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Committee on Industry, Research and Energy

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OPINION

of the Committee on Industry, Research and Energy

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

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

Rapporteur for opinion (*): Henna Virkkunen

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

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SHORT JUSTIFICATION

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

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

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

Transferable exclusivity vouchers

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

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

Unmet medical needs

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

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

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

address UMN.

The Regulatory Sandbox

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

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

Addressing medicine shortages

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

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

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

Conclusion

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

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

AMENDMENTS

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

Amendment 1
Proposal for a regulation

Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1 a) Ensuring that Europeans receive the medicines they need, when they need them, regardless of where they live in the EU is a central objective of the European Health Union. Boosting the competitiveness of the European pharmaceutical industry, whilst also ensuring better availability of medicines and more equal and timely access for patients is a key deliverable of the proposed EU pharmaceutical reform.

Amendment 2
Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) The Pharmaceutical Strategy for Europe marks a turning point with the addition of further key objectives and by ***creating*** a modern framework that makes innovative and established medicinal products available to patients and healthcare systems at affordable prices, while ensuring security of supply and addressing environmental concerns.	(2) The Pharmaceutical Strategy for Europe marks a turning point with the addition of further key objectives and by ***supporting a conducive environment for the research, development, and manufacturing of pharmaceuticals within the Union along with*** a modern framework that makes innovative and established medicinal products available to patients and healthcare systems at affordable prices, while ensuring security of supply and addressing environmental concerns.

Amendment 3
Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2 a) The digital transformation of health and care will help increase the capacity of healthcare systems to deliver more personalised and effective health and care with less resource wasting. This regulation will contribute to the delivery

	of healthcare to European citizens, the design of health technologies and their manufacturing to be more sustainable by reducing energy consumption, waste, pollution and the release of harmful substances, including pharmaceuticals, into the environment.

Amendment 4
Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) Addressing unequal patient access of medicinal products has become a key priority of the Pharmaceutical Strategy for Europe as has been highlighted by the Council and the European Parliament. Member States have called for revised mechanisms and incentives for development of medicinal products tailored to the level of unmet medical need, while ensuring patient access and availability of medicinal products in all Member States.	(3) Addressing unequal patient access of medicinal products has become a key priority of the Pharmaceutical Strategy for Europe as has been highlighted by the Council and the European Parliament. Member States ***and the Parliament*** have called for revised mechanisms and incentives for development of medicinal products tailored to the level of unmet medical need, while ensuring patient access and availability of medicinal products in all Member States.

Amendment 5
Proposal for a regulation
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5 a) The pharmaceutical framework should be aligned with the EU's ambitions in industry, digitalization, and trade, acknowledging the critical role of the European life sciences sector, especially the pharmaceutical industry, in upholding the EU's competitive edge. Bolstering robust European research and development is crucial for European sovereignty within the ambit of a globally competitive geopolitical landscape. The pharmaceutical legislative framework should be attuned to the broader EU industrial strategy, echoing the Council's

emphasis from 23 March 2023 on amplifying incentives for investment in innovation and the 2016 Council's guidance that any amendments, including those affecting the incentive system, should not hinder the creation of drugs for rare disease treatment. Advancements in innovation are pivotal for enhancing patient health outcomes and the wider public health sector.

Amendment 6
Proposal for a regulation
Recital 5 b (new)

Text proposed by the Commission	*Amendment*
	(5 b) Beyond cooperating along the value chain of knowledge and know-how production and valorisation or within the knowledge triangle (research-education-innovation), it is in the EU's strategic interest to also reach out and cooperate with other countries outside the EU and on other continents. This applies in particular for multi-lateral cooperation on global health issues with countries associated to Horizon Europe but also with other partner countries and regions in the world. Involving international partners should lead to increased scientific knowledge among partner countries allowing to address global health challenges across the world, thus creating sustainable growth and jobs.

Amendment 7
Proposal for a regulation
Recital 9

Text proposed by the Commission	*Amendment*
(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	(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

level.

authorise them at Union level.

Amendment 8
Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission	*Amendment*
	(26 a) Research in the pharmaceutical sector has a decisive role in alleviating patients' conditions and improving public health. Favourable but balanced rules, facilitating innovation and sufficient protection to encourage such research, including through regulatory sandboxes, will contribute to make the EU markets more attractive and to promote the development of efficacious, safe, accessible, and affordable innovations for antimicrobial resistance. Research and innovation should continue to ensure the highest standards in health products.

Amendment 9
Proposal for a regulation
Recital 29

Text proposed by the Commission	*Amendment*
(29) Legal entities that are not engaged in an economic activity such as universities, public bodies, research centres or not-for-profit organisations, represent an important source of innovation and should also benefit from this support scheme. Whereas it should be possible to take account of the particular situation of these entities on an individual basis, such support can best be achieved by means of a dedicated support scheme, including administrative support and through the reduction, deferral and waiver of fees.	(29) Legal entities that are not engaged in an economic activity such as universities, public bodies, research centres or not-for-profit organisations, represent an important source of ***research in unmet medical needs, research in different subpopulations, repurposing, optimisation and*** innovation and should also benefit from this support scheme. Whereas it should be possible to take account of the particular situation of these entities on an individual basis, such support can best be achieved by means of a dedicated support scheme, including administrative support and through the reduction, deferral and waiver of fees.

Amendment 10
Proposal for a regulation
Recital 30 a (new)

Text proposed by the Commission	*Amendment*
	(30 a) For informed policy development, the Agency should maintain its authority to carry out pilot programs, fostering a regulatory environment that is adaptive to future challenges. Efforts like the 2022 pilot program that provided augmented assistance to academic and non-profit developers of advanced therapy medicinal products should inform policy decisions and refine regulatory guidance.

Amendment 11
Proposal for a regulation
Recital 36

Text proposed by the Commission	*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, 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.	(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. ***Their evaluation will continue to encompass all the necessary expertise for each product as part of the rapporteur teams, with the possibility for CHMP and PRAC to call upon additional scientific experts to provide specific input and advice on specific aspects raised during the evaluation. In addition patients and healthcare professionals will be part of the pool of experts and will also be brought into EMA's work according to their expertise in a certain disease area.*** The CHMP and PRAC consists of experts from all Member States while working parties ***and expert groups*** 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. ***Information regarding the composition and work of the committees and working groups should be publically available.***

Amendment 12
Proposal for a regulation
Recital 39

Text proposed by the Commission	*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	(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.

mechanism to consumers, patients ***and their caregivers***, healthcare professionals, industry, associations representing payers, ***academia,*** or other stakeholders, as relevant.

