit the validity of the marketing authorisation to five years.

Amendment

deleted

Or. en

Amendment 58

Proposal for a regulation Article 17 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Where the validity of the marketing authorisation is limited to five years, the marketing authorisation holder shall apply to the Agency for a renewal of the marketing authorisation at least nine months before the marketing authorisation ceases to be valid.

Amendment

The marketing authorisation holder shall apply to the Agency for a renewal of the marketing authorisation at least nine months before the marketing authorisation ceases to be valid.

Amendment 59

Proposal for a regulation

Article 17 – paragraph 2 – subparagraph 3

Text proposed by the Commission

Where a renewal application has been submitted ***in accordance with the second subparagraph***, the marketing authorisation shall remain valid until a decision is adopted by the Commission in accordance with Article 13.

Amendment

Where a renewal application has been submitted, the marketing authorisation shall remain valid until a decision is adopted by the Commission in accordance with Article 13.

Or. en

Amendment 60

Proposal for a regulation

Article 17 – paragraph 2 – subparagraph 4

Text proposed by the Commission

The marketing authorisation may be renewed on the basis of a re-evaluation by the Agency of the benefit-risk balance. Once renewed, the marketing authorisation shall be valid for an ***unlimited period***.

Amendment

The marketing authorisation may be renewed on the basis of a re-evaluation by the Agency of the benefit-risk balance. Once renewed, the marketing authorisation ***and any subsequent marketing authorisations*** shall be valid for an ***additional period of 10 years***.

Or. en

Amendment 61

Proposal for a regulation

Article 17 – paragraph 2 – subparagraph 4 a (new)

Text proposed by the Commission

Amendment

Where post-authorisation studies to be performed in accordance with Article

20(1) justify it, the Commission may decide to withdraw a marketing authorisation for a medicinal product based on evidence pointing to a risk to public health.

Or. en

Amendment 62

Proposal for a regulation

Article 18 – paragraph 2 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

Where specific conditions referred to in paragraph 1, point (c), are not fulfilled within the timeframe given by the Agency or the marketing authorisation holder does not provide duly justified reasons for not fulfilling the conditions, the Commission may suspend, revoke or vary the marketing authorisation 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

Amendment 63

Proposal for a regulation

Article 19 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Amendment

In emergency situations, a conditional marketing authorisation or a new conditional therapeutic indication referred to in the first subparagraph may be granted also where comprehensive non-clinical or pharmaceutical data have not been supplied.

In emergency situations, ***as referred to in Article 2(1) of Regulation (EU) 2022/2371***, a conditional marketing authorisation or a new conditional therapeutic indication referred to in the first subparagraph may be granted also where comprehensive non-clinical or pharmaceutical data have not been

supplied.

Or. en

Amendment 64

Proposal for a regulation Article 19 – paragraph 3

Text proposed by the Commission

3. Conditional marketing authorisations or a new conditional therapeutic indication granted pursuant to this Article shall be subject to specific obligations. Those specific obligations ***and, where appropriate***, the time limit for compliance shall be specified in the conditions to the marketing authorisation. Those specific obligations shall be reviewed annually by the Agency for the first three years after granting the authorisation and every two years thereafter.

Amendment

3. Conditional marketing authorisations or a new conditional therapeutic indication granted pursuant to this Article shall be subject to specific obligations. Those specific obligations, ***in particular for ongoing or new studies as referred to in paragraph 4 of this Article***, the time limit for compliance ***and penalties in accordance with Article 172 in cases of non-compliance***, shall be specified in the conditions to the marketing authorisation. Those specific obligations shall be reviewed annually by the Agency for the first three years after granting the authorisation and every two years thereafter.

Or. en

Amendment 65

Proposal for a regulation Article 19 – paragraph 4

Text proposed by the Commission

4. As part of the specific obligations referred to in paragraph 3, the marketing authorisation holder of a conditional marketing authorisation granted pursuant to this Article shall be required to complete ongoing studies, or to conduct new studies, with a view to confirming ***that the benefit-risk balance is favourable***.

Amendment

4. As part of the specific obligations referred to in paragraph 3, the marketing authorisation holder of a conditional marketing authorisation granted pursuant to this Article shall be required to complete ongoing studies, or to conduct new studies ***in accordance with Article 20***, with a view to confirming the ***safety and efficacy of the***

medicinal product. The Agency shall make relevant deadlines and criteria for ongoing and new studies publicly available.

Or. en

Amendment 66

Proposal for a regulation Article 19 – paragraph 6

Text proposed by the Commission

6. By way of derogation from Article 17(1), an initial conditional marketing authorisation granted pursuant to this Article shall be valid for one year, on a renewable basis for the first three years after granting the authorisation and every two years thereafter.

Amendment

6. By way of derogation from Article 17(1), an initial conditional marketing authorisation granted pursuant to this Article shall be valid for one year, on a renewable basis for the first three years after granting the authorisation and every two years thereafter. ***However, where the Commission terminates the recognition of a public health emergency in accordance with Article 23(2) of Regulation (EU) 2022/2371, the marketing authorisation holder shall pursue a marketing authorisation in accordance with Article 5 of this Regulation.***

Or. en

Amendment 67

Proposal for a regulation Article 19 – paragraph 7 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

Where specific conditions referred to in paragraph 3 are not fulfilled within the timeframe given by the Agency or the marketing authorisation holder does not provide duly justified reasons for not fulfilling the conditions, the Commission may suspend, revoke or vary the

marketing authorisation 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

Amendment 68

Proposal for a regulation Article 19 a (new)

Text proposed by the Commission

Amendment

Article 19a

Revocation of conditional marketing authorisation

The Commission may in justified cases revoke the conditional marketing authorisation that was granted in accordance with Article 19 where the benefit of the immediate availability of the medicinal product on the Union market no longer outweighs the risk due to missing confirming data or non-compliance with the obligations set out in Article 19.

Or. en

Amendment 69

Proposal for a regulation Article 20 – paragraph 1 – subparagraph 1 – introductory part

Text proposed by the Commission

Amendment

After the granting of a marketing authorisation, the Agency may consider that it is necessary that the marketing authorisation holder:

After the granting of a marketing authorisation, the Agency may **at any time** consider that it is necessary that the marketing authorisation holder:

Or. en

Amendment 70

Proposal for a regulation

Article 20 – paragraph 1 – subparagraph 2

Text proposed by the Commission

If this obligation would apply to several medicinal products, the Agency shall **encourage** the marketing authorisation holders concerned to conduct a joint post authorisation environmental risk assessment study.

Amendment

If this obligation would apply to several medicinal products, the Agency shall **oblige** the marketing authorisation holders concerned to conduct a joint post authorisation environmental risk assessment study.

Or. en

Amendment 71

Proposal for a regulation

Article 21 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Where a conditional marketing authorisation has been granted in accordance with Article 19, a post-authorisation efficacy study shall always be required in accordance with Article 19(4).

Or. en

Amendment 72

Proposal for a regulation

Article 23 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

A temporary emergency marketing authorisation granted in accordance with Article 30 shall leave the civil and criminal liability of the manufacturer and marketing authorisation holder

unaffected.

Or. en

Amendment 73

Proposal for a regulation

Article 24 – paragraph 1 – subparagraph 1

Text proposed by the Commission

In addition to the notification made pursuant to Article 116, the marketing authorisation holder shall notify the Agency without undue delay of any action they take to suspend the marketing of a medicinal product, to withdraw a medicinal product from the market, to request the withdrawal of a marketing authorisation or not to apply for the renewal of a marketing authorisation, together with ***the reasons*** for such action.

Amendment

In addition to the notification made pursuant to Article 116, the marketing authorisation holder shall notify the Agency without undue delay of any action they take to suspend the marketing of a medicinal product, to withdraw a medicinal product from the market, to request the withdrawal of a marketing authorisation or not to apply for the renewal of a marketing authorisation, together with ***detailed reasoning*** for such action.

Or. en

Amendment 74

Proposal for a regulation

Article 24 – paragraph 1 – subparagraph 2 – point f

Text proposed by the Commission

(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.

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; ***in such cases, the Agency shall immediately inform the Commission who is to be responsible for informing the relevant national and Union authorities.***

Or. en

Amendment 75

Proposal for a regulation

Article 24 – paragraph 1 – subparagraph 2 – point f a (new)

Text proposed by the Commission

Amendment

(fa) commercial considerations.

Or. en

Amendment 76

Proposal for a regulation

Article 24 – paragraph 1 – subparagraph 3

Text proposed by the Commission

Amendment

Where the action referred to in the first subparagraph is to withdraw a medicinal product from the market, the marketing authorisation holder shall provide information on the impact of such withdrawal on patients who are already being treated.

Where the action referred to in the first subparagraph is to withdraw a medicinal product from the market, the marketing authorisation holder shall provide information on the impact of such withdrawal on patients who are already being treated ***with the medicinal product, as well as indicate any potential alternative therapeutic equivalent.***

Or. en

Amendment 77

Proposal for a regulation

Article 24 – paragraph 4

Text proposed by the Commission

Amendment

4. Where the marketing authorisation holder intends to permanently withdraw the marketing authorisation for a ***critical*** medicinal product, the marketing authorisation holder shall, prior to the notification referred to in paragraph 1, offer, on reasonable terms, to transfer the marketing authorisation to a third party that

4. Where the marketing authorisation holder intends to permanently withdraw the marketing authorisation for a medicinal product, the marketing authorisation holder shall, prior to the notification referred to in paragraph 1, offer, on ***fair and*** reasonable terms, to transfer the marketing authorisation to a third party that has

has declared its intention to place that **critical** medicinal product on the market, or to use the pharmaceutical non-clinical and clinical documentation contained in the file of the medicinal product for the purposes of submitting an application in accordance with Article 14 of [revised Directive 2001/83/EC].

declared its intention to place that medicinal product on the market, or to use the pharmaceutical non-clinical and clinical documentation contained in the file of the medicinal product for the purposes of submitting an application in accordance with Article 14 of [revised Directive 2001/83/EC].

