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Committee on the Environment, Public Health and Food Safety

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AMENDMENTS
417 - 631

Draft report
Tiemo Wölken
(PE753.550v02-00)

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

Proposal for a regulation
(COM(2023)0193 – C9-0144/2023 – 2023/0131(COD))

Amendment 417
István Ujhelyi

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

Or. en

Amendment 418
Tilly Metz

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	(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.***	distribution of incentives, a modulation of market exclusivity has been introduced; orphan medicinal products addressing high unmet medical needs benefit from the longest market exclusivity, while market exclusivity for well-established use orphan medicinal products, requiring less investment, is the shortest.

Or. en

Amendment 419
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Billy Kelleher

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 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; ***pioneering*** orphan medicinal products addressing ***areas where there is a total lack of approved treatments*** 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.

Or. en

Amendment 420

Tomislav Sokol

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 incentivise research***, innovation*** and development of orphan medicinal products, to ensure market predictability and to ensure a fair distribution of incentives, a modulation of market exclusivity has been introduced; ***designated as a breakthrough*** orphan medicinal products 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.

Or. en

Amendment 421
Andrey Slabakov

Proposal for a regulation
Recital 103

Text proposed by the Commission	*Amendment*
(103) ***In order to encourage*** faster and wider access also to orphan medicinal products***, an additional period of one year of market exclusivity is granted to orphan medicinal products for a*** Union market ***launch, with the exception of well-established use medicinal products***.	(103) ***Ensuring*** faster and wider access also to orphan medicinal products ***remains a Union-wide issue. This impacts in particular Member States with smaller purchasing power, smaller populations, and therefore with smaller rare disease patient populations. The result is reduced or delayed access to treatments that are available on the*** Union market***, but not in each Member State. Solutions can only be found through joint action that involves manufacturers, national and Union-level regulators, Member States, clinicians and***

patients.

Or. en

Amendment 422
Tilly Metz

Proposal for a regulation
Recital 103

Text proposed by the Commission	*Amendment*
(103) In order to encourage faster and wider access also to orphan medicinal products, an additional period of ***one year*** of market exclusivity is granted to orphan medicinal products for a Union market launch, with the exception of well-established use medicinal products.	(103) In order to encourage faster and wider access also to orphan medicinal products, an additional period of ***six months*** of market exclusivity is granted to orphan medicinal products for a Union market launch, with the exception of well-established use medicinal products.

Or. en

Amendment 423
Andrey Slabakov

Proposal for a regulation
Recital 103 a (new)

Text proposed by the Commission	*Amendment*
	(103 a) Information is key to ensuring access to novel treatments for patients with rare diseases. Large dispariteis remain between Member States as to the level of information access for both clinicians and patients. Without addressing this crucial break of communication starting at the manufacturer of a novel orphan medicinal product and ending with the relevant patient population, awareness of and takeup of novel treatments will remain low. Clinicians must continuously be kept up-to-date with developments in the fields of rare diseases, in order to provide their patients with the best

possible treatment. In order to address this gap, action is needed across the board, starting with applicants for a marketing authorisation for an orphan medicinal product. They must prove their commitment to continuously provide the necessary information not only in the Member States where their treatments are sold, but within the entire Union. This can only be achieved with the support of the Agency and with the full cooperation of national and Union-level professional and patient organisations. Member States should take all necessary measures to ensure financial and structural support enabling the flow of information.

Or. en

Amendment 424
Andrey Slabakov

Proposal for a regulation
Recital 103 b (new)

Text proposed by the Commission	*Amendment*
	(103 b) Informing clinicians and other medical professionals of available orphan medicinal products placed on the Union markets should be accopmanied by measures ensuring their upskilling. Member States must invest in the creation of Centres of Excellence for one or a group of rare diseases, with the material base and skilled professionals to offer the latest available treatments. These Centres may be established on a national or regional level. Furthermore, Member States may elect to enter into cooperation and co-financing, in order to establish joint Centres of Excellence, based on their patient populations, territorial proximity, ease of access/travel and material conditions.

Or. en

Amendment 425
Andrey Slabakov

Proposal for a regulation
Recital 103 c (new)

Text proposed by the Commission	*Amendment*
	(103 c) The Union must build on the successful implementation since 2017 of the European Reference Networks (ERNs) for rare diseases. As highlighted in the EU Joint Action on Rare Diseases Plan, the support for and cooperation with the ERNs must be enchanced both from the public and private sectors. Therefore, applicants for market authorisation of orphan medicinal products must prove that they have put in place robust pathways for partnering with ERNs and for the exchange and use of relevant data. Member States must guarantee appropriate levels of funding - an estimated €77 million, in order to realise the full potential of the ERNs.

Or. en

Amendment 426
Andrey Slabakov

Proposal for a regulation
Recital 103 d (new)

Text proposed by the Commission	*Amendment*
	(103 d) Presently, conditions under which a patient may travel from one Member State to another to receive medical care and reimbursement are established in the Directive 2011/24/EU on patients' rights in cross-border healthcare, as well as in Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems. Patients seeking

	cross-border healthcare continue to face issues with regards to their rights, partially due to the incomplete transposition of Directive 2011/24/EU by all Member States. For many patient populations in certain Member States these pathways remain the only way to seek treatment for rare diseases, which are available in other Member States. Directive 2011/24/EU must, therefore, be fully transposed and used by all Member States to guarantee their patients access to orphan medicinal products put on the Union markets.

Or. en

Amendment 427
Tilly Metz

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).	***deleted***

Or. en

Amendment 428
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Billy Kelleher, Erik Poulsen

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	(104) ***To maximise the potential benefit of clinical research, continued exploration of new indications should be***

year of market exclusivity is provided for a new therapeutic indication (with a maximum of two indications).

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.***

Or. en

Amendment 429
Maria Angela Danzì

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) ***Undertaking*** research ***and clinical trials for a rare disease is a complex and time-consuming activity, mainly because of the small patient population and the lack of knowledge typical of many rare diseases without authorised treatment. Knowledge and experience acquired with clinical trials in an indication is not immediately transferable to*** a new ***indication, but may provide important guidance. Therefore, research into new*** therapeutic ***indications should be rewarded. Industry must be provided with sufficient incentives to continue exploring new indications and to ensure that patients benefit from incremental innovation and to support new technologies to move to other*** indications***;***

Or. it

Amendment 430
Andrey Slabakov

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) ***Undertaking research and clinical trials for a rare disease is complex and time-consuming, especially due to the small patient population and lack of knowledge that characterises many rare diseases with no authorised treatment. Using the knowledge and experience gained from clinical evidence in one indication is not immediately transferable into a new indication, but it can provide important insights. Therefore,*** research into and development of new therapeutic indications ***should be rewarded. Sufficient incentives should be*** provided ***so that it is viable for industry to continue exploring new*** indications ***and ensure patients benefit from incremental innovation and support new technologies to move into additional indications;***

Or. en

Amendment 431
Andrey Slabakov

Proposal for a regulation
Recital 104 a (new)

Text proposed by the Commission	*Amendment*
	(104 a) To address patient needs and maximise the potential benefit of clinical research, innovation should be rewarded where possible. In the case of Orphan Medicinal Products, should a developer identify multiple applications for an active

substance, this should be rewarded without acting as a barrier to access. Where a marketing authorisation holder receives a second marketing authorisation for the same active substance, three additional years of market exclusivity should be provided. 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 be 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.

Or. en

Amendment 432
Andrey Slabakov

Proposal for a regulation
Recital 105

Text proposed by the Commission	*Amendment*
(105) This Regulation includes several provisions aimed to avoid not-justified benefits being derived from the market exclusivity and to improve accessibility of medicinal products by ensuring faster entry of generics and biosimilars, and similar medicinal products on the market. It also clarifies the concurrence of market exclusivity with data protection and defines situations when a similar medicinal product may be granted a marketing authorisation, despite the ongoing market exclusivity.	(105) This Regulation includes several provisions aimed to avoid not-justified benefits being derived from the market exclusivity and to improve accessibility of medicinal products by ensuring faster entry of generics and biosimilars, and similar medicinal products on the market***, i.e. on day one after the market exclusivity expires***. It also clarifies the concurrence of market exclusivity with data protection and defines situations when a similar medicinal product may be granted a marketing authorisation, despite the ongoing market exclusivity. ***The market exclusivity of the orphan medicinal product shall not prevent the submission, validation, assessment of an application for and granting of a marketing authorisation for a similar medicinal product, including***

generics and biosimilars, where the remainder of the duration of the initial market exclusivity is less than two years.

Or. en

Amendment 433
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Ondřej Knotek, Billy Kelleher, Erik Poulsen, Dacian Cioloş

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 meeting 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 developped in consultation with the Member States and patient organisations

as well as, where relevant, other interested parties.

Or. en

Justification

This amendment is in line with the Parliament's call for an EU Action Plan on rare and neglected diseases (European Parliament resolution of 10 July 2020 on the EU's public health strategy post-COVID-19)

https://www.europarl.europa.eu/doceo/document/TA-9-2020-0205_EN.html

Amendment 434
Maria Angela Danzì

Proposal for a regulation
Recital 106

Text proposed by the Commission	*Amendment*
(106) Before a medicinal product for human use is placed on the market in one or more Member States, it has to have undergone extensive studies, including non-clinical tests and clinical trials, to ensure that it is safe, of high quality and effective for use in the target population. It is ***important*** that such studies are undertaken also on the paediatric population in order to ensure that medicinal products are appropriately authorised for use in the paediatric population, and to improve the information available on the use of medicinal products in the various paediatric population. It is also important that medicinal products are presented in dosages and formulations adequate for the use in children.	(106) Before a medicinal product for human use is placed on the market in one or more Member States, it has to have undergone extensive studies, including non-clinical tests and clinical trials, to ensure that it is safe, of high quality and effective for use in the target population. It is ***imperative*** that such studies are undertaken also on the paediatric population in order to ensure that medicinal products are appropriately authorised for use in the paediatric population, and to improve the information available on the use of medicinal products in the various paediatric population. It is also important that medicinal products are presented in dosages and formulations adequate for the use in children.

Or. it

Justification

The obligation introduced by the Paediatric Regulation to carry out paediatric studies cannot be abolished. Therefore, the wording 'is important' is not appropriate and should be changed to 'is imperative'.

Amendment 435
Andrey Slabakov

Proposal for a regulation
Recital 110

Text proposed by the Commission	*Amendment*
(110) In order to not endanger the health of children and avoid to expose them to unnecessary clinical trials, the obligation to agree and conduct paediatric studies in children should be waived when the medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population, the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for children or the disease for which the medicinal product is intended occurs only in adult populations. ***Nevertheless, in the last case, if on the basis of existing scientific evidence, the medicinal product due to its molecular mechanism of action is expected to be effective against a different disease in children, the obligation should be maintained.***	(110) In order to not endanger the health of children and avoid to expose them to unnecessary clinical trials, the obligation to agree and conduct paediatric studies in children should be waived when the medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population, the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for children or the disease for which the medicinal product is intended occurs only in adult populations.

Or. en

Amendment 436
Maria Angela Danzì

Proposal for a regulation
Recital 112

Text proposed by the Commission	*Amendment*
(112) With a view to ensuring that research is conducted only when safe and ethical and that the requirement for study data in the paediatric population does not block or delay the authorisation of medicinal products for other populations, the Agency may defer the initiation or completion of some or all of the measures	(112) With a view to ensuring that research is conducted only when safe and ethical and that the requirement for study data in the paediatric population does not block or delay the authorisation of medicinal products for other populations, the Agency may defer the initiation or completion of some or all of the measures

contained in a paediatric investigation plan for a limited period of time. ***Such*** deferral ***should be extended only in duly justified cases***.	contained in a paediatric investigation plan for a limited period of time. ***The length of the*** deferral ***shall be specified in a decision of the Agency and shall ensure that the PIP is completed no more than two years after the marketing authorisation for other populations is granted***.

Or. it

Justification

One of the main problems, even during the period covered by the Paed. Regulation is the time it takes for paediatric indications/formulations to arrive on the market after the approval of the MA of the adult product. It often takes 7 years or longer. It is unethical to maintain this large discrepancy and the delay should be reduced by urging sponsors to complete studies in good time.

Amendment 437
Andrey Slabakov

Proposal for a regulation
Recital 112

Text proposed by the Commission	*Amendment*
(112) With a view to ensuring that research is conducted only when safe and ethical and that the requirement for study data in the paediatric population does not block or delay the authorisation of medicinal products for other populations, the Agency may defer the initiation or completion of some or all of the measures contained in a paediatric investigation plan ***for a limited period of time***. Such deferral should be extended only in duly justified cases.	(112) With a view to ensuring that research is conducted only when safe and ethical and that the requirement for study data in the paediatric population does not block or delay the authorisation of medicinal products for other populations, the Agency may defer the initiation or completion of some or all of the measures contained in a paediatric investigation plan. Such deferral should be extended only in duly justified cases.

Or. en

Amendment 438
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Billy Kelleher, Erik Poulsen

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.