Amendment 13
Proposal for a regulation
Recital 42 a (new)

Text proposed by the Commission

Amendment

(42 a) Beyond cooperating along the value chain of knowledge and know-how production and valorisation or within the knowledge triangle (research-education-innovation), it is in the EU's strategic interest to also reach out and cooperate with other countries outside the EU. This applies in particular to multi-lateral cooperation on global health issues with countries associated to Horizon Europe but also with other partner countries and regions in the world. Involving international partners should lead to increased scientific knowledge among partner countries allowing to address global health challenges across the world, thus creating sustainable growth and jobs.

Amendment 14
Proposal for a regulation
Recital 43

Text proposed by the Commission

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

(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***, providing due***

products for human use.

justification to the Agency.

Amendment 15
Proposal for a regulation
Recital 45 a (new)

Text proposed by the Commission	*Amendment*
	(45 a) Particular attention should be given to the gender balance of clinical trials so that women can fully and safely benefit from medicines throughout their life-course.

Amendment 16
Proposal for a regulation
Recital 51

Text proposed by the Commission	*Amendment*
(51) As a general rule a marketing authorisation should be granted for an unlimited time; however, one renewal may be decided only on justified grounds related to the safety of the medicinal product.	(51) ***Given that the marketing authorisation holder has to forthwith submit any new data that might impact the benefit-risk balance of its products and given that the Agency has several tools available to continuously monitor the benefits and risks of authorised medicines, such as assessment of PSURs, signal detection and referrals, regulatory action will be taken as needed throughout the lifecycle of the product. Therefore,*** as a general rule a marketing authorisation should be granted for an unlimited time; however, one renewal may be decided only on justified grounds related to the safety of the medicinal product.

Amendment 17
Proposal for a regulation
Recital 79

Text proposed by the Commission	*Amendment*
(79) The creation of a voucher rewarding the development of priority antimicrobials through an additional year	(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 further give the possibility to the Commission to revoke the voucher under certain circumstances.	of regulatory data protection ***, in combination with a set of push and pull incentives scheme, constitutes an alternative able*** 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 further give the possibility to the Commission to revoke the voucher under certain circumstances.

Amendment 18
Proposal for a regulation
Recital 79 a (new)

Text proposed by the Commission	*Amendment*
	(79 a) In order to address the threat of antimicrobial resistance and its impact on public health and national healthcare budgets, the development and uptake of new economic models, pilot projects and push and pull incentives to boost the development of new therapies, diagnostics, antibiotics, medical devices and alternatives to using antimicrobials should be supported. Providing Member States with a toolkit of push and pull incentives will be decisive in tackling the growing negative impacts caused by antimicrobial resistance and will serve to address this market failure.

Amendment 19
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.	(80) A transferable data exclusivity voucher ***and other push and pull incentives schemes to boost the development of priority antimicrobials*** 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.

Amendment 20
Proposal for a regulation
Recital 87 a (new)

Text proposed by the Commission	*Amendment*
	(87 a) For medicinal products that are likely to offer an exceptional therapeutic advancement in the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the Union, with a view to enabling earlier availability for patients, the Agency should be able to perform a 'phased review' of data packages concerning finalised tests and trials before a formal application for marketing authorisation is submitted, to allow a more efficient assessment of medicinal products, while guaranteeing a high level of human health protection.

Amendment 21
Proposal for a regulation
Recital 96 a (new)

Text proposed by the Commission	*Amendment*
	(96 a) The regulatory pathway can be uncertain and lack flexibility towards the unique challenges of orphan medicinal products, both in the way developers are required to meet evidentiary standards and in the interactions between developers and the regulatory actors. Therefore, the Agency should develop a dedicated and tailored procedure for early engagement with developers of orphan medicinal products with a view to ensuring that more orphan medicinal product candidates are successful on the regulatory pathway, while managing resources in an efficient way.

Amendment 22
Proposal for a regulation
Recital 102

Text proposed by the Commission	*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. 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.	(102) In order to ***incentivize investment and innovation,*** research and development of orphan ***medicines where either no other treatment exists or, if other treatments already exist, they would constitute a significant benefit to the target population***, a modulation of market exclusivity has been introduced***. Such modulation is science-driven and informed by the principles that guide research, with incentives based on the concrete barriers, unique attributes, and needs for development of novel therapies that address patient needs; four main incentive archetypes are foreseen by the Regulation, each*** addressing ***unique*** needs ***and knowledge gaps in research;*** market exclusivity for well-established use orphan ***medicines***, 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 23
Proposal for a regulation
Recital 104

Text proposed by the Commission	*Amendment*
(104) To reward research into and development of new therapeutic indications, an additional period of one year of market exclusivity is provided for a new therapeutic indication (with a maximum of two indications).	(104) ***To maximise the potential benefit of clinical research, continued exploration of new indications should be encouraged.*** To reward research into and development of new therapeutic indications, an additional period of one year of market exclusivity is provided for a new therapeutic indication (with a maximum of two indications) ***To continue incentivising innovation, especially in underserved areas, while also allowing generic entry, any subsequent new orphan marketing authorisations granted to the marketing authorisation holder should receive three years of market exclusivity bound to the indication, not the active substance. This will allow generic competition in the first two orphan indications, while allowing for continued research for those patients who could still benefit.***

Amendment 24
Proposal for a regulation
Recital 105 a (new)

Text proposed by the Commission	*Amendment*
	(105 a) One of the overarching goals of this Regulation is to help meet the medical needs of patients with rare diseases, to improve the affordability of orphan medicinal products and the patient access to orphan medicinal products across the Union, and to encourage innovation in areas of need. While other Union programmes and policies also contribute to these goals, people living with a rare disease continue to face common

	challenges that are many and multifactorial, including delayed diagnoses, lack of available transformative treatments, and difficulties to access treatments where they live, reflecting the fragmentation of the market across the Member States. The European added value to addressing the needs of people living with a rare disease being exceptionally high due to the rarity of patients, experts, data, and resources, it is appropriate for the Commission to develop, to complement this Regulation, a dedicated framework for rare diseases to bridge relevant legislation, policies and programmes, and support national strategies with a view to better meet the unmet needs of people living with rare diseases and their carers. This framework should be needs driven and goals based, and developed in consultation with the Member States and patient organisations as well as, where relevant, other interested parties.

Amendment 25
Proposal for a regulation
Recital 126

Text proposed by the Commission	*Amendment*
(126) It is necessary to take measures for the supervision of medicinal products authorised by the Union, and in particular for the intensive supervision of undesirable effects of these medicinal products within the framework of Union pharmacovigilance activities, so as to ensure the rapid withdrawal from the market of any medicinal product presenting a negative benefit-risk balance under normal conditions of use.	(126) It is necessary to take measures for the supervision of medicinal products authorised by the Union, and in particular for the intensive supervision of undesirable effects of these medicinal products***, and the collection of real-world data*** within the framework of Union pharmacovigilance activities, so as to ensure the rapid withdrawal from the market of any medicinal product presenting a negative benefit-risk balance under normal conditions of use.