Or. en

Amendment 78

Proposal for a regulation

Article 24 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. The marketing authorisation holder from which the marketing authorisation has been transferred to a third party shall notify the Agency of the transfer as soon as possible. The information regarding the transfer provided shall be made publicly available.

Or. en

Amendment 79

Proposal for a regulation

Article 25 – paragraph 1 – subparagraph 3

Text proposed by the Commission

Amendment

As soon as the relevant patent or supplementary protection certificate referred to in point (a) expires, the marketing authorisation holder shall withdraw the initial or duplicate marketing authorisation.

As soon as the relevant patent or supplementary protection certificate referred to in point (a) expires, the marketing authorisation holder shall **immediately** withdraw the initial or duplicate marketing authorisation.

Or. en

Amendment 80

Proposal for a regulation Article 26 – paragraph 10

Text proposed by the Commission

10. The Agency **may** adopt detailed guidelines laying down format and content of notifications referred to in paragraphs 3 and 5, and data exchange under this Article.

Amendment

10. The Agency **shall** adopt detailed guidelines laying down format and content of notifications referred to in paragraphs 3 and 5, and data exchange under this Article.

Or. en

Amendment 81

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

Text proposed by the Commission

Amendment

The Committee shall also draw up an opinion whenever there is disagreement concerning the evaluation of medicinal products through the mutual recognition procedure.

Or. en

Amendment 82

Proposal for a regulation Article 30 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

Where a medicinal product receives a temporary emergency marketing authorisation in accordance with this Article, robust transparency measures and standards shall be put in place by the Agency. Those measures shall include the timely publication of all relevant information on approved medicinal

products and medical devices and of clinical data, including clinical trial protocols. The public information regarding clinical trials and marketing authorisation decisions shall be published in accordance with Article 17 of Regulation (EU) 2022/123.

Or. en

Amendment 83

Proposal for a regulation

Article 31 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) when recognition of the public health emergency has been terminated, the marketing authorisation holder shall be required to apply for a marketing authorisation in accordance with Article 34 without undue delay.

Or. en

Amendment 84

Proposal for a regulation

Article 32 – paragraph 2 – subparagraph 1

Text proposed by the Commission

Amendment

The Agency shall review any new evidence provided by the developer, the Member States or the Commission, or any other evidence that comes to its attention, in particular evidence that might influence the benefit-risk balance of the medicinal product concerned.

The Agency shall ***without undue delay*** review any new evidence provided by the developer, the Member States or the Commission, or any other evidence that comes to its attention, in particular evidence that might influence the benefit-risk balance of the medicinal product concerned.

Or. en

Amendment 85

Proposal for a regulation Article 34 – paragraph 1

Text proposed by the Commission

The temporary emergency marketing authorisation shall cease to be valid when the Commission terminates the recognition of a public health emergency in accordance with Article 23(2) and (4) of Regulation (EU) 2022/2371.

Amendment

The temporary emergency marketing authorisation shall cease to be valid when the Commission terminates the recognition of a public health emergency in accordance with Article 23(2) and (4) of Regulation (EU) 2022/2371 ***or when sufficient data have been collected in order to grant a conditional marketing authorisation in accordance with Article 19.***

Or. en

Amendment 86

Proposal for a regulation Article 35 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(da) a conditional marketing authorisation has been granted.

Or. en

Amendment 87

Proposal for a regulation Article 37 – paragraph 1

Text proposed by the Commission

Amendment

When the temporary marketing authorisation of a medicinal product is suspended or revoked for reasons other than the safety of the medicinal product, or if that temporary emergency marketing authorisation ceases to be valid, Member States may, in exceptional circumstances,

When the temporary marketing authorisation of a medicinal product is suspended or revoked for reasons other than the safety of the medicinal product, or if that temporary emergency marketing authorisation ceases to be valid, Member States may, in exceptional circumstances,

allow for a transitional period, the supply of the medicinal product to patients who are already being treated with it.

allow for a transitional period, the supply of the medicinal product to patients who are already being treated with it.

Conditions for manufacturing, use, supply and safety monitoring and the compliance with related good manufacturing, and pharmacovigilance practices shall continue to apply during that period.

Or. en

Amendment 88

Proposal for a regulation Chapter III – title

Text proposed by the Commission

INCENTIVES FOR THE
DEVELOPMENT OF ‘PRIORITY
ANTIMICROBIALS’

Amendment

***ADDRESSING PHARMACEUTICAL
MARKET FAILURES IN THE UNION
AND FURTHER INCENTIVES FOR
THE RESEARCH AND
DEVELOPMENT OF PRIORITY
ANTIMICROBIALS***

Or. en

Amendment 89

Proposal for a regulation Article 40

Text proposed by the Commission

Article 40

***Granting the right to a transferable data
exclusivity voucher***

***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***

Amendment

deleted

paragraph 3, under the conditions referred to in paragraph 4 based on a scientific assessment by the Agency.

2. The voucher referred to in paragraph 1 shall give the right to its holder to an additional 12 months of data protection for one authorised medicinal product.

3. 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:

(a) it represents a new class of antimicrobials;

(b) its mechanism of action is distinctly different from that of any authorised antimicrobial in the Union;

(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.

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.

4. To be granted the voucher by the Commission, the applicant shall:

(a) demonstrate capacity to supply the priority antimicrobial in sufficient quantities for the expected needs of the Union market;

(b) provide information on all direct financial support received for research related to the development of the priority antimicrobial.

Within 30 days after the marketing authorisation is granted, the marketing authorisation holder shall make the

information referred to in point (b) accessible to the public via a dedicated webpage and shall communicate, in a timely manner the electronic link to that webpage to the Agency.

Or. en

Amendment 90

Proposal for a regulation Article 40 a (new)

Text proposed by the Commission

Amendment

Article 40a

Establishment and role of the European Medicines Facility

- 1. The European Medicines Facility (‘EMF’) is hereby established.***
- 2. The main missions and responsibilities of the EMF shall be:***
 - (a) setting out a long-term vision of health priorities in the public interest at a Union level in the form of a strategic roadmap with a number of specific purpose-led R&D projects; in the elaboration of the strategic roadmap, the EMF shall engage in transparent consultation with relevant stakeholders, including scientific communities, Union public health authorities, patient and consumer organisations as well as the relevant agencies established at Union level;***
 - (b) establishing, as a priority, a portfolio of priority pharmaceutical R&D projects addressing at least the following therapeutic areas:***
 - (i) the development of priority antimicrobials provided for in the ‘WHO priority pathogens list for R&D of new antibiotics’, specifically those listed as priority 1 (critical) or priority 2 (high), or***

taking into account as a priority any equivalent list of priority pathogens adopted at Union level;

(ii) the development of medicinal products for high unmet medical needs as referred to in Article 70(1) of this Regulation and unmet medical needs as referred to in Article 83 of [revised Directive 2001/83/EC], in particular for conditions not sufficiently addressed by the private sector and where the private R&D pipeline is unlikely to deliver on medicinal products and therapies;

(iii) the development of medicinal products for which the private sector charges excessive prices and for which alternatives or generic alternatives are non-existent or unaffordable;

Or. en

Amendment 91

Proposal for a regulation Article 41

Text proposed by the Commission

Amendment

Article 41

deleted

Transfer and use of the voucher

1. A voucher may be used to extend the data protection for a period of 12 months of the priority antimicrobial or another medicinal product authorised in accordance with this Regulation of the same or different marketing authorisation holder.

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 may only be used if the marketing authorisation of the priority

antimicrobial for which the right was initially granted has not been withdrawn.

2. To use the voucher, its owner shall apply for a variation of the marketing authorisation concerned in accordance with Article 47 to extend the data protection.

3. A voucher may be transferred to another marketing authorisation holder and shall not be transferred further.

4. A marketing authorisation holder to whom a voucher is transferred shall notify the Agency of the transfer within 30 days, stating the value of the transaction between the two parties. The Agency shall make this information publicly available.

Or. en

Amendment 92

Proposal for a regulation Article 41 a (new)

Article 41a

Additional measures to incentivise the creation of antimicrobials

1. The Commission shall furthermore establish a Union push and pull incentive scheme to promote and accelerate the development of novel antimicrobials, as well as promote increased access to existing and newly developed antimicrobials. Member States shall be encouraged to participate in the Union level scheme.

2. The Commission is empowered to adopt delegated acts in accordance with Article 175 to supplement this Regulation by further defining the scheme and its funding and shall at least include the development of the following incentives in such delegated acts:

(a) research grants under Union funds with conditionalities linked to the

affordability and supply of new and existing antimicrobials;

(b) milestone prizes for novel antimicrobial developers with conditionalities linked to the affordability and supply of new and existing antimicrobials;

(c) voluntary joint procurement with subscription payment mechanisms or market entry rewards that delink or partially delink revenues and sales;

(d) ‘play or pay’ fee systems in which pharmaceutical companies are subject to a levy on the sale of their existing medicinal products, unless they prove an equivalent investment in antibiotic research and development.

3. The Union push and pull incentive scheme shall be coordinated and managed by the Commission.

4. By ... [one year after the date of entry into force of this Regulation], the Commission shall have developed, and commenced the implementation of, the Union push and pull incentive scheme.

5. By ... [5 years after the date of entry into force of this Regulation], the Commission shall present a report to the European Parliament and to the Council reviewing the application of the scheme laid down in this Article. The report shall also assess the interplay between the ongoing work of the EMF and the effectiveness of the Union push and pull incentive scheme.

Or. en

Amendment 93

**Proposal for a regulation
Article 42**

Article 42

deleted

Validity of the voucher

1. A voucher shall cease to be valid in the following cases:

(a) where the Commission adopts a decision in accordance with Article 47 to extend the data protection of the receiving medicinal product;

(b) where it is not used within 5 years from the date it was granted.

2. The Commission may revoke the voucher prior to its transfer as referred to in Article 41(3) if a request for supply, procurement or purchase of the priority antimicrobial in the Union has not been fulfilled.

3. Without prejudice to patent rights, or supplementary protection certificates⁶⁹, if a priority antimicrobial is withdrawn from the Union market prior to expiry of the periods of market and data protection laid down in Articles 80 and 81 of [revised Directive 2001/83/EC], those periods shall not prevent the validation, authorisation and placing on the market of a medicinal product using the priority antimicrobial as a reference medicinal product in accordance with Chapter II, Section 2 of [revised Directive 2001/83].

