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Committee on Industry, Research and Energy

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AMENDMENTS
37 - 349

Draft opinion
Henna Virkkunen
(PE754.772v01-00)

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))

AM_Com_LegOpinion

Amendment 37
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Recital 1 a (new)

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

Or. en

Amendment 38
Francesca Donato

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1 a) The European Parliament resolution of 12 July 2023 on the COVID-19 pandemic: lessons learned and recommendations for the future 2022/2076 (INI);

Or. en

Amendment 39
Francesca Donato

Proposal for a regulation
Recital 1 b (new)

Text proposed by the Commission	*Amendment*

	(1 b) European Parliament Resolution 2022/2076 calls for further investment in research and development activities geared towards achieving public interest objectives (Article 296) and 'calls on the Commission to use industrial, intellectual property and pharmaceutical strategies to encourage public funding for research and development projects in order to comply with the principle of open science and to close the persistent gap in research and medicine production through partnerships, technology transfer and the creation of open research centres' (Article 590);

Or. en

Amendment 40
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Recital 2

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

Or. en

Amendment 41
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2 a) The digital transformation of health and care will help increase the capacity of healthcare systems to deliver more personalised and effective health and care with less resource wasting. This regulation will contribute to the delivery of healthcare to European citizens, the design of health technologies and their manufacturing to be more sustainable by reducing energy consumption, waste, pollution and the release of harmful substances, including pharmaceuticals, into the environment.

Or. en

Amendment 42
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Recital 2 b (new)

Text proposed by the Commission	*Amendment*
	(2 b) It is of outmost importance to involve patients and healthy citizens, healthcare professionals, providers and payers, public health authorities and regulators, researchers or innovators from academia and industry - early in the knowledge generation or technology development process, including through patient and citizen engagement, community involvement or other forms of social innovation approaches, such that research and innovation activities are adjusted to the users' particular expectations, needs, constraints and potential.

Or. en

Amendment 43

Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Recital 3

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

Or. en

Amendment 44
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5 a) The pharmaceutical framework should be aligned with the EU's ambitions in industry, digitalization, and trade, acknowledging the critical role of the European life sciences sector, especially the pharmaceutical industry, in upholding the EU's competitive edge. Bolstering robust European research and development is crucial for European sovereignty within the ambit of a globally competitive geopolitical landscape. The pharmaceutical legislative framework should be attuned to the broader EU industrial strategy, echoing the Council's emphasis from 23 March 2023 on amplifying incentives for investment in innovation and the 2016 Council's guidance that any amendments, including

those affecting the incentive system, should not hinder the creation of drugs for rare disease treatment. Advancements in innovation are pivotal for enhancing patient health outcomes and the wider public health sector.

Or. en

Amendment 45
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Recital 5 a (new)

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

Or. en

Amendment 46
Henna Virkkunen

Proposal for a regulation
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5 a) The pharmaceutical framework should be consistent with overarching EU industrial policy, including the Council Conclusions from 23 March 2023 which stressed the importance of strengthening incentives for investment in innovation and the 2016 Council Conclusions which stress any revision, including to the incentive framework, should not discourage the development of medicinal products needed for the treatment of rare diseases; increased innovation will further support patient outcomes and public health;

Or. en

Justification

The European Commission has emphasized the significance of preserving a competitive pharmaceutical environment in Europe. Simultaneously, Member States have tasked the Commission with reviewing pharmaceutical legislation, emphasizing that innovation, the foundation of any discussion on access, should not be discouraged. It is crucial to explicitly articulate this intention in the Directive to avoid any ambiguity regarding the revision's spirit, which aims for a robust and competitive pharmaceutical ecosystem.

Amendment 47
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Recital 9

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

Or. en

Amendment 48

Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) Promising medicinal products that have the potential to significantly address patients' unmet medical needs should benefit from early and enhanced scientific support. Such support will ultimately help patients benefit from new therapies as early as possible.	(20) Promising medicinal products that have the potential to significantly address patients' unmet medical needs should benefit from early and enhanced scientific support***, including through supporting innovative patient-relevant in vitro and in silico technologies which are key to the development of these products***. Such support will ultimately help patients benefit from new therapies as early as possible.

Or. en

Amendment 49
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Recital 26 a (new)

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

Or. en

Amendment 50
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 29

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

Or. en

Amendment 51
Francesca Donato

Proposal for a regulation
Recital 29 a (new)

Text proposed by the Commission	*Amendment*
	(29 a) The Bonn Declaration includes in the definition of freedom of scientific research the right to critical debate, the protection of plurality of voices, the 'right to freely define questions, choose and develop theories, collect empirical material and use sound academic research methods to question recognised knowledge and advance new ideas'; the "right to share, disseminate and publish

its results openly, including through training and teaching"; "the freedom of researchers to express their views without being penalised by the system in which they work or by government or government censorship or discrimination";

Or. en

Amendment 52
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Recital 30

Text proposed by the Commission	*Amendment*
(30) The Agency should be empowered to give scientific recommendations on whether a product under development, which could potentially fall under the mandatory scope of the centralised procedure, meets the scientific criteria to be a medicinal product. Such an advisory mechanism would address, as early as possible, questions related to borderline cases with other areas such as substances of human origin, cosmetics or medical devices, which may arise as science develops. To ensure that recommendations given by the Agency take into account the views of equivalent advisory mechanisms in other legal frameworks, the Agency should consult the relevant advisory or regulatory bodies.	(30) The Agency should be empowered to give scientific recommendations on whether a product under development, which could potentially fall under the mandatory scope of the centralised procedure, meets the scientific criteria to be a medicinal product ***such as an advanced therapy medicinal products (ATMPs)***. Such an advisory mechanism would address, as early as possible, questions related to borderline cases with other areas such as substances of human origin, cosmetics or medical devices, which may arise as science develops. To ensure that recommendations given by the Agency take into account the views of equivalent advisory mechanisms in other legal frameworks, the Agency should consult the relevant advisory or regulatory bodies. ***For Advanced Therapy Medicinal Products (ATMPs), the European Medicines Agency's (EMA) working group dedicated to ATMPs should seek input from the Substances of Human Origin (SoHO) Coordination Board when dealing with cases that are not clearly defined.***

Or. en

Amendment 53
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Recital 30 a (new)

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

Or. en

Amendment 54
Cristian-Silviu Buşoi

Proposal for a regulation
Recital 35

Text proposed by the Commission	*Amendment*
(35) The Agency's scientific committees should be ***able to delegate some of*** their evaluation duties ***to*** working parties which should be open to experts from the scientific world and appointed for this purpose, whilst retaining complete responsibility for the scientific opinions issued by them.	(35) The Agency's scientific committees should be ***supported for*** their evaluation duties ***by*** working parties which should be open to experts from the scientific world and appointed for this purpose ***and by additional experts drawn from the pool of accredited experts***, whilst retaining complete responsibility for the scientific opinions issued by them.

Or. en

Amendment 55
Patrizia Toia, Beatrice Covassi

Proposal for a regulation
Recital 36

Text proposed by the Commission	*Amendment*
(36) The expertise of the Committee for Advanced Therapies (CAT), the Committee for Orphan Medicinal Products (COMP), the Paediatric Committee (PDCO) and Committee for Herbal Medicinal Products (HMPC) is retained through working groups, working parties and a pool of experts who are organised based on different domains and who are giving input to the CHMP and PRAC. The CHMP and PRAC consists of experts from all Member States while working parties consist in majority of experts appointed by the Member States, based on their expertise, and of external experts. The model of rapporteurs remains unchanged. Representation of patients and health care professionals, with expertise in all areas, including rare and paediatric diseases, is increased at the CHMP and PRAC, in addition to the dedicated working groups representing patients and health care professionals.	(36) The expertise of the Committee for Advanced Therapies (CAT), the Committee for Orphan Medicinal Products (COMP), the Paediatric Committee (PDCO) and Committee for Herbal Medicinal Products (HMPC) is retained through working groups, working parties and a pool of experts who are organised based on different domains and who are giving input to the CHMP and PRAC. The CHMP and PRAC consists of experts from all Member States while working parties consist in majority of experts appointed by the Member States, based on their expertise, and of external experts. ***In addition, the Paediatric Committee's competences and expertise with reference to the scientific assessment and agreement of paediatric investigation plans and other matters of paediatric interest not falling under the PRAC and CHMP responsibilities, will be retained into a Paediatric Working Party, composed of experts in different medical areas, which should provide scientific support and expertise to all Bodies of the Agency on matters related to paediatric medicinal products development and use.*** The model of rapporteurs remains unchanged. Representation of patients and health care professionals, with expertise in all areas, including rare and paediatric diseases, is increased at the CHMP and PRAC, in addition to the dedicated working groups representing patients and health care professionals.

Or. en

Amendment 56
Cristian-Silviu Buşoi

Proposal for a regulation

Recital 36

Text proposed by the Commission	*Amendment*
(36) The expertise of the Committee for Advanced Therapies (CAT), the Committee for Orphan Medicinal Products (COMP), the Paediatric Committee (PDCO) and Committee for Herbal Medicinal Products (HMPC) is retained through working groups, working parties and a pool of experts who are organised based on different domains and who are giving input to the CHMP and PRAC. The CHMP and PRAC consists of experts from all Member States while working parties consist in majority of experts appointed by the Member States, based on their expertise, and of external experts. The model of rapporteurs remains unchanged. Representation of patients and health care professionals, with expertise in all areas, including rare and paediatric diseases, is increased at the CHMP and PRAC, in addition to the dedicated working groups representing patients and health care professionals.	(36) The expertise of the Committee for Advanced Therapies (CAT), the Committee for Orphan Medicinal Products (COMP), the Paediatric Committee (PDCO) and Committee for Herbal Medicinal Products (HMPC) is retained through working groups, working parties and a pool of experts who are organised based on different domains and who are giving input to the CHMP and PRAC. ***Their evaluation will continue to encompass all the necessary expertise for each product as part of the rapporteur teams, with the possibility for CHMP and PRAC to call upon additional scientific experts to provide specific input and advice on specific aspects raised during the evaluation. In addition patients and healthcare professionals will be part of the pool of experts and will also be brought into EMA's work according to their expertise in a certain disease area.*** The CHMP and PRAC consists of experts from all Member States while working parties ***and expert groups*** consist in majority of experts appointed by the Member States, based on their expertise, and of external experts. The model of rapporteurs remains unchanged. Representation of patients and health care professionals, with expertise in all areas, including rare and paediatric diseases, is increased at the CHMP and PRAC, in addition to the dedicated working groups representing patients and health care professionals.

Or. en

Amendment 57
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Recital 36

Text proposed by the Commission	*Amendment*
(36) The expertise of the Committee for Advanced Therapies (CAT), the Committee for Orphan Medicinal Products (COMP), the Paediatric Committee (PDCO) and Committee for Herbal Medicinal Products (HMPC) is retained through working groups, working parties and a pool of experts who are organised based on different domains and who are giving input to the CHMP and PRAC. The CHMP and PRAC consists of experts from all Member States while working parties consist in majority of experts appointed by the Member States, based on their expertise, and of external experts. The model of rapporteurs remains unchanged. Representation of patients and health care professionals, with expertise in all areas, including rare and paediatric diseases, is increased at the CHMP and PRAC, in addition to the dedicated working groups representing patients and health care professionals.	(36) The expertise of the Committee for Advanced Therapies (CAT), the Committee for Orphan Medicinal Products (COMP), the Paediatric Committee (PDCO) and Committee for Herbal Medicinal Products (HMPC) is retained through working groups, working parties and a pool of experts who are organised based on different domains and who are giving input to the CHMP and PRAC. The CHMP and PRAC consists of experts from all Member States while working parties consist in majority of experts appointed by the Member States, based on their expertise, and of external experts. The model of rapporteurs remains unchanged. Representation of patients and health care professionals, with expertise in all areas, including rare and paediatric diseases, is increased at the CHMP and PRAC, in addition to the dedicated working groups representing patients and health care professionals. ***The composition, responsibilities, operating methods, and areas of expertise of the Committees, Working Parties, and Working Groups, along with their work programs and suggestions, will be disclosed to the public and may be opened for stakeholder feedback.***

Or. en

Amendment 58
Pernille Weiss

Proposal for a regulation
Recital 36

Text proposed by the Commission	*Amendment*
(36) The expertise of the Committee for Advanced Therapies (CAT), the Committee for Orphan Medicinal Products (COMP), the Paediatric Committee	(36) The expertise of the Committee for Advanced Therapies (CAT), the Committee for Orphan Medicinal Products (COMP), the Paediatric Committee

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

(PDCO) and Committee for Herbal Medicinal Products (HMPC) is retained through working groups, working parties and a pool of experts who are organised based on different domains and who are giving input to the CHMP and PRAC. The CHMP and PRAC consists of experts from all Member States while working parties consist in majority of experts appointed by the Member States, based on their expertise, and of external experts. The model of rapporteurs remains unchanged. Representation of patients***, their caregivers*** and health care professionals, with expertise in all areas, including rare and paediatric diseases, is increased at the CHMP and PRAC, in addition to the dedicated working groups representing patients and health care professionals. ***Information regarding the composition and work of the committees and working groups should be publically available.***

Or. en

Amendment 59
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) To allow for a more informative decision making and for exchange of information and pooling of knowledge on general issues of scientific or technical nature related to the tasks of the Agency regarding medicinal products for human use, in particular to scientific guidelines on unmet medical needs and the design of clinical trials, or other studies and the generation of evidence along the life cycle of medicinal product, the Agency should be able to have recourse to a consultation process of authorities or bodies active along the life cycle of medicinal products. These authorities could be, as appropriate,	(39) To allow for a more informative decision making and for exchange of information and pooling of knowledge on general issues of scientific or technical nature related to the tasks of the Agency regarding medicinal products for human use, in particular to scientific guidelines on unmet medical needs and the design of clinical trials, or other studies and the generation of evidence along the life cycle of medicinal product, the Agency should be able to have recourse to a consultation process of authorities or bodies active along the life cycle of medicinal products. These authorities could be, as appropriate,

representatives from Heads of Medicines Agencies, the Clinical Trial Coordination and Advisory Group, the SoHO Coordination Board, the Coordination Group on Health Technology Assessment, Medical Devices Coordination Group, medical devices national competent authorities, national competent authorities for pricing and reimbursement of medicines, national insurance funds or healthcare payers. The Agency should also be able to extend the consultation mechanism to consumers, patients, healthcare professionals, industry, associations representing payers, or other stakeholders, as relevant.

representatives from Heads of Medicines Agencies, the Clinical Trial Coordination and Advisory Group, the SoHO Coordination Board, the Coordination Group on Health Technology Assessment, Medical Devices Coordination Group, medical devices national competent authorities, national competent authorities for pricing and reimbursement of medicines, national insurance funds or healthcare payers. The Agency should also be able to extend the consultation mechanism to consumers, patients ***and their caregivers***, healthcare professionals, industry, associations representing payers, ***academia,*** or other stakeholders, as relevant.