Amendment 26
Proposal for a regulation

Recital 129

Text proposed by the Commission	*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 take initiative to update the summary of product characteristics in case new efficacy or safety data has an impact on the benefit-risk balance of a medicinal product.	(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 ***and real-world data***, 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 safety data has an impact on the benefit-risk balance of a medicinal product. ***In such case, the Agency and the marketing authorisation holder should collaborate to determine the particulars of any such update.***

Amendment 27
Proposal for a regulation
Recital 132 a (new)

Text proposed by the Commission	*Amendment*
	(132 a) To ensure patients' access to innovative medicines, it is appropriate to establish common rules for the testing and authorisation of innovative medicinal products and innovative technologies related to such products that, due to their exceptional nature or characteristics, are expected to not completely fit the EU medicines regulatory framework.

Amendment 28
Proposal for a regulation

Recital 132 b (new)

Text proposed by the Commission	*Amendment*
	(132 b) Regulatory sandboxes may be set up when it is not possible to develop the medicinal product or category of products in compliance with the requirements applicable to medicinal products due to scientific or regulatory challenges arising from characteristics or methods related to the product, and those characteristics or methods positively and distinctively contribute to the quality, safety or efficacy of the medicinal product or category of products or provide a major advantage contribution to patient access to treatment.

Amendment 29
Proposal for a regulation
Recital 132 c (new)

Text proposed by the Commission	*Amendment*
	(132 c) The objectives of the regulatory sandboxes should be to enable competent authorities to offer advice to potential marketing authorization applicants to ensure adherence to this Regulation, or other pertinent EU legislation as applicable; to assist prospective marketing authorization applicants in the experimentation and advancement of innovative medicinal products or product categories and to contribute to evidence-based regulatory learning within a managed setting and identify possible future adaptations of the legal framework and increase legal certainty.

Amendment 30
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.	(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. ***It is important to ensure that SMEs and startups can easily access sandboxes in order to be able to contribute with their knowhow and experience.*** Regulatory sandboxes ***are controlled frameworks that*** 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 ***strict*** regulatory supervision ensuring that ***robust*** safeguards are in place***. They allow the authorities tasked with implementing and enforcing the legislation to exercise on a case-by-case basis and in exceptional circumstances a degree of flexibility in relation to testing innovative technologies, for the benefit of bringing these products to patients without compromising the standards of quality, safety and efficacy***. 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.

Amendment 31
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.	(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. ***Whenever possible, priority should be given to the use of non-animal approaches.***

Amendment 32
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.	(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. ***It is of utmost importance to ensure a harmonised implementation of these provisions across Member States.*** Where appropriate, adapted frameworks may be developed by the Commission on the basis of the results of a regulatory sandbox.

Amendment 33
Proposal for a regulation
Recital 136

Text proposed by the Commission	*Amendment*
(136) Shortages of medicinal products represent a growing threat to public health, with potential serious risks to the health of patients in the Union and impacts on the right of patients to access appropriate medical treatment. The root causes of shortages are multifactorial, with challenges identified along the entire pharmaceutical value chain, from quality and manufacturing problems. In particular, shortages of medicinal products can result from supply chain disruptions and vulnerabilities affecting the supply of key ingredients and components. Therefore, ***all*** marketing authorisation holders should have shortage prevention plans in place, to prevent shortages. The Agency should provide guidance to marketing authorisation holders on approaches to streamline the implementation of those plans.	(136) Shortages of medicinal products represent a growing threat to public health, with potential serious risks to the health of patients in the Union and impacts on the right of patients to access appropriate medical treatment ***, including longer delays or interruptions in care or therapy, longer periods of hospitalisation, increased risks of exposure to falsified medicinal products, medication errors, adverse effects resulting from the substitution of unavailable medicinal products with alternative ones, significant psychological distress for patients and increased costs for healthcare systems.***. The root causes of shortages are multifactorial, with challenges identified along the entire pharmaceutical value chain, from quality and manufacturing problems. In particular, shortages of medicinal products can result from supply chain disruptions and vulnerabilities affecting the supply of key ingredients and components. Therefore, marketing authorisation holders ***of critical medicinal products*** should have shortage prevention plans in place, to prevent shortages. The Agency should provide guidance to marketing authorisation holders on approaches to streamline the implementation of those plans. ***Preventing and monitoring shortages should also go through better use of data, including from existing IT systems such as the European Medicines Verification System which can aid in the monitoring and timely response to supply shortages, and has the potential to detect supply issues through predictive models.***

Amendment 34
Proposal for a regulation
Recital 137

Text proposed by the Commission	*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.	(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 as long as these measures do not have a negative impact on the security of supply of other Member States.***

Amendment 35
Proposal for a regulation
Recital 138

Text proposed by the Commission	*Amendment*
(138) The national competent authorities should be empowered to monitor shortages of medicinal products that are authorised through both national and centralised procedures, based on notifications of marketing authorisation holders. The Agency should be empowered to monitor shortages of medicinal products that are authorised through the centralised procedure, also based on notifications of marketing authorisation holders. When critical shortages are identified, both national competent authorities and the Agency should work in a coordinated manner to manage those critical shortages, whether the medicinal product concerned	(138) The national competent authorities ***and the Agency*** should be empowered to monitor shortages of medicinal products that are authorised through both national and centralised procedures, based on notifications of marketing authorisation holders ***in a centralised, digitalised and automated system***. The Agency should be empowered to monitor shortages of medicinal products that are authorised through the centralised procedure, also based on notifications of marketing authorisation holders. When critical shortages are identified, both national competent authorities and the Agency should work in a coordinated manner to

by the critical shortage is covered by a centralised marketing authorisation or a national marketing authorisation. Marketing authorisation holders and other relevant entities must provide the relevant information to inform the monitoring. Wholesale distributors and other persons or legal entities, including patient organisations or health care professionals, may also report a shortage of a given medicinal product marketed in the Member State concerned to the competent authority. The Executive Steering Group on Shortages and Safety of Medicinal Products ('the Medicines Shortages Steering Group' (MSSG)) already established within the Agency pursuant to Regulation (EU) 2022/123 of the European Parliament and of the Council[56] , should adopt a list of critical shortages of medicinal products and ensure monitoring of those shortages by the Agency. The MSSG should also adopt a list of critical medicinal products authorised in accordance with [revised Directive 2001/83/EC] or this Regulation to ensure monitoring of the supply of those products. The MSSG may provide recommendations on measures to be taken by marketing authorisation holders, the Member States, the Commission and other entities to resolve any critical shortage or to ensure the security of supply of those critical medicinal products to the market. Implementing acts can be adopted by the Commission to ensure that appropriate measures, including the establishment or maintenance of contingency stocks, are taken by marketing authorisation holders, wholesale distributors or other relevant entities.