⁶⁹ Regulation (EC) No 469/2009 of the European Parliament and of the Council, (OJ L 152, 16.6.2009, p. 1).

Or. en

Amendment 94

**Proposal for a regulation
Article 43**

Text proposed by the Commission

Amendment

Article 43

deleted

Duration of application of Chapter III

This Chapter shall apply until [Note to OP: insert the date of 15 years after the date of entry into force of this Regulation] or until the date when the Commission has granted a total of 10 vouchers in accordance with this Chapter, whichever date is the earliest.

Or. en

Amendment 95

Proposal for a regulation

Article 45 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. Where specific conditions referred to in paragraph 1 to 4 are not fulfilled within the timeframe given by the Agency or the marketing authorisation holder does not provide duly justified reasons for not fulfilling the conditions, the Commission may vary the marketing authorisation of the affected medicinal product accordingly and update the summary of the product characteristics and package leaflets 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

Amendment 96

Proposal for a regulation

Article 47 – paragraph 1

Text proposed by the Commission

1. An application for variation of a centralised marketing authorisation by the marketing authorisation holder shall be made electronically in the formats made available by the Agency, unless the variation is an update by the marketing authorisation holder of their information held in a database.

Amendment

1. An application for variation of a centralised marketing authorisation by the marketing authorisation holder shall be made electronically in the formats made available by the Agency, unless the variation is an update by the marketing authorisation holder of their information held in a database. ***The electronic format shall include a baseline sequence in regards to the Common Technical Document (CTD).***

Or. en

Amendment 97

Proposal for a regulation

Article 48 – paragraph 1 – subparagraph 1

Text proposed by the Commission

An entity not engaged in an economic activity ('not-for-profit entity') may submit to the Agency or to a competent authority of the Member State substantive non-clinical or clinical evidence for a new therapeutic indication ***that is expected to fulfil an unmet medical need.***

Amendment

An entity not engaged in an economic activity ('not-for-profit entity') may submit to the Agency or to a competent authority of the Member State substantive non-clinical or clinical evidence for a new therapeutic indication.

Or. en

Amendment 98

Proposal for a regulation

Article 48 – paragraph 1 – subparagraph 2

Text proposed by the Commission

The Agency may, at the request of a Member State, the Commission, or on its own initiative and on the basis of all available evidence make a scientific

Amendment

The Agency may, at the request of a Member State, the Commission, or on its own initiative and on the basis of all available evidence make a scientific

evaluation of the benefit-risk of the use of a medicinal product with a new therapeutic indication ***that concerns an unmet medical need***.

evaluation of the benefit-risk of the use of a medicinal product with a new therapeutic indication.

Or. en

Amendment 99

Proposal for a regulation Article 48 – paragraph 2

Text proposed by the Commission

2. In cases where the opinion is favourable, marketing authorisation holders of the medicinal products concerned shall submit a variation to update the product information with the new therapeutic indication.

Amendment

2. In cases where the opinion is favourable, marketing authorisation holders of the medicinal products concerned shall ***be notified and given the possibility to comment. After consultation with the marketing authorisation holder, the Agency may*** submit a variation to update the product information with the new therapeutic indication. ***The marketing authorisation holder shall inform relevant stakeholders, such as healthcare professionals, of the added indication.***

Or. en

Amendment 100

Proposal for a regulation Article 48 – paragraph 3

Text proposed by the Commission

3. ***Article 81(2), point (c) of [revised Directive 2001/83/EC] shall not apply for variations under this Article.***

Amendment

deleted

Or. en

Amendment 101

Proposal for a regulation

Article 52 – paragraph 6 – point c a (new)

Text proposed by the Commission

Amendment

(ca) the inspectors are free of any conflicts of interest.

Or. en

Amendment 102

Proposal for a regulation

Article 54 – paragraph 4 – subparagraph 1

Text proposed by the Commission

Amendment

Under the joint audit programme, the auditors shall issue an audit report after each audit. The audit report shall include, where relevant, appropriate recommendations on measures that the Member State concerned shall consider to **take to** ensure that its relevant quality system and its enforcement activities are consistent with Union quality standards.

Under the joint audit programme, the auditors shall issue an audit report after each audit. The audit report shall include, where relevant, appropriate recommendations on measures that the Member State concerned shall consider to ensure that its relevant quality system and its enforcement activities are consistent with Union quality standards.

Or. en

Amendment 103

Proposal for a regulation

Article 54 – paragraph 6

Text proposed by the Commission

Amendment

6. The compilation of Union procedures on inspections and exchange of information referred to in Article 3(1) of Directive 2017/1572 shall be updated **by** the Agency to cover rules applicable to the functioning, structure, and tasks of the joint audit programme.

6. The compilation of Union procedures on inspections and exchange of information referred to in Article 3(1) of Directive 2017/1572 shall be updated, **whenever needed, by** the Agency to cover rules applicable to the functioning, structure, and tasks of the joint audit

programme.

Or. en

Amendment 104

Proposal for a regulation Article 55 – paragraph 5

Text proposed by the Commission

5. In cases referred to in paragraph 4, the Member State shall ensure that healthcare professionals are rapidly informed of its action and the reasons for the action. Networks set up by professional associations may be used to this effect. The Member States shall inform the Commission and the Agency of actions taken for this purpose.

Amendment

5. In cases referred to in paragraph 4, the Member State shall ensure ***by all means possible*** that healthcare professionals are rapidly informed of its action and the reasons for the action. Networks set up by professional associations may be used to this effect. The Member States shall inform the Commission and the Agency of actions taken for this purpose.

Or. en

Amendment 105

Proposal for a regulation Article 58 – paragraph 4

Text proposed by the Commission

4. The Agency shall include in the European public assessment report the key areas of the scientific advice once the corresponding marketing authorisation decision has been taken in relation to the medicinal product, after deletion of any information of a commercially confidential nature.

Amendment

4. The Agency shall include in the European public assessment report the key areas of the scientific advice ***as well as a detailed log of the pre-submission activities of the medicinal product, including the names of the experts involved,*** once the corresponding marketing authorisation decision has been taken in relation to the medicinal product, after deletion of any information of a commercially confidential nature.

Or. en

Amendment 106

Proposal for a regulation Article 58 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. The Agency shall, to the greatest extent possible, ensure that there is a separation between those responsible for providing scientific advice to a given medicinal product developer and those subsequently responsible for the evaluation of the marketing authorisation application for the same medicinal product.

When appointing rapporteurs for the purpose of evaluating marketing authorisation applications, the Agency's Committee on Medicinal Products for Human Use shall duly take into account any involvement of individuals as coordinators in providing scientific advice for the same medicinal product in the pre-submission stage of activities.

If, in exceptional cases, the Agency appoints as rapporteur an expert who had a prominent role in providing scientific advice on the same medicinal product during the pre-submission stage of activities, the Agency shall document and publish detailed information for the decision with the European public assessment report. The Agency shall nonetheless ensure that at least one of two rapporteurs had no prominent role in the pre-submission activities for that medicinal product.

Where a separation between those responsible for providing scientific advice to a given medicinal product developer and those subsequently responsible for the evaluation of the marketing authorisation application for the same medicinal product is not possible, it shall be recorded in the summary minutes of the

Amendment 107

Proposal for a regulation

Article 60 – paragraph 1 – introductory part

Text proposed by the Commission

1. The Agency may offer enhanced scientific and regulatory support, including as applicable consultation with other bodies as referred to in Articles 58 and 59 and accelerated assessment mechanisms, for certain medicinal products that, based on preliminary evidence submitted by the developer fulfil the following conditions:

Amendment

1. The Agency may offer enhanced scientific and regulatory support, including as applicable consultation with other bodies as referred to in Articles 58 and 59 and accelerated assessment mechanisms, for certain medicinal products that, based on preliminary evidence submitted by the developer fulfil ***at least one of*** the following conditions:

Amendment 108

Proposal for a regulation

Article 60 – paragraph 1 – point c

Text proposed by the Commission

(c) are expected to be of major interest from the point of view of public health, in particular as regards therapeutic innovation, taking into account the early stage of development, or antimicrobials with any of the characteristics mentioned in Article 40(3).

Amendment

(c) are expected to be of major interest from the point of view of public health, in particular as regards therapeutic innovation, ***including advanced therapy medicinal products***, taking into account the early stage of development, or antimicrobials with any of the characteristics mentioned in Article 40(3).

Amendment 109

Proposal for a regulation

Article 60 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. Where a priority medicinal product benefits from enhanced scientific and regulatory support from the Agency, the European public assessment report shall include a specific section on the Agency's pre-submission activities, and information on the key areas of the scientific advice and regulatory support provided and on the follow-up by the requester, including corresponding information and data which show that the conditions for the PRIME scheme have been fulfilled.

Or. en

Amendment 110

Proposal for a regulation

Article 63 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) the condition affects not more than five in 10 000 persons in the Union when the application for an orphan designation is submitted;

(a) the condition affects not more than five in 10 000 persons in the Union when the application for an orphan designation is submitted **or the medicinal product is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the Union and, without incentives, it is unlikely that the marketing of the medicinal product in the Union would generate a sufficient return to justify the necessary investment;**

Or. en

Amendment 111

Proposal for a regulation

Article 65 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(ca) detailed reasons for the transferring of the orphan designation

Or. en

Amendment 112

Proposal for a regulation

Article 66 – paragraph 5

Text proposed by the Commission

Amendment

5. At any time, an orphan designation may be withdrawn at the request of the orphan medicine sponsor.

5. At any time, an orphan designation may be withdrawn at the request of the orphan medicine sponsor. ***The orphan medicine sponsor shall provide a reasoned justification for the withdrawal request which shall be made publicly available.***

Or. en

Amendment 113

Proposal for a regulation

Article 67 – paragraph 3 – point f a (new)

Text proposed by the Commission

Amendment

(fa) where applicable, any request made in accordance with Article 66(2) and any decisions taken in that respect.