Or. en

Amendment 60
Pernille Weiss

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) To allow for a more informative decision making and for exchange of information and pooling of knowledge on general issues of scientific or technical nature related to the tasks of the Agency regarding medicinal products for human use, in particular to scientific guidelines on unmet medical needs and the design of clinical trials, or other studies and the generation of evidence along the life cycle of medicinal product, the Agency should be able to have recourse to a consultation process of authorities or bodies active along the life cycle of medicinal products. These authorities could be, as appropriate, representatives from Heads of Medicines Agencies, the Clinical Trial Coordination and Advisory Group, the SoHO Coordination Board, the Coordination Group on Health Technology Assessment,	(39) To allow for a more informative decision making and for exchange of information and pooling of knowledge on general issues of scientific or technical nature related to the tasks of the Agency regarding medicinal products for human use, in particular to scientific guidelines on unmet medical needs and the design of clinical trials, or other studies and the generation of evidence along the life cycle of medicinal product, the Agency should be able to have recourse to a consultation process of authorities or bodies active along the life cycle of medicinal products. These authorities could be, as appropriate, representatives from Heads of Medicines Agencies, the Clinical Trial Coordination and Advisory Group, the SoHO Coordination Board, the Coordination Group on Health Technology Assessment,

Medical Devices Coordination Group, medical devices national competent authorities, national competent authorities for pricing and reimbursement of medicines, national insurance funds or healthcare payers. The Agency should also be able to extend the consultation mechanism to consumers, patients, healthcare professionals, industry, associations representing payers, or other stakeholders, as relevant.	Medical Devices Coordination Group, medical devices national competent authorities, national competent authorities for pricing and reimbursement of medicines, national insurance funds or healthcare payers. The Agency should also be able to extend the consultation mechanism to consumers, patients, ***their caregivers,*** healthcare professionals***,*** ***acdemia***, industry, associations representing payers, or other stakeholders, as relevant.

Or. en

Amendment 61
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) To allow for a more informative decision making and for exchange of information and pooling of knowledge on general issues of scientific or technical nature related to the tasks of the Agency regarding medicinal products for human use, in particular to scientific guidelines on unmet medical needs and the design of clinical trials, or other studies and the generation of evidence along the life cycle of medicinal product, the Agency should be able to have recourse to a consultation process of authorities or bodies active along the life cycle of medicinal products. These authorities could be, as appropriate, representatives from Heads of Medicines Agencies, the Clinical Trial Coordination and Advisory Group, the SoHO Coordination Board, the Coordination Group on Health Technology Assessment, Medical Devices Coordination Group, medical devices national competent authorities, national competent authorities for pricing and reimbursement of medicines, national insurance funds or	(39) To allow for a more informative decision making and for exchange of information and pooling of knowledge on general issues of scientific or technical nature related to the tasks of the Agency regarding medicinal products for human use, in particular to scientific guidelines on unmet medical needs and the design of clinical trials, or other studies and the generation of evidence along the life cycle of medicinal product, the Agency should be able to have recourse to a consultation process of authorities or bodies active along the life cycle of medicinal products. These authorities could be, as appropriate, representatives from Heads of Medicines Agencies, the Clinical Trial Coordination and Advisory Group, the SoHO Coordination Board, the Coordination Group on Health Technology Assessment, Medical Devices Coordination Group, medical devices national competent authorities, national competent authorities for pricing and reimbursement of medicines, national insurance funds or

healthcare payers. The Agency should also be able to extend the consultation mechanism to consumers, patients, healthcare professionals, industry, associations representing payers, or other stakeholders, as relevant.	healthcare payers. The Agency should also be able to extend the consultation mechanism to consumers, patients, healthcare professionals, industry, associations representing payers, ***academia*** or other stakeholders, as relevant.

Or. en

Amendment 62
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 41 a (new)

Text proposed by the Commission	*Amendment*
	(41 a) Protecting global health is one of the priorities of the EU and under Article 178 of the Treaty, the Union should take into account the development policy aspects in any measure and promote the creation of conditions fit for human beings worldwide. To this end, this Regulation should particularly allow for the development of efficacious, safe, accessible, and affordable innovations to address global public health needs, including antimicrobial resistance, poverty-related and neglected diseases, widespread tropical disease and ensure high quality standards for medicinal products that are exported.

Or. en

Amendment 63
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Recital 42 a (new)

Text proposed by the Commission	*Amendment*
	(42 a) Beyond cooperating along the

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

Or. en

Amendment 64
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Recital 43

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

Or. en

Amendment 65
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 45 a (new)

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

Or. en

Amendment 66
Cristian-Silviu Buşoi

Proposal for a regulation
Recital 51

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

Or. en

Amendment 67
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 51

Text proposed by the Commission	*Amendment*
(51) As a general rule a marketing authorisation should be granted for an unlimited ***time; however, one renewal may be decided only*** on justified grounds related to the safety of the medicinal product.	(51) As a general rule a marketing authorisation ***for products other than generics*** should be granted for ***a period of five years in order to allow for the integration of real world evidence and re-assessment of the risk-benefit balance and in case of orphan medicines, also the related criteria related to population size and generated profit, once renewed, the marketing authorisation shall be valid for*** an unlimited ***period, unless the Agency decides*** on justified grounds related to the safety of the medicinal product ***to proceed with an additional five-year renewal period or revocation of the marketing authorisation***.

Or. en

Amendment 68
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Recital 53 a (new)

Text proposed by the Commission	*Amendment*
	(53 a) The distinct properties of advanced therapy medicinal products (ATMPs) create substantial infrastructural and knowledge hurdles, along with systemic obstacles, making the 'release and continuous supply' of many ATMPs across all 27 Member States within a brief period challenging. It is essential to investigate alternative care options to ensure the availability of these therapies throughout the Member States, potentially utilizing frameworks for cross-border healthcare access, like Directive 2011/24/EU and Regulation (EC) No 883/2004.

Or. en

Amendment 69
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Recital 60

Text proposed by the Commission	*Amendment*
(60) Regulatory decision-making on the development, authorisation and supervision of medicinal products may be supported by access and analysis of health data, including real world data, where appropriate, i.e. health data generated outside of clinical studies. The Agency should be able to use such data, including via the Data Analysis and Real World Interrogation Network (DARWIN) and the European Health Data Space interoperable infrastructure. Through these capabilities the Agency may take advantage of all the potential of supercomputing, artificial intelligence and big data science to fulfil its mandate, without compromising privacy rights. Where necessary the Agency may cooperate with the competent authorities of the Member States towards this objective.	(60) Regulatory decision-making on the development, authorisation and supervision of medicinal products may be supported by access and analysis of health data, including real world data, where appropriate, i.e. health data generated outside of clinical studies ***and/or through the use of in silico methods, such as computational modelling and simulation (CM&S) which includes PBPK, molecular modelling and mechanistic modelling, digital twin & artificial intelligence (AI)***. The Agency should be able to use such data, including via the Data Analysis and Real World Interrogation Network (DARWIN) and the European Health Data Space interoperable infrastructure. Through these capabilities the Agency may take advantage of all the potential of supercomputing, artificial intelligence and big data science to fulfil its mandate, without compromising privacy rights. Where necessary the Agency may cooperate with the competent authorities of the Member States towards this objective.

Or. en

Amendment 70
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 65

Text proposed by the Commission	*Amendment*
(65) In the preparation of scientific	(65) In the preparation of scientific

advice and in duly justified cases, the Agency should ***also*** be able to consult authorities established in other relevant Union legal acts or other public bodies established in the Union, as applicable. These may include experts in clinical trials, medical devices, substances of human origin or any other as required for the provision of the scientific advice in question.	advice and in duly justified cases, the Agency should ***promote an open discussion about latest scientific developments and the update of scientific guidelines and should*** be able to consult authorities established in other relevant Union legal acts or other public bodies established in the Union, as applicable. These may include experts in clinical trials, medical devices, substances of human origin or any other as required for the provision of the scientific advice in question.

Or. en

Amendment 71
Andreas Glück

Proposal for a regulation
Recital 71 a (new)

Text proposed by the Commission	*Amendment*
	(71 a) Phased reviews have been a success during the COVID-19 Pandemic and led to a rapid authorisation of the urgently needed vaccines. An application in times outside of public health emergencies is therefore appropriate and the precedure should be extended to 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. Moreover, the Commission shall evaluate the performance of the phased reviews with the aim to further expand the category of medicinal products for which this procedure may apply.

Or. en

Justification

See AM on Article 6 – paragraph 2 – subparagraph 1

Amendment 72
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Recital 73

Text proposed by the Commission	*Amendment*
(73) To optimise the use of resources for both applicants for marketing authorisations and competent authorities assessing such applications, a single assessment of an active substance master file should be introduced. The outcome of the assessment should be issued through a certificate. To avoid duplication of assessment, the use of an active substance master file certificate should be mandatory for subsequent applications or marketing authorisations for medicinal products for human use containing that active substance from an active substance master file certification holder. The Commission should be empowered to establish the procedure for the single assessment of an active substance master file. To further optimise the use of resources, the Commission should be empowered to extend the certification scheme to additional quality master files**,** e.g. in case of novel excipients, adjuvants, radiopharmaceutical precursors ***and*** active substance intermediates***, when the intermediate is a chemical active substance by itself or*** used in ***conjugation with a biological substance***.	(73) To optimise the use of resources for both applicants for marketing authorisations and competent authorities assessing such applications, a single assessment of an active substance master file should be introduced. The outcome of the assessment should be issued through a certificate. To avoid duplication of assessment, the use of an active substance master file certificate should be mandatory for subsequent applications or marketing authorisations for medicinal products for human use containing that active substance from an active substance master file certification holder. The Commission should be empowered to establish the procedure for the single assessment of an active substance master file. To further optimise the use of resources, the Commission should be empowered to extend the certification scheme to additional ***master files, such as*** quality master files ***for active substances other than chemical active substances or for other substances present or used in the manufacture of a medicinal product*** e.g. in case of novel excipients, adjuvants, ***raw materials, viral vectors and other starting materials, growth media,*** radiopharmaceutical precursors**,** active substance intermediates ***and conjugates, or such as platform technology master files for platform technologies*** used in ***the manufacturing process of one or more medicinal products***.

Or. en

Amendment 73
Nicola Danti, Susana Solís Pérez

Proposal for a regulation
Recital 77

Text proposed by the Commission	*Amendment*
(77) The development of antimicrobial resistance is a growing concern and the pipeline of effective antimicrobials is obstructed due to a market failure; it is therefore necessary to consider new measures to promote the development of priority antimicrobials that are effective against antimicrobial resistance and to support undertakings, often SMEs, which choose to invest in this area.	(77) The development of antimicrobial resistance is a growing concern and the pipeline of effective antimicrobials is obstructed due to a market failure; it is therefore necessary to consider new measures to promote the development of priority antimicrobials that are effective against antimicrobial resistance and to support undertakings, often SMEs, which choose to invest in this area. ***The Union should thus establish a mechanism of AMR Designation to identify medicinal products that can contribute to the fight against AMR and to support the targetting of R&D and access incentives.***

Or. en

Justification

It is proposed to introduce a designation for products aimed at combating antimicrobial resistance (article 40a), mirroring the procedure for orphan designation foreseen by the Commission proposal.

Amendment 74
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 77

Text proposed by the Commission	*Amendment*
(77) The development of antimicrobial resistance is a growing concern and the pipeline of effective antimicrobials is obstructed due to a market failure; it is therefore necessary to consider new measures to promote the development of priority antimicrobials that are effective	(77) The development of antimicrobial resistance is a growing concern and the pipeline of effective antimicrobials is obstructed due to a market failure; it is therefore necessary to consider new measures to promote the development of priority antimicrobials that are effective

against antimicrobial resistance and to support undertakings, often SMEs, which choose to invest in this area.

against antimicrobial resistance and to support undertakings, often SMEs ***and not-for profit entities***, which choose to invest in this area.