communicate the necessary information to patients, consumers, and healthcare professionals, including on estimated duration and available alternatives, and manage those critical shortages, whether the medicinal product concerned by the critical shortage is covered by a centralised marketing authorisation or a national marketing authorisation. Marketing authorisation holders and other relevant entities must provide the relevant information to inform the monitoring. Wholesale distributors and other persons or legal entities, including ***importers, manufacturers, suppliers,*** patient ***and consumer*** organisations or health care professionals, may also report a shortage of a given medicinal product marketed in the Member State concerned to the competent authority ***or the Agency***. The Executive Steering Group on Shortages and Safety of Medicinal Products ('the Medicines Shortages Steering Group' (MSSG)) already established within the Agency pursuant to Regulation (EU) 2022/123 of the European Parliament and of the Council[56] , should adopt a list of critical shortages of medicinal products and ensure monitoring of those shortages by the Agency. The MSSG should also adopt a list of critical medicinal products authorised in accordance with [revised Directive 2001/83/EC] or this Regulation to ensure monitoring of the supply of those products. The MSSG may provide recommendations on measures to be taken by marketing authorisation holders, the Member States, the Commission and other entities to resolve any critical shortage or to ensure the security of supply of those critical medicinal products to the market. Implementing acts can be adopted by the Commission to ensure that appropriate measures, including the establishment or maintenance of contingency stocks, are taken by marketing authorisation holders, wholesale distributors or other relevant entities.

[56] 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).

[56] 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).

Amendment 36
Proposal for a regulation
Recital 138 a (new)

Text proposed by the Commission	*Amendment*
	(138 a) To avoid that measures foreseen or taken by a Member State to prevent or mitigate a shortage at national level when responding to the legitimate needs of its citizen increase the risk of shortages in another Member State, the Agency should assess those measures with regards to their potential or actual impact on the availability and security of supply in other Member States and at European level, and inform of its assessment the Member States and the MSSG.

Amendment 37
Proposal for a regulation
Recital 138 b (new)

Text proposed by the Commission	*Amendment*
	(138 b) One of the aims of this Regulation is to set out a framework for the activities to be deployed by the Member States and the Agency to improve the Union's capacity to react efficiently and in a coordinated manner to support shortage management and security of supply of medicinal products, in particular critical medicinal products, to EU citizens, at all times. Those shortages are a persistent problem that has been increasingly affecting the health and lives of Union

citizens for decades and the root causes are multifactorial. Therefore, this Regulation should be a first step towards improving the Union response to that persistent problem. The Commission should subsequently expand that framework to continue addressing the causes of shortages of medicinal products, and better prevent and mitigate their effects.

Amendment 38
Proposal for a regulation
Recital 138 c (new)

Text proposed by the Commission	*Amendment*
	(138 c) To complement this Regulation and as a first step to a more structural, long term approach to reduce Union dependencies for critical medicines and ingredients, particularly for products where there are only a few supplying manufacturers or countries, the Commission should propose by (OP: 24 months after the date of entry into force of this Regulation) a legislative initiative for an EU Critical Medicines Act for supporting the European green, digital manufacturing of key medicines, active pharmaceutical ingredients, and intermediate pharmaceutical ingredients for which the Union is dependent on one country or a limited number of manufacturers.

Amendment 39
Proposal for a regulation
Recital 138 d (new)

Text proposed by the Commission	*Amendment*
	(138 d) It is appropriate for the Commission to build upon the Communication addressing medicine shortages in the European Union of 24 October 2023 and the many tools which

	can be used to promote a coordinated industrial approach, bringing together public and private actors from the European health and industrial ecosystem.

Amendment 40
Proposal for a regulation
Article 2 – paragraph 2 – point 4

Text proposed by the Commission	*Amendment*
(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);	(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);

Amendment 41
Proposal for a regulation
Article 2 – paragraph 2 – point 8 a (new)

Text proposed by the Commission	*Amendment*
	(8 a) 'paediatric population' means that part of the population aged between birth and 18 years.

Amendment 42
Proposal for a regulation
Article 2 – paragraph 2 – point 8 b (new)

Text proposed by the Commission	*Amendment*
	(8 b) 'paediatric investigation plan' means a research and development programme aimed at ensuring that the necessary data are generated determining the conditions in which a medicinal product may be authorised to treat the paediatric population.

Amendment 43

Proposal for a regulation
Article 2 – paragraph 2 – point 12

Text proposed by the Commission	*Amendment*
(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.	(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 ***or of a CE-marked medicial device*** does not meet the demand for that medicinal product ***or medicial device*** in that Member State.

Amendment 44
Proposal for a regulation
Article 2 – paragraph 2 – point 12 a (new)

Text proposed by the Commission	*Amendment*
	(12 a) '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.

Amendment 45
Proposal for a regulation
Article 2 – paragraph 2 – point 12 b (new)

Text proposed by the Commission	*Amendment*
	(12 b) 'demand' means the request for a medicinal product by a healthcare professional or patient in response to clinical 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.

Amendment 46
Proposal for a regulation
Article 4 – title

Text proposed by the Commission	*Amendment*
Member State authorisation of ***generics of***	Member State authorisation of ***specific***

centrally authorised medicinal products

categories of medicinal products

Amendment 47
Proposal for a regulation
Article 4 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the application for marketing authorisation is submitted in accordance with Article 9 of [revised Directive 2001/83/EC];	(a) the application for marketing authorisation is submitted in accordance with Article 9***, 10, 13*** of [revised Directive 2001/83/EC]***, or for active substances used in fixed dose combination medicinal products that have previously been used in the composition of authorised medicinal products***;

Amendment 48
Proposal for a regulation
Article 6 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
The documentation shall include a declaration to the effect that clinical trials carried out outside the Union meet the ethical requirements of Regulation (EU) No 536/2014. Those particulars and documentation shall take account of the unique, Union nature of the authorisation requested and, otherwise than in exceptional cases relating to the application of the law on trademarks pursuant to Regulation (EU) 2017/1001 of the European Parliament and of the Council[66] , shall include the use of a single name for the medicinal product. The use of a single name does not exclude the use of additional qualifiers where necessary to identify different presentations of the medicinal product concerned.	The documentation shall include a declaration to the effect that clinical trials carried out outside the Union meet the ethical requirements of Regulation (EU) No 536/2014. Those particulars and documentation shall take account of the unique, Union nature of the authorisation requested and, otherwise than in exceptional cases relating to the application of the law on trademarks pursuant to Regulation (EU) 2017/1001 of the European Parliament and of the Council[66] , shall include the use of a single name for the medicinal product. The use of a single name does not exclude***:***
	(a) the use of additional qualifiers where necessary to identify different presentations of the medicinal product concerned***;***

	(b) the use of identified versions of the summary of product characteristics as referred to in article 62 of [Revised Directive] in situations where elements of the product information are still covered by patent law or supplementary protection certificates for medicinal products.
[66] Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark (OJ L 154, 16.6.2017, p. 1).	[66] Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark (OJ L 154, 16.6.2017, p. 1).