Or. en

Amendment 114

Proposal for a regulation Article 68 – paragraph 2

Text proposed by the Commission

2. Medicinal products designated as orphan medicinal products under the provisions of this Regulation shall be eligible for incentives made available by the Union and by the Member States to support research into, and the development and availability of, orphan medicinal products and in particular aid for research for small- and medium-sized undertakings provided for in framework programmes for research and technological development.

Amendment

2. Medicinal products designated as orphan medicinal products under the provisions of this Regulation shall be eligible for incentives made available by the Union and by the Member States to support research into, and the development and availability of, orphan medicinal products and in particular aid for research for small- and medium-sized undertakings **and not-for-profit organisations** provided for in framework programmes for research and technological development.

Or. en

Amendment 115

Proposal for a regulation Article 70 – paragraph 1 – introductory part

Text proposed by the Commission

1. An orphan medicinal product shall be considered as addressing a high unmet medical need where it fulfils the following requirements:

Amendment

1. An orphan medicinal product shall be considered as addressing a high unmet medical need where it fulfils the following **two** requirements:

Or. en

Amendment 116

Proposal for a regulation Article 70 – paragraph 1 – point b

Text proposed by the Commission

(b) the use of the orphan medicinal product results in a **meaningful** reduction

Amendment

(b) the use of the orphan medicinal product results in a **substantial** reduction in

in disease morbidity or mortality for the relevant patient population.

disease morbidity or mortality for the relevant patient population.

Or. en

Amendment 117

Proposal for a regulation Article 70 – paragraph 3

Text proposed by the Commission

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.

Amendment

3. Where the Agency adopts scientific guidelines for the application of this Article, it shall consult the Commission, the authorities or bodies **and other relevant stakeholders** referred to in Article 162.

Or. en

Amendment 118

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

Text proposed by the Commission

(a) **nine** years for orphan medicinal products other than those referred to in points (b) and (c);

Amendment

(a) **eight** years for orphan medicinal products other than those referred to in points (b), **(ba)** and (c);

Or. en

Amendment 119

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

Text proposed by the Commission

Amendment

(ba) five years for a new orphan therapeutic indication of medicinal products which have already received

marketing authorisation in the Union ;

Or. en

Amendment 120

Proposal for a regulation

Article 71 – paragraph 2 – point c

Text proposed by the Commission

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

Amendment

(c) ***three*** years for orphan medicinal products which have been authorised in accordance with Article 13 of [revised Directive 2001/83/EC].

Or. en

Amendment 121

Proposal for a regulation

Article 71 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. For the medicinal products referred to in paragraph 2, points (ba) and (c), the market exclusivity in respect of the orphan indication shall not prevent the entry of generic and biosimilar medicinal products on the market, provided that they are for other uses that are not subject to the market protection applicable in accordance with paragraph 2.

The periods set out in paragraph 2, points (a) and (b), of this Article may however be reduced to five years if, by the end of the fourth year in respect of the medicinal product concerned, it is established by the Agency that the criteria laid down in Article 63(1), point (a), are no longer met, inter alia, where it is shown on the basis of available evidence that the product is sufficiently profitable not to justify

maintenance of market exclusivity. To that end, a Member State shall inform the Agency that the criterion on the basis of which market exclusivity was granted may not be met and the Agency shall then initiate the procedure laid down in Article 67(2). The sponsor shall provide the Agency with the information necessary for that purpose.

Or. en

Amendment 122

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.

deleted

The procedures set out in Articles 82(2) to (5) [of revised Directive 2001/83/EC] shall accordingly apply to the prolongation of market exclusivity.

Or. en

Amendment 123

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

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.

three 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 124

Proposal for a regulation Article 72 – paragraph 4

Text proposed by the Commission

4. Article 71(3) equally applies to the prolongations of market exclusivity referred to in **paragraphs 1 and 2**.

Amendment

4. Article 71(3) equally applies to the prolongations of market exclusivity referred to in **paragraph 1**.

Or. en

Amendment 125

Proposal for a regulation Article 74 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission

(b) following the acceptance by the Agency of a justified request from an applicant in accordance with paragraph 3.

Amendment

(b) following the acceptance by the Agency of a **duly** justified request from an applicant in accordance with paragraph 3.

Or. en

Amendment 126

Proposal for a regulation Article 74 – paragraph 3

Text proposed by the Commission

3. When it is not possible, on the basis

Amendment

3. When it is not possible, on the basis

of scientifically justified reasons, to have a complete paediatric development plan in accordance with the timing given in Article 76(1) an applicant may submit a justified request to the Agency to utilise the procedure mentioned in paragraph 2. The Agency has 20 days to accept or refuse the request and shall immediately inform the applicant and state the reasons for refusal.

of scientifically justified reasons, to have a complete paediatric development plan in accordance with the timing given in Article 76(1) an applicant may submit a **duly** justified request to the Agency to utilise the procedure mentioned in paragraph 2. The Agency has 20 days to accept or refuse the request and shall immediately inform the applicant and state the reasons for refusal.

Or. en

Amendment 127

Proposal for a regulation

Article 75 – paragraph 1 – point a

Text proposed by the Commission

(a) that the specific medicinal product or class of medicinal products is likely to be ineffective or unsafe in part or all of the paediatric population;

Amendment

(a) that the specific medicinal product or class of medicinal products is **very** likely to be ineffective or unsafe in part or all of the paediatric population;

Or. en

Amendment 128

Proposal for a regulation

Article 94 – paragraph 2 – subparagraph 3

Text proposed by the Commission

If for justified scientific reasons it is not possible to submit the summary of the result of the trial within 6 months it shall be submitted to the EU database at the latest within twelve months after the trial has ended. The justification for the delay needs also to be submitted in the EU database.

Amendment

If for justified scientific reasons it is not possible to submit the summary of the result of the trial within 6 months it shall be submitted to the EU database at the latest within twelve months after the trial has ended. The justification for the delay needs also to be submitted in the EU database. ***Non-compliance with Regulation (EU) No 536/2014 shall be subject to penalties.***

Or. en

Amendment 129

Proposal for a regulation

Article 104 – paragraph 1 – subparagraph 1 – introductory part

Text proposed by the Commission

The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a European medicines web-portal for the dissemination of information on medicinal products authorised or to be authorised in the Union. By means of that portal, the Agency shall make public the following:

Amendment

The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a European medicines web-portal for the dissemination of information on medicinal products authorised or to be authorised in the Union. By means of that portal, the Agency shall make public the following. ***The dedicated webportal shall be set up in accordance with Directive (EU) 2016/2102 of the European Parliament and of the Council^{1a}:***

^{1a} Directive (EU) 2016/2102 of the European Parliament and of the Council of 26 October 2016 on the accessibility of the websites and mobile applications of public sector bodies (OJ L 327, 2.12.2016, p. 1).

Or. en

Amendment 130

Proposal for a regulation

Article 104 – paragraph 1 – subparagraph 1 – point c

Text proposed by the Commission

(c) ***a summary of*** the risk management plans for medicinal products authorised in accordance with this Regulation;

Amendment

(c) the risk management plans for medicinal products authorised in accordance with this Regulation ***and the accompanying summaries of the risk management plans;***

Or. en

Amendment 131

Proposal for a regulation

Article 104 – paragraph 1 – subparagraph 2

Text proposed by the Commission

The summaries referred to in point (c) shall include a description of any additional risk minimisation measures.

Amendment

The ***risk mitigation plans and*** summaries referred to in point (c) shall include a description of any additional risk minimisation measures.

Or. en

Amendment 132

Proposal for a regulation

Article 104 – paragraph 3 – subparagraph 2

Text proposed by the Commission

Information in such register shall be publicly available, unless restrictions are necessary to protect commercially confidential information. For the purpose of setting up such register, the Agency may request marketing authorisation holders and competent authorities to submit results of any such study already completed for products authorised in the Union within [OP please add the date = 24 months after the date of application of this Regulation].

Amendment

Information in such register shall be publicly available ***and be easily accessible on the Agency's website***, unless restrictions are necessary to protect commercially confidential information. For the purpose of setting up such register, the Agency may request marketing authorisation holders and competent authorities to submit results of any such study already completed for products authorised in the Union within [OP please add the date = 24 months after the date of application of this Regulation].

Or. en

Amendment 133

Proposal for a regulation

Article 105 – paragraph 3

Text proposed by the Commission

3. The Agency shall, in consultation

Amendment

3. The Agency shall, in consultation

with the Commission, Member States and ***interested*** parties, draw up a detailed guide regarding the monitoring of medical literature and the entry of relevant information into the Eudravigilance database.

with the Commission, Member States and ***their relevant authorities, as well as other relevant*** parties, ***including experts from academia***, draw up a detailed guide regarding the monitoring of medical literature and the entry of relevant information into the Eudravigilance database.

Or. en

Amendment 134

Proposal for a regulation Article 113

Text proposed by the Commission

Amendment

[...]

deleted

Or. en

Amendment 135

Proposal for a regulation Article 114

Text proposed by the Commission

Amendment

Article 114

deleted

Products developed under a sandbox

1. When authorising a clinical trial application for products covered by a regulatory sandbox, Member States shall take the sandbox plan referred to in Article 113(1) into consideration.

2. A medicinal product developed as part of a regulatory sandbox may be placed on the market only when authorised in accordance with this Regulation. The initial validity of such authorisation shall not exceed the duration of the regulatory sandbox. The authorisation may be prolonged at the

request of the marketing authorisation holder.

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 [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.

4. For medicinal products developed as part of a regulatory sandbox for which a marketing authorisation has been granted in accordance with paragraph 2 and where appropriate paragraph 3, the summary of product characteristics and the package leaflet shall indicate that the medicinal product has been developed as part of a regulatory sandbox.

5. Without prejudice to Article 195 of [revised Directive 2001/83/EC], the Commission shall suspend a marketing authorisation granted in accordance with paragraph 2, where the regulatory sandbox has been suspended or revoked in accordance with Article 113(7).

6. The Commission shall immediately vary the marketing authorisation to take account of the mitigation measures taken in accordance with Article 115.