Or. en

Amendment 75
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Recital 77 a (new)

Text proposed by the Commission	*Amendment*
	(77 a) The above mentioned market failures highlight the need for considering the establishment of a mission oriented R&D and manufacturing infrastructure at Union level which acts in the public interest. This initiative should be tasked to research and develop novel antimicrobials as well as other areas of unmet medical need, to respond to health threats and emergencies, to support the Union to overcome market failures, to conduct treatment optimisation studies and to prevent shortages and guarantee security of supply of critical medicinal products.

Or. en

Amendment 76
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 78

Text proposed by the Commission	*Amendment*
(78) To be considered a 'priority antimicrobial', a medicinal product should represent a real advancement against antimicrobial resistance and should therefore bring forward non-clinical and	(78) To be considered a 'priority antimicrobial', a medicinal product should represent a real advancement against antimicrobial resistance and should therefore bring forward non-clinical and

clinical data that underpin a significant clinical benefit with respect to antimicrobial resistance. When assessing the conditions for antibiotics, the Agency shall take into account the prioritisation of pathogens as regards the risk of antimicrobial resistance provided for in the 'WHO priority pathogens list for R&D of new antibiotics', specifically those listed as priority 1 (critical) or priority 2 (high) or in case there is an equivalent list of priority pathogens adopted at Union level, the Agency should take such Union list into account as a priority.

clinical data that underpin a significant clinical benefit with respect to antimicrobial resistance. When assessing the conditions for antibiotics, the Agency shall take into account the prioritisation of pathogens as regards the risk of antimicrobial resistance provided for in the 'WHO priority pathogens list for R&D of new antibiotics', specifically those listed as priority 1 (critical) or priority 2 (high) or in case there is an equivalent list of priority pathogens adopted at Union level, the Agency should take such Union list into account as a priority. ***In order to address market failures for the development of antimicrobials, the priority focus should be on the research and development and subsequent production and fair distribution of new antimicrobials. However, addressing AMR will not be solved by R&D alone. To ensure prudent use of existing antibiotics, the Authority should also support the development and procurement of rapid diagnostic tools to ensure appropriate prescriptions.***

Or. en

Amendment 77
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 78 a (new)

Text proposed by the Commission	*Amendment*
	(78 a) As the Commission's study on bringing antimicrobial medical countermeasures to the market[1a] demonstrated, different kinds of push and pull incentives are needed to face this public health emergency. These tools may include market entry rewards, advance purchase agreements, milestone payments, innovation prizes, or subscription payments. In order to maximize the benefits from such public

investments, the allocation of these financial and other incentives should respect the following principles and conditions of open science, affordability and EU-wide availability of developed products, delinking revenue from sale volumes of procured products, full transparency of all received funding and purchase agreements, gradient incentive scheme that rewards according to the innovation level, and the development of a stewardship and access plans. These principles and conditions should ensure that public money will be allocated with the objective of a rapid public return on investment for patients.

[1a] [1] https://op.europa.eu/en/publication-detail/-/publication/51b2c82c-c21b-11ed-8912-01aa75ed71a1/language-en/format-PDF/source-282347876

Or. en

Amendment 78
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 78 b (new)

Text proposed by the Commission	*Amendment*
	(78 b) The principle of open science is pivotal to ensure rapid progress in the field of scientific research for priority antimicrobials. Over the past 30 years, the lack of sharing of results, failed trials and ongoing research has created bottlenecks for scientific development and contributes to the current market failure for the placing on the market of new antimicrobials. It is therefore of the utmost importance to have a paradigm shift towards open science, particularly in the area of publicly-funded research, to reduce duplication of research, allow for

peer-verification of results and building further evidence based on most recent findings, as to making research and development funding efforts more efficient.

Or. en

Amendment 79
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 79

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

Or. en

Amendment 80
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Recital 79

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

Or. en

Amendment 81
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

Proposal for a regulation
Recital 79

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

further give the possibility to the Commission to revoke the voucher under certain circumstances.	establish strict conditions of granting, transfer and use of the voucher and to further give the possibility to the Commission to revoke the voucher under certain circumstances.

Or. en

Amendment 82
Laura Ballarín Cereza

Proposal for a regulation
Recital 79 a (new)

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

Or. en

Amendment 83
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Recital 80

Text proposed by the Commission	*Amendment*
(80) A transferable data exclusivity voucher should only be available to those antimicrobial products that bring a significant clinical benefit with respect to	***deleted***

antimicrobial resistance, and which have the characteristics described in this Regulation. It is also necessary to ensure that an undertaking which receives this incentive is in turn capable to supply the medicinal product to patients across the Union in sufficient quantities and to provide information on all funding received for research related to its development in order to provide a full account of the direct financial support given to the medicinal product.

Or. en

Amendment 84
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 80

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

Or. en

Amendment 85
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

Proposal for a regulation
Recital 80

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

Or. en

Amendment 86
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 81

Text proposed by the Commission	*Amendment*
(81) To ensure a high level of transparency and complete information on the economic effect of the transferable data exclusivity voucher, notably as regards the risk of overcompensation of investment, a developer of a priority antimicrobial is required to provide information on all direct financial support received for research related to the development of the priority antimicrobial. The declaration should include direct financial support received from any	***deleted***

source worldwide.

Or. en

Amendment 87
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Recital 81

Text proposed by the Commission	*Amendment*
(81) To ensure a high level of transparency and complete information on the economic effect of the transferable data exclusivity voucher, notably as regards the risk of overcompensation of investment, a developer of a priority antimicrobial is required to provide information on all direct financial support received for research related to the development of the priority antimicrobial. The declaration should include direct financial support received from any source worldwide.	***deleted***

Or. en

Amendment 88
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Recital 82

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

a maximum level of transparency and trust.

Or. en

Amendment 89
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 82

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

Or. en

Amendment 90
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 83

Text proposed by the Commission	*Amendment*
(83) The provisions related to transferable data exclusivity vouchers shall be applicable for a specified period from the entry into force of this Regulation or until a maximum number of vouchers are granted by the Commission in order to limit the total cost of the measure to Member State health	***deleted***

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

Or. en

Amendment 91
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Recital 83

Text proposed by the Commission	*Amendment*
(83) The provisions related to transferable data exclusivity vouchers shall be applicable for a specified period from the entry into force of this Regulation or until a maximum number of vouchers are granted by the Commission in order to limit the total cost of the measure to Member State health systems. The limited application of the measure will also provide the possibility to assess the effect of the measure in addressing the market failure in the development of new antimicrobials addressing antimicrobial resistance and assess the cost on national health systems. Such assessment will provide the necessary knowledge to decide whether to extend the application of the measure.	***deleted***

Or. en

Amendment 92
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation

Recital 84

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

Or. en

Amendment 93
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 84

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

Or. en

Amendment 94
Cristian-Silviu Buşoi

Proposal for a regulation
Recital 87 a (new)

Text proposed by the Commission	*Amendment*
	(87 a) For medicinal products that are likely to offer an exceptional therapeutic advancement in the diagnosis, prevention

or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the Union, with a view to enabling earlier availability for patients, the Agency should be able to perform a 'phased review' of data packages concerning finalised tests and trials before a formal application for marketing authorisation is submitted, to allow a more efficient assessment of medicinal products, while guaranteeing a high level of human health protection.

Or. en

Amendment 95
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Recital 87 a (new)

Text proposed by the Commission	*Amendment*
	(87 a) Recalls the European Parliament's resolution from 10 July 2020 concerning the EU's post-COVID-19 public health strategy, which called for an EU Action Plan specifically targeting rare diseases.

Or. en

Amendment 96
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 90

Text proposed by the Commission	*Amendment*
(90) Objective criteria for the orphan designation based on the prevalence of the life-threatening or chronically debilitating condition for which diagnosis, prevention or treatment is sought and the existence of no satisfactory method of diagnosis,	(90) Objective criteria for the orphan designation based on the prevalence of the life-threatening or chronically debilitating condition for which diagnosis, prevention or treatment is sought and the existence of no satisfactory method of diagnosis,

prevention or treatment of the condition in question that has been authorised in the Union should be maintained; a prevalence of not more than five affected persons per 10 000 is generally regarded as the appropriate threshold. The orphan designation criterion on the basis of return on investment has been abolished, ***since it has never been used***.	prevention or treatment of the condition in question that has been authorised in the Union should be maintained; a prevalence of not more than five affected persons per 10 000 is generally regarded as the appropriate threshold. The orphan designation criterion on the basis of return on investment has been abolished, ***nevertheless, products may still lose the orphan status in cases where the population criterion is no longer met or when sufficient profit was generated after five years on the market***.

Or. en

Amendment 97
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 90 a (new)

Text proposed by the Commission	*Amendment*
	(90 a) The aim of intellectual property and regulatory incentives is to benefit society and promote innovation in areas of public health and unmet medical needs, such as rare diseases. It is of utmost importance that such incentives are not misused or abused, nor pose threats to affordability and patient access to treatments. In particular, the practice of artificially subdividing diseases to create subgroups of patients in order to fall under the orphan medicine prevalence criterion should be prohibited.

Or. en

Amendment 98
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Recital 92 a (new)

Text proposed by the Commission	*Amendment*
	(92 a) Significant benefit should remain the main determining factor for eligibility for orphan status when assessing an orphan medicinal product that meets the incidence threshold.

Or. en

Amendment 99
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Recital 92 b (new)

Text proposed by the Commission	*Amendment*
	(92 b) What constitutes significant benefit in a patient population can change over time, therefore, the concept should remain sufficiently flexible to ensure a future-proof regulatory framework while ensuring predictability through additional guidance developped in consultation with patient organisations.

Or. en

Amendment 100
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Recital 93

Text proposed by the Commission	*Amendment*
(93) If a satisfactory method of diagnosis, prevention or treatment of the condition in question has already been authorised in the Union, the orphan medicinal product will have to be of significant benefit to those affected by that condition. In this context, a medicinal product authorised in one Member State is	(93) If a satisfactory method of diagnosis, prevention or treatment of the condition in question has already been authorised in the Union, the orphan medicinal product will have to be of significant benefit to those affected by that condition. In this context, a medicinal product authorised in one Member State is

generally deemed as being authorised in the Union. It is not necessary for it to have Union authorisation or to be authorised in all Member States to be considered as a satisfactory method. In addition, commonly used methods of diagnosis, prevention or treatment that are not subject to a marketing authorisation may be considered satisfactory if there is scientific evidence of their efficacy and safety. In certain cases, medicinal products prepared for an individual patient in a pharmacy according to a medical prescription, or according to the prescriptions of a pharmacopoeia and intended to be supplied directly to patients served by the pharmacy, may be considered as satisfactory treatment if they are well known and safe and this is a general practice for the relevant patient population in the Union.	generally deemed as being authorised in the Union. It is not necessary for it to have Union authorisation or to be authorised in all Member States to be considered as a satisfactory method. In addition, commonly used methods of diagnosis, prevention or treatment that are not subject to a marketing authorisation may be considered satisfactory if there is scientific evidence of their efficacy and safety. In certain cases, medicinal products prepared for an individual patient in a pharmacy according to a medical prescription, or according to the prescriptions of a pharmacopoeia and intended to be supplied directly to patients served by the pharmacy, may be considered as satisfactory treatment if they are well known and safe and this is a general practice for the relevant patient population in the Union. ***This provision is applicable solely to medicinal products that are not classified as advanced therapy medicinal products and do not contain complex active substances.***
	Or. en

Amendment 101
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Recital 96 a (new)

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

regulatory pathway, while managing resources in an efficient way.

Or. en

Amendment 102
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 100

Text proposed by the Commission	*Amendment*
(100) Orphan medicinal products addressing a high unmet medical need prevent, diagnose or treat conditions where either no other method of prevention, diagnosis or treatment exists or, if such method already exists, they would bring exceptional therapeutic advancement. In both cases, the criterion of ***meaningful*** reduction in disease morbidity or mortality for the relevant patient population should ensure that only most effective medicinal products are covered. The Agency should draw up scientific guidelines on the category of 'orphan medicinal products addressing a high unmet medical need'.	(100) Orphan medicinal products addressing a high unmet medical need prevent, diagnose or treat conditions where either no other method of prevention, diagnosis or treatment exists or, if such method already exists, they would bring exceptional therapeutic advancement. In both cases, the criterion of ***substantial*** reduction in disease morbidity or mortality for the relevant patient population should ensure that only most effective medicinal products are covered. The Agency should draw up scientific guidelines on the category of 'orphan medicinal products addressing a high unmet medical need'.

Or. en

Amendment 103
Henna Virkkunen

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***;***	(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***

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.

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

Justification

Expressing reservations, there is apprehension about employing terms like HUMN to categorize therapies and influence incentive structures. Acknowledging the importance of fostering innovation where it is most essential, the concern is to avoid stifling innovation in areas where patients could still gain from additional research. This approach moves beyond relying solely on the concept of HUMN, aiming to guarantee that all individuals with rare diseases reap the benefits of ongoing research.

Amendment 104
Ville Niinistö
on behalf of the Verts/ALE Group

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	(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.***	longest market exclusivity, while market exclusivity for well-established use orphan medicinal products, requiring less investment, is the shortest.