Or. en

Amendment 439
Tomislav Sokol

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, 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 ***the*** basis ***of the totality of evidence made available to the Agency***, the Agency should ***be able to propose updates to*** the summary of product characteristics in case new ***evidence*** 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.

Or. en

Amendment 440
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Billy Kelleher, Erik Poulsen

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.***

Or. en

Amendment 441
Tilly Metz

Proposal for a regulation
Recital 132

Text proposed by the Commission	*Amendment*
(132) The Union and Member States have developed a scientific evidence-based process that allows competent authorities to determine the relative effectiveness of new or existing medicinal products. This process focuses specifically on the added value of a medicinal product in comparison with other new or existing health technologies ***However, this evaluation should not be conducted in the context of*** the marketing authorisation***, for which it is agreed that the fundamental criteria*** should ***be retained. It is useful in this respect to allow for the possibility of gathering information on the methods used by the Member States to determine the therapeutic benefit obtained by each new medicinal product***.	(132) The Union and Member States have developed a scientific evidence-based process that allows competent authorities to determine the relative effectiveness of new or existing medicinal products. This process focuses specifically on the added value of a medicinal product in comparison with other new or existing health technologies***. To ensure that medicine developers generate the right type of data for regulators throughout the market access pathway,*** the marketing authorisation ***applicants*** should ***submit, unless where duly justified and ethical, data from active-control clinical trials. This is important to avoid the unnecessary repetition of clinical studies, and to uphold high scientific standards and ethical principles at the point of marketing authorisation***.

Or. en

Amendment 442
Tomislav Sokol, Stelios Kympouropoulos

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.

Or. en

Amendment 443
Frédérique Ries

Proposal for a regulation
Recital 132 a (new)

Text proposed by the Commission	*Amendment*
	(132 a) To ensure 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 Union medicines regulatory framework.

Or. en

Amendment 444
Frédérique Ries

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.

Or. en

Amendment 445
Tomislav Sokol

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.

Or. en

Amendment 446
Tomislav Sokol

Proposal for a regulation
Recital 132 c (new)

Text proposed by the Commission	*Amendment*
	(132 c) The objectives of the regulatory sandboxes should be: for the Agency and national competent authorities to increase their understanding of technical and scientific developments, to allow developers in a controlled environment to test and develop innovative medicinal products and related technologies that are not fitting the current regulatory framework, as agreed with the competent authorities, and to identify possible future adaptations of the legal framework.

Or. en

Amendment 447
Frédérique Ries

Proposal for a regulation
Recital 132 c (new)

Text proposed by the Commission	*Amendment*
	(132 c) The regulatory sandboxes will allow for the Agency and national competent authorities to increase their understanding of technical and scientific developments, for developers to test and develop in a controlled environment innovative medicinal products and related technologies that do not fit the current regulatory framework, in agreement with the competent authorities, and make it possible to identify possible future adaptations of the legal framework.

Or. en

Amendment 448
Tilly Metz

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	***deleted***

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.

Or. en

Amendment 449
Tomislav Sokol, Stelios Kympouropoulos

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	(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 ***significant*** 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 which, by providing*** a structured context for experimentation, enable where appropriate in a real-world environment the testing of

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.

innovative technologies, products, services or approaches – at the moment ***particularly*** 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. ***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.

Or. en

Amendment 450
Frédérique Ries

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	(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***

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.

access sandboxes in order to be able to contribute with their knowhow and experience. Regulatory sandboxes ***are controlled frameworks which, by providing*** 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. ***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.

Or. en

Amendment 451
Maria Angela Danzì

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	(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.	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 ***non-pharmacological therapies,*** 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, including where medical devices or in vitro diagnostics are used as combined*** 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.

Or. it

Justification

The regulatory sandboxes' scope of application must be as wide as possible with a view to fostering technological developments, including improvements to drug-device combination products.

Amendment 452
Billy Kelleher, Catherine Amalric

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,	(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.

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, ***regulatory methods*** 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, including where medical devices or in-vitro diagnostics are used as combination*** 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.

Or. en

Amendment 453
Andrey Slabakov

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	(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.

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, ***regulatory methods,*** 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 including where medical devices or in-vitro diagnostics are used as combination*** 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.

Or. en

Amendment 454
Stelios Kympouropoulos

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	(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.	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 ***technologies, such as in silico methods, predictive medicine, and data analytics,*** 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.

Or. en

Justification

The in silico methods present an acknowledged potential to support regulatory risk assessment, as recognized by the European Commission (https://data.europa.eu/doi/10.2788/98567), which justifies their inclusion in the provisions related to regulatory sandboxes.

Amendment 455
Fulvio Martusciello

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	(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.	real-world evidence, especially at a very early stage of development of a medicinal product, which can be particularly ***significant*** 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 ***particularly*** 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.

Or. en

Amendment 456
Tilly Metz

Proposal for a regulation
Recital 134

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

Or. en

Amendment 457
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Billy Kelleher, Erik Poulsen, Dacian Cioloş

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.***

Or. en

Amendment 458
Sirpa Pietikäinen

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***, the environment***, 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.

Or. en

Amendment 459
Tomislav Sokol

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 ***current*** levels of protection need to be respected.

Or. en

Amendment 460
Fulvio Martusciello

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 ***current*** levels of protection need to be respected.

Or. en

Amendment 461
István Ujhelyi

Proposal for a regulation
Recital 134 a (new)

Text proposed by the Commission	*Amendment*
	(134 a) Member States may introduce or maintain more robust provisions than those provided for in this Regulation with regard to the security of supply of and the availability of medicinal products, only in consistent and coordinated way.

Or. en

Amendment 462
Tilly Metz

Proposal for a regulation
Recital 135

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

Or. en

Amendment 463
Tomislav Sokol

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	(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 ***and comprehensive*** plan outlining the ***specificities*** of the sandbox as well as describing the products to be covered. A regulatory sandbox should be

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.	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 ***suitable***, adapted frameworks may be developed by the Commission on the basis of the results of a regulatory sandbox.

Or. en

Amendment 464
Fulvio Martusciello

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 ***specificities*** 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 ***suitable***, adapted frameworks may be developed by the Commission on the basis of the results of a regulatory sandbox.

Or. en

Amendment 465
Tiemo Wölken

Proposal for a regulation
Recital 135 a (new)

Text proposed by the Commission	*Amendment*
	(135 a) The EU market for medicines remains fragmented, despite the EU having a single market and being the second largest market for pharmaceuticals in the world. The organisation of healthcare systems is a national competence of Member States: this allows decisions closer to the patient, but also brings major divergences in both pricing and patient access. Better and closer coordination between national authorities opens the door to a more efficient and effective supply of medicines throughout the EU. The reform of the EU pharmaceutical legislation is essential to take the work on critical shortages and security of supply forward, building a pharmaceutical ecosystem that is competitive, future-proof and with a single market in medicines benefitting all Europeans. Furthermore, its goal are to prevent or mitigate critical shortages at EU level and to assure a particular focus on the critical medicines for which security of supply needs to be assured in the EU at all times, in normal times, and in times of crisis.

Or. en

Amendment 466
Tiemo Wölken

Proposal for a regulation
Recital 135 b (new)

Text proposed by the Commission	*Amendment*
	(135 b) More often, Member States experienced critical shortages of certain antibiotics, endangering the health of patients and risking the development of antimicrobial resistance. These critical

shortages were the result of changing infection patterns, which strongly increased demand. On the supply side, the long lead times needed to boost production made it difficult to respond quickly. This experience underlined the need for a dedicated effort – from the industry, as well as from Member States and the EU level to address the issue of critical shortages.

Or. en

Amendment 467
Andrey Slabakov

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. The root causes of shortages are multifactorial***. The primary root cause of shortages is the economic model for medicines in Europe, and especially for generic medicines. Other*** challenges ***can be*** 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 and strategic medicinal products, and especially those that do not have alternatives,*** 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.

Or. en

Amendment 468
Dolors Montserrat

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. 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 ***for critical medicinal products, and especially those that do not have alternatives***, 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 Veryfication System, which can aid in the monitoring and timely response to supply shortages, and has the potential to detect***

supply issues through predictive models.

Or. en

Amendment 469
Nathalie Colin-Oesterlé

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***, which have increased twentyfold over the past 20 years in the European Union, are a genuine*** health ***scourge***, 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***, while 45% of medicinal products marketed in the EU are not produced in the EU and 80 to 85% of the active ingredients are imported from China and India***. Therefore, all marketing authorisation holders should have shortage prevention plans in place to prevent shortages ***of medicinal products included on the Union list of critical medicinal products, and in particular medicines of health and strategic interest (MHSI)***. The Agency should provide guidance to marketing authorisation holders on approaches to streamline the implementation of those plans.

Or. fr

Amendment 470

Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Ondřej Knotek, Billy Kelleher, Erik Poulsen

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, 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.

Or. en

Amendment 471
István Ujhelyi

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. 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.

Or. en

Amendment 472
Marian-Jean Marinescu

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	(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 ***to parallel trade*** . In particular, shortages of medicinal products can result from supply chain disruptions and vulnerabilities affecting the supply of key ingredients and components.

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.	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.

Or. en

Justification

price differences among Member States, quite substantial in some cases, favour parallel trade that sometimes lead to a medicine crisis in some Member States

Amendment 473
István Ujhelyi

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. ***To combat certain shortages, medicinal products prepared for individual patients in a pharmacy according to a medical prescription "magistral formula", or according to the pharmacopoeia and intended to be supplied directly to patients served by the pharmacy "officinal formula", may be***

used. Member States may introduce or maintain additional robust measures to achieve security of supply of medicines, only when in consistent and coordinated way with the safeguards provided for in this Regulation.

Or. en

Amendment 474
Tiemo Wölken

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. ***To counter certain shortages, medicinal products prepared for individual patients in a pharmacy according to a medical prescription "magistral formula", or according to the pharmacopoeia and intended to be supplied directly to patients served by the pharmacy "officinal formula", may be used. 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.***

Or. en

Amendment 475
Sirpa Pietikäinen

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. ***To combat certain shortages, medicinal products prepared for individual patients in a pharmacy according to a medical prescription "magistral formula", or according to the pharmacopoeia and intended to be supplied directly to patients served by the pharmacy "officinal formula", may be used.***

Or. en

Amendment 476
Nathalie Colin-Oesterlé

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 ***combat shortages of medicinal products,*** a better security of supply for medicinal products in the internal market ***is a key element contributing*** to a high level of public health protection***;*** it is appropriate***, therefore,*** 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***, in particular by making security of supply a criterion as important as the price in public pharmacy contracts and in medicine-related procurement***. 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.

Or. fr

Amendment 477
Catherine Amalric, Max Orville, Billy Kelleher, Erik Poulsen, Dacian Cioloş

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	(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***, while allowing Member States to adopt or maintain legislation ensuring a higher degree of protection***

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.

against medicine shortages, in respect of the commitments taken in the framework of the "Voluntary Solidarity Mechanism for medicines". 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.

Or. en

Amendment 478
Andrey Slabakov

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 may indroduce measures to ensure the security of supply of critical or strategic medicinal products on national level according their needs.***

Or. en

Amendment 479
Andrey Slabakov, Elisabetta De Blasis

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 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	(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***. 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 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 ***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

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***.	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 ***creation of strategic reserves*** are taken.
[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).

Or. en

Amendment 480
Susana Solís Pérez, Frédérique Ries

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	(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***. When critical shortages are identified, both national competent authorities and the Agency should work in a coordinated manner to manage those

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 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.

[56] Regulation (EU) 2022/123 of the European Parliament and of the Council of

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 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.

[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).

25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1).

Or. en

Amendment 481
Tilly Metz

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 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	(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 ***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 ***and register such information in the European Shortages Monitoring Platform***. 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***

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.***

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. 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, 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

[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).

Or. en

Amendment 482
Catherine Amalric, Max Orville, Billy Kelleher, Dacian Cioloş

Proposal for a regulation
Recital 138

Text proposed by the Commission	*Amendment*
(138) The national competent authorities should be empowered to monitor shortages	(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 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

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 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. ***Health professional and patient organisations should be consulted before the adoption of the list.*** 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

measures, including the establishment or maintenance of ***contingency stocks***, are taken by marketing authorisation holders, wholesale distributors or other relevant entities.	medicinal products to the market. Implementing acts can be adopted by the Commission to ensure that appropriate measures, including the establishment or maintenance of ***minimum safety-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).

Or. en

Amendment 483
Nathalie Colin-Oesterlé

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 by the critical shortage is covered by a centralised marketing authorisation or a national marketing authorisation. Marketing authorisation holders and other	(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 ***continuously and in real time***, also based on notifications of marketing authorisation holders. ***To this end, the Agency should set up a European platform on stocks of medicinal products which is continuously updated in real time with data transmitted by the competent authorities of the Member States, marketing authorisation holders and wholesale distributors.*** When critical shortages are identified, both national

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**.**

competent authorities and the Agency should work in a coordinated manner to 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 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***, prioritising medicines of health and strategic interest (MHSI),*** 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. ***These recommendations may relate to national stockpiling initiatives to ensure that they are proportionate to needs and do not have undesirable consequences, such as supply tensions in other Member States.*** 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).