Or. en

Amendment 136

Proposal for a regulation Article 115

Article 115

deleted

General sandbox provisions

1. 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).

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.

2. Participants in the regulatory sandbox, in particular the marketing authorisation holder of the medicinal product concerned, shall remain liable under applicable Union and Member States liability legislation for any harm inflicted on third parties as a result from the testing taking place in the sandbox. They shall inform the Agency without undue delay of any information which might entail the amendment of the regulatory sandbox or concerns the quality, safety or efficacy of products developed as part of a regulatory sandbox.

3. The modalities and the conditions of the operation of the regulatory sandboxes, including the eligibility criteria and the procedure for the application, selection, participation and exiting from the sandbox, and the rights and obligations of the participants shall be set out in implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 173(2).

4. *The Agency with input from Member States shall submit annual reports to the Commission on the results from the implementation of a regulatory sandbox, including good practices, lessons learnt and recommendations on their setup and, where relevant, on the application of this Regulation and other Union legal acts supervised within the sandbox. These reports shall be made publicly available by the Commission.*

5. *The Commission shall review the reports and put forward, as appropriate, legislative proposals with a view to update the regulatory framework referred to in Article 113(2) or delegated acts in accordance with Article 28 of [revised Directive 2001/83/EC].*

Or. en

Amendment 137

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

Text proposed by the Commission

(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).

Amendment

(d) a temporary disruption in supply of a medicinal product in a given Member State 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).

Or. en

Amendment 138

Proposal for a regulation Article 117 – paragraph 1

Text proposed by the Commission

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.

Amendment

1. ***By ... [12 months after the date of entry into force of this Regulation],*** the marketing authorisation holder as defined in Article 116(1) shall ***prepare*** a shortage prevention plan ***and send it to the competent authority as defined in Article 116(1),*** for any medicinal product placed on the market. ***The shortage prevention plan shall be kept up to date and ready to be sent to the public authority upon its request.*** 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

Amendment 139

Proposal for a regulation Article 117 – paragraph 2

Text proposed by the Commission

2. The Agency, in collaboration with the working party referred to in Article 121(1), ***point (c), shall*** draw up guidance to marketing authorisation holders as defined in Article 116(1) to put in place the shortage prevention plan.

Amendment

2. The Agency ***shall***, in collaboration with the working party referred to in Article 121(1) ***and after consultation with healthcare professionals and patient and consumer organisations,*** draw up guidance to marketing authorisation holders as defined in Article 116(1) to put in place the shortage prevention plan.

Or. en

Amendment 140

Proposal for a regulation

Article 117 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. The shortage prevention plans shall be made available to healthcare professionals and patient and consumer organisations on a dedicated website by the competent authority.

Or. en

Amendment 141

Proposal for a regulation

Article 118 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Amendment

Based on the reports referred to in Articles 120(1) and 121(1), point (c), information referred to in Articles 119, 120(2) and 121 and the notification made pursuant to Article 116(1), points (a) to (d), the competent authority concerned as referred to in Article 116(1) shall continuously monitor any potential or actual shortage of those medicinal products.

Based on the reports referred to in Articles 120(1) and 121(1), point (c), information referred to in Articles 119, 120(2) and 121 **of this Regulation, the information contained in the repositories system referred to in Article 67(2), second subparagraph, point (e), of [revised Directive 2001/83/EC]**, and the notification made pursuant to Article 116(1), points (a) to (d), **of this Regulation**, the competent authority concerned as referred to in Article 116(1) **of this Regulation** shall continuously monitor any potential or actual shortage of those medicinal products.

Or. en

Amendment 142

Proposal for a regulation

Article 118 – paragraph 2

Text proposed by the Commission

2. For the purposes of paragraph 1, the competent authority concerned as defined in Article 116(1) may request any additional information from the marketing authorisation holder as defined in Article 116(1). In particular, it may request the marketing authorisation holder to submit a shortage mitigation plan in accordance with Article 119(2), a risk assessment of impact of suspension, cessation or withdrawal in accordance with Article 119(3), or the shortage prevention plan referred to in Article 117. The competent authority concerned **may** set a deadline for the submission of the information requested.

Amendment

2. For the purposes of paragraph 1, the competent authority concerned as defined in Article 116(1) may request any additional information from the marketing authorisation holder as defined in Article 116(1). In particular, it may request the marketing authorisation holder to submit a shortage mitigation plan in accordance with Article 119(2), a risk assessment of impact of suspension, cessation or withdrawal in accordance with Article 119(3), or the shortage prevention plan referred to in Article 117. The competent authority concerned **shall** set a deadline for the submission of the information requested.

Or. en

Amendment 143

Proposal for a regulation

Article 120 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. For the purposes of the reporting in accordance with Article 118(1) and for the early detection of supply shortages, wholesalers shall transmit the information set out in Part Va of Annex IV to the competent authorities of the Member States in a timely manner.

Or. en

Amendment 144

Proposal for a regulation

Article 120 – paragraph 2

Text proposed by the Commission

2. For the purposes of Article 118(1), where relevant, upon request from the competent authority concerned as defined in Article 116(1), entities including other marketing authorisation holders as defined in Article 116(1), importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public shall provide any information requested in a timely manner.

Amendment

2. For the purposes of Article 118(1), where relevant, upon request from the competent authority concerned as defined in Article 116(1), entities including other marketing authorisation holders as defined in Article 116(1), importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public shall provide any **relevant** information requested in a timely manner.

Or. en

Amendment 145

Proposal for a regulation

Article 121 – paragraph 1 – point b

Text proposed by the Commission

(b) publish information on actual shortages of medicinal products, ***in cases in which*** that competent authority has assessed the shortage, on a publicly available website;

Amendment

(b) publish information on ***all expected or*** actual shortages of medicinal products, ***the reason for the shortage, as well as measures taken to counter the expected or actual shortage, as soon as*** that competent authority has assessed the shortage ***and provided clear recommendations and possible alternatives to healthcare professionals and patients,*** on a publicly available ***and user-friendly*** website;

Or. en

Amendment 146

Proposal for a regulation

Article 121 – paragraph 2 – point f

Text proposed by the Commission

(f) inform the Agency of any actions foreseen or taken by that Member State to mitigate the shortage at national level.

Amendment

(f) inform the Agency of any actions foreseen or taken by that Member State to mitigate the shortage at national level ***without undue delay.***

Or. en

Amendment 147

Proposal for a regulation

Article 121 – paragraph 5 – point a

Text proposed by the Commission

(a) report to the Agency on any information received from the marketing authorisation holder as defined in Article 116(1) of the medicinal product concerned or from other actors pursuant to Article ***120(2)***;

Amendment

(a) report to the Agency on any information received from the marketing authorisation holder as defined in Article 116(1) of the medicinal product concerned or from other actors pursuant to Article ***120(1a) and (2)***;

Or. en

Amendment 148

Proposal for a regulation

Article 122 – paragraph 4 – introductory part

Text proposed by the Commission

4. For the purposes of fulfilling the tasks referred to in Articles 118(1), 123 and 124, the Agency shall ensure the following, in consultation with the working party referred to in Article 121(1), point (c):

Amendment

4. For the purposes of fulfilling the tasks referred to in Articles 118(1), 123 and 124, the Agency shall ensure the following, in consultation with the working party referred to in Article 121(1), point (c) ***and in consultation with relevant patient and consumer organisations:***

Or. en

Amendment 149

Proposal for a regulation Article 122 – paragraph 6

Text proposed by the Commission

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 systems and databases, without duplication of reporting.

Amendment

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 systems and **where relevant, with** other relevant IT systems and databases, without duplication of reporting. **The Agency shall work towards making the ESMP fully digitalised.**

Or. en

Amendment 150

Proposal for a regulation Article 124 – paragraph 2 – subparagraph 2

Text proposed by the Commission

For the purposes of this paragraph, the Agency **may** set a deadline for the submission of the information requested.

Amendment

For the purposes of this paragraph, the Agency **shall** set a deadline for the submission of the information requested.

Or. en

Amendment 151

Proposal for a regulation Article 124 – paragraph 3

Text proposed by the Commission

3. The Agency shall establish within its web-portal referred to in Article 104 a publicly available webpage that provides information on actual critical shortages of medicinal products **in cases in which** the

Amendment

3. The Agency shall establish within its web-portal referred to in Article 104 a publicly available **and user-friendly** webpage that provides information on **all** actual critical shortages of medicinal

Agency ***has assessed the shortage and has provided*** recommendations to healthcare professionals and patients. This webpage shall also provide references to the lists of actual shortages published by the competent authorities of the Member State pursuant to Article 121(1), point (b).

products, ***including the reasons for the shortages. After assessing the shortages, the Agency shall provide*** recommendations to healthcare professionals and patients. This webpage shall also provide references to the lists of actual shortages published by the competent authorities of the Member State pursuant to Article 121(1), point (b)

Or. en

Amendment 152

Proposal for a regulation

Article 125 – paragraph 1 – point c

Text proposed by the Commission

(c) ***take into account*** the recommendations referred to in Article 123(4);

Amendment

(c) ***comply with*** the recommendations referred to in Article 123(4);

Or. en

Amendment 153

Proposal for a regulation

Article 125 – paragraph 1 – point f

Text proposed by the Commission

(f) inform the Agency of the end date of the critical shortage.

Amendment

(f) inform the Agency of the end date of the critical shortage ***without undue delay***;

Or. en

Amendment 154

Proposal for a regulation

Article 125 – paragraph 1 – point f a (new)

Text proposed by the Commission

Amendment

(fa) inform the Agency of the cause of the critical shortage no later than 14 working days after it has been resolved.

Or. en

Amendment 155

Proposal for a regulation Article 127 – paragraph 1

Text proposed by the Commission

1. The competent authority of the Member State shall identify critical medicinal products in that Member State, using the methodology set out in Article 130(1), point (a).

Amendment

1. The competent authority of the Member State shall, ***after consultation with healthcare professionals and national patient and consumer organisations***, identify critical medicinal products in that Member State, using the methodology set out in Article 130(1), point (a).