Or. en

Amendment 105
Susana Solís Pérez, Klemen Grošelj

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 106
Ville Niinistö
on behalf of the Verts/ALE Group

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 107
Ville Niinistö
on behalf of the Verts/ALE Group

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 108
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Recital 104

Text proposed by the Commission	*Amendment*
(104) To reward research into and development of new therapeutic indications, an additional period of one year of market exclusivity is provided for a new therapeutic indication (with a maximum of two indications).	(104) ***To maximise the potential benefit of clinical research, continued exploration of new indications should be encouraged.*** To reward research into and development of new therapeutic indications, an additional period of one

year of market exclusivity is provided for a new therapeutic indication (with a maximum of two indications). ***To continue incentivising innovation, especially in underserved areas, while also allowing generic entry, any subsequent new orphan marketing authorisations granted to the marketing authorisation holder should receive three years of market exclusivity bound to the indication, not the active substance. This will allow generic competition in the first two orphan indications, while allowing for continued research for those patients who could still benefit.***

Or. en

Amendment 109
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Recital 105 a (new)

Text proposed by the Commission	*Amendment*
	(105 a)) One of the overarching goals of this Regulation is to help meet the medical needs of patients with rare diseases, to improve the affordability of orphan medicinal products and the patient access to orphan medicinal products across the Union, and to encourage innovation in areas of need. While other Union programmes and policies also contribute to these goals, people living with a rare disease continue to face common challenges that are many and multifactorial, including delayed diagnoses, lack of available transformative treatments, and difficulties to access treatments where they live, reflecting the fragmentation of the market across the Member States. The European added value to addressing the needs of people living with a rare disease being exceptionally high due to the rarity of patients, experts, data, and resources, it is

appropriate for the Commission to develop, to complement this Regulation, a dedicated framework for rare diseases to bridge relevant legislation, policies and programmes, and support national strategies with a view to better meet the unmet needs of people living with rare diseases and their carers. This framework should be needs driven and goals based, and developped in consultation with the Member States and patient organisations as well as, where relevant, other interested parties.

Or. en

Amendment 110
Francesca Donato

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***, strictly respecting the timing and phases of the clinical trial***. 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.

Or. en

Amendment 111
Francesca Donato

Proposal for a regulation
Recital 109

Text proposed by the Commission	*Amendment*
(109) During public health emergencies, in order not to delay a prompt authorisation of a medicinal product intended for the treatment or the prevention of a condition related to the public health emergency, there should be a possibility to temporarily waive the requirements concerning paediatric studies to be submitted at the moment of marketing authorisation.	***deleted***

Or. en

Amendment 112
Susana Solís Pérez, Klemen Grošelj

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 113
Susana Solís Pérez, Klemen Grošelj

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 114
Francesca Donato

Proposal for a regulation
Recital 131

Text proposed by the Commission	*Amendment*
(131) It is necessary to provide for the coordinated implementation of Union procedures for the marketing authorisation of medicinal products, and of the marketing authorisation procedures of Member States which have already been harmonised to a considerable degree by	(131) It is necessary to provide for the coordinated implementation of Union procedures for the marketing authorisation of medicinal products, and of the marketing authorisation procedures of Member States which have already been harmonised to a considerable degree by

[revised Directive 2001/83/EC].	[revised Directive 2001/83/EC] ***and respect clinical drug trial times***.

Or. en

Amendment 115
Ville Niinistö
on behalf of the Verts/ALE Group

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 116
Cristian-Silviu Buşoi

Proposal for a regulation
Recital 132 a (new)

Text proposed by the Commission	*Amendment*
	(132 a) To ensure medicines' 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 117
Cristian-Silviu Buşoi

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 118
Cristian-Silviu Buşoi

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 119
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 133

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

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 120
Cristian-Silviu Buşoi

Proposal for a regulation
Recital 133

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

legislation.	***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 121
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Recital 133

Text proposed by the Commission	*Amendment*
(133) Regulatory sandboxes can provide the opportunity for advancing regulation through proactive regulatory learning, enabling regulators to gain better regulatory knowledge and to find the best means to regulate innovations based on real-world evidence, especially at a very early stage of development of a medicinal product, which can be particularly important in the face of high uncertainty and disruptive challenges, as well as when preparing new policies. Regulatory sandboxes provide a structured context for experimentation, enable where appropriate in a real-world environment the testing of innovative technologies, products, services or approaches – at the moment especially in the context of digitalisation or the use of artificial intelligence and machine learning in the life cycle of medicinal products from drug discovery, development to the administration of medicinal products – for a limited time and in a limited part of a sector or area under regulatory supervision	(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 ***strict*** regulatory

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.	supervision ensuring that ***robust*** 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 122
Ville Niinistö
on behalf of the Verts/ALE Group

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 123
Susana Solís Pérez, Klemen Grošelj

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 124
Ville Niinistö
on behalf of the Verts/ALE Group

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 125
Laura Ballarín Cereza, Nicolás González Casares

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	(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.

particularities of the sandbox as well as describing the products to be covered. A regulatory sandbox should be limited in duration and may be terminated at any time based on public health considerations. The learning stemming from a regulatory sandbox should inform future changes to the legal framework to fully integrate the particular innovative aspects into the medicinal product regulation. ***It is of utmost importance to ensure a harmonised implementation of these provisions across Member States.*** Where appropriate, adapted frameworks may be developed by the Commission on the basis of the results of a regulatory sandbox.

Or. en

Amendment 126
Pilar del Castillo Vera

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	(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

plans.

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 127
Susana Solís Pérez, Klemen Grošelj

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 128
Patrizia Toia, Beatrice Covassi

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, 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 129
Margarita de la Pisa Carrión

on behalf of the ECR Group

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

Justification

The level of detail required in a shortage prevention plan (SPP) triggers to additional bureaucracy work and is burdensome for small and mid-sized companies, particularly due to their limited resources. Moreover, it should be considered to limit this requirement to critical medicines and exclude products, such as ATMPs and OMPs, which are unlikely to face shortage issues, but rather require unique and tailored go-to-market models and distribution requirements (e.g., direct-to-hospital supplies).

Amendment 130
Henna Virkkunen

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

Justification

The level of detail required in a shortage prevention plan (SPP) triggers to additional bureaucracy work and is burdensome for small and mid-sized companies, particularly due to their limited resources. Moreover, it should be considered to limit this requirement to critical medicines and exclude products, such as ATMPs and OMPs, which are unlikely to face shortage issues, but rather require unique and tailored go-to-market models and distribution requirements (e.g., direct-to-hospital supplies).

Amendment 131
Laura Ballarín Cereza, Nicolás González Casares

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,	(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.

including the procedures and the respective roles and obligations of concerned entities in this Regulation. It is important to ensure continued supply of medicinal products, which is often taken for granted across Europe. This is especially true for the most critical medicinal products which are essential to ensure the continuity of care, the provision of quality healthcare and guarantee a high level of public health protection in Europe. ***Member States should be able to introduce or maintain more robust measures to achieve security of supply for medicines than the safeguards provided for in this Regulation as long as these measures do not have a negative impact on the security of supply of other Member States.***

Or. en

Amendment 132
Susana Solís Pérez, Klemen Grošelj

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.	(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

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***.

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.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 133
Patrizia Toia, Beatrice Covassi

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

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

may also report a shortage of a given medicinal product marketed in the Member State concerned to the competent authority ***or the Agency***. The Executive Steering Group on Shortages and Safety of Medicinal Products ('the Medicines Shortages Steering Group' (MSSG)) already established within the Agency pursuant to Regulation (EU) 2022/123 of the European Parliament and of the Council[56] , should adopt a list of critical shortages of medicinal products and ensure monitoring of those shortages by the Agency. The MSSG should also adopt a list of critical medicinal products authorised in accordance with [revised Directive 2001/83/EC] or this Regulation to ensure monitoring of the supply of those products. The MSSG may provide recommendations on measures to be taken by marketing authorisation holders, the Member States, the Commission and other entities to resolve any critical shortage or to ensure the security of supply of those critical medicinal products to the market. Implementing acts can be adopted by the Commission to ensure that appropriate measures, including the establishment or maintenance of ***strategic*** contingency stocks, are taken by marketing authorisation holders, wholesale distributors or other relevant entities. ***In case of emergencies and on the basis of the notifications received, the Agency should be empowered to redirect medicinal products available in strategic contingency stocks for quick access and agile mobilization of medicines, medical supplies, and equipment in order to facilitate the response to health emergencies of any kind and to support the health network***

[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).

(OJ L 20, 31.1.2022, p. 1).

Or. en

Amendment 134
Andreas Glück

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	(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

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.	Parliament and of the Council[56] , should adopt a list of critical shortages of medicinal products and ensure monitoring of those shortages by the Agency. The MSSG should also adopt a list of critical medicinal products authorised in accordance with [revised Directive 2001/83/EC] or this Regulation to ensure monitoring of the supply of those products. The MSSG may provide recommendations on measures to be taken by marketing authorisation holders, the Member States, the Commission and other entities to resolve any critical shortage or to ensure the security of supply of those critical medicinal products to the market. Implementing acts can be adopted by the Commission to ensure that appropriate measures, including the establishment or maintenance of contingency stocks, are taken by marketing authorisation holders, wholesale distributors or other relevant entities.
[56] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1).	[56] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1).

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 135
Ville Niinistö
on behalf of the Verts/ALE Group

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 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	(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 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[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

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.***	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).	[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 136
Ville Niinistö
on behalf of the Verts/ALE Group

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 137
Susana Solís Pérez, Klemen Grošelj

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 138
Susana Solís Pérez, Klemen Grošelj

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 139
Susana Solís Pérez, Klemen Grošelj

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

Amendment 140
Susana Solís Pérez, Klemen Grošelj

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 141
Susana Solís Pérez, Klemen Grošelj

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 142
Francesca Donato

Proposal for a regulation
Recital 147

Text proposed by the Commission	*Amendment*
(147) Consequently, it is particularly difficult to conduct multi-centre clinical trials with investigational medicinal products that contain or consist of GMOs involving several Member States.	(147) Consequently, it is particularly difficult ***- although it can be justified in accordance with the precautionary principle -*** to conduct multi-centre clinical trials with investigational medicinal products that contain or consist of GMOs involving several Member States.

Or. en

Amendment 143
Francesca Donato

Proposal for a regulation
Recital 151

Text proposed by the Commission	*Amendment*
(151) The requirement for the holding of authorisation of manufacturing and import of investigational medicinal	***deleted***

products in the Union in accordance with Article 61(2), point (a), of Regulation (EU) No 536/2014 should be extended to investigational medicinal products containing or consisting of GMOs in Directive 2009/41/EC.

Or. en

Amendment 144
Susana Solís Pérez, Klemen Grošelj

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 145
Laura Ballarín Cereza, Nicolás González Casares

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

Text proposed by the Commission	*Amendment*
(4) 'orphan ***medicine*** sponsor' means	(4) 'orphan ***medicinal products***

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);	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 146
Susana Solís Pérez, Klemen Grošelj

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 147
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 148
Patrizia Toia, Beatrice Covassi

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

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

Or. en

Amendment 149
Patrizia Toia, Beatrice Covassi

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

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

Or. en

Amendment 150
Ville Niinistö
on behalf of the Verts/ALE Group

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	***deleted***

fall in the scope of this Regulation, pursuant to a specific plan and for a limited time under regulatory supervision.

Or. en

Amendment 151
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 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, pursuant to a specific plan and for a limited time under regulatory supervision.

Or. en

Amendment 152
Susana Solís Pérez, Klemen Grošelj

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

Text proposed by the Commission	*Amendment*
	(11 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 153

Susana Solís Pérez, Klemen Grošelj

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

Text proposed by the Commission	*Amendment*
	(11 b) '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 154
Susana Solís Pérez, Klemen Grošelj

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

Text proposed by the Commission	*Amendment*
	(11 c) '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

Amendment 155
Susana Solís Pérez, Klemen Grošelj

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 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 demand for that medicinal product ***or medical device at a national level, whatever the cause***

Or. en

Amendment 156
Laura Ballarín Cereza, Nicolás González Casares

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

Text proposed by the Commission	*Amendment*
	(14 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 157
Laura Ballarín Cereza, Nicolás González Casares

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

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

Or. en

Amendment 158

Susana Solís Pérez, Klemen Grošelj

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 159
Pilar del Castillo Vera

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 160
Pilar del Castillo Vera

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 161

Susana Solís Pérez, Klemen Grošelj

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 162
Pilar del Castillo Vera

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 163
Pilar del Castillo Vera

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*
Point (b), first subparagraph, shall not	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.

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 164
Susana Solís Pérez

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 165
Susana Solís Pérez, Klemen Grošelj

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 166
Susana Solís Pérez, Klemen Grošelj

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

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

concerned.

(b) The use 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.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 167
Susana Solís Pérez, Klemen Grošelj

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 168
Andreas Glück

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

Text proposed by the Commission	*Amendment*
For medicinal products that are likely to offer an exceptional therapeutic advancement in the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the Union, the Agency may, following the advice of the Committee for Medicinal Products for Human Use regarding the maturity of the data related to the development, offer to the applicant a phased review of complete data packages for individual modules of particulars and documentation as referred to in paragraph 1.	For ***orphan medicinal products and*** medicinal products that are likely to offer an exceptional therapeutic advancement in the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the Union, the Agency may, following the advice of the Committee for Medicinal Products for Human Use regarding the maturity of the data related to the development, offer to the applicant a phased review of complete data packages for individual modules of particulars and documentation as referred to in paragraph 1.