Or. fr

Amendment 484
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Billy Kelleher, Erik Poulsen, Dacian Cioloş

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 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,	(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 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.

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. ***The MSSG should develop in coordination with the Agency a Voluntary Solidarity Mechanism to allow Member States where stocks of important medicines are critically low and where other available options have been exhausted to send out on a voluntary basis a notification, to which other Members States may respond on a voluntary basis to provide temporary relief. This mechanism should leverage existing structures, including the European Shortages Monitoring Platform ('ESMP'), established by Regulation (EU) 2022/123, and should invite manufacturers and wholesalers to participate where relevant.***

[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).

Or. en

Amendment 485
Marian-Jean Marinescu

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 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	(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 by the critical shortage is covered by a centralised marketing authorisation or a national marketing authorisation ***and to identify the cause or causes of the respective critical shortage. If the critical shortage is triggered by a marketing authorisation holder, wholesale distributor or other legal entity, the Commission should be able to impose sanctions***. 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

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).

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.

[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).

Or. en

Justification

Identifying the causes of shortages and the responsibilities are crucial for future preventive actions.

Amendment 486
Andreas Glück, Peter Liese

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 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	(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 ***and the information available in the European Medicines Verifications System (EMVS)***. 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 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

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.	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).

Or. en

Justification

Data on the flow of medicinal products are available at large scale in the European Medicines Verifications System (EMVS). This data should be used as well in order to monitor shortages within the Union.

Amendment 487
Tilly Metz

Proposal for a regulation
Recital 138 a (new)

Text proposed by the Commission	*Amendment*
	(138 a) To facilitate appropriate communication between patients and consumers, on the one hand, and

competent authorities on the other, Member States should collect data on the impact of shortages of medicinal products on patients and consumers, and share relevant information through the MSSG, in order to inform approaches to management of shortages of medicinal products. Marketing authorisation holders should set up and maintain a minimum safety stock of critical medicinal products which shall be sufficient to cover two months demand of all Member States where the product has been placed on the market. Delegated 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. The setting up of safety stocks of critical medicinal products should not hamper the availability and affordability of these products or harm the environment by inappropriate disposals at both European and global level. Given the global nature of pharmaceutical supply chains, the safety stocks should be proportionate and take into account the potential impacts on shortages in other Member States and third countries. In order to avoid any interruption of access to critical medicinal products, national competent authorities may, in duly justified cases, grant an exemption from stockpiling obligations to the marketing authorisation holder, upon request, or adopt other complementary measures on the safety of stocks

Or. en

Amendment 488
Catherine Amalric, Max Orville, Billy Kelleher, Frédérique Ries, Andreas Glück, Dacian Cioloş

Proposal for a regulation
Recital 138 a (new)

Text proposed by the Commission	*Amendment*
	(138 a) In addition to existing and planned policy, legislative and regulatory measures, the Union need a strategic and coordinated industrial approach to ensure the security of supply of the most critical medicines. The Critical Medicines Alliance and the future Critical Medicines Act could allow national authorities, industry, civil society representatives, the Commission and the EU agencies to develop together coordinated actions at Union level against the shortages of medicines, in compliance with the competition rules and the Union's international commitments. The future Critical Medicines Act could support the European green, digital manufacturing of critical medicines, APIs and intermediate ingredients, diversify the EU pharmaceutical supply chains and secure the strategic autonomy of critical medicines.

Or. en

Amendment 489
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Billy Kelleher, Dacian Cioloş

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.

Or. en

Amendment 490
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Billy Kelleher, Dacian Cioloş

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.

Or. en

Amendment 491
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Andreas Glück, Billy Kelleher, Dacian Cioloş

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.

Or. en

Justification

This echoes the call launched in May 2023 by 19 Member States under Belgian coordination for an EU Critical Medicines Act. Available at https://www.rijksoverheid.nl/binaries/rijksoverheid/documenten/publicaties/2023/04/28/iz-1048167-b-311-non-paper-security-of-medicines-supply-280423/iz-1048167-b-311-non-paper-security-of-medicines-supply-280423.pdf

Amendment 492
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Billy Kelleher, Dacian Cioloş

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.

Or. en

Amendment 493
Nathalie Colin-Oesterlé

Proposal for a regulation
Recital 139 a (new)

Text proposed by the Commission	*Amendment*
	(139a) The list of critical medicinal products drawn up at Union level should harmonise existing national lists and should not create confusion for the different actors in the pharmaceutical sector.

Or. fr

Amendment 494
Nathalie Colin-Oesterlé

Proposal for a regulation
Recital 139 b (new)

Text proposed by the Commission	*Amendment*
	(139b) The creation of one of more non-profit pharmaceutical undertakings capable of producing certain medicines of health and strategic interest (MHSI) whose situation is critical or which are no longer profitable for pharmaceutical firms should complement and guarantee security of supply and prevent possible shortages of critical medicinal products.

Or. fr

Amendment 495

Nathalie Colin-Oesterlé

Proposal for a regulation
Recital 139 c (new)

Text proposed by the Commission	*Amendment*
	(139c) Policies on the pricing of pharmaceutical products which only contain expenditure have a negative effect on the reliability of supply. The competent authorities of the Member States should be able to recommend an increase in the prices of products for which a risk of shortages or market consolidation has been identified.

Or. fr

Amendment 496
Nathalie Colin-Oesterlé

Proposal for a regulation
Recital 139 d (new)

Text proposed by the Commission	*Amendment*
	(139d) The Covid-19 pandemic showed that introducing temporary regulatory flexibility measures in the event of a public health emergency can help tackle shortages of medicinal products.

Or. fr

Amendment 497
Nathalie Colin-Oesterlé

Proposal for a regulation
Recital 139 e (new)

Text proposed by the Commission	*Amendment*
	(139e) Pharmaceutical firms operate according to the just-in-time method, which can leave manufacturers

vulnerable to supply shocks where there are unanticipated production and supply chain interruptions and fluctuations in market demand.

Or. fr

Amendment 498
Nathalie Colin-Oesterlé

Proposal for a regulation
Recital 139 f (new)

Text proposed by the Commission	*Amendment*
	(139f) Public procurement procedures can be an effective tool for tackling shortages of medicinal products. At Member State level, invitations to tender based solely on price and where there is only one bidder increase the risk of shortages of medicinal products by strongly eroding prices, reducing the number of suppliers on the market. At Union level, joint procurement should be recognised as a tool to tackle critical shortages, in particular during a health crisis, as demonstrated by the Covid-19 pandemic.

Or. fr

Amendment 499
Stanislav Polčák

Proposal for a regulation
Recital 140

Text proposed by the Commission	*Amendment*
(140) It is recognised that improved access to information contributes to public awareness, gives the public the opportunity to express its observations and enables authorities to take due account of those observations. The general public should	(140) It is recognised that improved access to information contributes to public awareness ***and increases public trust***, gives the public the opportunity to express its observations and enables authorities to take due account of those observations.

therefore have access to information in the Union Register of medicinal products, the Eudravigilance database and the manufacturing and wholesale distribution database, after the deletion of any commercially confidential information by the competent authority. Regulation (EC) No 1049/2001 of the European Parliament and of the Council[57]gives the fullest possible effect to the right of public access to documents and lays down the general principles and limits on such access. The Agency should therefore give the widest possible access to the documents while carefully balancing the right for information with existing data protection requirements. Certain public and private interests, such as personal data and commercially confidential information, should be protected by way of exception in accordance with Regulation (EC) No 1049/2001.

The general public should therefore have access to information in the Union Register of medicinal products, the Eudravigilance database and the manufacturing and wholesale distribution database, after the deletion of any commercially confidential information by the competent authority. Regulation (EC) No 1049/2001***[1]*** of the European Parliament and of the Council gives the fullest possible effect to the right of public access to documents and lays down the general principles and limits on such access. The Agency should therefore give the widest possible access to the documents while carefully balancing the right for information with existing data protection requirements. Certain public and private interests, such as personal data and commercially confidential information, should be protected by way of exception in accordance with Regulation (EC) No 1049/2001. ***[1] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).***

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[57] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

Or. cs

Amendment 500
Tilly Metz

Proposal for a regulation
Recital 140

Text proposed by the Commission	*Amendment*
(140) It is recognised that improved access to information contributes to public	(140) It is recognised that improved access to information contributes to public

awareness, gives the public the opportunity to express its observations and enables authorities to take due account of those observations. The general public should therefore have access to information in the Union Register of medicinal products, the Eudravigilance database and the manufacturing and wholesale distribution database, after the deletion of any commercially confidential information by the competent authority. Regulation (EC) No 1049/2001 of the European Parliament and of the Council[57] gives the fullest possible effect to the right of public access to documents and lays down the general principles and limits on such access. The Agency should therefore give the widest possible access to the documents ***while carefully balancing the right for information with existing data protection requirements***. Certain public and private interests, such as personal data and commercially confidential information, should be protected by way of exception in accordance with Regulation (EC) No 1049/2001.	awareness, gives the public the opportunity to express its observations and enables authorities to take due account of those observations. The general public should therefore have access to information in the Union Register of medicinal products, the Eudravigilance database and the manufacturing and wholesale distribution database, after the deletion of any commercially confidential information by the competent authority ***and have full access to the data on environmental risks***. Regulation (EC) No 1049/2001 of the European Parliament and of the Council[57] gives the fullest possible effect to the right of public access to documents and lays down the general principles and limits on such access. The Agency should therefore give the widest possible access to the documents. Certain public and private interests, such as personal data and commercially confidential information, should be protected by way of exception in accordance with Regulation (EC) No 1049/2001.
[57] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).	[57] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

Or. en

Justification

deleted sentence as too vague and not necessary as explained better in the following sentence

Amendment 501
Tilly Metz

Proposal for a regulation
Recital 141

Text proposed by the Commission	*Amendment*
(141) To ensure the enforcement of certain obligations relating to the marketing authorisation for medicinal products for human use granted in accordance with this Regulation, the Commission should be able to impose financial penalties. When assessing the responsibility for failures to comply with those obligations and imposing such penalties, it is important that means exist to address the fact that marketing authorisation holders could be part of a wider economic entity. Otherwise, there is a clear and identifiable risk that the responsibility for a failure to comply with those obligations could be evaded, which might have an impact on the ability to impose effective, proportional and dissuasive penalties. The penalties imposed should be effective, proportionate and dissuasive, having regard to the circumstances of the specific case. For the purposes of ensuring legal certainty in the conduct of the infringement procedure, ***it is necessary to set maximum amounts for*** penalties***. Those maximum amounts should not be linked to the*** turnover ***of a particular medicinal product but the economic*** entity ***involved***.	(141) To ensure the enforcement of certain obligations relating to the marketing authorisation for medicinal products for human use granted in accordance with this Regulation, the Commission should be able to impose financial penalties. When assessing the responsibility for failures to comply with those obligations and imposing such penalties, it is important that means exist to address the fact that marketing authorisation holders could be part of a wider economic entity. Otherwise, there is a clear and identifiable risk that the responsibility for a failure to comply with those obligations could be evaded, which might have an impact on the ability to impose effective, proportional and dissuasive penalties. The penalties imposed should be effective, proportionate and dissuasive, having regard to the circumstances of the specific case. For the purposes of ensuring legal certainty in the conduct of the infringement procedure, ***the non-compliance of an entity with any requirements or obligations under this Regulation, including the supply of incorrect, incomplete or misleading information to competent authorities, should be subject to*** penalties ***of up to 20 000 000 EUR, or in the case of an undertaking, up to 5% of its total worldwide annual*** turnover ***for the preceding financial year, whichever is higher. In case of ongoing non-compliance, the competent authority should be able to fine the*** entity ***with fines for each day of delay, which shall be transparent and proportionate***.

Or. en

Amendment 502
Andrey Slabakov

Proposal for a regulation

Recital 141

Text proposed by the Commission	*Amendment*
(141) To ensure the enforcement of certain obligations relating to the marketing authorisation for medicinal products for human use granted in accordance with this Regulation, the Commission should be able to impose financial penalties. When assessing the responsibility for failures to comply with those obligations and imposing such penalties, it is important that means exist to address the fact that marketing authorisation holders could be part of a wider economic entity. Otherwise, there is a clear and identifiable risk that the responsibility for a failure to comply with those obligations could be evaded, which might have an impact on the ability to impose effective, proportional and dissuasive penalties. The penalties imposed should be effective, proportionate and dissuasive, having regard to the circumstances of the specific case. For the purposes of ensuring legal certainty in the conduct of the infringement procedure, it is necessary to set maximum amounts for penalties. Those maximum amounts should not be linked to the turnover of a particular medicinal product but the economic entity involved.	(141) To ensure the enforcement of certain obligations relating to the marketing authorisation for medicinal products for human use granted in accordance with this Regulation, the Commission should be able to impose ***appropriate and adequate*** financial penalties. When assessing the responsibility for failures to comply with those obligations and imposing such penalties, it is important that means exist to address the fact that marketing authorisation holders could be part of a wider economic entity. Otherwise, there is a clear and identifiable risk that the responsibility for a failure to comply with those obligations could be evaded, which might have an impact on the ability to impose effective, proportional and dissuasive penalties. The penalties imposed should be effective, proportionate and dissuasive, having regard to the circumstances of the specific case. For the purposes of ensuring legal certainty in the conduct of the infringement procedure, it is necessary to set maximum amounts for penalties. Those maximum amounts should not be linked to the turnover of a particular medicinal product but the economic entity involved.