Or. en

Amendment 156

Proposal for a regulation Article 127 – paragraph 4

Text proposed by the Commission

4. For the purposes of the identification of critical medicinal products referred to in paragraph 1, the competent authority of the Member State may request relevant information from other entities including other marketing authorisation holders, importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal

Amendment

4. For the purposes of the identification of critical medicinal products referred to in paragraph 1, the competent authority of the Member State may request relevant information from other entities including other marketing authorisation holders, importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal

entities that are authorised or entitled to supply medicinal products to the public.

entities that are authorised or entitled to supply medicinal products to the public.
Those actors shall state whether the information provided to the competent authority of the Member States contains any commercially confidential information, provide a justification for that statement and indicate the information in question.

Or. en

Amendment 157

Proposal for a regulation Article 129 – paragraph 1

Text proposed by the Commission

For the purposes of Article 127(4) and Article 130(2), point (c), and Article 130(4), point (c), where relevant, upon request from the competent authority concerned as defined in Article 116(1), entities including other marketing authorisation holders as defined in Article 116(1), importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public shall provide any information requested in a timely manner.

Amendment

For the purposes of Article 127(4) and Article 130(2), point (c), and Article 130(4), point (c), where relevant, upon request from the competent authority concerned as defined in Article 116(1), entities including other marketing authorisation holders as defined in Article 116(1), importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public shall provide any information ***pro-actively where they deem it necessary or as*** requested in a timely manner.

Or. en

Amendment 158

Proposal for a regulation Article 130 – paragraph 1 – subparagraph 1 – introductory part

Text proposed by the Commission

The Agency shall, in collaboration with the working party referred to in Article 121(1), point (c), ensure the following:

Amendment

The Agency shall, in collaboration with the working party referred to in Article 121(1), point (c) ***and after consultation with patient organisations***, ensure the following:

Or. en

Amendment 159

Proposal for a regulation

Article 130 – paragraph 1 – subparagraph 1 – point a

Text proposed by the Commission

(a) develop a common methodology to identify critical medicinal products, including the evaluation of vulnerabilities with respect to the supply chain of those medicines, in consultation, ***where appropriate***, with relevant stakeholders;

Amendment

(a) develop a common methodology to identify critical medicinal products, including the evaluation of ***the therapeutic indication***, vulnerabilities ***and the availability of appropriate alternatives*** with respect to the supply chain of those medicines, in consultation with ***patient and consumer organisations, as well as other*** relevant stakeholders;

Or. en

Amendment 160

Proposal for a regulation

Article 131 – paragraph 1

Text proposed by the Commission

1. Following the reporting referred to in Article 130, paragraph 2, second subparagraph, and Article 130(5), the MSSG shall consult the working party referred to in Article 121(1), point (c). Based on this consultation, the MSSG shall propose a Union list of critical medicinal products authorised to be placed on the

Amendment

1. Following the reporting referred to in Article 130, paragraph 2, second subparagraph, and Article 130(5), the MSSG shall consult the working party referred to in Article 121(1), point (c), ***and patient and consumer organisations, as well as other relevant stakeholders as set out in Article 162 of this Regulation***.

market of a Member State pursuant to Article 5 of [revised Directive 2001/83/EC] and for which coordinated Union level action is necessary (“the Union list of critical medicinal products”).

Based on this consultation, the MSSG shall propose a Union list of critical medicinal products authorised to be placed on the market of a Member State pursuant to Article 5 of [revised Directive 2001/83/EC] and for which coordinated Union level action is necessary (“the Union list of critical medicinal products”).

Or. en

Amendment 161

Proposal for a regulation Article 131 – paragraph 2

Text proposed by the Commission

2. The MSSG *may* propose updates to the Union list of critical medicines to the Commission, where necessary.

Amendment

2. The MSSG *shall* propose updates to the Union list of critical medicines to the Commission, where necessary.

Or. en

Amendment 162

Proposal for a regulation Article 132 – paragraph 1

Text proposed by the Commission

1. Following the adoption of the Union list of critical medicinal products pursuant to Article 131(3), in consultation with the Agency and the working party referred to in Article 121(1), point (c), the MSSG may provide recommendations, in accordance with the methods referred to in Article 130(1), point (d), on appropriate security of supply measures to marketing authorisation holders as defined in Article 116(1), the Member States, the Commission or other entities. Such measures may include recommendations on diversification of suppliers *and*

Amendment

1. Following the adoption of the Union list of critical medicinal products pursuant to Article 131(3), in consultation with the Agency and the working party referred to in Article 121(1), point (c), the MSSG may provide recommendations, in accordance with the methods referred to in Article 130(1), point (d), on appropriate security of supply measures to marketing authorisation holders as defined in Article 116(1), the Member States, the Commission or other entities. Such measures may include recommendations on diversification of suppliers, inventory

inventory management.

management *and pricing mechanisms and cost-containment measures*.

Or. en

Amendment 163

Proposal for a regulation

Article 133 – paragraph 1 – point c

Text proposed by the Commission

(c) *take into account* the recommendations referred to in Article 132(1);

Amendment

(c) *comply with* the recommendations referred to in Article 132(1);

Or. en

Amendment 164

Proposal for a regulation

Article 134 – paragraph 1 – introductory part

Text proposed by the Commission

1. The Commission *may, where it considers it appropriate and necessary:*

Amendment

1. The Commission *shall:*

Or. en

Amendment 165

Proposal for a regulation

Article 134 – paragraph 2

Text proposed by the Commission

2. The Commission, taking into consideration the information or the opinion, referred to in paragraph 1, or MSSG recommendations, may decide to adopt an implementing act to improve security of supply. *The implementing act*

Amendment

2. The Commission, taking into consideration the information or the opinion, referred to in paragraph 1, or MSSG recommendations, may decide to adopt an implementing act to improve security of supply *and* other relevant

may impose contingency stock requirements of active pharmaceutical ingredient or finished dosage forms, or other relevant measures required to improve security of supply, on marketing authorisation holders, wholesale distributors ***or*** other relevant entities.

measures required to improve security of supply, on marketing authorisation holders, wholesale distributors ***and*** other relevant entities.

Or. en

Amendment 166

Proposal for a regulation Article 134 a (new)

Text proposed by the Commission

Amendment

Article 134a

General provisions

- 1. Member States may introduce or maintain more robust provisions than those provided for in this Regulation with regard to the security of supply of and the availability of medicinal products.***
- 2. The implementation of this Regulation shall in no circumstances constitute grounds for a reduction of the level of safeguards already afforded by Member States with regard to the security and availability of supply of medicinal products. Where Member States detect infringements of measures in relation to Chapter X, penalties in accordance with Article 171(1) shall be imposed without undue delay.***

Or. en

Amendment 167

Proposal for a regulation Article 138 – paragraph 1 – subparagraph 2 – point a

Text proposed by the Commission

(a) coordinating the scientific evaluation of the quality, safety and efficacy of medicinal products for human use, which are subject to Union marketing authorisation procedures;

Amendment

(a) coordinating the scientific evaluation of the quality, safety and efficacy of medicinal products for human use, which are subject to Union marketing authorisation procedures; ***the Agency, after consulting with relevant national authorities and national bodies responsible for pricing and reimbursement in accordance with Article 162 and the health technology coordination group established by Article 3 of Regulation (EU) 2021/2282, shall set out binding uniform standards for the design of scientific studies.***

Or. en

Amendment 168

Proposal for a regulation

Article 138 – paragraph 1 – subparagraph 2 – point n

Text proposed by the Commission

(n) creating a database on medicinal products for human use, to be accessible to the general public, and ensuring that it is updated, and managed independently of pharmaceutical companies; the database is to facilitate the search for information already authorised for package leaflets; it is to include a section on medicinal products for human use authorised for the treatment of children; the information provided to the general public is to be worded in an appropriate and comprehensible manner;

Amendment

(n) creating a ***user-friendly*** database on medicinal products for human use, to be accessible to the general public, and ensuring that it is updated, and managed independently of pharmaceutical companies; the database is to facilitate the search for information already authorised for package leaflets; it is to include a section on medicinal products for human use authorised for the treatment of children; the information provided to the general public is to be worded in an appropriate and comprehensible manner;

Or. en

Amendment 169

Proposal for a regulation

Article 138 – paragraph 1 – subparagraph 2 – point zl

Text proposed by the Commission

(zl) drawing up scientific guidelines to facilitate the implementation of the definitions established in this Regulation and in [revised Directive 2001/83], and for the environmental risk assessment of medicinal products for human use, in consultation with the Commission and the Member States.

Amendment

(zl) drawing up scientific guidelines to facilitate the implementation of the definitions established in this Regulation and in [revised Directive 2001/83], and for the environmental risk assessment of medicinal products for human use, in consultation with the Commission and the Member States ***and relevant stakeholders, including research institutions, healthcare professionals, and patient and consumer organisations.***

Or. en

Amendment 170

Proposal for a regulation

Article 138 – paragraph 1 – subparagraph 2 – point zl a (new)

Text proposed by the Commission

Amendment

(zla) where scientific guidelines are provided, the Agency shall ensure that such guidelines are always kept up-to-date and based on the latest scientific developments.

Or. en

Amendment 171

Proposal for a regulation

Article 138 – paragraph 2 – subparagraph 1

Text proposed by the Commission

Amendment

The database provided for in paragraph 1, point (n), shall include all medicinal

The database provided for in paragraph 1, point (n), shall include all medicinal

products for human use authorised in the Union together with the summaries of product characteristics, the package leaflet and the information shown on the labelling. Where relevant, it shall include the electronic links to the dedicated webpages where the marketing authorisation holders have reported the information pursuant to Article 40(4), point (b), and Article 57 of [revised Directive 2001/83/EC].

products for human use authorised in the Union together with the summaries of product characteristics, the package leaflet and the information shown on the labelling, ***as well as Member States where the medicinal product is placed on the market.*** Where relevant, it shall include the electronic links to the dedicated webpages where the marketing authorisation holders have reported the information pursuant to Article 40(4), point (b), and Article 57 of [revised Directive 2001/83/EC].