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 169
Susana Solís Pérez, Klemen Grošelj

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 170
Laura Ballarín Cereza, Nicolás González Casares

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

Text proposed by the Commission	*Amendment*
The marketing authorisation applicant shall not carry out animal tests in case scientifically satisfactory non-animal testing methods are available.	The marketing authorisation applicant shall not carry out animal tests in case scientifically satisfactory non-animal testing methods are available. ***Where scientifically satisfactory non-animal testing methods are not available, applicants that use animal testing shall ensure that the principle of replacement, reduction and refinement of animal testing for scientific purposes has been applied in compliance with Directive 2010/63/EU with regard to any animal study conducted for the purpose of supporting the application.***

Or. en

Amendment 171
Susana Solís Pérez, Klemen Grošelj

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 172
Susana Solís Pérez, Nicola Danti

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 173
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

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 174
Laura Ballarín Cereza, Nicolás González Casares

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; ***for the purpose of this point, 'hazards for human health' includes the risks to the health of human beings other than the treated patient as the risk to the treated patient shall be assessed as part of the benefit-risk assessment of the medicinal product;***

Or. en

Amendment 175
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Article 9 – paragraph 2

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

Or. en

Amendment 176
András Gyürk, Ernő Schaller-Baross

Proposal for a regulation
Article 9 a (new)

Text proposed by the Commission	*Amendment*
	Article 9a
	Availability plan
	1. The applicant shall submit an availability plan to the Agency. The availability plan shall describe the modalities by which the authorised medicinal product is made available during the period of regulatory data protection or patent, in a Member States where the medicinal product is needed.

applicant shall submit an availability plan to the Agency. The availability plan shall describe the modalities by which the authorised medicinal product is made available during the period of regulatory data protection or patent, in a Member States where the medicinal product is needed.

2. The Committee for Medicinal Products for Human Use shall assess the availalibility plan and request modification thereto, if it comes to the conclusion that the foreseen modalities do not guarantee timely access to patients. In case of such a request the applicant shall adjust the availability plan.

Or. en

Amendment 177
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Article 10 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where within 90 days of the validation of the marketing authorisation application and during the assessment the Committee for Medicinal Products for Human Use considers that the submitted data are not of sufficient quality or maturity to complete the assessment, the assessment can be terminated. The Committee for Medicinal Products for Human Use shall summarise the deficiencies in writing. On this basis, the Agency shall inform the applicant accordingly and set a time limit to address the deficiencies. The application shall be suspended until the applicant addresses the deficiencies. If the applicant fails to address those deficiencies within the time limit set by the Agency, the application shall be considered as ***withdrawn***.	2. Where within 90 days of the validation of the marketing authorisation application and during the assessment the Committee for Medicinal Products for Human Use considers that the submitted data are not of sufficient quality or maturity to complete the assessment, the assessment can be terminated. The Committee for Medicinal Products for Human Use shall summarise the deficiencies in writing. On this basis, the Agency shall inform the applicant accordingly and set a ***reasonable*** time limit to address the deficiencies. The application shall be suspended until the applicant addresses the deficiencies. If the applicant fails to address those deficiencies within the time limit set by the Agency, the application shall be considered as ***refused***.

Or. en

Amendment 178
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Article 12 – paragraph 4 – point h

Text proposed by the Commission	*Amendment*
(h) where appropriate, details of any recommended obligation to conduct any other post-authorisation studies to improve the safe and effective use of the medicinal product;	(h) where appropriate, details of any recommended obligation to conduct any other post-authorisation studies***, including post-authorisation treatment optimisation studies,*** to improve the safe and effective use of the medicinal product;

Or. en

Amendment 179
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Article 12 – paragraph 4 – point m a (new)

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

Or. en

Amendment 180
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Article 12 – paragraph 4 – point m b (new)

Text proposed by the Commission	*Amendment*
	(m b) where applicable, a confirmation as to whether the medicinal product satisfies the criteria of Article 83 of [revised Directive 2001/83/EC] regarding medicinal products addressing an unmet medical need;

Or. en

Amendment 181
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 5

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

Or. en

Amendment 182
Francesca Donato

Proposal for a regulation
Article 13 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4 a. the benefit/risk balance is objectively favourable and any adverse reactions are not statistically relevant

Or. en

Amendment 183
Massimiliano Salini, Aldo Patriciello

Proposal for a regulation
Article 15 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) the environmental risk assessment is incomplete or insufficiently substantiated by the applicant or if the risks identified in the environmental risk assessment have not been sufficiently addressed by the applicant;	***deleted***

Or. en

Amendment 184
Pernille Weiss

Proposal for a regulation
Article 15 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) the environmental risk assessment is incomplete or insufficiently substantiated by the applicant or if the risks identified in the environmental risk assessment have not been sufficiently addressed by the applicant;	***deleted***

Or. en

Justification

See amendment to Article 15 – paragraph 1 a (new).

Amendment 185
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Article 15 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) the environmental risk assessment is incomplete or insufficiently substantiated by the applicant or if the risks	(d) the environmental risk assessment is incomplete or insufficiently substantiated by the applicant or if the risks

identified in the environmental risk assessment have not been sufficiently addressed by the applicant;	identified in the environmental risk assessment have not been sufficiently addressed by the ***risk mitigation measures proposed by the*** applicant ***in accordance with Article 22(3) of [revised Directive 2001/83/EC]***;

Or. en

Amendment 186
Henna Virkkunen

Proposal for a regulation
Article 15 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) the ***environmental risk assessment is incomplete or insufficiently substantiated by the applicant or if the risks identified in the*** environmental risk assessment ***have not been sufficiently addressed by the applicant;***	(d) the ***content or timelines of post-authorisation studies to further clarify*** environmental risk assessment***, as required in article 20(c), cannot be agreed.***

Or. en

Justification

Refusing the initial marketing authorization based on environmental risk assessments that rely on post-marketing data or where scientific consensus is lacking (e.g., antimicrobial resistance) is not suitable. Strengthening data collection post-approval through binding and time-constrained commitments would enhance environmental risk assessment science. For expedited submissions (e.g., PRIME) or cases with late indication changes affecting patient populations, environmental risk data may be unavailable and should not hinder patient access.

Amendment 187
Massimiliano Salini, Aldo Patriciello

Proposal for a regulation
Article 15 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) ***the environmental risk assessment is incomplete or insufficiently***	(d) ***there is no agreement on the content or timing of post-authorisation***

substantiated by the applicant or if the risks identified in the environmental risk assessment ***have not been sufficiently addressed by the applicant;***	***studies to further explain*** environmental risk assessment***, as stated by article 20(c).***

Or. en

Amendment 188
Pernille Weiss

Proposal for a regulation
Article 15 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. The marketing authorisation may furthermore be refused if, after verification of the particulars and documentation submitted in accordance with Article 6, the view is taken that the environmental risk assessment is incomplete or insufficiently substantiated by the applicant or if the risks identified in the environmental risk assessment have not been sufficiently addressed by the applicant.

Or. en

Justification

See amendment to Article 15 – paragraph 1 – point d.

Amendment 189
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Article 16 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency shall immediately publish the assessment report on the medicinal product for human use and the reasons for its opinion in favour of granting marketing authorisation, after deletion of any	The Agency shall immediately publish the assessment report on the medicinal product for human use and the reasons for its opinion in favour of granting marketing authorisation, after deletion of any

information of a commercially confidential nature.	information of a commercially confidential nature ***and following consultation of patients' organisations***.

Or. en

Amendment 190
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Article 16 – paragraph 3 – subparagraph 2 – indent 1

Text proposed by the Commission	*Amendment*
– a summary of the assessment ***report written in a manner that is understandable to the public. The summary shall contain in particular a section relating to the conditions of use*** of the ***medicinal product;***	– ***the complete environmental risk assessment submitted to the Agency by the marketing authorisation applicant as well as*** a summary of ***environmental risk assessment studies and their results as submitted by the marketing authorisation holder and*** the assessment of the ***environmental risk assessment and the information referred to in Article 22(5) of [revised Directive 2001/83/EC] by the Agency.***

Or. en

Amendment 191
Laura Ballarín Cereza, Nicolás González Casares

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

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

Or. en

Amendment 192
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Article 17 – paragraph 2 – subparagraph 4 a (new)

Text proposed by the Commission	*Amendment*
	Where post-authorisation studies to be performed in accordance with Article 20(1) justify it, the Commission may decide to withdraw a marketing authorisation for a medicinal product based on evidence pointing to a risk to public health.

Or. en

Amendment 193
Francesca Donato

Proposal for a regulation
Article 18 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(c a) clinical studies on all aspects of efficacy and safety have been carried out with a monitoring period of at least six months, demonstrating in a sufficiently clear and reliable manner both the efficacy and safety of the medicinal product and the total absence of serious or lethal adverse effects

Or. en

Amendment 194
Francesca Donato

Proposal for a regulation
Article 18 – paragraph 1 – point c b (new)

Text proposed by the Commission	*Amendment*
	(c b) clinical studies are conducted

under external supervision by independent parties subject to confidentiality for commercial purposes, but who are able to report to the Agency on the correctness and completeness of the trials carried out

Or. en

Amendment 195
Francesca Donato

Proposal for a regulation
Article 18 – paragraph 1 – point c c (new)

Text proposed by the Commission	*Amendment*
	(c c) for medicines authorised in an emergency, there must be an active pharmacovigilance system – not only passive – also in the consources of the subjects on which the medicine is administered outside the clinical trial.

Or. en

Amendment 196
Francesca Donato

Proposal for a regulation
Article 19 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
In duly justified cases, to meet an unmet medical need of patients, as referred to in Article 83(1), point (a), of [revised Directive 2001/83/EC], a conditional marketing authorisation or a new conditional therapeutic indication to an existing marketing authorisation authorised under this Regulation may be granted by the Commission to a medicinal product that is likely to address the unmet medical need in accordance with Article 83(1), point (b), of [revised Directive	In duly justified cases, to meet an unmet medical need of patients, as referred to in Article 83(1), point (a), of [revised Directive 2001/83/EC], a conditional marketing authorisation or a new conditional therapeutic indication to an existing marketing authorisation authorised under this Regulation may be granted by the Commission to a medicinal product that is likely to address the unmet medical need in accordance with Article 83(1), point (b), of [revised Directive

2001/83/EC], prior to the submission of comprehensive clinical data provided that the benefit of the immediate availability on the market of that medicinal product outweighs the risk inherent in the fact that additional data are still required.	2001/83/EC], prior to the submission of comprehensive clinical data provided that the benefit of the immediate availability on the market of that medicinal product outweighs the risk inherent in the fact that additional data are still required. ***The benefit-risk assessment must be based on reliable, clear and verifiable data and not approximate and based on presumptive or generic assessments.***

Or. en

Amendment 197
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Article 19 – paragraph 1 – subparagraph 2

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

Or. en

Amendment 198
Francesca Donato

Proposal for a regulation
Article 19 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Conditional marketing authorisations or a new conditional therapeutic indication referred to in paragraph 1 may be granted only if the benefit-risk balance of the medicinal	2. Conditional marketing authorisations or a new conditional therapeutic indication referred to in paragraph 1 may be granted only if the benefit-risk balance of the medicinal

product is favourable and the applicant is likely to be able to provide comprehensive data.	product is favourable and the applicant is likely to be able to provide comprehensive data. ***the benefit-risk assessment must be based on reliable, clear and verifiable data and not approximate and based on presumptive or generic assessments.***

Or. en

Amendment 199
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Article 19 – paragraph 3

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

Or. en

Amendment 200
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Article 19 – paragraph 4

Text proposed by the Commission	*Amendment*
4. As part of the specific obligations referred to in paragraph 3, the marketing authorisation holder of a conditional marketing authorisation granted pursuant to this Article shall be required to complete	4. As part of the specific obligations referred to in paragraph 3, the marketing authorisation holder of a conditional marketing authorisation granted pursuant to this Article shall be required to complete

ongoing studies, or to conduct new studies, with a view to confirming that the benefit-risk balance is favourable.	ongoing studies, or to conduct new studies, with a view to confirming that the benefit-risk balance is favourable. ***The Agency will establish and publish specific deadlines and criteria for meeting these conditions, making them accessible to the public.***

Or. en

Amendment 201
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Article 19 – paragraph 4

Text proposed by the Commission	*Amendment*
4. As part of the specific obligations referred to in paragraph 3, the marketing authorisation holder of a conditional marketing authorisation granted pursuant to this Article shall be required to complete ongoing studies, or to conduct new studies, with a view to confirming ***that the benefit-risk balance is favourable***.	4. As part of the specific obligations referred to in paragraph 3, the marketing authorisation holder of a conditional marketing authorisation granted pursuant to this Article shall be required to complete ongoing studies, or to conduct new studies ***in accordance with Article 20***, with a view to confirming ***the safety and efficacy of the medicinal product. The Agency shall make relevant deadlines and criteria for ongoing and new studies publicly available***.

Or. en

Amendment 202
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Article 19 – paragraph 6

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

two years thereafter.	two years thereafter. ***However, where the Commission terminates the recognition of a public health emergency in accordance with Article 23(2) of Regulation (EU) 2022/2371, the marketing authorisation holder shall pursue a marketing authorisation in accordance with Article 5 of this Regulation.***

Or. en

Amendment 203
Francesca Donato

Proposal for a regulation
Article 19 – paragraph 8 a (new)

Text proposed by the Commission	*Amendment*
	8 a. the benefit-risk assessment should be reassessed every two months on the basis of new available data on the safety and efficacy of the product, on the possible lethal effects of the disease, including when treated, and on the availability of therapeutic solutions to treat it.