Or. en

Amendment 503
Stanislav Polčák

Proposal for a regulation
Recital 141

Text proposed by the Commission	*Amendment*
(141) To ensure the enforcement of certain obligations relating to the marketing authorisation for medicinal	(141) To ensure the enforcement of certain obligations relating to the marketing authorisation for medicinal

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

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

Or. cs

Amendment 504
Tilly Metz

Proposal for a regulation
Recital 143

Text proposed by the Commission	*Amendment*
(143) To ensure uniform conditions for the implementation of this Regulation in relation to marketing authorisations for medicinal products for human use, implementing powers should be conferred on the Commission. The implementing powers related to the granting of centralised marketing authorisations and for suspending, revoking or withdrawing those authorisations***, for granting vouchers,*** establishing and modifying	(143) To ensure uniform conditions for the implementation of this Regulation in relation to marketing authorisations for medicinal products for human use, implementing powers should be conferred on the Commission. The implementing powers related to the granting of centralised marketing authorisations and for suspending, revoking or withdrawing those authorisations establishing and modifying decisions on the regulatory

regulatory sandboxes and decisions on the regulatory status of medicinal products should be exercised in accordance with Regulation (EU) 182/2011**.**

status of medicinal products should be exercised in accordance with Regulation (EU) 182/2011

Or. en

Amendment 505
Frédérique Ries, Catherine Amalric, Max Orville, Billy Kelleher

Proposal for a regulation
Recital 143

Text proposed by the Commission	*Amendment*
(143) To ensure uniform conditions for the implementation of this Regulation in relation to marketing authorisations for medicinal products for human use, implementing powers should be conferred on the Commission. The implementing powers related to the granting of centralised marketing authorisations and for suspending, revoking or withdrawing those authorisations, ***for granting vouchers,*** establishing and modifying regulatory sandboxes and decisions on the regulatory status of medicinal products should be exercised in accordance with Regulation (EU) 182/2011.	(143) To ensure uniform conditions for the implementation of this Regulation in relation to marketing authorisations for medicinal products for human use, implementing powers should be conferred on the Commission. The implementing powers related to the granting of centralised marketing authorisations and for suspending, revoking or withdrawing those authorisations, establishing and modifying regulatory sandboxes and decisions on the regulatory status of medicinal products should be exercised in accordance with Regulation (EU) 182/2011.

Or. en

Amendment 506
Catherine Amalric, Max Orville

Proposal for a regulation
Recital 143

Text proposed by the Commission	*Amendment*
(143) To ensure uniform conditions for the implementation of this Regulation in relation to marketing authorisations for medicinal products for human use, implementing powers should be conferred	(143) To ensure uniform conditions for the implementation of this Regulation in relation to marketing authorisations for medicinal products for human use, implementing powers should be conferred

on the Commission. The implementing powers related to the granting of centralised marketing authorisations and for suspending, revoking or withdrawing those authorisations, ***for granting vouchers,*** establishing and modifying regulatory sandboxes and decisions on the regulatory status of medicinal products should be exercised in accordance with Regulation (EU) 182/2011.	on the Commission. The implementing powers related to the granting of centralised marketing authorisations and for suspending, revoking or withdrawing those authorisations, establishing and modifying regulatory sandboxes and decisions on the regulatory status of medicinal products should be exercised in accordance with Regulation (EU) 182/2011.

Or. en

Amendment 507
Susana Solís Pérez, Ondřej Knotek

Proposal for a regulation
Recital 145

Text proposed by the Commission	*Amendment*
(145) Experience shows that, in clinical trials with investigational medicinal products containing or consisting of GMOs, the procedure to achieve compliance with the requirements of Directives 2001/18/EC and 2009/41/EC as regards the environmental risk assessment and consent by the competent authority of a Member State is complex and can take a significant amount of time.	(145) Experience shows that, in clinical trials with investigational medicinal products containing or consisting of GMOs***, including some advanced therapy medicinal products***, the procedure to achieve compliance with the requirements of Directives 2001/18/EC and 2009/41/EC as regards the environmental risk assessment and consent by the competent authority of a Member State is complex and can take a significant amount of time.

Or. en

Amendment 508
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Ondřej Knotek, Billy Kelleher, Erik Poulsen

Proposal for a regulation
Recital 145

Text proposed by the Commission	*Amendment*
(145) Experience shows that, in clinical trials with investigational medicinal	(145) Experience shows that, in clinical trials with investigational medicinal

products containing or consisting of GMOs, the procedure to achieve compliance with the requirements of Directives 2001/18/EC and 2009/41/EC as regards the environmental risk assessment and consent by the competent authority of a Member State is complex and can take a significant amount of time.

products containing or consisting of GMOs***, including some advanced therapy medicinal products***, the procedure to achieve compliance with the requirements of Directives 2001/18/EC and 2009/41/EC as regards the environmental risk assessment and consent by the competent authority of a Member State is complex and can take a significant amount of time.

Or. en

Amendment 509
Stelios Kympouropoulos

Proposal for a regulation
Recital 145

Text proposed by the Commission	*Amendment*
(145) Experience shows that, in clinical trials with investigational medicinal products containing or consisting of GMOs, the procedure to achieve compliance with the requirements of Directives 2001/18/EC and 2009/41/EC as regards the environmental risk assessment and consent by the competent authority of a Member State is complex and can take a significant amount of time.	(145) Experience shows that, in clinical trials with investigational medicinal products containing or consisting of GMOs***, including some ATMPs***, the procedure to achieve compliance with the requirements of Directives 2001/18/EC and 2009/41/EC as regards the environmental risk assessment and consent by the competent authority of a Member State is complex and can take a significant amount of time.

Or. en

Amendment 510
Anders Vistisen
on behalf of the ID Group
Aurélia Beigneux

Proposal for a regulation
Recital 149

Text proposed by the Commission	*Amendment*
(149) It is therefore appropriate to envisage a centralised assessment of the	(149) It is therefore appropriate to envisage a centralised assessment of the

ERA involving experts from the national competent authorities.	ERA involving experts from the national competent authorities ***before and establish a science- and risk-based approach***.

Or. en

Amendment 511
Tilly Metz

Proposal for a regulation
Recital 149

Text proposed by the Commission	*Amendment*
(149) It is therefore appropriate to envisage a centralised assessment of the ERA involving experts from the national competent authorities.	(149) It is therefore appropriate to envisage a centralised assessment of the ERA involving experts from the national competent authorities ***and the Environmental Risk Assessment working party***.

Or. en

Amendment 512
Stanislav Polčák

Proposal for a regulation
Recital 154

Text proposed by the Commission	*Amendment*
(154) This Regulation is based on the double legal basis of Article 114 and Article 168(4), point (c), TFEU. It aims at achieving an internal market as regards medicinal products for human use, taking as a base a high level of protection of health. At the same time, this Regulation sets high standards of quality and safety for medicinal products in order to meet common safety concerns as regards these products. Both objectives are being pursued simultaneously. These two objectives are inseparably linked and one is not secondary to another. Regarding Article 114 TFEU, this Regulation	(154) This Regulation is based on the double legal basis of Article 114 and Article 168(4), point (c), TFEU. It aims at achieving an internal market as regards medicinal products for human use, taking as a base a high level of protection of health. At the same time, this Regulation sets high standards of quality and safety for medicinal products in order to meet common safety concerns as regards these products. Both objectives are being pursued simultaneously. These two objectives are inseparably linked and one is not secondary to another. Regarding Article 114 TFEU, this Regulation

establishes a European Medicines Agency and provides specific provision with regard to the central authorisation of medicinal products, therefore ensuring the functioning of the internal market and the free movement of medicinal products. Regarding Article 168(4), point (c), TFEU, this Regulation sets high standards of quality and safety for medicinal products.	***regulates the functioning of the*** European Medicines Agency***, established by Regulation (EC) No 726/2004,*** and provides specific provision with regard to the central authorisation of medicinal products, therefore ensuring the functioning of the internal market and the free movement of medicinal products. Regarding Article 168(4), point (c), TFEU, this Regulation sets high standards of quality and safety for medicinal products.

Or. cs

Amendment 513
Maria Angela Danzì

Proposal for a regulation
Recital 155

Text proposed by the Commission	*Amendment*
(155) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, the rights of the child, respect for private and family life, the protection of personal data and the freedom of art and science.	(155) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, the rights of the child, respect for private and family life, the protection of personal data and the freedom of art and science. ***To this end, specific actions will be established to reduce the gap between paediatric medicinal products, including speeding up the development and marketing of paediatric medicinal products, providing funds for paediatric research and setting which paediatric medicinal products are a priority with a view to covering unmet needs.***

Or. it

Justification

Children's rights seem to be only partially recognised in the proposal. The establishment of a paediatric working group with a view to maintaining the PDCO's role in the sector, reviewing the provision of funds for research, reviewing the identification and definition of unmet

therapeutic needs, etc.

Amendment 514
Tilly Metz

Proposal for a regulation
Recital 155

Text proposed by the Commission	*Amendment*
(155) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, the rights of the child, respect for private and family life, the protection of personal data and the freedom of art and science.	(155) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, the rights of the child, respect for private and family life, the protection of personal data and the freedom of art and science. ***Similarly, this Regulation respects the Aarhus Convention which protects every person's right to live in a healthy environment.***

Or. en

Amendment 515
Maria Angela Danzì

Proposal for a regulation
Recital 156

Text proposed by the Commission	*Amendment*
(156) The objective of this Regulation is to ensure the authorisation of high quality medicinal products, including for paediatric patients and patients suffering from rare diseases throughout the Union. Where this objective cannot be sufficiently achieved by the Member States but can rather, by reason of its scale, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union.	(156) The objective of this Regulation is to ensure the authorisation of high quality medicinal products, including for paediatric patients and patients suffering from rare diseases throughout the Union. Where this objective cannot be sufficiently achieved by the Member States***, such as in the case of the development of paediatric medicinal products,*** but can rather, by reason of its scale, be better achieved at Union level, the Union may adopt measures, in accordance with the principle

In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.	of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

Or. it

Justification

As is well known and highlighted in the paediatric regulation, the Member States cannot sufficiently improve the availability of medicines tested for paediatric use. It seems appropriate to provide for special measures at EU level on the basis of the principle of subsidiarity.

Amendment 516
Cyrus Engerer

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
This Regulation lays down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use at Union level, establishes rules and procedures at Union and at Member State level relating to the security of supply of medicinal products and lays down the governance provisions of the European Medicines Agency ('the Agency') established by Regulation (EC) No 726/2004 which shall carry out the tasks relating to medicinal products for human use that are laid down in this Regulation, Regulation (EU) No 2019/6 and other relevant Union legal acts.	This Regulation lays down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use at Union level, establishes rules and procedures at Union and at Member State level relating to the ***monitoring and managamenet of shortages and critical shortages and*** security of supply of medicinal products and lays down the governance provisions of the European Medicines Agency ('the Agency') established by Regulation (EC) No 726/2004 which shall carry out the tasks relating to medicinal products for human use that are laid down in this Regulation, Regulation (EU) No 2019/6 and other relevant Union legal acts.

Or. en

Amendment 517
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Billy Kelleher,

Dacian Cioloş

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
This Regulation lays down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use at Union level, establishes rules and procedures at Union and at Member State level relating to the security of supply of medicinal products and lays down the governance provisions of the European Medicines Agency ('the Agency') established by Regulation (EC) No 726/2004 which shall carry out the tasks relating to medicinal products for human use that are laid down in this Regulation, Regulation (EU) No 2019/6 and other relevant Union legal acts.	This Regulation lays down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use at Union level, establishes rules and procedures at Union and at Member State level relating to the ***monitoring and management of shortages and critical shortages and*** security of supply of medicinal products**,** and lays down the governance provisions of the European Medicines Agency ('the Agency') established by Regulation (EC) No 726/2004 which shall carry out the tasks relating to medicinal products for human use that are laid down in this Regulation, Regulation (EU) No 2019/6 and other relevant Union legal acts.

Or. en

Amendment 518
Tilly Metz

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
This Regulation lays down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use at Union level, establishes rules and procedures at Union and at Member State level relating to the security of supply of medicinal products and lays down the governance provisions of the European Medicines Agency ('the Agency') established by Regulation (EC) No 726/2004 which shall carry out the tasks relating to medicinal products for human use that are laid down	This Regulation lays down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use at Union level, establishes rules and procedures at Union and at Member State level relating to the security of supply of medicinal products and lays down the governance provisions of the European Medicines Agency ('the Agency') established by Regulation (EC) No 726/2004 which shall carry out the tasks relating to medicinal products for human use that are laid down

in this Regulation, Regulation (EU) No 2019/6 and other relevant Union legal acts.	in this Regulation, Regulation (EU) No 2019/6***, Regulation No 2022/123, Regulation No 536/2014*** and other relevant Union legal acts.