Amendment 49
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 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.	For ***orphan medicinal products and*** medicinal products that are likely to offer an exceptional therapeutic 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.

Amendment 50
Proposal for a regulation
Article 6 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Where appropriate, the application may include an active substance master file certificate or an application for an active substance master file or any other quality master file certificate or application as referred to in Article 25 of [revised	4. Where appropriate, the application may include an active substance master file certificate or an application for an active substance master file or any other quality master file certificate or application as referred to in Article 25 ***and Article 26*** of

Directive 2001/83/EC].	[revised Directive 2001/83/EC].

Amendment 51
Proposal for a regulation
Article 6 – paragraph 5 – subparagraph 2

Text proposed by the Commission	*Amendment*
The marketing authorisation applicant shall not carry out animal tests in case scientifically satisfactory non-animal testing methods are available.	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.***

Amendment 52
Proposal for a regulation
Article 40 – paragraph 1

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

Amendment 53
Proposal for a regulation
Article 40 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. The voucher referred to in paragraph 1 shall give the right to its holder to an additional ***period*** of data protection for one authorised medicinal product ***as set out according to paragraph 3 of this Article***.

Amendment 54
Proposal for a regulation
Article 40 – paragraph 3 – subparagraph 1 – introductory part

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

Amendment 55
Proposal for a regulation
Article 40 – paragraph 3 – subparagraph 1 – point a

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

Amendment 56
Proposal for a regulation
Article 40 – paragraph 3 – subparagraph 1 – point b

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

Amendment 57
Proposal for a regulation
Article 40 – paragraph 3 – subparagraph 1 – point c

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

Amendment 58
Proposal for a regulation
Article 40 – paragraph 3 – subparagraph 2

Text proposed by the Commission	*Amendment*
In the scientific assessment of ***the criteria*** referred to in the first subparagraph, ***and in the case of antibiotics,*** the Agency shall ***take*** into account the 'WHO priority pathogens list for R&D of new antibiotics', or an equivalent list established at Union level.	In the scientific assessment of ***priority antibiotics as*** referred to in the first subparagraph, the Agency shall ***develop a set of criteria taking*** into account the 'WHO priority pathogens list for R&D of new antibiotics', or an equivalent list established at Union level***, health system benefits, including with regard to safety and ease of administration, and pharmacological benefits, including novelty of the product***.

Amendment 59
Proposal for a regulation
Article 40 – paragraph 4 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) demonstrate capacity to supply the priority antimicrobial in sufficient quantities for the expected needs of the Union market;	(a) demonstrate ***and ensure*** capacity to supply the priority antimicrobial in sufficient quantities for the expected needs of the Union market;

Amendment 60
Proposal for a regulation
Article 40 – paragraph 4 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) provide information on all direct financial support received for research	(b) provide information on all direct financial support received for research

related to the development of the priority antimicrobial.

from any public authority of publicly funded body based in the European Union related to the development of the priority antimicrobial.

Amendment 61
Proposal for a regulation
Article 40 a (new)

Text proposed by the Commission	*Amendment*
	Article 40a
	Push and pull incentives scheme to boost the development of priority antimicrobials
	1. The Commission shall establish a Union push and pull incentives scheme to promote and urgently 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, which shall include i.a. the following incentives:
	(a) research grants under Union funds;
	(b) milestone prizes for novel antimicrobial developers;
	(c) voluntary joint procurement with subscription payment mechanisms or market entry rewards that delink or partially delink revenues and sales;
	3. The Union push and pull incentives 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 incentives scheme.

	5. By ... [7 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.

Amendment 62
Proposal for a regulation
Article 41 – paragraph 1 – subparagraph 2

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

Amendment 63
Proposal for a regulation
Article 68 – paragraph 2

Text proposed by the Commission	*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 provided for in framework programmes for research and technological development.	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 entities*** provided for in framework programmes for research and technological development.

Amendment 64
Proposal for a regulation
Article 68 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2 a. For the purpose of paragraph 2, the Commission shall assess the criteria to

	qualify as a micro, small and medium-sized enterprise, taking into account the specificities of this type of enterprises in the pharmaceutical sector under the scope of this Regulation.

Amendment 65
Proposal for a regulation
Article 70

Text proposed by the Commission	*Amendment*
Article 70	***deleted***
Orphan medicinal products addressing a high unmet medical need	
1. An orphan medicinal product shall be considered as addressing a high unmet medical need where it fulfils the following requirements:	
(a) there is no medicinal product authorised in the Union for such condition orwhere, despite medicinal products being authorised for such condition in the Union, the applicant demonstrates that the orphan medicinal product, in addition to having a significant benefit, will bring exceptional therapeutic advancement;	
(b) the use of the orphan medicinal product results in a meaningful reduction in disease morbidity or mortality for the relevant patient population.	
2. A medicinal product for which an application has been submitted in accordance with Article 13 of [revised Directive 2001/83/EC] shall not be considered as addressing a high unmet medical need.	
3. Where the Agency adopts scientific guidelines for the application of this Article, it shall consult the Commission and the authorities or bodies referred to in Article 162.	

Amendment 66
Proposal for a regulation
Article 71 – paragraph 2 – point a

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

Amendment 67
Proposal for a regulation
Article 71 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) ***ten*** years for orphan medicinal products ***addressing a high unmet medical need as referred to in Article 70***;	(b) ***twelve*** years for orphan medicinal products ***where no satisfactory treatment has been approved in the Union for the indication in question***;

Amendment 68
Proposal for a regulation
Article 71 – paragraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(b a) Ten years for orphan medicinal products where one of the following criteria applies:
	(i) fewer than three orphan medicinal products have been approved in the Union for the indication in question;
	(ii) despite medicinal products being authorised for the indication in question, none has been approved in the Union for the relevant subpopulation that is covered by the therapeutic indication of the new medicinal product;
	(iii) an orphan medicinal product has been approved in the Union for the indication, but the new orphan medical product will represent a new mechanism of action or technology, and will result in significant reduction in disease morbidity or mortality for the relevant patient

population, or a major contribution to the quality of life of the relevant population.