Or. en

Amendment 204
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Article 19 a (new)

Text proposed by the Commission	*Amendment*
	Article19a
	Revocation of conditional marketing authorisation
	The Commission may in justified cases revoke the conditional marketing authorisation that was granted in accordance with Article 19 where the

	benefit of the immediate availability of the medicinal product on the Union market no longer outweighs the risk due to missing confirming data or noncompliance with the obligations set out in Article 19.

Or. en

Amendment 205
Francesca Donato

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

Text proposed by the Commission	*Amendment*
After the granting of a marketing authorisation, the Agency ***may consider that it is necessary that the marketing authorisation*** holder:	After the granting of a marketing authorisation, the Agency ***shall require the*** holder ***of the agency to***:

Or. en

Amendment 206
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Article 20 – paragraph 1 – subparagraph 2

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

Or. en

Amendment 207
Francesca Donato

Proposal for a regulation
Article 20 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3 a. The competent authorities of the Member States may withdraw the authorisation for placing on the market the presence of statistically relevant evidence of adverse reactions and serious side effects and shall reserve the same possibility of withdrawal until the labelling and package leaflet of the medicinal product concerned has been updated with those serious side effects

Or. en

Amendment 208
Francesca Donato

Proposal for a regulation
Article 21

Text proposed by the Commission	*Amendment*
Article 21	***deleted***
Post authorisation efficacy studies	
The Commission is empowered to adopt delegated acts in accordance with Article 175, to supplement this Regulation by determining the situations in which post-authorisation efficacy studies may be required under Article 12(4), point (g), and Article 20(1), point (b).	

Or. en

Amendment 209
Andreas Glück

Proposal for a regulation
Article 23 – paragraph 1

Text proposed by the Commission	*Amendment*

The granting of a marketing authorisation shall not affect the civil or criminal liability of the manufacturer or of the marketing authorisation holder pursuant to the applicable national law in Member States.	The granting of a ***marketing authorisation as well as the granting of a temporary emergency*** marketing authorisation shall not affect the civil or criminal liability of the manufacturer or of the marketing authorisation holder pursuant to the applicable national law in Member States.

Or. en

Justification

The experience during the COVID-19 Pandemic has shown that there should not be any doubts about the liability of marketing authorisation holders.

Amendment 210
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Article 24 – paragraph 1 – subparagraph 2 – point f

Text proposed by the Commission	*Amendment*
(f) a serious risk to the environment or to public health via the environment has been identified and not sufficiently addressed by the marketing authorisation holder.	(f) a serious risk to the environment or to public health via the environment has been identified and not sufficiently addressed by the marketing authorisation holder***; in such cases, the Agency shall immediately inform the Commission who is to be responsible for informing the relevant national and Union authorities***.

Or. en

Amendment 211
Susana Solís Pérez, Klemen Grošelj

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

Text proposed by the Commission	*Amendment*
	(f a) a decision driven by commercial considerations, while safeguarding any information that is of a commercially confidential nature.

Or. en

Amendment 212
Laura Ballarín Cereza, Nicolás González Casares

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

Text proposed by the Commission	*Amendment*
	(f a) commercial considerations

Or. en

Amendment 213
Pilar del Castillo Vera

Proposal for a regulation
Article 24 – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
Where the action referred to in the first subparagraph is to withdraw a medicinal product from the market, the marketing authorisation holder shall provide information on the impact of such withdrawal on patients who are already being treated.	Where the action referred to in the first subparagraph is to withdraw a medicinal product ***with no alternative therapeutic equivalent*** from the market, the marketing authorisation holder shall provide information on the impact of such withdrawal on patients who are already being treated.

Or. en

Amendment 214
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Article 24 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Where the marketing authorisation holder intends to permanently withdraw the marketing authorisation for a critical medicinal product, the marketing	4. Where the marketing authorisation holder intends to permanently withdraw the marketing authorisation for a critical medicinal product, the marketing

authorisation holder shall, prior to the notification referred to in paragraph 1, offer, on reasonable terms, to transfer the marketing authorisation to a third party that has declared its intention to place that critical medicinal product on the market, or to use the pharmaceutical non-clinical and clinical documentation contained in the file of the medicinal product for the purposes of submitting an application in accordance with Article 14 of [revised Directive 2001/83/EC].	authorisation holder shall, prior to the notification referred to in paragraph 1, offer, on reasonable terms, to transfer the marketing authorisation to a third party that has declared its intention to place that critical medicinal product on the market, or to use the pharmaceutical non-clinical and clinical documentation contained in the file of the medicinal product for the purposes of submitting an application in accordance with Article 14 of [revised Directive 2001/83/EC]. ***When a marketing authorization is transferred to a new holder, said change shall be reported to the Agency within a 30-day timeframe and include the financial details of the transaction between the transferring parties. This information is then to be made accessible to the public by the Agency.***

Or. en

Amendment 215
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Article 25 – paragraph 1 – subparagraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) if one of its indications ***or*** pharmaceutical forms is protected by a patent or a supplementary protection certificate in one or more Member States;	(a) if one of its indications***, posologies,*** pharmaceutical forms***, methods or routes of administration or any other element*** is protected by a patent or a supplementary protection certificate in one or more Member States;

Or. en

Amendment 216
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Article 25 – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
As soon as the relevant patent or supplementary protection certificate referred to in point (a) expires, the marketing authorisation holder shall withdraw the initial or duplicate marketing authorisation.	As soon as the relevant patent or supplementary protection certificate referred to in point (a) expires, the marketing authorisation holder shall withdraw the initial or duplicate marketing authorisation ***or where appropriate vary the term of the marketing authorisation to include the relevant SmPC information for which the corresponding patent(s) or supplementary protection certificate(s) has(ve) expired***.

Or. en

Amendment 217
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Article 26 – paragraph 3

Text proposed by the Commission	*Amendment*
3. When applying paragraph 1, the Member State shall notify the Agency.	3. When applying paragraph 1, the Member State shall notify the Agency***, which shall make the notification publicly available***.

Or. en

Amendment 218
Pernille Weiss

Proposal for a regulation
Article 26 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
When compassionate use is envisaged by a Member State, the Committee for Medicinal Products for Human Use, after consulting the manufacturer or the applicant, may adopt opinions on the conditions for use, the conditions for distribution and the patients targeted. The	When compassionate use is envisaged by a Member State***, or by the applicant or sponsor***, the Committee for Medicinal Products for Human Use, after consulting the manufacturer or the applicant, may adopt opinions on the conditions for use, the conditions for distribution and the

opinions shall be updated where necessary.	patients targeted. The opinions shall be updated where necessary.

Or. en

Amendment 219
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Article 26 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Agency shall keep an up-to-date list of the opinions adopted in accordance with paragraph 4 and shall publish it on its website.	6. The Agency shall keep an up-to-date list of the opinions adopted in accordance with paragraph 4 and shall publish it ***in a centralized database for compassionate use programs*** on its website.

Or. en

Amendment 220
Pernille Weiss

Proposal for a regulation
Article 26 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Agency shall keep an up-to-date list of the opinions adopted in accordance with paragraph 4 and shall publish it on its website.	6. The Agency shall keep an up-to-date list of the opinions adopted in accordance with paragraph 4 and shall publish it on its website ***in an accessible, searchable data format***.

Or. en

Amendment 221
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Article 29 – paragraph 1

Text proposed by the Commission	*Amendment*
Without prejudice to the law on the protection of industrial and commercial property, medicinal products for human use which have been authorised in accordance with this Regulation shall benefit from the periods of regulatory protection set out in Chapter VII of [revised Directive 2001/83/EC].	Without prejudice to the law on the protection of industrial and commercial property, medicinal products for human use which have been authorised in accordance with this Regulation shall benefit from the periods of regulatory protection set out in Chapter VII of [revised Directive 2001/83/EC]. ***The granting of periods of regulatory protection shall be published and updated where appropriate by the Agency in a designated registry.***

Or. en

Amendment 222
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

Proposal for a regulation
Article 30 – paragraph 1

Text proposed by the Commission	*Amendment*
During a public health emergency, the Commission may grant a temporary emergency marketing authorisation ('TEMA') for medicinal products intended for the treatment, prevention or medical diagnosis of a serious or ***life-threatening*** disease or condition which are directly related to the public health emergency, prior to the submission of the complete quality, non-clinical, clinical data and environmental data and information.	During a public health emergency, the Commission may grant a temporary emergency marketing authorisation ('TEMA') ***or a new temporary emergency therapeutic indication, including when grouped with an extension of an existing marketing authorisation under this Regulation,*** for medicinal products intended for the treatment, prevention or medical diagnosis of a serious or ***life-threatening*** disease or condition which are directly related to the public health emergency, prior to the submission of the complete quality, non-clinical, clinical data and environmental data and information.

Or. en

Amendment 223
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

Proposal for a regulation
Article 31 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
A temporary emergency marketing authorisation may be granted only after the recognition of a public health emergency at Union level in accordance with Article 23 of Regulation (EU) 2022/2371 of the European Parliament and of the ***Council***[67] and where the following requirements are met:	A temporary emergency marketing authorisation ***or a temporary emergency therapeutic indication, including when grouped with an extension of the marketing authorisation,*** may be granted only after the recognition of a public health emergency at Union level in accordance with Article 23 of Regulation (EU) 2022/2371 of the European Parliament and of the ***Council67*** and where the following requirements are met:

[67] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26).

Or. en

Amendment 224
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

Proposal for a regulation
Article 31 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) there is no other satisfactory method of treatment, prevention or diagnosis authorised or sufficiently available in the Union or, if such method is already available, the temporary emergency marketing authorisation of the medicinal product will contribute to address the public health emergency;	(a) there is no other satisfactory method of treatment, prevention or diagnosis authorised or sufficiently available in the Union or, if such method is already available, the temporary emergency marketing authorisation ***or temporary emergency therapeutic indication*** of the medicinal product***, including when grouped with an extension of the marketing authorisation,*** will contribute to address the public health emergency;

Or. en

Amendment 225
Francesca Donato

Proposal for a regulation
Article 31 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) there is no other satisfactory method of treatment, prevention or diagnosis authorised or sufficiently available in the Union or, if such method is already available***, the temporary emergency marketing authorisation of the medicinal product will contribute to address the public health emergency***;	(a) there is no other satisfactory method of treatment, prevention or diagnosis authorised or sufficiently available in the Union or, if such method is already available;

Or. en

Amendment 226
Francesca Donato

Proposal for a regulation
Article 31 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) based on the scientific evidence available, the Agency issues an opinion concluding that the medicinal product could be effective in treating, preventing or diagnosing the disease or condition directly related to the public health emergency, and the known ***and potential*** benefits of the product outweigh the known and potential risks of the product, taking into consideration the threat posed by the public health emergency.	(b) based on the scientific evidence available, the Agency issues an opinion concluding that the medicinal product could be effective in treating, preventing or diagnosing the disease or condition directly related to the public health emergency, and the known benefits of the product outweigh the known and potential risks of the product, taking into consideration the threat posed by the public health emergency.

Or. en

Amendment 227

Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Article 32 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency shall transmit without undue delay to the Commission the scientific opinion and its updates and any recommendations on the temporary emergency marketing authorisation.	3. The Agency shall transmit without undue delay to the Commission the scientific opinion and its updates and any recommendations on the temporary emergency marketing authorisation ***or temporary emergency therapeutic indication, including when grouped with an extension of the marketing authorisation***.

Or. en

Amendment 228
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

Proposal for a regulation
Article 33 – paragraph 2

Text proposed by the Commission	*Amendment*
2. On the basis of the scientific opinion of the Agency referred to in paragraph 1, the Commission shall set specific conditions with respect to the temporary emergency marketing authorisation, in particular the conditions for manufacturing, use, supply and safety monitoring and the compliance with related good manufacturing, and pharmacovigilance practices. If necessary, the conditions may specify the batches of the medicinal product concerned by the temporary emergency marketing authorisation.	2. On the basis of the scientific opinion of the Agency referred to in paragraph 1, the Commission shall set specific conditions with respect to the temporary emergency marketing authorisation, in particular the conditions for manufacturing, use, supply and safety monitoring and the compliance with related good manufacturing, and pharmacovigilance practices. If necessary, the conditions may specify the batches of the medicinal product concerned by the temporary emergency marketing authorisation***, after consultation with the applicant or marketing authorisation holder***.

Or. en

Amendment 229
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

Proposal for a regulation
Article 33 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Those specific conditions and, where appropriate, the time limit for compliance shall be specified in the conditions to the marketing authorisation and shall be reviewed annually by the Agency.	4. Those specific conditions and, where appropriate, the time limit for compliance shall be specified in the conditions to the marketing authorisation and shall be reviewed annually by the Agency***, in consultation with the applicant or marketing authorisation holder***.

Or. en

Amendment 230
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

Proposal for a regulation
Article 34 – paragraph 1

Text proposed by the Commission	*Amendment*
The temporary emergency marketing authorisation shall cease to be valid when the Commission terminates the recognition of a public health emergency in accordance with Article 23(2) and (4) of Regulation (EU) 2022/2371.	The temporary emergency marketing authorisation ***or temporary emergency therapeutic indication, including when grouped with an extension of the marketing authorisation,*** shall cease to be valid when the Commission terminates the recognition of a public health emergency in accordance with Article 23(2) and (4) of Regulation (EU) 2022/2371.