Or. en

Amendment 519
Nathalie Colin-Oesterlé

Proposal for a regulation
Article premier – paragraph 1

Text proposed by the Commission	*Amendment*
This Regulation lays down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use at Union level, establishes rules and procedures at Union and at Member State level relating to the security of supply of medicinal products and lays down the governance provisions of the European Medicines Agency ('the Agency') established by Regulation (EC) No 726/2004 which shall carry out the tasks relating to medicinal products for human use that are laid down in this Regulation, Regulation (EU) No 2019/6 and other relevant Union legal acts.	This Regulation lays down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use at Union level, establishes rules and procedures at Union and at Member State level relating to ***tackling shortages and to*** the security of supply of medicinal products and lays down the governance provisions of the European Medicines Agency ('the Agency') established by Regulation (EC) No 726/2004 which shall carry out the tasks relating to medicinal products for human use that are laid down in this Regulation, Regulation (EU) No 2019/6 and other relevant Union legal acts.

Or. fr

Amendment 520
Stanislav Polčák

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
This Regulation lays down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use at Union	This Regulation lays down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use at Union

level, establishes rules and procedures at Union and at Member State level relating to the security of supply of medicinal products and lays down the governance ***provisions*** of the European Medicines Agency ('the Agency') established by Regulation (EC) No 726/2004 which shall carry out the tasks relating to medicinal products for human use that are laid down in this Regulation, Regulation (EU) No 2019/6 and other relevant Union legal acts.	level, establishes rules and procedures at Union and at Member State level relating to the security of supply of medicinal products and lays down ***rules on*** the governance ***and functioning*** of the European Medicines Agency ('the Agency') established by Regulation (EC) No 726/2004 which shall carry out the tasks relating to medicinal products for human use that are laid down in this Regulation, Regulation (EU) No 2019/6 and other relevant Union legal acts.

Or. cs

Amendment 521
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Ondřej Knotek, Billy Kelleher, Erik Poulsen

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

Or. en

Amendment 522
Andrey Slabakov, Elisabetta De Blasis

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	(4) 'orphan ***medicinal product*** 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

Article 64(4);	to in Article 64(4);

Or. en

Amendment 523
Tomislav Sokol

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

Or. en

Amendment 524
Fulvio Martusciello

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

Or. en

Amendment 525
Anders Vistisen
on behalf of the ID Group
Aurélia Beigneux

Proposal for a regulation

Article 2 – paragraph 2 – point 7

Text proposed by the Commission	*Amendment*
(7) 'significant benefit' means a clinically relevant advantage or a major contribution to patient care of an orphan medicinal product ***if such an advantage or contribution benefits a substantial part of the target population;***	(7) 'significant benefit' means a clinically relevant advantage or a major contribution to patient care of an orphan medicinal product

Or. en

Amendment 526
Stelios Kympouropoulos, Pernille Weiss

Proposal for a regulation
Article 2 – paragraph 2 – point 7

Text proposed by the Commission	*Amendment*
(7) 'significant benefit' means a clinically relevant advantage or a major contribution to patient care of an orphan medicinal product ***if such an advantage or contribution benefits a substantial part of the target population***;	(7) 'significant benefit' means a clinically relevant advantage or a major contribution to patient care of an orphan medicinal product;

Or. en

Amendment 527
Fulvio Martusciello

Proposal for a regulation
Article 2 – paragraph 2 – point 7

Text proposed by the Commission	*Amendment*
(7) 'significant benefit' means a clinically relevant advantage or a major contribution to patient care of an orphan medicinal product ***if such an advantage or contribution benefits a substantial part of the target population***;	(7) 'significant benefit' means a clinically relevant advantage or a major contribution to patient care of an orphan medicinal product;

Or. en

Amendment 528
Massimiliano Salini, Francesca Peppucci

Proposal for a regulation
Article 2 – paragraph 2 – point 7

Text proposed by the Commission	*Amendment*
(7) 'significant benefit' means a clinically relevant advantage or a major contribution to patient care of an orphan medicinal product ***if such an advantage or contribution benefits a substantial part of the target population;***	(7) 'significant benefit' means a clinically relevant advantage or a major contribution to patient care of an orphan medicinal product

Or. en

Amendment 529
Tomislav Sokol

Proposal for a regulation
Article 2 – paragraph 2 – point 7

Text proposed by the Commission	*Amendment*
(7) 'significant benefit' means a clinically relevant advantage or a major contribution to patient care of an orphan medicinal product if such an advantage or contribution benefits a ***substantial*** part of the target population;	(7) 'significant benefit' means a clinically relevant advantage or a major contribution to patient care of an orphan medicinal product if such an advantage or contribution benefits a ***relevant*** part of the target population;

Or. en

Amendment 530
Andrey Slabakov

Proposal for a regulation
Article 2 – paragraph 2 – point 7

Text proposed by the Commission	*Amendment*
(7) 'significant benefit' means a clinically relevant advantage or a major contribution to patient care of an orphan	(7) 'significant benefit' means a clinically relevant advantage or a major contribution to patient care of an orphan

medicinal product if such an advantage or contribution benefits a ***substantial*** part of the target population;	medicinal product if such an advantage or contribution benefits a ***relevant*** part of the target population;

Or. en

Amendment 531
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Billy Kelleher, Erik Poulsen

Proposal for a regulation
Article 2 – paragraph 2 – point 7 a (new)

Text proposed by the Commission	*Amendment*
	(7 a) 'adverse reaction' means a response to a medicinal product that is noxious and unintended, and includes medication errors and uses outside of the terms of the marketing authorisation, including the misuse and abuse of the medication product;

Or. en

Justification

Necessary to ensure consistency in the reporting and recording of adverse reactions with National Competent Authorities and for the Eudravigilance database.

Amendment 532
Marian-Jean Marinescu

Proposal for a regulation
Article 2 – paragraph 2 – point 7 a (new)

Text proposed by the Commission	*Amendment*
	(7 a) 'adverse reaction' means a response to a medical that is noxious and includes medication errors and uses outside of the terms of the marketing authorisation, including the misuse and abuse of the medication product;

Or. en

Justification

Adverse reaction is not defined in the regulation although the term is used throughout.

Amendment 533
István Ujhelyi

Proposal for a regulation
Article 2 – paragraph 2 – point 7 a (new)

Text proposed by the Commission	*Amendment*
	(7 a) 'adverse reaction' means a response to a medical that is noxious and unintended and includes medication errors and uses outside of the terms of the marketing authorisation, including the misuse and abuse of the medication product;

Or. en

Amendment 534
Tiemo Wölken

Proposal for a regulation
Article 2 – paragraph 2 – point 7 a (new)

Text proposed by the Commission	*Amendment*
	(7 a) 'adverse reaction' means an effect on a person in response to a medicinal product that is noxious and unintended;

Or. en

Amendment 535
Tilly Metz

Proposal for a regulation
Article 2 – paragraph 2 – point 8 – point a

Text proposed by the Commission	*Amendment*
(a) greater efficacy than an authorised	(a) greater efficacy than an authorised

medicinal orphan medicinal product in a substantial part of the target population;	medicinal orphan medicinal product in a substantial part of the target population***, as assessed by effect on a clinically meaningful endpoint in adequate and well controlled clinical trial showing a comparative efficacy claim for two different medicinal product***;

Or. en

Justification

Aligning with current definition of clinical superiority as laid down in the IA which will continue to apply: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:103:0005:0008:EN:PDF

Amendment 536
Tilly Metz

Proposal for a regulation
Article 2 – paragraph 2 – point 8 – point b

Text proposed by the Commission	*Amendment*
(b) greater safety than an authorised medicinal product in a substantial part of the target population;	(b) greater safety than an authorised medicinal product in a substantial part of the target population ***based on direct comparative trial***;

Or. en

Amendment 537
Maria Angela Danzì

Proposal for a regulation
Article 2 – paragraph 2 – point 9 a (new)

Text proposed by the Commission	*Amendment*
	(9a) 'Paediatric population' means the proportion of the population aged between infancy and 18.

Or. it

Justification

To emphasise its relevance, the definition of 'paediatric population' should be reinstated under the regulation.

Amendment 538
Maria Angela Danzì

Proposal for a regulation
Article 2 – paragraph 2 – point 9 b (new)

Text proposed by the Commission	*Amendment*
	(9b) 'Paediatric investigation plan' means a research and development programme designed to ensure that the requisite data are generated determining the conditions in which a medicinal product may be authorised to treat the paediatric population;

Or. it

Justification

Stressing the importance of the paediatric investigation plan as the main tool to promote the development of paediatric medicine in all age groups. Its definition should be reintegrated into the regulation.

Amendment 539
Maria Angela Danzì

Proposal for a regulation
Article 2 – paragraph 2 – point 9 c (new)

Text proposed by the Commission	*Amendment*
	(9c) 'Medicinal product authorised for a paediatric indication' means a medicinal product authorised for use in all or part of the paediatric population and for which the details of the indication authorised are specified in the summary of product characteristics drawn up in accordance with Article 4 of the [revised directive];

Or. it

Justification

This definition clarifies what a paediatric medicinal product is and the need to include details of the approved indication/dosage/formulation in the summary of product characteristics. This clarification is also intended to prevent confusion with the PUMA definition concerning the type of marketing authorisation, not the product itself.

Amendment 540
Tiemo Wölken

Proposal for a regulation
Article 2 – paragraph 2 – point 10

Text proposed by the Commission	*Amendment*
(10) 'regulatory sandbox' means a regulatory framework during which it is possible to develop, validate and test in a controlled environment innovative or adapted regulatory solutions that facilitate the development and authorisation of innovative products which are likely to fall in the scope of this Regulation, pursuant to a specific plan and for a limited time under regulatory supervision.	***deleted***

Or. en

Amendment 541
Tilly Metz

Proposal for a regulation
Article 2 – paragraph 2 – point 10

Text proposed by the Commission	*Amendment*
(10) 'regulatory sandbox' means a regulatory framework during which it is possible to develop, validate and test in a controlled environment innovative or adapted regulatory solutions that facilitate the development and authorisation of innovative products which are likely to fall in the scope of this Regulation, pursuant to a specific plan and for a	***deleted***

limited time under regulatory supervision.

Or. en

Amendment 542
Stelios Kympouropoulos

Proposal for a regulation
Article 2 – paragraph 2 – point 10

Text proposed by the Commission	*Amendment*
(10) 'regulatory sandbox' means a regulatory framework during which it is possible to develop, validate and test in a controlled environment innovative or adapted regulatory solutions that facilitate the development and authorisation of innovative products which ***are likely to fall in the scope of this Regulation***, pursuant to a specific plan and for a limited time under regulatory supervision.	(10) 'regulatory sandbox' means a regulatory framework during which it is possible to develop, validate and test in a controlled environment innovative or adapted regulatory solutions***, including, when applicable, the use of real-world evidence, in silico methods, digital twin, and AI,*** that facilitate the development and authorisation of innovative products which ***can be regulated as medicinal products or other categories of products***, pursuant to a specific plan and for a limited time under regulatory supervision.

Or. en

Justification

Regulatory sandboxes offer a structured framework experimentation and advancement of regulation via proactive regulatory learning. Including real-world evidence, in silico methods and AI in the definition of regulatory sandboxes is important to leverage its potential in supporting regulatory risk assessment.

Amendment 543
Pernille Weiss

Proposal for a regulation
Article 2 – paragraph 2 – point 10

Text proposed by the Commission	*Amendment*
(10) 'regulatory sandbox' means a regulatory framework during which it is possible to develop, validate and test in a	(10) 'regulatory sandbox' means a regulatory framework during which it is possible to develop, validate and test in a

controlled environment innovative or adapted regulatory solutions that facilitate the development and authorisation of innovative products ***which are likely to fall in the scope of this Regulation***, pursuant to a specific plan and for a limited time under regulatory supervision.	controlled environment innovative or adapted regulatory solutions that facilitate the development and authorisation of innovative products, pursuant to a specific plan and for a limited time under regulatory supervision.

Or. en

Amendment 544
Fulvio Martusciello

Proposal for a regulation
Article 2 – paragraph 2 – point 10

Text proposed by the Commission	*Amendment*
(10) 'regulatory sandbox' means a regulatory framework during which it is possible to develop, validate and test in a controlled environment innovative or adapted regulatory solutions that facilitate the development and authorisation of innovative products which ***are likely to fall in the scope of this Regulation,*** pursuant to a specific plan and for a limited time under regulatory supervision.	(10) 'regulatory sandbox' means a regulatory framework during which it is possible to develop, validate and test in a controlled environment innovative or adapted regulatory solutions that facilitate the development and authorisation of innovative products which ***might be regulated as medicinal products or other categories of products*** pursuant to a specific plan and for a limited time under regulatory supervision.