Amendment 69
Proposal for a regulation
Article 71 – paragraph 2 – point c

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

Amendment 70
Proposal for a regulation
Article 71 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(c a) twelve years for orphan medicinal products addressing requirements.

Amendment 71
Proposal for a regulation
Article 71 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where a marketing authorisation holder holds more than one orphan marketing authorisations for the same active substance, those authorisations shall not benefit from separate market exclusivity periods. The duration of the market exclusivity shall start from the date when the first orphan marketing authorisation was granted in the Union.	3. Where a marketing authorisation holder holds more than one orphan marketing authorisations for the same active substance***, other than in cases foreseen in Article 72 (2), subparagraph 2***, those authorisations shall not benefit from separate market exclusivity periods. The duration of the market exclusivity shall start from the date when the first orphan marketing authorisation was granted in the Union.

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

Text proposed by the Commission	*Amendment*
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.	***deleted***

Amendment 73
Proposal for a regulation
Article 72 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
The period of market exclusivity shall be prolonged by an additional ***12*** months for orphan medicinal products referred to in Article 71(2), points (a) and (b), if at least two years before the end of the exclusivity period, the orphan marketing authorisation holder obtains a marketing authorisation for one or more new therapeutic indications for a different orphan condition.	The period of market exclusivity shall be prolonged by an additional ***18*** 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.

Amendment 74
Proposal for a regulation
Article 72 – paragraph 2 – subparagraph 2

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

Amendment 75
Proposal for a regulation
Article 72 – paragraph 2 a (new)

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

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

Amendment 76
Proposal for a regulation
Article 72 – paragraph 2 b (new)

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

Amendment 77
Proposal for a regulation
Article 72 – paragraph 2 c (new)

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

are reflected in the summary of the product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned. The 24 month extension of the period of market exclusivity shall be reflected in the marketing authorisation.

Amendment 78
Proposal for a regulation
Article 72 – paragraph 2 d (new)

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

Amendment 79
Proposal for a regulation
Article 72 – paragraph 2 e (new)

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

Amendment 80
Proposal for a regulation
Article 72 – paragraph 3

Text proposed by the Commission	*Amendment*
3. ***The*** orphan medicinal products ***which benefit from the prolongation of market exclusivity referred to in the paragraph 2 shall not benefit from the additional period of data protection*** referred to in Article ***81(2), point (d), of***	3. ***Upon request from the applicant, the period of market exclusivity for*** orphan medicinal products referred to in Article ***71(2), points (a) and (b) shall be prolonged by an additional 24 months where an application for orphan marketing authorisation is submitted in***

[revised Directive 2001/83/EC].	***respect of a designated orphan medicinal product and that application includes the results of all studies conducted in compliance with an agreed paediatric investigation plan***.

Amendment 81
Proposal for a regulation
Article 96 – paragraph 1

Text proposed by the Commission	*Amendment*
Paediatric medicinal products 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, paediatric medicinal products.	Paediatric medicinal products shall be eligible for incentives made available by the Union and by the Member States to support ***the additional efforts necessary in this field, such as clinical trials and*** research into, and the development and availability of, paediatric medicinal products.

Amendment 82
Proposal for a regulation
Article 113 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(b a) The creation of a regulatory sandbox is intended to fulfil the following objectives:
	(a) enabling competent authorities to offer advice to potential marketing authorization applicants to ensure adherence to this Regulation, or other pertinent EU legislation as applicable;
	(b) assisting prospective marketing authorization applicants in the experimentation and advancement of innovative medicinal products or product categories;
	(c) contribute to evidence-based regulatory learning within a managed setting and identify possible future adaptations of the legal framework and increase legal certainty.

Amendment 83
Proposal for a regulation
Article 113 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
The regulatory sandbox shall set out a regulatory framework, including scientific requirements, for the development and, where appropriate clinical trials and placing on the market of a product referred to in paragraph 1 under the conditions set out in this Chapter. The regulatory sandbox may allow targeted derogations to this Regulation, [revised Directive 2001/83/EC] ***or*** Regulation (EC) 1394/2007 under the conditions set out in Article 114.	The regulatory sandbox shall set out a regulatory framework, including scientific requirements, for the development and, where appropriate clinical trials and placing on the market of a product referred to in paragraph 1 under the conditions set out in this Chapter. The regulatory sandbox may allow targeted derogations to this Regulation, [revised Directive 2001/83/EC]**,** Regulation (EC) 1394/2007 under the conditions set out in Article 114. ***By [12 months after the date of entering into force of this Regulation], the Commission shall make an assessment of other relevant Union legislation, including the Regulation on medical devices, and, where appropriate, draw up a list for which this Article shall apply, and where appropriate, present a legislative proposal.***

Amendment 84
Proposal for a regulation
Article 113 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency shall monitor the field of emerging medicinal products and may request information and data from marketing authorisation holders, developers, independent experts and researchers, and representatives of healthcare professionals and of patients and may engage with them in preliminary discussions.	3. The Agency shall monitor the field of emerging medicinal products and may request information and data from marketing authorisation holders, developers, independent experts and researchers, and representatives of healthcare professionals and of patients and may engage with them in preliminary discussions. ***The Agency may establish a dialogue framework with regulatory bodies both within and outside the Union to aid in its oversight role. Additionally, the Agency is tasked with creating and***

routinely revising a roster of nascent medicinal or health products that could be considered for a regulatory sandbox environment.

Amendment 85
Proposal for a regulation
Article 113 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Agency shall be responsible for developing a sandbox plan based on data submitted by developers of eligible products and following appropriate consultations. The plan shall set out clinical, scientific and regulatory justification for a sandbox, including the identification of the requirements of this Regulation, [revised Directive 2001/83/EC] ***and*** Regulation (EC) 1394/2007 that cannot be complied with and a proposal for alternative or mitigation measures, where appropriate. The plan shall also include a proposed timeline for the duration of the sandbox. Where appropriate, the Agency shall also propose measures in order to mitigate any possible distortion of market conditions as a consequence of establishing a regulatory.	5. The Agency shall be responsible for developing a sandbox plan based on data submitted by developers of eligible products and following appropriate consultations ***including, where relevant, with academia, HTA bodies, patients and their caregivers, healthcare professionals, sponsors, or developers***. The plan shall set out clinical, scientific and regulatory justification for a sandbox, including the identification of the requirements of this Regulation, [revised Directive 2001/83/EC]**,** Regulation (EC) 1394/2007 that cannot be complied with and a proposal for alternative or mitigation measures, where appropriate. The plan shall also include a proposed timeline for the duration of the sandbox. Where appropriate, the Agency shall also propose measures in order to mitigate any possible distortion of market conditions as a consequence of establishing a regulatory.