Or. en

Amendment 231
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

Proposal for a regulation
Article 34 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*

When the temporary emergency marketing authorisation or temporary emergency therapeutic indication, including when grouped with an extension of the marketing authorisation, ceases to be valid in accordance with paragraph 1 of this Article, to avoid any disruption in supply of the medicinal product concerned, the Agency may set a transitional period after consultation with the marketing authorisation holder.

Or. en

Amendment 232
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

Proposal for a regulation
Article 35 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	Where the Commission adopts any such implementing act, the provisions of Article 34, paragraph 1a shall apply.

Or. en

Amendment 233
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

Proposal for a regulation
Article 36 – paragraph 2

Text proposed by the Commission	*Amendment*
For the purpose of regulatory data protection, the temporary emergency marketing authorisation and any subsequent marketing authorisation, as referred to in subparagraph 1, shall be considered as part of the same global marketing authorisation.	For the purpose of regulatory data protection, the temporary emergency marketing authorisation ***or temporary emergency therapeutic indication, including when grouped with an extension of the marketing authorisation,*** and any subsequent marketing authorisation, as referred to in subparagraph 1, shall be considered as part of the same global marketing authorisation.

Or. en

Amendment 234
Francesca Donato

Proposal for a regulation
Article 37

Text proposed by the Commission	*Amendment*
Article 37	***deleted***
Transitional period	
When the temporary marketing authorisation of a medicinal product is suspended or revoked for reasons other than the safety of the medicinal product, or if that temporary emergency marketing authorisation ceases to be valid, Member States may, in exceptional circumstances, allow for a transitional period, the supply of the medicinal product to patients who are already being treated with it.	

Or. en

Amendment 235
Francesca Donato

Proposal for a regulation
Article 39

Text proposed by the Commission	*Amendment*
Article 39	***deleted***
Withdrawal of authorisations granted in accordance with Article 3(2) of [revised Directive 2001/83/EC]	
When the Commission has granted a temporary emergency marketing authorisation in accordance with Article 33, Member States shall withdraw any authorisation granted in accordance with Article 3(2) of [revised Directive 2001/83/EC] for the use of medicinal products containing the same active	

substance for any indications that are subject to the temporary marketing authorisation.

Or. en

Amendment 236
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Chapter III – title

Text proposed by the Commission	*Amendment*
III ***INCENTIVES FOR THE DEVELOPMENT OF 'PRIORITY ANTIMICROBIALS'***	III ***deleted***

Or. en

Amendment 237
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 40

Text proposed by the Commission	*Amendment*
Article 40	***deleted***
Granting the right to a transferable data exclusivity voucher	
1. Following a request by the applicant when applying for a marketing authorisation, the Commission may, by means of implementing acts, grant a transferable data exclusivity voucher to a 'priority antimicrobial' referred to in paragraph 3, under the conditions referred to in paragraph 4 based on a scientific assessment by the Agency.	
2. The voucher referred to in paragraph 1 shall give the right to its holder to an additional 12 months of data protection	

for one authorised medicinal product.

3.

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

(a) it represents a new class of antimicrobials;

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

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

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

4.

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

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

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

Within 30 days after the marketing authorisation is granted, the marketing authorisation holder shall make the information referred to in point (b) accessible to the public via a dedicated webpage and shall communicate, in a timely manner the electronic link to that webpage to the Agency.

Or. en

Amendment 238
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Article 40

Text proposed by the Commission	*Amendment*
Article 40	***deleted***
Granting the right to a transferable data exclusivity voucher	
1. Following a request by the applicant when applying for a marketing authorisation, the Commission may, by means of implementing acts, grant a transferable data exclusivity voucher to a 'priority antimicrobial' referred to in paragraph 3, under the conditions referred to in paragraph 4 based on a scientific assessment by the Agency.	
2. The voucher referred to in paragraph 1 shall give the right to its holder to an additional 12 months of data protection for one authorised medicinal product.	
3.	
An antimicrobial shall be considered 'priority antimicrobial' if preclinical and clinical data underpin a significant clinical benefit with respect to antimicrobial resistance and it has at least one of the following characteristics:	
(a) it represents a new class of antimicrobials;	
(b) its mechanism of action is distinctly different from that of any authorised antimicrobial in the Union;	
(c) it contains an active substance not previously authorised in a medicinal product in the Union that addresses a multi-drug resistant organism and serious or life threatening infection.	
In the scientific assessment of the criteria	

referred to in the first subparagraph, and in the case of antibiotics, the Agency shall take into account the 'WHO priority pathogens list for R&D of new antibiotics', or an equivalent list established at Union level.

4.

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

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

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

Within 30 days after the marketing authorisation is granted, the marketing authorisation holder shall make the information referred to in point (b) accessible to the public via a dedicated webpage and shall communicate, in a timely manner the electronic link to that webpage to the Agency.

Or. en

Amendment 239
Massimiliano Salini, Aldo Patriciello

Proposal for a regulation
Article 40 – paragraph 1

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

assessment by the Agency ***or alternatively incentives already implemented in other domains such as rare diseases***.

Or. en

Amendment 240
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a regulation
Article 40 – paragraph 1

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

Or. en

Amendment 241
Pilar del Castillo Vera

Proposal for a regulation
Article 40 – paragraph 1

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

assessment by the Agency.

Or. en

Amendment 242
Pernille Weiss

Proposal for a regulation
Article 40 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The voucher referred to in paragraph 1 shall give the right to its holder to an additional ***12 months*** of data protection for one authorised medicinal product.	2. The voucher referred to in paragraph 1 shall give the right to its holder to an additional ***period*** of data protection for one authorised medicinal product ***as set out according to paragraph 3 of this Article***.

Or. en

Amendment 243
Pilar del Castillo Vera

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

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

Or. en

Amendment 244
Pernille Weiss

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

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

Or. en

Amendment 245
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

Text proposed by the Commission	*Amendment*
An antimicrobial shall be considered ‘priority antimicrobial’ if preclinical and clinical data underpin a significant ***clinical benefit with respect to antimicrobial resistance and it has at least one of the following characteristics:***	An antimicrobial shall be considered ‘priority antimicrobial’ if preclinical and clinical data underpin a significant ***through advances in current antibiotics or through new emerging mechanisms of action.***

Or. en

Amendment 246
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

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

Or. en

Amendment 247

Pernille Weiss

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

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

Or. en

Amendment 248
Pilar del Castillo Vera

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

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

Or. en

Amendment 249
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

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

Or. en

Amendment 250
Pilar del Castillo Vera

Proposal for a regulation

Article 40 – paragraph 3 – subparagraph 1 – point b

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

Or. en

Amendment 251
Pernille Weiss

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

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

Or. en

Amendment 252
Pernille Weiss

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

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

Or. en

Amendment 253
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

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

Or. en

Amendment 254
Pilar del Castillo Vera

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

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

Or. en

Amendment 255
Pernille Weiss

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

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

	pharmacological benefits, including novelty of the product.

Or. en

Amendment 256
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

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

Or. en

Amendment 257
Pilar del Castillo Vera

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

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

Or. en

Amendment 258
Pernille Weiss

Proposal for a regulation
Article 40 – paragraph 3 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	The Agency shall develop a weighting of each criteria and a corresponding scoring system allowing priority antimicrobials to be designated one of three categories of vouchers according to its expected impact on combatting antimicrobial resistance. The agency shall assign each voucher category a corresponding financial value which will be payed to the applicant following the auction process set out in Article 41.

Or. en

Amendment 259
Andreas Glück

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

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

Or. en

Justification

Only demonstrating capacity is not enough. Supply of the new antimicrobial should be ensured within the limits of the applicant.

Amendment 260
Pilar del Castillo Vera

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

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

Or. en

Amendment 261
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
(b) provide information on all direct financial support received for research related to the development of the priority antimicrobial.	(b) provide information on all direct ***EU*** financial support received for research related to the development of the priority antimicrobial.

Or. en

Amendment 262
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Article 40 a (new)

Text proposed by the Commission	*Amendment*
	Article 40a
	Push and pull incentives scheme to boost the development of priority antimicrobials
	1. The Commission shall establish a Union push and pull incentives scheme to promote and urgently accelerate the development of priority antimicrobials. Member States shall be encouraged to participate in the Union level scheme.
	2. An antimicrobial shall be considered 'priority antimicrobial' if preclinical and

clinical data underpin a significant clinical benefit with respect to antimicrobial resistance and it has at least one of the following characteristics:

(a) it represents a new class of antimicrobials;

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

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

In the scientific assessment of the criteria referred to in the first subparagraph, and in the case of antibiotics, the Agency shall take into account the 'WHO priority pathogens list for R&D of new antibiotics', specifically those listed as priority 1 (critical) or priority 2 (high), or an equivalent list established at Union level

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

(a) research grants under Union fund with conditionalities linked to the affordability and supply of new and existing antimicrobials;

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

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

(d) an annual revenue guarantee scheme, aimed at securing access to antibiotics in line with the 2021 Health Council

Conclusions.

4. The Union push and pull incentives scheme shall be coordinated and managed by the Commission. provide information on all direct financial support received for research related to the development of the priority antimicrobial.

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

5. By ... [six years after the date of entry into force of this Regulation], the Commission shall present a report to the European Parliament and to the Council reviewing the application of the scheme laid down in this Article.

Or. en

Amendment 263
Nicola Danti, Susana Solís Pérez

Proposal for a regulation
Article 40 a (new)

Text proposed by the Commission	*Amendment*
	Article 40a
	Procedure for AMR designation
	1 An antimicrobial medicinal product developed to address priority pathogens shall be granted an AMR designation where the antimicrobial medicinal sponsor can demonstrate that the following requirements are met:
	a) the product is intended for the diagnosis, prevention or treatment of a pathogen included in the 'WHO priority pathogens list for R&D of new antibiotics', or an equivalent list established at Union level;
	b) there exists no satisfactory method of diagnosis, prevention or treatment of the

condition in question that has been authorised in the Union or, where such method exists, that the medicinal product would be of significant benefit to those affected by that condition.

2. The antimicrobial medicinal product sponsor shall submit an application for the designation of the orphan medicinal product to the Agency at any stage of the development of the medicinal product before the application for marketing authorisation referred to in Articles 5 and 6 is submitted.

3. The application of the antimicrobial medicinal sponsor shall be accompanied by the following particulars and documentation:

a) name or corporate name and permanent address of the sponsor;

b) active substances of the medicinal product;

c) proposed condition for which it is intended or the proposed therapeutic indication;

d) justification that the criteria laid down in paragraph 1 of this Article are met, and a description of the stage of development, including the expected therapeutic indication.

4. The Agency shall adopt a decision granting or refusing the orphan designation based on the criteria referred to in paragraph 1 of this Article within 90 days of the receipt of a valid application.

5. Designated antimicrobial medicinal products shall be considered as addressing an unmet medical need as referred to in Article 83 of [Proposal for a Directive on the Union code relating to medicinal products for human use].

Or. en

Justification

It is proposed to introduce a designation for products aimed at combating antimicrobial

resistance, mirroring the procedure for orphan designation foreseen by the Commission proposal.

Amendment 264
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Article 40 a (new)

Text proposed by the Commission	*Amendment*
	Article40a
	Push and pull incentives scheme to boost the development of priority antimicrobials
	1. The Commission shall establish a Union push and pull incentives scheme to promote and urgently accelerate the development of novel antimicrobials, as well as promote increased access to existing and newly developed antimicrobials. Member States shall be encouraged to participate in the Union level scheme.
	2. The Commission is empowered to adopt delegated acts in accordance with Article 175 to supplement this Regulation by further defining the scheme and its funding, which shall include i.a. the following incentives:
	(a) research grants under Union funds;
	(b) milestone prizes for novel antimicrobial developers;
	(c) voluntary joint procurement with subscription payment mechanisms or market entry rewards that delink or partially delink revenues and sales;
	3. The Union push and pull incentives scheme shall be coordinated and managed by the Commission.
	4. By ... [one year after the date of entry into force of this Regulation], the Commission shall have developed, and commenced the implementation of the Union push and pull incentives scheme.

5. By ... [7 years after the date of entry into force of this Regulation], the Commission shall present a report to the European Parliament and to the Council reviewing the application of the scheme laid down in this Article.

Or. en

Amendment 265
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Article 41

Text proposed by the Commission	*Amendment*
Article 41	***deleted***
Transfer and use of the voucher	
1.	
A voucher may be used to extend the data protection for a period of 12 months of the priority antimicrobial or another medicinal product authorised in accordance with this Regulation of the same or different marketing authorisation holder.	
A voucher shall only be used once and in relation to a single centrally authorised medicinal product and only if that product is within its first four years of regulatory data protection.	
A voucher may only be used if the marketing authorisation of the priority antimicrobial for which the right was initially granted has not been withdrawn.	
2. To use the voucher, its owner shall apply for a variation of the marketing authorisation concerned in accordance with Article 47 to extend the data protection.	
3. A voucher may be transferred to another marketing authorisation holder and shall not be transferred further.	