Or. en

Amendment 545
Tomislav Sokol

Proposal for a regulation
Article 2 – paragraph 2 – point 10

Text proposed by the Commission	*Amendment*
(10) 'regulatory sandbox' means a regulatory framework during which it is possible to develop, validate and test in a controlled environment innovative or adapted regulatory solutions that facilitate the development and authorisation of	(10) 'regulatory sandbox' means a regulatory framework during which it is possible to develop, validate and test in a controlled environment innovative or adapted regulatory solutions that facilitate the development and authorisation of

innovative products which ***are likely to fall in the scope of this Regulation,*** pursuant to a specific plan and for a limited time under regulatory supervision.	innovative products which ***might be regulated as medicinal products or other categories of products pursuant to a specific plan and for a limited time under regulatory supervision.***

Or. en

Amendment 546
Kateřina Konečná

Proposal for a regulation
Article 2 – paragraph 2 – point 11

Text proposed by the Commission	*Amendment*
(11) 'critical medicinal product' means a medicinal product for which insufficient supply results in serious harm or risk of serious harm to patients and identified using the methodology pursuant to Article 130(1), point (a).	(11) 'critical medicinal product' means a medicinal product for which insufficient supply results in serious harm or risk of serious harm to patients ***or does not allow to satisfy priority health care needs of the population,*** and identified using the methodology pursuant to Article 130(1), point (a).

Or. en

Justification

Limiting 'critical medicines' to situations whereby insufficient supply would result in 'serious harm' to the patient is quite restrictive, as it could potentially leave out of the list medicines that are considered essential and frequently used, such as analgesics for mild to moderate pain.

Amendment 547
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 2 – paragraph 2 – point 11

Text proposed by the Commission	*Amendment*
(11) 'critical medicinal product' means a medicinal product for which insufficient supply results in serious harm or risk of serious harm to patients ***and*** identified	(11) 'critical medicinal product' means a medicinal product for which insufficient supply results in serious harm or risk of serious harm to patients ***in the short or***

using the methodology pursuant to Article 130(1), point (a).	***medium term and which has been*** identified using the methodology pursuant to Article 130(1), point (a).

Or. fr

Amendment 548
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 2 – paragraph 2 – point 11 a (new)

Text proposed by the Commission	*Amendment*
	(11a) 'medicine of health and strategic interest' (MHSI) means a medicinal product for which an interruption in treatment poses an immediate danger to the life of the patient.

Or. fr

Amendment 549
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Ondřej Knotek, Billy Kelleher, Erik Poulsen

Proposal for a regulation
Article 2 – paragraph 2 – point 11 a (new)

Text proposed by the Commission	*Amendment*
	(11 a) 'demand' means the request for a medicinal product or a medical device by a healthcare professional or patient in response to clinical need; the demand is satisfactorily met when the medicinal product or the medical device is acquired in appropriate time and in sufficient quantity to allow continuity of the best care of patients;

Or. en

Justification

Definition adopted in the Extension of the Mandate of the European Medicines Agency

Amendment 550
Catherine Amalric, Max Orville, Billy Kelleher, Erik Poulsen

Proposal for a regulation
Article 2 – paragraph 2 – point 11 a (new)

Text proposed by the Commission	*Amendment*
	(11 a) 'demand' means the request for a medicinal product or a medical device by a healthcare professional or patient in response to clinical need; the demand is satisfactorily met when the medicinal product or the medical device is acquired in appropriate time and in sufficient quantity to allow continuity of the best care of patients;

Or. en

Amendment 551
Kateřina Konečná

Proposal for a regulation
Article 2 – paragraph 2 – point 11 a (new)

Text proposed by the Commission	*Amendment*
	(11 a) 'demand' means the request for a medicinal product by a healthcare professional or patient in response to clinical need; the demand is satisfactorily met when the medicinal product is acquired in appropriate time and in sufficient quantity to allow continuity of the best care of patients;

Or. en

Amendment 552
Cyrus Engerer

Proposal for a regulation
Article 2 – paragraph 2 – point 11 a (new)

Text proposed by the Commission	*Amendment*
	(11 a) 'demand' means the request for a medicinal product by a healthcare or patient in response to clinical need; the demand is satisfactorily met when the medicinal products is acequired in appropriate time and in sufficient quantity to allow continuity of provision of the best care to patients. Wholesalers are usually a key supply link between market authorization holders and the users of medicines, and in those cases, in order to estimate demand, the quantity requested in wholesale orders should be considered;

Or. en

Amendment 553
Tiemo Wölken

Proposal for a regulation
Article 2 – paragraph 2 – point 11 a (new)

Text proposed by the Commission	*Amendment*
	(11 a) 'demand' means the request for a medicinal product by a healthcare professional or patient in response to clinical need; the demand is satisfactorily met when the medicinal product is acquired in appropriate time and in sufficient quantity to allow continuity of provision of the best care to patients; Wholesalers are usually a key supply link between MAHs and the users of medicines, and in those cases, in order to estimate demand, the quantity requested in wholesale orders should be considered;

Or. en

Amendment 554
Andrey Slabakov

Proposal for a regulation
Article 2 – paragraph 2 – point 11 a (new)

Text proposed by the Commission	*Amendment*
	(11 a) 'demand' means the request for a medicinal product by a healthcare professional or patient in response to a clinical need; the demand is satisfactorily met when the medicinal product is acquired in appropriate time and in sufficient quantity to allow continuity of the care of patients;

Or. en

Amendment 555
Tomislav Sokol

Proposal for a regulation
Article 2 – paragraph 2 – point 11 a (new)

Text proposed by the Commission	*Amendment*
	(11 a) 'demand' means the request for a medicinal product by a healthcare professional or patient in response to clinical need; the demand is satisfactorily met when the medicinal product is acquired in appropriate time and in sufficient quantity to allow continuity of the best care of patients.

Or. en

Amendment 556
Margarita de la Pisa Carrión

Proposal for a regulation
Article 2 – paragraph 2 – point 11 a (new)

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

clinical need; the demand is satisfactorily met when the medicinal product is acquired in appropriate time and in sufficient quantity and quality to allow the continuous fulfillment of the needs of the patients in the member state in question.

Or. en

Justification

Regulation (EU) 2022/123 of 25 January 2022 on a reinforced rolefor the European Medicines Agency in crisis preparedness andmanagement for medicinal products and medical devices providesfor a more exhaustive definition of 'Shortage' including areference to 'Supply' and 'Demand'. In order to ensure aconsistent and workable definition of medicine shortage in allMember States it is essential that the definitions of shortage,supply and demand be similar in both Regulations to enable dataexchange and comparison.Demand must acknowledge the importance of finding sufficientand quality medical products that ensure that medical need iscovered safely.

Amendment 557
Andrey Slabakov, Elisabetta De Blasis

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 does not meet the demand for that medicinal product ***at a national level, regardless of the cause***.

Or. en

Amendment 558
Nathalie Colin-Oesterlé

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

Text proposed by the Commission	*Amendment*
(12) 'shortage' means a situation in	(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.	which the supply***, as defined by Regulation 2022/123[1 b],*** of a medicinal product that is authorised and placed on the market in a Member State does not meet the demand***, as defined by Regulation 2022/123,*** for that medicinal product in that Member State***, whatever the cause***.

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

Or. fr

Amendment 559
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Ondřej Knotek, Billy Kelleher, Erik Poulsen

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 authorised and placed on the market in a Member State ***or of a CE-marked medical device*** does not meet demand for that medicinal product ***or medical device at a national level, whatever the cause***

Or. en

Amendment 560
Catherine Amalric, Max Orville, Billy Kelleher, Erik Poulsen

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 medical device*** does not meet the demand for that medicinal product ***or medical device*** in that Member State***, whatever the cause***.

Or. en

Amendment 561
István Ujhelyi

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 does not meet the ***needs of patients’*** demand for that medicinal product in that Member State***, whatever the cause***.

Or. en

Amendment 562
Tilly Metz

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 does not meet the demand for that medicinal product in that Member State***, whatever the cause***.

Or. en

Justification

As was the EP's key priority in the EMA Mandate regulation, we shall keep the 'whatever the cause' in this definition, as we did in Regulation 2022/123, for consistency

Amendment 563
Kateřina Konečná

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 does not meet the demand for that medicinal product in that Member State ***whatever the cause***.

Or. en

Amendment 564
Frédérique Ries, Susana Solís Pérez, Max Orville, Ondřej Knotek, Billy Kelleher, Erik Poulsen

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 or medical device that is placed on the market by a marketing authorisation holder or a manufacturer;

Or. en

Justification

Definition adopted in the Extension of the mandate of the European Medicines Agency.

Amendment 565
Catherine Amalric, Max Orville, Billy Kelleher, Erik Poulsen

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 or medical device that is placed on the market by a marketing authorisation holder or a manufacturer;

Or. en

Amendment 566
Kateřina Konečná

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;

Or. en

Amendment 567
Tomislav Sokol

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 authorization holder or a manufacturer.

Or. en

Amendment 568
Andrey Slabakov, Elisabetta De Blasis

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 or medical device that is placed on the market by a marketing authorisation holder or a manufacturer;

Or. en

Amendment 569
Margarita de la Pisa Carrión

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 authorization holder or a manufacturer.

Or. en

Justification

Regulation (EU) 2022/123 of 25 January 2022 on a reinforced rolefor the European Medicines Agency in crisis preparedness andmanagement for medicinal products and medical devices providesfor a more exhaustive definition of 'Shortage' including areference to 'Supply' and 'Demand'. In order to ensure aconsistent and workable definition of medicine shortage in allMember States it is essential that the definitions of shortage,supply and demand be similar in both Regulations to enable dataexchange and comparison.Demand must acknowledge the importance of finding sufficientand quality medical products that ensure that medical need iscovered safely.

Amendment 570
Cyrus Engerer

Proposal for a regulation

Article 2 – paragraph 2 – point 13

Text proposed by the Commission	*Amendment*
(13) ‘critical shortage in the Member State’ means a shortage of a medicinal product, for which there is no ***appropriate*** alternative medicinal product available on the market in that Member State, and that shortage cannot be resolved.	(13) ‘critical shortage in the Member State’ means a shortage of a medicinal product, for which there is no ***therapeutical*** alternative medicinal product available on the market in that Member State, and that shortage cannot be resolved.

Or. en

Amendment 571
Tiemo Wölken

Proposal for a regulation
Article 2 – paragraph 2 – point 13

Text proposed by the Commission	*Amendment*
(13) ‘critical shortage in the Member State’ means a shortage of a medicinal product, for which there is no appropriate alternative ***medicinal product*** available on the market in that Member State, and that shortage cannot be resolved.	(13) ‘critical shortage in the Member State’ means a shortage of a medicinal product, for which there is no appropriate ***therapeutical*** alternative available on the market in that Member State, and that shortage cannot be resolved.

Or. en

Amendment 572
Catherine Amalric, Max Orville, Billy Kelleher, Erik Poulsen

Proposal for a regulation
Article 2 – paragraph 2 – point 14 a (new)

Text proposed by the Commission	*Amendment*
	(14 a) 'Healthcare professionals' organisations' means not-for-profit organisations that have an interest in patient care, and where healthcare professionals represent a majority of members in governing bodies.

Or. en

Amendment 573
Tiemo Wölken

Proposal for a regulation
Article 2 – paragraph 2 – point 14 a (new)

Text proposed by the Commission	*Amendment*
	(14 a) 'clock stops' means a period of time during which the evaluation of a medicine is officially stopped, while the applicant prepares responses to questions from the regulatory authority. The clock resumes when the applicant has sent its responses.

Or. en

Amendment 574
Catherine Amalric, Max Orville, Billy Kelleher, Erik Poulsen

Proposal for a regulation
Article 2 – paragraph 2 – point 14 b (new)

Text proposed by the Commission	*Amendment*
	(14 b) 'Patients' organisations' means as not-for-profit organisations which are patient focused, and where patients and/or carers (the latter when patients are unable to represent themselves) represent a majority of members in governing bodies.

Or. en

Amendment 575
Cyrus Engerer

Proposal for a regulation
Article 2 – paragraph 2 – point 14 a (new)

Text proposed by the Commission	*Amendment*

(14 a) 'unavailability' means a situation a product has not been launched, has been permanently withdrawn or marketing has been ceased or suspended.