Amendment 86
Proposal for a regulation
Article 115 – paragraph 4

Text proposed by the Commission	*Amendment*
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	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***, cases in which a regulatory sandbox had to be suspended or revoked as established in Article 113***

Regulation and other Union legal acts supervised within the sandbox. These reports shall be made publicly available by the Commission.	***(8)***, 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.

Amendment 87
Proposal for a regulation
Article 115 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5 a. By ... [12 months after the date of entry into force of this Regulation], in order to ensure a harmonised approach across Member States and support to the implementation of the regulatory sandboxes, the Commission, in consultation with the Agency, shall issue guidelines, without prejudice to other Union legislative acts. Where necessary, the guidelines should be updated to incorporate any relevant findings in the annual reports submitted by the Agency, as established in the fourth paragraph of this Article.

Amendment 88
Proposal for a regulation
Article 116 – paragraph 1 a (new)

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

with Article 118(1).

not possible and where duly justified, as soon as they become aware of such temporary disruption**.**

The temporary disruption in supply of a medicinal product for which another pack size of that same product is available shall not need to be notified. The Agency shall make available the information to the concerned Member State, to allow the Member State to monitor any potential or actual shortage in accordance with Article 118(1).

Amendment 89
Proposal for a regulation
Article 117 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The marketing authorisation holder as defined in Article 116(1) shall have in place and keep up to date a shortage prevention plan, for any medicinal product placed on the market. To put in place the shortage prevention plan, the marketing authorisation holder shall include the minimum set of information set out in Part V of Annex IV and take into account the guidance drawn up by the Agency according to paragraph 2.	1. ***By ... [12 months after the date of entry into force of this Regulation],*** 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 ***critical*** medicinal product placed on the market ***and send it to the competent authority upon request. The Commission is empowered to adopt delegated acts in accordance with Article 175 to supplement this Regulation by determining medicinal products for which a shortage prevention plan shall be maintained and kept up to date, including due to the lack of availability of alternatives***. 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 90
Proposal for a regulation
Article 117 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. The Agency, in collaboration with the working party referred to in Article 121(1), point (c), ***patients´ organisations and healthcare professionals and other interested parties*** shall draw up guidance to marketing authorisation holders as defined in Article 116(1) to put in place the shortage prevention plan.

Amendment 91
Proposal for a regulation
Article 120 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Wholesale distributors and other persons or legal entities that are authorised or entitled to supply medicinal products authorised to be placed on the market of a Member State pursuant to Article 5 of [revised Directive 2001/83/EC] to the public ***may*** report a shortage of a given medicinal product marketed in the Member State concerned to the competent authority in that Member State.	1. Wholesale distributors and other persons or legal entities that are authorised or entitled to supply medicinal products authorised to be placed on the market of a Member State pursuant to Article 5 of [revised Directive 2001/83/EC] to the public ***shall*** report a shortage of a given medicinal product marketed in the Member State concerned to the competent authority in that Member State ***and shall transmit the information set out in Part V of Annex IV to the competent authorities of the Member States without undue delay or as frequently as requested by the competent authority***.

Amendment 92
Proposal for a regulation
Article 120 – paragraph 2

Text proposed by the Commission	*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	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.	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.

Amendment 93
Proposal for a regulation
Article 120 – paragraph 2 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	Commercially sensitive information shall only be available to the relevant authorities and shall be handled in accordance with applicable legislation and transparency provisions set in Regulation 1049/2001.

Amendment 94
Proposal for a regulation
Article 121 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(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;	(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 provide clear recommendations and possible alternatives to healthcare professionals and patients***, on a publicly available ***and user-friendly*** website;

Amendment 95
Proposal for a regulation
Article 121 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(c a) assess information on potential or actual deficiencies provided by marketing authorisation holders authorised to

	market in a Member State in accordance with Article 5 of [Directive 2001/83/EC as revised] as defined in paragraph 1 of Article 116, importers and manufacturers of medicinal products or active ingredients and relevant suppliers thereof, wholesale distributors, associations representing interested parties or other legal persons or entities which are authorised or authorised to supply medicinal products to the public.

Amendment 96
Proposal for a regulation
Article 121 – paragraph 2 – point f

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

Amendment 97
Proposal for a regulation
Article 121 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2 a. After the expansion of the ESMP referred to in article 122 (6) and for the purpose of articles 118 (1), and 121 (2), point (a), competent authorities of the Member States shall set up national IT systems which are interoperable with the ESMP and allow for the automated exchange of information with the ESMP while avoiding duplication of reporting.

Amendment 98
Proposal for a regulation
Article 121 – paragraph 5 – point d

Text proposed by the Commission	*Amendment*
(d) inform the Agency of any actions	(d) ***without undue delay*** inform the

foreseen or taken by that Member State in accordance with points (b) and (c) and report on any other actions taken to mitigate or resolve the critical shortage in the Member State, as well as the results of these actions.	Agency of any actions foreseen or taken by that Member State in accordance with points (b) and (c) and report on any other actions taken to mitigate or resolve the critical shortage in the Member State, as well as the results of these actions.

Amendment 99
Proposal for a regulation
Article 122 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. For the purpose of article 118 and based on the information provided pursuant to articles 121 (1), point (d), and 121 (2), the Agency shall assess the actions taken or foreseen by a Member State to mitigate a shortage at national level with regards to any potential or actual negative impacts of these actions on the availability and security of supply in another Member State and at European level. The Agency shall inform the Member State in question of its assessment in a timely manner and the MSSG and the Member States potentially or actually impacted through the single point of contact working party referred to in Article 3(6) of Regulation (EU) 2022/123. The Agency shall also inform the Commission of its assessment.

Amendment 100
Proposal for a regulation
Article 122 – paragraph 4 – introductory part

Text proposed by the Commission	*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):	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 ***relevant patient and consumer organisations and*** the working party referred to in Article 121(1), point (c):

Amendment 101
Proposal for a regulation
Article 122 – paragraph 6

Text proposed by the Commission	*Amendment*
6. For the purposes of implementing this Regulation, the Agency shall expand the scope of the ESMP. The Agency shall ensure that, where relevant, data is interoperable between the ESMP, Member States' IT systems and other relevant IT systems and databases, without duplication of reporting.	6. For the purposes of implementing this Regulation, the Agency shall expand the scope of the ESMP ***and include, among others, information on the duration, reasons and mitigation measures of medicine shortages***. 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 102
Proposal for a regulation
Article 122 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6 a. The Agency shall assess measures notified by competent authorities of the Member States under Article 121 with regard to possible effects on the availability of medicines in other Member States, and shall where relevant report its findings to the Commission.