Or. en

Amendment 172

Proposal for a regulation

Article 138 – paragraph 2 – subparagraph 3

Text proposed by the Commission

Where appropriate, the database shall also include references to clinical trials currently being carried out or already completed, contained in the clinical trials database provided for in Article 81 of Regulation (EU) No 536/2014.

Amendment

The database shall also include references to clinical trials currently being carried out or already completed, contained in the clinical trials database provided for in Article 81 of Regulation (EU) No 536/2014.

Or. en

Amendment 173

Proposal for a regulation

Article 142 – paragraph 1 – point j a (new)

Text proposed by the Commission

Amendment

(ja) an ad hoc working group on Advanced Therapy Medicinal Products ;

Or. en

Amendment 174

Proposal for a regulation

Article 142 – paragraph 1 – point j b (new)

Text proposed by the Commission

Amendment

**(jb) an ad hoc working group on
Orphan Medicinal Products ;**

Or. en

Amendment 175

Proposal for a regulation

Article 142 – paragraph 1 – point j c (new)

Text proposed by the Commission

Amendment

**(jc) an ad hoc working group on
Paediatric Committee ;**

Or. en

Amendment 176

Proposal for a regulation

Article 142 – paragraph 1 – point k a (new)

Text proposed by the Commission

Amendment

**(ka) create a pool of experts from
Member States and relevant stakeholders
to work in the ad hoc working groups; the
members shall be selected based on
relevant experience in relation to the
different ad hoc working groups, so they
can contribute to the regulatory support
and scientific advice procedures, and they
shall be free of any conflicts of interest.**

Or. en

Amendment 177

Proposal for a regulation Article 147 – title

Text proposed by the Commission

Conflict of interest

Amendment

Transparency and conflict of interest

Or. en

Amendment 178

Proposal for a regulation Article 147 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Members of the Management Board, members of the committees, rapporteurs and experts shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an ***annual*** declaration of their financial ***interests***. ***All indirect interests which could relate to this industry shall be entered in a register held by the Agency which is accessible to the public, on request, at the Agency's offices.***

Amendment

Members of the Management Board, members of the committees, rapporteurs and experts ***shall carry out their activities in an independent, impartial and transparent manner. They*** shall not have financial or other interests in the pharmaceutical industry which could affect their ***independence or*** impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an ***annual*** declaration of their financial ***and other*** interests ***and update it whenever necessary. They shall disclose any other facts of which they become aware that might in good faith reasonably be expected to involve, or give rise to, a conflict of interest.***

Or. en

Amendment 179

Proposal for a regulation Article 147 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Amendment

The Agency's code of conduct shall provide for the implementation of this Article with particular reference to the acceptance of gifts.

deleted

Or. en

Amendment 180

Proposal for a regulation Article 147 – paragraph 2

Text proposed by the Commission

Amendment

2. Members of the Management Board, members of the committees, rapporteurs and experts who participate in meetings or working groups of the Agency shall declare, at each meeting, any specific interests which could be considered to be prejudicial to their independence with respect to the items on the agenda. These declarations shall be made available to the public.

2. Members of the Management Board, members of the committees, rapporteurs and experts who participate in meetings or working groups of the Agency shall declare, at each meeting, any specific interests which could be considered to be prejudicial to their independence ***or impartiality*** with respect to the items on the agenda. These declarations shall be made available to the public. ***Where the Agency decides that a declared interest constitutes a conflict of interest, that representative shall not take part in any discussions or decision-making, or obtain any information concerning that item of the agenda. Such declarations of representatives and the decision of the Commission shall be recorded in the summary minutes of the meeting.***

Or. en

Amendment 181

Proposal for a regulation Article 147 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Patients, clinical experts and other relevant experts shall declare any financial and other interests relevant to the joint work in which they are due to participate. Such declarations and any actions taken as a result shall be recorded in the summary minutes of the meeting and in the outcome documents of the joint work in question.

Or. en

Amendment 182

Proposal for a regulation

Article 147 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2b. All indirect interests which could relate to the pharmaceutical industry shall be entered in a register held by the Agency which is accessible to the public.

The Agency's code of conduct shall provide for the implementation of this Article with particular reference to the acceptance of gifts.

Or. en

Amendment 183

Proposal for a regulation

Article 148 – paragraph 3 – point a a (new)

Text proposed by the Commission

Amendment

(aa) four co-opted members chosen by the Committee among experts proposed by Member States or the Agency on the basis of their specific scientific competence and expertise, with a view to ensuring that the

relevant expertise is available within the Committee for the purpose of working groups and ad-hoc working groups in the field of advanced therapy medicinal products, paediatric medicinal products, herbal medicinal products and orphan medicinal products.

Or. en

Amendment 184

Proposal for a regulation Article 150 – title

Text proposed by the Commission

Scientific working parties and scientific advisory groups

Amendment

Scientific ***working parties, ad-hoc*** working groups and scientific advisory groups

Or. en

Amendment 185

Proposal for a regulation Article 150 – paragraph 3 – subparagraph 2

Text proposed by the Commission

The majority of the members of the working parties shall consist of experts from the competent authorities of the Member States. Where appropriate, the Committee for Human Medicinal Products may, following consultation with the Management Board, set a minimum number of experts from the competent authorities in a working party.

Amendment

The majority of the members of the working parties shall consist of experts from the competent authorities of the Member States. ***Patient representatives shall also be included as members of the working parties.*** Where appropriate, the Committee for Human Medicinal Products may, following consultation with the Management Board, set a minimum number of experts from the competent authorities in a working party.

Or. en

Amendment 186

Proposal for a regulation Article 153 – paragraph 1

Text proposed by the Commission

At the request of the Commission, the Agency shall, in respect of authorised medicinal products for human use, collect any available information on methods that Member States' competent authorities use to determine the added therapeutic value that any new medicinal product for human use provides.

Amendment

At the request of the Commission, the Agency shall, in respect of authorised medicinal products for human use, collect any available information on methods that Member States' competent authorities use to determine the added therapeutic value that any new medicinal product for human use provides. ***Guidelines for the determination of added therapeutic value shall be drawn up in collaboration with patient organisations.***

Or. en

Amendment 187

Proposal for a regulation Article 162 – paragraph 2

Text proposed by the Commission

2. The Agency ***may*** extend the consultation process to patients, medicine developers, healthcare professionals, industries or other stakeholders, ***as relevant.***

Amendment

2. The Agency ***shall*** extend the consultation process to patients, medicine developers, healthcare professionals, industries or other ***relevant*** stakeholders.

Or. en

Amendment 188

Proposal for a regulation Article 166 – paragraph 1

Text proposed by the Commission

1. To support its public health tasks and in particular the evaluation and

Amendment

1. To support its public health tasks and in particular the evaluation and

monitoring medicinal products or the preparation of regulatory decisions and scientific opinions, the Agency may process personal health data, from sources other than clinical trials, for the purpose of improving the robustness of its scientific assessment or verifying claims of the applicant or marketing authorisation holder in the context of the evaluation or supervision of medicinal product.

monitoring medicinal products or the preparation of regulatory decisions and scientific opinions, the Agency may process personal health data, from sources other than clinical trials, ***including the Eudravigilance database, electronic health data obtained pursuant to the applicable rules of the European Health Data Space***, for the purpose of improving the robustness of its scientific assessment or verifying claims of the applicant or marketing authorisation holder in the context of the evaluation or supervision of medicinal product.

Or. en

Amendment 189

Proposal for a regulation

Article 166 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

Such data shall in particular include personal electronic health data as defined in Regulation (EU) .../... [draft EHDS Regulation 2022/0140(COD)] and where relevant, data from monitoring studies on the use, effectiveness and safety of medicinal products intended for treatment, prevention, or the diagnosis of disease, including health data provided by public authorities and data as referred to in Article 20, first paragraph, point (b), of Regulation (EU) 2022/123.

Or. en

Amendment 190

Proposal for a regulation

Article 166 – paragraph 2

Text proposed by the Commission

2. The Agency may consider and decide upon additional evidence available, independently from the data submitted by the marketing authorisation applicant or marketing authorisation holder. On that basis, the summary of product characteristics shall be updated if the additional evidence has an impact on the benefit-risk balance of a medicinal product.

Amendment

2. The Agency may consider and decide upon additional evidence available, independently from the data submitted by the marketing authorisation applicant or marketing authorisation holder. On that basis, the summary of product characteristics shall be updated if the additional evidence has an impact on the benefit-risk balance of a medicinal product. ***Such update shall only take place after the consultation with the marketing authorisation applicant or marketing authorisation holder concerned.***

Or. en

Amendment 191

Proposal for a regulation

Article 169 – paragraph 1 – subparagraph 2 – point b

Text proposed by the Commission

(b) as regards special categories of personal data, is strictly necessary and subject to appropriate safeguards, which may include pseudonymisation.

Amendment

(b) as regards special categories of personal data, is strictly necessary and subject to appropriate safeguards, which may include ***anonymisation and pseudonymisation requirements and techniques, data minimisation and retention measures, specific organisational measures and access controls on a ‘need to know’ basis and other appropriate measures, confidentiality requirements, and fundamental rights of data subjects as set out in Regulations (EU) 2016/679 and (EU) 2018/1725.***

Or. en

Amendment 192

Proposal for a regulation Article 169 – paragraph 3

Text proposed by the Commission

Amendment

3. *The processing of personal data by the Agency in the context of this Article shall be guided by the principles of transparency, explainability, fairness, and accountability.* ***deleted***

Or. en

Amendment 193

Proposal for a regulation Article 171 – paragraph 1

Text proposed by the Commission

Amendment

1. Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, without delay, notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.

1. ***By ... [six months after the date of entry into force of this Regulation],*** Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, without delay, notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.

Or. en

Amendment 194

Proposal for a regulation Article 172 – paragraph 1

Text proposed by the Commission

1. The Commission **may** impose financial penalties in the form of fines or periodic penalty payments on the marketing authorisations holder granted under this Regulation if they fail to comply with any of the obligations laid down in Annex II in connection with the marketing authorisations.