Or. en

Amendment 576
Tiemo Wölken

Proposal for a regulation
Article 3 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of marketing authorisation in accordance with this Regulation is in the interest of patients' health at Union level, including as regards antimicrobial resistance and medicinal products for public health emergencies;	(a) the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of marketing authorisation in accordance with this Regulation is in the interest of patients' health at Union level, including as regards antimicrobial resistance and ***potential countermeasures such as bacteriophages and*** medicinal products for public health emergencies;

Or. en

Amendment 577
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Billy Kelleher

Proposal for a regulation
Article 4 – title

Text proposed by the Commission	*Amendment*
Member State authorisation of ***generics of centrally authorised*** medicinal products	Member State authorisation of ***specific categories of*** medicinal products

Or. en

Amendment 578
Dolors Montserrat

Proposal for a regulation
Article 4 – title

Text proposed by the Commission	*Amendment*
Member State authorisation of ***generics of centrally authorised*** medicinal products	Member State authorisation of ***certain categories of*** medicinal products

Or. en

Amendment 579
Andrey Slabakov

Proposal for a regulation
Article 4 – title

Text proposed by the Commission	*Amendment*
Member State authorisation of ***generics of centrally authorised*** medicinal products	Member State authorisation of ***certain categories of*** medicinal products

Or. en

Amendment 580
Andrey Slabakov

Proposal for a regulation
Article 4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
A ***generic*** medicinal product ***of a reference medicinal product authorised by the Union*** may be authorised by the competent authorities of the Member States in accordance with [revised Directive 2001/83/EC] under the following conditions:	A medicinal product may be authorised by the competent authorities of the Member States in accordance with [revised Directive 2001/83/EC] under the following conditions:

Or. en

Amendment 581
Dolors Montserrat

Proposal for a regulation
Article 4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
A ***generic*** medicinal product ***of a reference medicinal product authorised by the Union*** may be authorised by the competent authorities of the Member States in accordance with [revised Directive 2001/83/EC] under the following conditions:	A medicinal product may be authorised by the competent authorities of the Member States in accordance with [revised Directive 2001/83/EC] under the following conditions:

Or. en

Amendment 582
Andrey Slabakov

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***;

Or. en

Amendment 583
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Billy Kelleher

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	(a) the application for marketing authorisation is submitted in accordance with Article 9***, 10, 13*** of [revised Directive

2001/83/EC];	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***;

Or. en

Amendment 584
Dolors Montserrat

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***;

Or. en

Amendment 585
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Billy Kelleher

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*
Point (b), first subparagraph, shall not apply to those parts of summary of product characteristics and package leaflet referring to indications, posologies, pharmaceutical forms, methods or routes of administration or any other way in which the medicinal product may be used which were still covered by a patent or a supplementary protection certificate for medicinal products at the time when the ***generic*** medicinal product was marketed and where	Point (b), first subparagraph, shall not apply to those parts of summary of product characteristics and package leaflet referring to indications, posologies, pharmaceutical forms, methods or routes of administration or any other way in which the medicinal product may be used which were still covered by a patent or a supplementary protection certificate for medicinal products at the time when the medicinal product was marketed and where the

the applicant for the ***generic*** medicinal product has requested not to include this information in their marketing authorisation.	applicant for the medicinal product has requested not to include this information in their marketing authorisation.

Or. en

Amendment 586
Dolors Montserrat

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*
Point (b), first subparagraph, shall not apply to those parts of summary of product characteristics and package leaflet referring to indications, posologies, pharmaceutical forms, methods or routes of administration or any other way in which the medicinal product may be used which were still covered by a patent or a supplementary protection certificate for medicinal products at the time when the ***generic*** medicinal product was marketed and where the applicant for the ***generic*** medicinal product has requested not to include this information in their marketing authorisation.	Point (b), first subparagraph, shall not apply to those parts of summary of product characteristics and package leaflet referring to indications, posologies, pharmaceutical forms, methods or routes of administration or any other way in which the medicinal product may be used which were still covered by a patent or a supplementary protection certificate for medicinal products at the time when the medicinal product was marketed and where the applicant for the medicinal product has requested not to include this information in their marketing authorisation.

Or. en

Amendment 587
Andrey Slabakov

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*
Point (b), first subparagraph, shall not apply to those parts of summary of product characteristics and package leaflet referring to indications, posologies, pharmaceutical forms, methods or routes of administration	Point (b), first subparagraph, shall not apply to those parts of summary of product characteristics and package leaflet referring to indications, posologies, pharmaceutical forms, methods or routes of administration

or any other way in which the medicinal product may be used which were still covered by a patent or a supplementary protection certificate for medicinal products at the time when the ***generic*** medicinal product was marketed and where the applicant for the ***generic*** medicinal product has requested not to include this information in their marketing authorisation.	or any other way in which the medicinal product may be used which were still covered by a patent or a supplementary protection certificate for medicinal products at the time when the medicinal product was marketed and where the applicant for the medicinal product has requested not to include this information in their marketing authorisation.

Or. en

Amendment 588
Andrey Slabakov

Proposal for a regulation
Article 5 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Within 20 days of receipt of an application, the Agency shall check whether all the information and documentation required in accordance with Article 6 have been submitted, that the application does not contain critical deficiencies that may prevent the evaluation of the medicinal product and decide whether the application is valid.	5. Within 20 days of receipt of an application, the Agency shall check whether all the information and documentation required in accordance with Article 6 have been submitted, that the application does not contain critical deficiencies ***as defined in guidelines established under paragraph 7*** that may prevent the evaluation of the medicinal product and decide whether the application is valid.

Or. en

Amendment 589
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Billy Kelleher

Proposal for a regulation
Article 5 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Within 20 days of receipt of an application, the Agency shall check whether all the information and	5. Within 20 days of receipt of an application, the Agency shall check whether all the information and

documentation required in accordance with Article 6 have been submitted, that the application does not contain critical deficiencies that may prevent the evaluation of the medicinal product and decide whether the application is valid.	documentation required in accordance with Article 6 have been submitted, that the application does not contain critical deficiencies ***as defined in guidelines established under paragraph 7*** that may prevent the evaluation of the medicinal product and decide whether the application is valid.

Or. en

Amendment 590
Andrey Slabakov

Proposal for a regulation
Article 5 – paragraph 6 – subparagraph 3

Text proposed by the Commission	*Amendment*
If the applicant fails to provide the missing information and documentation within the time limit, the application shall be considered to have been withdrawn.	***deleted***

Or. en

Amendment 591
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Billy Kelleher

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] ,	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.	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.
	(c) the use of additional qualifiers where necessary to identify different presentations of the medicinal product concerned.
[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).

Or. en

Amendment 592
Tilly Metz

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	The documentation shall include a ***substantiated*** 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

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.	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.
[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).

Or. en

Amendment 593
Tilly Metz

Proposal for a regulation
Article 6 – paragraph 1 – subparagraph 2 – point 1 (new)

Text proposed by the Commission	*Amendment*
	(1) Applications for market authorisation shall provide evidence from comparative studies with a standard-of-care active comparator, including, but not limited to, randomised controlled trials. In exceptional curcumstances, where such studies cannot be provided for scientifically substantiated reasons, the applicant shall submit such duly justified reasoning to the Agency as part of the application for marketing authorisation. The Agency shall set the scientific guidelines on criteria for proposing a comparator for a clinical trial, taking into account the results of the consultation of the Commission and the authorities or bodies involved in the mechanism of consultation referred to in Article 162 of this Regulation.

Or. en

Justification

Comparative data should be the standard rather than the bonus already when it comes to authorisation of medicines, it would make it easier to then conduct HTA assessment and pricing and reimbursement decisions where this data is typically required, requiring comparative data would result in more robust evidence at the time of marketing authorisation and it would reduce duplication of clinical studies

Amendment 594
Tilly Metz

Proposal for a regulation
Article 6 – paragraph 1 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	Applications for marketing authorisation shall include patient experience data (PROMs/PREMs) in the marketing application dossier. Where such data cannot be provided, the applicant should provide a justification to the Agency.

Or. en

Justification

In order to ensure medicines serve the need of patients, measuring patient experiences in clinical studies and reporting on them to regulators is crucial

Amendment 595
Margarita de la Pisa Carrión

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	For medicinal products that are likely to offer an exceptional therapeutic advancement ***or expected to be of major interest from the point of view of public health*** in the diagnosis in the ***diagnosis***, 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, ***or upon***

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.

request of the applicant offer to the applicant a phased review of complete data packages for individual modules of particulars and documentation as referred to in paragraph 1.

Or. en

Amendment 596
Tomislav Sokol

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 medicinal products that are likely to offer an exceptional therapeutic advancement in the diagnosis ***or expected to be of major interest from the point of view of public health***, 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.

Or. en

Amendment 597
István Ujhelyi

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***	For medicinal products that are likely to offer an exceptional therapeutic advancement ***or are expected to be of major interest from the point of view of public health***, the Agency may, following

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.

the advice of the Committee for Medicinal Products for Human Use regarding the maturity of the data ***or following a request of the applicant*** related to the development, offer to the applicant a phased review of complete data packages for individual modules of particulars and documentation as referred to in paragraph 1.

Or. en

Amendment 598
Tilly Metz

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 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 ***conditions with no authorised alternatives, particularly*** in the Union ***during a public health emergency or other major event***, 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.

Or. en

Amendment 599
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Ondřej Knotek, Billy Kelleher, Erik Poulsen, Dacian Cioloş

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 medicinal products that are likely to offer an exceptional therapeutic advancement in the diagnosis, prevention or treatment***, including with regard to the quality of life of a relevant patient population or subpopulation,*** 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.

Or. en

Amendment 600
Ondřej Knotek, Frédérique Ries, Billy Kelleher

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 medicinal products that are likely to offer an exceptional therapeutic advancement in the diagnosis, prevention or treatment***, including the improvement of quality of life of certain patient's groups,*** 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.

Or. en

Amendment 601
Stelios Kympouropoulos

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 medicinal products that are likely to offer an exceptional therapeutic advancement ***or are expected to be of great interest for public health*** 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.

Or. en

Amendment 602
Andreas Glück, Frédérique Ries, Catherine Amalric

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	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

documentation as referred to in paragraph 1.	particulars and documentation as referred to in paragraph 1.

Or. en

Justification

The procedure of rolling reviews proved to be very valuable during the COVID-19 Pandemic. An extension to orphan medicinal products is appropriate as medicinal products should reach patients as fast as possible.

Amendment 603
Tiemo Wölken

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 medicinal products***, during a public health emergency or to address a major event,*** 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, ***after the Commission has recognised a public health emergency at Union level in accordance with Article 23(1) of Regulation (EU) 2022/2371 and*** following the advice of the Committee for Medicinal Products for Human Use regarding the maturity of the data related to the development, offer to the applicant a phased review of complete data packages for individual modules of particulars and documentation as referred to in paragraph 1.

Or. en

Amendment 604
István Ujhelyi

Proposal for a regulation
Article 6 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
The Agency may at any stage suspend or cancel the phased review, where the Committee for Medicinal Products for Human Use considers that the submitted data are not of sufficient maturity or where it is considered that the medicinal product no longer fulfils an exceptional therapeutic advancement. The Agency shall inform the applicant accordingly.	The Agency may at any stage suspend or cancel the phased review, where the Committee for Medicinal Products for Human Use considers that the submitted data are not of sufficient maturity or where it is considered that the medicinal product no longer fulfils an exceptional therapeutic advancement ***or is no longer expected to be of major interest from the point of view of public health***. The Agency shall inform the applicant accordingly.

Or. en

Amendment 605
Stelios Kympouropoulos

Proposal for a regulation
Article 6 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
The Agency may at any stage suspend or cancel the phased review, where the Committee for Medicinal Products for Human Use considers that the submitted data are not of sufficient maturity or where it is considered that the medicinal product no longer fulfils an exceptional therapeutic advancement. The Agency shall inform the applicant accordingly.	The Agency may at any stage suspend or cancel the phased review, where the Committee for Medicinal Products for Human Use considers that the submitted data are not of sufficient maturity or where it is considered that the medicinal product no longer fulfils an exceptional therapeutic advancement ***or does no longer present great interest for public health***. The Agency shall inform the applicant accordingly.

Or. en

Amendment 606
Tomislav Sokol

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

Or. en

Amendment 607
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Billy Kelleher, Erik Poulsen

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 Directive 2001/83/EC].	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 master file certificate or application as referred to in Article 25 ***and Article 26*** of [revised Directive 2001/83/EC].

Or. en

Amendment 608
Susana Solís Pérez, Frédérique Ries, Catherine Amalric

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. ***When scientifically reliable non-animal testing alternatives are unavailable, applicants utilizing animal testing must adhere to the***

principles of replacement, reduction, and refinement of animal testing for scientific purposes. This adherence must be in accordance with Directive 2010/63/EU for any animal study carried out to support their application.

Or. en

Amendment 609
Tilly Metz

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 ***New Approach Methodologies (NAMs), particularly*** non-animal testing methods are available. ***The Agency shall in its annual report highlight key observations and best practices in the replacement, reduction and refinement of animal testing submitted by applicants.***

Or. en

Amendment 610
Stanislav Polčák

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 ***testing*** in case scientifically satisfactory non-animal testing methods are available***, or where the results of animal studies previously carried out by the applicant or others may be used for the medicinal product***.

Or. cs

Amendment 611
Maria Angela Danzì

Proposal for a regulation
Article 6 – paragraph 6 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency shall ensure that the opinion of the Committee for Medicinal Products for Human Use is given within ***180*** days after receipt of a valid application. In the case of a medicinal product for human use containing or consisting of genetically modified organisms, the opinion of that Committee shall take into account the evaluation of the environmental risk assessment in accordance with Article 8.	The Agency shall ensure that the opinion of the Committee for Medicinal Products for Human Use is given within ***150*** days after receipt of a valid application. In the case of a medicinal product for human use containing or consisting of genetically modified organisms, the opinion of that Committee shall take into account the evaluation of the environmental risk assessment in accordance with Article 8.