Amendment 103
Proposal for a regulation
Article 124 – paragraph 3

Text proposed by the Commission	*Amendment*
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 Agency ***has assessed the shortage and has provided*** recommendations to healthcare	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 products***, including the reasons for the shortages. After assessing the shortages,***

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).	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).

Amendment 104
Proposal for a regulation
Article 125 – paragraph 1 – point f a (new)

Text proposed by the Commission	*Amendment*
	(f a) inform the Agency of the cause of the critical shortage.

Amendment 105
Proposal for a regulation
Article 129 – paragraph 1

Text proposed by the Commission	*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 requested in a timely manner.	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 ***and by the deadline set by the Agency and provide updates whenever necessary***.

Amendment 106
Proposal for a regulation
Article 129 – paragraph 1 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	Commercially sensitive information shall only be available to the relevant authorities and shall be handled in accordance with applicable legislation and transparency provisions set in Regulation 1049/2001'.

Amendment 107
Proposal for a regulation
Article 164 – paragraph 5

Text proposed by the Commission	*Amendment*
5. For not-for-profit entities, the Commission shall adopt specific provisions clarifying the definitions, establishing waivers, reductions or deferrals of fees, as appropriate, in accordance with the procedure referred to in Article 10 and Article 12 of [revised Regulation (EC) No 297/95].	5. For not-for-profit entities, the Commission shall adopt specific provisions clarifying the definitions, establishing waivers, reductions or deferrals of fees, as appropriate, in accordance with the procedure referred to in Article 10 and Article 12 of [revised Regulation (EC) No 297/95]. ***These incentives are designed, inter alia, to alleviate financial and administrative burdens and promote innovation.***

Amendment 108
Proposal for a regulation
Article 167 – paragraph 2

Text proposed by the Commission	*Amendment*
For the purposes of the first subparagraph, the Agency shall actively identify and implement cybersecurity best practices ***adopted within Union institutions, bodies, offices and agencies*** for preventing, detecting, mitigating, and responding to cyber attacks.	For the purposes of the first subparagraph, the Agency shall actively ***take measures to ensure its compliance with a high common level of cybersecurity within Union entities,*** identify and implement ***up-to-date*** cybersecurity best practices for preventing, detecting, mitigating, and responding to cyber attacks.

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

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

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

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

PROCEDURE – COMMITTEE ASKED FOR OPINION

Title	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
References	COM(2023)0193 – C9-0144/2023 – 2023/0131(COD)
Committee responsible Date announced in plenary	ENVI 14.9.2023
Opinion by Date announced in plenary	ITRE 14.9.2023
Associated committees - date announced in plenary	14.9.2023
Rapporteur for the opinion Date appointed	Henna Virkkunen 5.10.2023
Discussed in committee	28.11.2023
Date adopted	22.2.2024
Result of final vote	+: 35 –: 27 0: 1
Members present for the final vote	Hildegard Bentele, Tom Berendsen, Michael Bloss, Marc Botenga, Martin Buschmann, Cristian-Silviu Buşoi, Jerzy Buzek, Maria da Graça Carvalho, Ignazio Corrao, Beatrice Covassi, Josianne Cutajar, Nicola Danti, Marie Dauchy, Nicolás González Casares, Christophe Grudler, Henrike Hahn, Robert Hajšel, Ivo Hristov, Ivars Ijabs, Romana Jerković, Seán Kelly, Łukasz Kohut, Zdzisław Krasnodębski, Marisa Matias, Eva Maydell, Marina Mesure, Angelika Niebler, Ville Niinistö, Johan Nissinen, Mauri Pekkarinen, Tsvetelina Penkova, Morten Petersen, Manuela Ripa, Sara Skyttedal, Maria Spyraki, Riho Terras, Grzegorz Tobiszowski, Henna Virkkunen, Pernille Weiss
Substitutes present for the final vote	Pascal Arimont, Laura Ballarín Cereza, Jakop G. Dalunde, Margarita de la Pisa Carrión, Francesca Donato, Alicia Homs Ginel, Alin Mituța, Luděk Niedermayer, Susana Solís Pérez
Substitutes under Rule 209(7) present for the final vote	Alexander Bernhuber, Sara Cerdas, Ibán García Del Blanco, Mircea-Gheorghe Hava, Radan Kanev, Guy Lavocat, Javi López, Karen Melchior, Nikos Papandreou, Jessica Polfjärd, Bergur Løkke Rasmussen, Caroline Roose, Birgit Sippel, Dragoș Tudorache, Axel Voss

FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

35	+
ECR	Zdzisław Krasnodębski, Johan Nissinen, Margarita de la Pisa Carrión, Grzegorz Tobiszowski
PPE	Pascal Arimont, Hildegard Bentele, Tom Berendsen, Alexander Bernhuber, Cristian-Silviu Buşoi, Jerzy Buzek, Maria da Graça Carvalho, Mircea-Gheorghe Hava, Radan Kanev, Seán Kelly, Eva Maydell, Angelika Niebler, Luděk Niedermayer, Jessica Polfjärd, Sara Skyttedal, Maria Spyraki, Riho Terras, Henna Virkkunen, Axel Voss, Pernille Weiss
Renew	Nicola Danti, Christophe Grudler, Ivars Ijabs, Guy Lavocat, Karen Melchior, Alin Mituța, Mauri Pekkarinen, Morten Petersen, Bergur Løkke Rasmussen, Susana Solís Pérez, Dragoș Tudorache

27	-
NI	Martin Buschmann, Francesca Donato
S&D	Laura Ballarín Cereza, Sara Cerdas, Beatrice Covassi, Josianne Cutajar, Ibán García Del Blanco, Nicolás González Casares, Robert Hajšel, Alicia Homs Ginel, Ivo Hristov, Romana Jerković, Łukasz Kohut, Javi López, Nikos Papandreou, Tsvetelina Penkova, Birgit Sippel
The Left	Marc Botenga, Marisa Matias, Marina Mesure
Verts/ALE	Michael Bloss, Ignazio Corrao, Jakop G. Dalunde, Henrike Hahn, Ville Niinistö, Manuela Ripa, Caroline Roose

1	0
ID	Marie Dauchy

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