Amendment

1. The Commission **shall** impose financial penalties in the form of fines or periodic penalty payments on the marketing authorisations holder granted under this Regulation if they fail to comply with any of the obligations laid down in Annex II in connection with the marketing authorisations. ***The penalties imposed by the Commission shall be effective, proportionate and dissuasive.***

Or. en

Amendment 195

**Proposal for a regulation
Article 180 – paragraph 13**

Text proposed by the Commission

13. By way of derogation from Article [Duration of application of Chapter III] vouchers granted until [Note to OP: insert the date of 15 years after the date of entry into force of this Regulation] or until the date when the Commission has granted a total of 10 vouchers in accordance with Chapter III, whichever date is the earliest, shall continue to be valid according to the conditions set out in Chapter III.

Amendment

deleted

Or. en

Amendment 196

**Proposal for a regulation
Annex I – point 3**

Text proposed by the Commission

3. Medicinal products for human use containing an active substance which on 20

Amendment

3. Medicinal products for human use containing an active substance which on 20

May 2004 was not authorised in the Union, excluding ***allergen products or*** herbal medicinal products, which shall in any case not be authorised by the Union.

May 2004 was not authorised in the Union, excluding herbal medicinal products, which shall in any case not be authorised by the Union.

Or. en

Amendment 197

Proposal for a regulation Annex II – point 25 a (new)

Text proposed by the Commission

Amendment

(25a) the obligation to notify the competent authority of the Member State and, where relevant, the Agency about cessation, withdrawal, temporary suspension or temporary disruption in accordance with the deadlines provided for in Article 116;

Or. en

Amendment 198

Proposal for a regulation Annex II – point 25 b (new)

Text proposed by the Commission

Amendment

(25b) the obligation to have in place and keep up to date a shortage prevention plan as provided for in Article 117;

Or. en

Amendment 199

Proposal for a regulation Annex II – point 25 c (new)

Text proposed by the Commission

Amendment

(25c) the obligation to comply with the recommendations and measures taken in case of a critical shortage as provided for in Article 125;

Or. en

Amendment 200

Proposal for a regulation Annex II – point 25 d (new)

Text proposed by the Commission

Amendment

(25d) the obligation to comply with the recommendations and measures taken in relation to critical medicinal products as provided for in Article 133.

Or. en

Amendment 201

Proposal for a regulation Annex IV – Part V a (new)

Text proposed by the Commission

Amendment

Part Va

For the purposes of reporting in accordance with Article 118(1) and for the early detection of supply shortages, wholesalers shall provide the following information in a timely manner:

1. Product availability information:

Product availabilities shall be reported per wholesale warehouse and shall be indexed as yes/no.

2. Service level information:

Service level information which captures

the level of fulfilment of wholesale orders by marketing authorisation holders and suppliers shall be reported. Such information involves comparing the quantity ordered with the quantity actually received at the product level. The resulting difference describes the service level.

Or. en

EXPLANATORY STATEMENT

The Rapporteur welcomes the long-awaited proposals on both the pharmaceutical Regulation and the Directive as a **centrepiece of the European Health Union**, which provide a much-needed revision for the crucial legislative framework providing the pharmaceutical rules in the Union. Given that the provisions set out in **both the Regulation and Directive are intrinsically interconnected**, the Rapporteur considers it essential that these legal texts are considered closely together.

This revision will help the Union to provide a high level of public health by ensuring quality, safety, and efficacy of medicinal products for European patients. Furthermore, it will be a step towards securing timely and equitable access for patients across all Member States. The Rapporteur is **committed to delivering on** the overarching objectives of ensuring **greater accessibility, affordability, and availability** of medicinal products for patients across the whole Union.

Furthermore, the Rapporteur **welcomes** the stepping away from the model of “one-size-fits-all” towards a **stepwise approach of incentive models**, where actual innovation is promoted and rewarded. The Rapporteur further builds on this principle in his approach to amendments on the modulation of incentives.

Increasingly in the past years the European Union has experienced occasions of shortages of critical and essential medicinal products, to the detriment of patients across the EU. The measures proposed by the European Commission are therefore very much welcomed, as we will be setting a framework to counter shortages, react efficiently and in a coordinated matter. Measures introduced include **shortage management and security of supply** of medicinal products and in particular critical medicinal products. Further developing the tasks and responsibilities of the EMA towards shortage prevention is another positive addition in the text.

In a similar vein, the Rapporteur is **positive** regarding the enhanced provisions on the **Environmental Risk Assessment** proposed by the Commission and the proposed **restructuring of the European Medicines Agency** that will facilitate streamlined procedures and accelerated marketing authorisations.

The Rapporteur is also **dubious** of Chapter IX of the proposal which introduces a **regulatory sandbox** for medicinal products. Firstly, the rapporteur considers the provisions in the Commission’s proposal vague in nature and has not been satisfied with explanations or examples of which types of products could be eligible for such a regulatory sandbox. The rapporteur also bases his decision of the deletion of this chapter after consultation with several stakeholders, and notably industry actors who expressed **reluctance with the introduction of another parallel regulatory framework**. The Rapporteur and several stakeholders consider that the frameworks within the pharmaceutical rules are broad and encompassing. There is concern that such a sandbox could provide a way of **circumventing rules and obligations laid down in the other frameworks** provided for in the Regulation. Additionally, the rapporteur would oppose derogations from the requirements set out in both the Regulation and the Directive, particularly with regards to the Environmental Risk Assessment.

Furthermore, the Rapporteur also perceives **shortcomings** within the Commission proposal,

notably on **incentives for the development of priority antimicrobials**.

Antimicrobial resistance is a rapidly increasing public health threat, already responsible for 35,000 deaths annually in the EU alone and 1.3 million deaths globally. In this regard, the Rapporteur recognises the severity of this issue and the need for the creation of new priority microbials as envisaged in the Regulation. It is also the conviction of the rapporteur that the EU must take action to prevent excessive use of antimicrobials and pharmaceutical waste in the environment, which contribute to the proliferation of antimicrobial resistance. However, the Rapporteur **expresses severe scepticism towards** the proposed solution of the **Transferable Exclusivity Voucher (TEV)** which are an indirect and non-transparent form pricing which will cost national health budgets in an unpredictable manner and delay the entry of generic medicines to the market, to the detriment of patients. It is incomprehensible to the Rapporteur that the Commission would propose such a measure without even the accompanying requirement and conditionality to guarantee supply of the priority antimicrobial from which the voucher was awarded. Additionally, the Rapporteur feels that safeguards are missing for the continuous supply of the antimicrobial after the voucher has been sold to another company.

In the absence of the TEV, the Rapporteur proposes the **establishment of the ‘European Medicines Facility’ (EMF)** as a Union Agency. The EMF should set out specific purpose led R&D projects focusing on health priorities in the public interest at a Union level. These projects should follow a strategic roadmap addressing **priority antimicrobials**, as well as medicinal products addressing **high unmet medical needs and unmet medical needs** which have not been sufficiently addressed by the private sector and where the private R&D pipeline is unlikely to deliver on medicinal products and therapies. The Rapporteur introduces the overarching idea of the EMF in this draft report and will further supplement the proposal in later amendments.

Additionally, the Rapporteur considers it necessary and complementary to mandate the Commission to establish a Union **push and pull incentives scheme** as an additional measure to incentivise the development of novel antibiotics which could include the likes of **market-entry rewards, ‘play or pay’ fees, or subscription payment mechanisms**.

This report also includes several smaller tweaks and more adaptations of a technical nature. However, the Rapporteur would like to briefly highlight increased emphasis on the **involvement of patients** and consumer organisations and the **strengthening of provisions on transparency** and conflicts of interests throughout the text.

Given the time constraints in the preparation of this draft report, the Rapporteur **reserves the right to further amend and supplement this draft report** with additional measures, clarifications and to further develop ideas introduced in the text. The Rapporteur is looking forward to **engaging constructively with all shadow rapporteurs** on this Regulation and equally the rapporteur and shadows on the Directive where coordination is necessary.

The list in the Annex of entities or persons from whom the rapporteur has received input from contains all contributions received, even if not all of it has been used in order to draft the report. Additionally, all meetings in regard to the Regulation can be found on the dedicated profile of the Rapporteur on the website of the European Parliament.

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

The following list is drawn up on a purely voluntary basis under the exclusive responsibility of the rapporteur. The rapporteur has received input from the following entities or persons in the preparation of the draft report:

Entity and/or person
EFPIA - European Federation of Pharmaceutical Industries and Associations
Medicines for Europe
Deutsche Sozialversicherung Europavertretung (DSV)
Deutsche Krankenhausgesellschaft e.V.
SIOP Europe
AbbVie
EURODIS - Rare Diseases Europe
Bundesärztekammer
Bundesverband der Arzneimittel-Hersteller e.V.
PHAGRO Bundesverband des pharmazeutischen Großhandels e. V.
Umweltbundesamt - German Environment Agency
European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
ACHSE e.V.
BioMarin Pharmaceutical Inc.
European Patients' Forum
European Brain Council
Edwards Lifesciences'
AESGP
European Social Insurance Platform (ESIP)
EurEau.
FRANCE ASSOS SANTÉ
Graphic packaging International
European patients Forum
Childhood Cancer International – Europe
BEAM Alliance
The International Association of Mutual Benefit Societies (AIM)
BPI German Pharmaceutical Industry Association
Standing Committee of European Doctors
Salud por Derecho
Dachverband der österreichischen Sozialversicherungen
European Medicines Agency
Bundesministerium für Gesundheit
Johnson & Johnson
BEUC

European Public Health Alliance
Deutsche Stiftung Weltbevölkerung
Médecins Sans Frontières
MSD
Affordable Medicines Europe
MLPS (Medical Leaflets = Patient Safety)
TRANSFORM Secretariat
PGEU
GSK
Alliance for Regenerative Medicine
European Association of Nuclear Medicine
UK Mission to the European Union
Verband der forschenden Pharma-Unternehmen (vfa)
European Chemical Industry Council - Cefic aisbl
Novartis
Sanofi
ECL - Access to medicines task force
Gesamtverband der Versicherer (GDV)
Bayer
ReAct
AnticancerFund
GIRP – European Healthcare Distribution Association
ProGenerika
Vaccines Europe