Or. it

Amendment 612
Tiemo Wölken

Proposal for a regulation
Article 6 – paragraph 6 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency shall ensure that the opinion of the Committee for Medicinal Products for Human Use is given within 180 days after receipt of a valid application. In the case of a medicinal product for human use containing or consisting of genetically modified organisms, the opinion of that Committee shall take into account the evaluation of the environmental risk assessment in accordance with Article 8.	The Agency shall ensure that the opinion of the Committee for Medicinal Products for Human Use is given within 180 days***, excluding clock stops,*** after receipt of a valid application. In the case of a medicinal product for human use containing or consisting of genetically modified organisms, the opinion of that Committee shall take into account the evaluation of the environmental risk assessment in accordance with Article 8.

Or. en

Amendment 613
Tomislav Sokol

Proposal for a regulation
Article 6 – paragraph 6 – subparagraph 2

Text proposed by the Commission	*Amendment*
On the basis of a duly reasoned request, the Committee for Medicinal Products for Human Use may call for the duration of the analysis of the scientific data in the file concerning the application for marketing authorisation to be extended.	On the basis of a duly reasoned request, the Committee for Medicinal Products for Human Use may call for the duration of the analysis of the scientific data in the file concerning the application for marketing authorisation to be extended***, once for an additional period of 30 days***.

Or. en

Amendment 614
Tomislav Sokol

Proposal for a regulation
Article 6 – paragraph 7 – subparagraph 1

Text proposed by the Commission	*Amendment*
When an application is submitted for a marketing authorisation in respect of medicinal products for human use which are of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may request an accelerated assessment procedure. ***The same shall apply for*** products referred to in Article ***60***. The request shall be duly substantiated.	When an application is submitted for a marketing authorisation in respect of medicinal products for human use ***or new therapeutic indications when grouped with an extension of the marketing authorisation,*** which ***provide an exceptional therapeutic advancement or*** are of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may request an accelerated assessment procedure. Products referred to in Article ***6(2) and article 60 shall qualify for this process by default***. The request shall be duly substantiated.

Or. en

Amendment 615
Tilly Metz

Proposal for a regulation
Article 6 – paragraph 7 – subparagraph 1

Text proposed by the Commission	*Amendment*
When an application is submitted for a marketing authorisation in respect of medicinal products for human use which are of major interest from the point of view of public health and in particular from the viewpoint of ***therapeutic innovation***, the applicant may request an accelerated assessment procedure. The same shall apply for products referred to in Article 60. The request shall be duly substantiated.	When an application is submitted for a marketing authorisation in respect of medicinal products for human use which are of major interest from the point of view of public health and in particular from the viewpoint of ***unmet medical need***, the applicant may request an accelerated assessment procedure. The same shall apply for products referred to in Article 60. The request shall be duly substantiated.

Or. en

Amendment 616
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Andreas Glück, Billy Kelleher, Erik Poulsen

Proposal for a regulation
Article 6 – paragraph 7 – subparagraph 2

Text proposed by the Commission	*Amendment*
If the Committee for Medicinal Products for Human Use accepts the request, the time-limit laid down in Article 6(6), first subparagraph, shall be reduced to ***150*** days.	If the Committee for Medicinal Products for Human Use accepts the request, the time-limit laid down in Article 6(6), first subparagraph, shall be reduced to ***120*** days.

Or. en

Amendment 617
Tomislav Sokol

Proposal for a regulation
Article 6 – paragraph 7 – subparagraph 2

Text proposed by the Commission	*Amendment*
If the Committee for Medicinal Products for Human Use accepts the request, the	If the Committee for Medicinal Products for Human Use accepts the request, the

time-limit laid down in Article 6(6), first subparagraph, shall be reduced to ***150*** days.	time-limit laid down in Article 6(6), first subparagraph, shall be reduced to ***120*** days.

Or. en

Amendment 618
Maria Angela Danzì

Proposal for a regulation
Article 6 – paragraph 7 – subparagraph 2

Text proposed by the Commission	*Amendment*
If the Committee for Medicinal Products for Human Use accepts the request, the time-limit laid down in Article 6(6), first subparagraph, shall be reduced to ***150*** days.	If the Committee for Medicinal Products for Human Use accepts the request, the time-limit laid down in Article 6(6), first subparagraph, shall be reduced to ***120*** days.

Or. it

Amendment 619
Maria Angela Danzì

Proposal for a regulation
Article 6 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	7a. An application for a marketing authorisation submitted pursuant to this Regulation for a medicinal product for human use that has not been granted a paediatric derogation shall be considered valid only if it includes the results of all paediatric studies performed and other information collected in accordance with an agreed paediatric investigation plan, as laid down in Article 6 of the revised [Directive 2001/83/EC];

Or. it

Justification

The obligation introduced under the Paediatric Regulation to carry out paediatric studies, the results of which should be submitted at the time of the application for marketing authorisation for new or already patented/certified medicinal products, should be clearly identified as a key part of the centralised marketing authorisation process.

Amendment 620
Tomislav Sokol

Proposal for a regulation
Article 6 a (new)

Text proposed by the Commission	*Amendment*
	Article6a
	Parallel application
	(1) During the scientific assessment of an initial marketing authorisation application of a medicinal product by the Agency, the applicant may submit to the Agency a separate parallel application for one or more new indications concerning the same medicinal product.
	(2) The parallel application shall be assessed by the Agency as a marketing authorisation application in accordance with this Regulation, subject to the following:
	a) to the extent the Committee for Medicinal Products for Human Use can assess the parallel application within the timeframe applicable to the initial marketing authorisation application, leading to the same outcome for both applications it shall group the applications and issue a single opinion.
	b) to the extent the said Committee cannot issue an opinion on the parallel application within the timeframe applicable to the initial marketing authorisation application, the parallel application shall be converted to a Type II variation application.
	c) if the initial marketing authorisation application is withdrawn or receives a

negative opinion from the Committee for Medicinal Products for Human Use, the Committee will pursue the assessment of the parallel application as a standalone marketing authorisation application.

Or. en

Amendment 621
Frédérique Ries, Catherine Amalric, Susana Solís Pérez, Max Orville, Andreas Glück, Billy Kelleher, Erik Poulsen

Proposal for a regulation
Article 6 a (new)

Text proposed by the Commission	*Amendment*
	Article6a
	Parallel application for one or more new indications
	(1) During the scientific assessment of an initial marketing authorisation application of a medicinal product by the Agency, the applicant may submit to the Agency a separate parallel application for one or more new indications concerning the same medicinal product.
	(2) The parallel application shall be assessed by the Agency as a marketing authorisation application in accordance with this Regulation, subject to the following:
	(a) To the extent the Committee for Medicinal Products for Human Use can assess the parallel application within the timeframe applicable to the initial marketing authorisation application, leading to the same outcome for both applications it shall group the applications and issue a single opinion.
	(b) To the extent the said Committee cannot issue an opinion on the parallel application within the timeframe applicable to the initial marketing authorisation application the parallel application shall be converted to a Type II

variation application in accordance with Commission Regulation (EC) No 1234/2008.

(c) If the initial marketing authorisation application is withdrawn or receives a negative opinion from the Committee for Medicinal Products for Human Use, the Committee will pursue the assessment of the parallel application as a standalone marketing authorisation application.

Or. en

Amendment 622
Stanislav Polčák

Proposal for a regulation
Article 7 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Without prejudice to Article 22 of [revised Directive 2001/83/EC], the marketing authorisation application of a medicinal product for human use containing or consisting of genetically modified organisms as defined in Article 2(2) of Directive 2001/18/EC shall be accompanied by an environmental risk assessment identifying and evaluating potential adverse effects of the genetically modified organisms on human health and the environment.	1. Without prejudice to Article 22 of [revised Directive 2001/83/EC], the marketing authorisation application of a medicinal product for human use containing or consisting of genetically modified organisms as defined in Article 2(2) of Directive 2001/18/EC shall be accompanied by an environmental risk assessment identifying and evaluating potential adverse effects of the genetically modified organisms on human health and the environment***, and shall set out measures to prevent or minimise such effects***.

Or. cs

Amendment 623
Sara Cerdas

Proposal for a regulation
Article 7 – paragraph 1

Text proposed by the Commission	*Amendment*

1. Without prejudice to Article 22 of [revised Directive 2001/83/EC], the marketing authorisation application of a medicinal product for human use containing or consisting of genetically modified organisms as defined in Article 2(2) of Directive 2001/18/EC shall be accompanied by an environmental risk assessment identifying and evaluating potential adverse effects of the genetically modified organisms on human health and the environment.	1. Without prejudice to Article 22 of [revised Directive 2001/83/EC], the marketing authorisation application of a medicinal product for human use containing or consisting of genetically modified organisms as defined in Article 2(2) of Directive 2001/18/EC shall be accompanied by an environmental risk assessment identifying and evaluating potential adverse effects of the genetically modified organisms on human ***and animal*** health**,** and the environment.

Or. en

Amendment 624
Tilly Metz

Proposal for a regulation
Article 7 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Without prejudice to Article 22 of [revised Directive 2001/83/EC], the marketing authorisation application of a medicinal product for human use containing or consisting of genetically modified organisms as defined in Article 2(2) of Directive 2001/18/EC shall be accompanied by an environmental risk assessment identifying and evaluating potential adverse effects of the genetically modified organisms on human health and the environment.	1. Without prejudice to Article 22 of [revised Directive 2001/83/EC], the marketing authorisation application of a medicinal product for human use containing or consisting of genetically modified organisms as defined in Article 2(2) of Directive 2001/18/EC shall be accompanied by an environmental risk assessment identifying and evaluating potential adverse effects of the genetically modified organisms on human health**,** ***animals*** and the environment.

Or. en

Amendment 625
Stanislav Polčák

Proposal for a regulation
Article 7 – paragraph 4 – introductory part

Text proposed by the Commission	*Amendment*

4. Articles 6 to 11 of [revised Directive ***2001/18/EC***] as well as Articles 4 to 13 of Directive 2009/41/EC shall not apply to operations related to the supply and clinical use, including the packaging and labelling, distribution, storage, transport, preparation for administration, administration, destruction or disposal of medicinal products containing or consisting of genetically modified organisms, with the exception of their manufacture, in any of the following cases:	4. Articles 6 to 11 of [revised Directive ***2001/83/EC***] as well as Articles 4 to 13 of Directive 2009/41/EC shall not apply to operations related to the supply and clinical use, including the packaging and labelling, distribution, storage, transport, preparation for administration, administration, destruction or disposal of medicinal products containing or consisting of genetically modified organisms, with the exception of their manufacture, in any of the following cases:

Or. cs

Amendment 626
Stanislav Polčák

Proposal for a regulation
Article 7 – paragraph 5 – subparagraph 1

Text proposed by the Commission	*Amendment*
In the cases referred to in paragraph 4, Member States shall implement appropriate measures to minimise ***foreseeable*** negative environmental impacts resulting from the intended or unintended release of the medicinal products containing or consisting of genetically modified organisms into the environment.	In the cases referred to in paragraph 4, Member States shall implement appropriate measures ***based on the precautionary principle*** to minimise negative environmental impacts resulting from the intended or unintended release of the medicinal products containing or consisting of genetically modified organisms into the environment.

Or. cs

Amendment 627
Anders Vistisen
on behalf of the ID Group

Proposal for a regulation
Article 7 – paragraph 5 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	By derogation from this Article, where the marketing authorisation application

concerns a medicinal product for human use containing or consisting of genetically modified organisms which comply with the criteria referred to in paragraph 3 of Article 5a of Regulation (EU) No 536/2014, Article 22 of [revised Directive 2001/83/EC] shall apply.

Or. en

Amendment 628
Anders Vistisen
on behalf of the ID Group

Proposal for a regulation
Article 7 – paragraph 5 – subparagraph 2 b (new)

Text proposed by the Commission	*Amendment*
	No later than [note to OP = five years after the date of entry into application of this Regulation], the Commission shall conduct an impact assessment of the Union legislation on genetically modified organisms* on medicinal products containing or consisting of genetically modified organisms and produce an evaluation report, taking into account the experience gained from the application of this Regulation, [revised Directive 2001/83/EC], Regulation (EU) No 536/2014 and Regulation (EU) 2020/1043. On the basis of the impact assessment and evaluation, the Commission shall come forward with a legislative proposal to amend this Regulation and [revised Directive 2001/83/EC] to lay down specific rules on environmental risk assessments for medicines containing or consisting of genetically modified organisms outside the scope of the general Union legislation on genetically modified organisations.

Or. en

Amendment 629
Catherine Amalric

Proposal for a regulation
Article 8 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) identification and characterisation of hazards for the environment, animals and for human health;	(b) identification and characterisation of hazards for the environment, animals and for human health ***throughout the life cycle of the medicine, including during its production***; ***these risks include those linked to the greenhouse gas emissions footprint;***

Or. en

Amendment 630
Tilly Metz

Proposal for a regulation
Article 8 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) identification and characterisation of hazards for the environment, animals and for human health;	(b) identification and characterisation of hazards for the environment, animals and for human ***and public*** health;

Or. en

Amendment 631
Sara Cerdas

Proposal for a regulation
Article 8 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) risk minimisation strategies proposed to address identified risks including specific containment measures to limit contact with the medicinal product.	(e) risk minimisation ***and mitigation*** strategies proposed to address identified risks including specific containment measures to limit contact with the medicinal product***, as well as any circular economy processes adopted***.

Or. en