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

Or. en

Amendment 266
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 41

Text proposed by the Commission	*Amendment*
Article 41	***deleted***
Transfer and use of the voucher	
1.	
A voucher may be used to extend the data protection for a period of 12 months of the priority antimicrobial or another medicinal product authorised in accordance with this Regulation of the same or different marketing authorisation holder.	
A voucher shall only be used once and in relation to a single centrally authorised medicinal product and only if that product is within its first four years of regulatory data protection.	
A voucher may only be used if the marketing authorisation of the priority antimicrobial for which the right was initially granted has not been withdrawn.	
2. To use the voucher, its owner shall apply for a variation of the marketing authorisation concerned in accordance with Article 47 to extend the data protection.	
3. A voucher may be transferred to another marketing authorisation holder	

and shall not be transferred further.

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

Or. en

Amendment 267
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
A voucher may be used to extend the data protection ***for a period of 12 months of the priority antimicrobial or another*** medicinal product authorised in accordance with this Regulation of the ***same or different marketing authorisation holder***.	A ***voucher granted by the Commission shall be subject to a public auction by the Agency. The financial value to be payed to the applicant by the winner of the auction is predetermined by the voucher category as set out in Article 40. Thus, those wishing to participate in the auction shall bid for the shortest data protection extension for which they are willing to pay the financial amount of the voucher category to the applicant. The*** voucher may be used to extend the data protection ***of a*** medicinal product authorised in accordance with this Regulation ***for the period*** of the ***winning bid***.

Or. en

Amendment 268
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
A voucher shall only be used once and in relation to a single centrally authorised	A voucher shall only be used once and in relation to a single centrally authorised

medicinal product and only if ***that product is within its first four*** years of regulatory data protection.	medicinal product and only if ***at least two*** years of regulatory data protection ***is remaining for that product***.

Or. en

Amendment 269
Pernille Weiss

Proposal for a regulation
Article 41 – paragraph 3

Text proposed by the Commission	*Amendment*
3. ***A*** voucher ***may be transferred to another marketing authorisation holder and*** shall not be transferred further.	3. ***When an auction is completed, and the*** voucher ***has been transfered to the auction winner, the voucher*** shall not be transferred further.

Or. en

Amendment 270
Pernille Weiss

Proposal for a regulation
Article 41 – paragraph 4

Text proposed by the Commission	*Amendment*
4. ***A marketing authorisation holder to whom a voucher is transferred shall notify the Agency of the transfer within 30 days, stating the value of the transaction between the two parties.*** The Agency shall make ***this*** information publicly available.	4. The Agency shall make information ***regarding the voucher category value and the lenght of data exclusivity extension of the winning bid*** publicly available.

Or. en

Amendment 271
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Article 42

Text proposed by the Commission	*Amendment*
Article 42	***deleted***
Validity of the voucher	
1. A voucher shall cease to be valid in the following cases:	
(a) where the Commission adopts a decision in accordance with Article 47 to extend the data protection of the receiving medicinal product;	
(b) where it is not used within 5 years from the date it was granted.	
2. The Commission may revoke the voucher prior to its transfer as referred to in Article 41(3) if a request for supply, procurement or purchase of the priority antimicrobial in the Union has not been fulfilled.	
3. Without prejudice to patent rights, or supplementary protection certificates[69] , if a priority antimicrobial is withdrawn from the Union market prior to expiry of the periods of market and data protection laid down in Articles 80 and 81 of [revised Directive 2001/83/EC], those periods shall not prevent the validation, authorisation and placing on the market of a medicinal product using the priority antimicrobial as a reference medicinal product in accordance with Chapter II, Section 2 of [revised Directive 2001/83].	
[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council, (OJ L 152, 16.6.2009, p. 1).	

Or. en

Amendment 272
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 42

Text proposed by the Commission	*Amendment*
Article 42	***deleted***
Validity of the voucher	
1. A voucher shall cease to be valid in the following cases:	
(a) where the Commission adopts a decision in accordance with Article 47 to extend the data protection of the receiving medicinal product;	
(b) where it is not used within 5 years from the date it was granted.	
2. The Commission may revoke the voucher prior to its transfer as referred to in Article 41(3) if a request for supply, procurement or purchase of the priority antimicrobial in the Union has not been fulfilled.	
3. Without prejudice to patent rights, or supplementary protection certificates[69] , if a priority antimicrobial is withdrawn from the Union market prior to expiry of the periods of market and data protection laid down in Articles 80 and 81 of [revised Directive 2001/83/EC], those periods shall not prevent the validation, authorisation and placing on the market of a medicinal product using the priority antimicrobial as a reference medicinal product in accordance with Chapter II, Section 2 of [revised Directive 2001/83].	
[69] Regulation (EC) No 469/2009 of the European Parliament and of the Council, (OJ L 152, 16.6.2009, p. 1).	

Or. en

Amendment 273
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 43

Text proposed by the Commission	*Amendment*
Article 43	***deleted***
Duration of application of Chapter III	
This Chapter shall apply until [Note to OP: insert the date of 15 years after the date of entry into force of this Regulation] or until the date when the Commission has granted a total of 10 vouchers in accordance with this Chapter, whichever date is the earliest.	

Or. en

Amendment 274
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Article 43 – paragraph 1

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

Or. en

Amendment 275
Pilar del Castillo Vera

Proposal for a regulation
Article 43 – paragraph 1

Text proposed by the Commission	*Amendment*
This Chapter shall apply ***until [Note to OP: insert the date of*** 15 years after the date of entry into force of this Regulation***] or until the date*** when the Commission has granted	This Chapter shall apply ***from the entry into force of this Regulation.*** 15 years after the date of entry into force of this Regulation***, or*** when the Commission has

a total of 10 vouchers in accordance with this Chapter, whichever date is the earliest.	granted a total of 10 vouchers in accordance with this Chapter, whichever date is the earliest***, the Commission shall submit a report to the European Parliament and to the Council containing a scientific assessment measuring progress towards sustainable antimicrobial research and development and according to future medical needs***.

Or. en

Amendment 276
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a regulation
Article 43 – paragraph 1

Text proposed by the Commission	*Amendment*
This Chapter shall apply ***until [Note to OP: insert the date of 15 years after the date of*** entry into force of this Regulation***] or until the date*** when the Commission has granted a total of 10 vouchers in accordance with this Chapter, whichever date is the earliest.	This Chapter shall apply ***from the*** entry into force of this Regulation***. 15 years or*** when the Commission has granted a total of 10 vouchers in accordance with this Chapter, whichever date is the earliest***, the Commission shall submit a report to the European Parliament and to the Council containing a scientific assessment measuring progress towards sustainable antimicrobial research and development and according to future medical needs***.

Or. en

Amendment 277
Pernille Weiss

Proposal for a regulation
Article 43 – paragraph 1

Text proposed by the Commission	*Amendment*
This Chapter shall ***apply until*** [Note to OP: insert the date of 15 years after the date of entry into force of this Regulation] or until	This Chapter shall ***be subject to a review by the Commission by*** [Note to OP: insert the date of 15 years after the date of entry

the date when the Commission has granted a total of 10 vouchers in accordance with this Chapter, whichever date is the earliest.	into force of this Regulation] or until the date when the Commission has granted a total of 10 vouchers in accordance with this Chapter, whichever date is the earliest.

Or. en

Amendment 278
Susana Solís Pérez

Proposal for a regulation
Article 48 – paragraph 1 – subparagraph 1

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

Or. en

Amendment 279
Susana Solís Pérez

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

Text proposed by the Commission	*Amendment*
The Agency may, at the request of a Member State, the Commission, or on its own initiative and on the basis of all available evidence make a scientific evaluation of the benefit-risk of the use of a medicinal product with a new therapeutic indication ***that concerns an unmet medical need***.	The Agency may, at the request of a Member State, the Commission, or on its own initiative and on the basis of all available evidence make a scientific evaluation of the benefit-risk of the use of a medicinal product with a new therapeutic indication.

Or. en

Amendment 280
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Article 48 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Article 81(2), point (c) of [revised Directive 2001/83/EC] ***shall not*** apply for variations under this Article.	3. Article 81(2), point (c) of [revised Directive 2001/83/EC] ***may*** apply for variations under this Article.

Or. en

Amendment 281
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

Proposal for a regulation
Article 56 – paragraph 1

Text proposed by the Commission	*Amendment*
Where the Agency concludes that a holder of a marketing authorisation granted in accordance with Article 19, including a new therapeutic indication granted referred to Article 19, failed to comply with the obligations laid down in the marketing authorisation, the Agency shall inform the Commission accordingly.	Where the Agency concludes that a holder of a marketing authorisation***, or a new therapeutic indication, including when grouped with an extension of the marketing authorisation,*** granted in accordance with Article 19, including a new therapeutic indication granted referred to Article 19, failed to comply with the obligations laid down in the marketing authorisation, the Agency shall inform the Commission accordingly.

Or. en

Amendment 282
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

Proposal for a regulation
Article 58 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
Such advice can also be requested for medicinal products referred to in Articles	Such advice can also be requested for medicinal products referred to in Articles

83 and 84 of [revised Directive 2001/83/EC].	83 and 84 of [revised Directive 2001/83/EC] ***and for medicinal products used with an in vitro diagnostic medical device***.

Or. en

Amendment 283
Susana Solís Pérez, Klemen Grošelj

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

Text proposed by the Commission	*Amendment*
	4 a. Disclosed conflicts of interest and the mitigating actions implemented by the concerned individual(s) must be documented in the abridged minutes of the meetings, following the stipulations of Article 147(2).

Or. en

Amendment 284
Susana Solís Pérez, Klemen Grošelj

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

Text proposed by the Commission	*Amendment*
	4 b. When granting scientific advice, the Agency shall ensure to the greatest extent possible that there is a separation between those responsible for providing scientific advice to a medicine developer and those subsequently involved in evaluating a marketing authorisation application for the same medicinal product. The Agency shall ensure that at least one of the two rapporteurs for a marketing authorisation application should not have taken part in any pre-submission activities concerning the medicinal product. The reasons for any

exceptions shall be documented and published with the European Public Assessment Report.

Or. en

Amendment 285
Pernille Weiss

Proposal for a regulation
Article 60 – paragraph 1 – introductory part

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

Or. en

Amendment 286
Susana Solís Pérez, Nicola Danti

Proposal for a regulation
Article 60 – paragraph 1 – introductory part

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

Or. en

Amendment 287
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

Proposal for a regulation
Article 60 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) are likely to address an unmet medical need as referred to in Article 83(1) of [revised Directive 2001/83/EC];	(a) are likely to address an unmet medical need as referred to in Article 83(1) ***and 83(2)*** of [revised Directive 2001/83/EC];

Or. en

Amendment 288
Josianne Cutajar

Proposal for a regulation
Article 60 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) are orphan medicinal products ***and are likely to address a high unmet medical need as referred to in Article 70(1)***;	(b) are orphan medicinal products;

Or. en

Amendment 289
Pernille Weiss

Proposal for a regulation
Article 60 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) are orphan medicinal products ***and are likely to address a high unmet medical need as referred to in Article 70(1)***;	(b) are orphan medicinal products ***or advanced therapy medicinal products***;

Or. en

Amendment 290
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Article 60 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) are orphan medicinal products ***and are likely to address a high unmet medical need as referred to in Article 70(1);***	(b) are ***innovative advanced therapy medicinal products or*** orphan medicinal products

Or. en

Amendment 291
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

Proposal for a regulation
Article 60 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) are expected to be of major interest from the point of view of public health, in particular as regards therapeutic innovation, taking into account the early stage of development, or antimicrobials with any of the characteristics mentioned in Article 40(3).	(c) ***provide an exceptional therapeutic advancement or*** are expected to be of major interest from the point of view of public health, in particular as regards therapeutic innovation, taking into account the early stage of development, or antimicrobials with any of the characteristics mentioned in Article 40(3).

Or. en

Amendment 292
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Article 60 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(c a) The Agency's working group on advanced therapy medicinal products is tasked with evaluating which products fulfill the criteria of innovative advanced therapy medicinal products as set out in

	point (b) of this article. The determinations made by the working group should take into account the progressive development inherent to advanced therapy medicinal products.

Or. en

Amendment 293
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Article 61 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
When forming the recommendation referred to in paragraph 1, the Agency shall consult, where appropriate, relevant advisory or regulatory bodies established in other Union legal acts in related fields. In the case of products which are based on substances of human origin, the Agency shall consult the Substances of Human Origin (SoHO) Coordination Board as established in Regulation (EU) No [reference to be added after adoption cf. COM(2022)338 final].	When forming the recommendation referred to in paragraph 1, the Agency shall consult, where appropriate, relevant advisory or regulatory bodies established in other Union legal acts in related fields. In the case of products which are based on substances of human origin, the Agency shall consult the Substances of Human Origin (SoHO) Coordination Board as established in Regulation (EU) No [reference to be added after adoption cf. COM(2022)338 final]***, and classify all products that are significantly manipulated or utilized in a non-homologous manner, as either a medicinal product or an advanced therapy medicinal product, whichever is applicable***.

Or. en

Amendment 294
Nicola Danti

Proposal for a regulation
Article 63 – paragraph 2

Text proposed by the Commission	*Amendment*
2. By way of derogation from	***deleted***

paragraph 1, point (a), and on the basis of a recommendation from the Agency, when the requirements specified in paragraph 1, point (a), are not appropriate due to the specific characteristics of certain conditions or any other scientific reasons, the Commission is empowered to adopt delegated acts in accordance with Article 175 in order to supplement paragraph 1, point (a), by setting specific criteria for certain conditions.

Or. en

Justification

It is important to ensure legal certainty for OMP sponsors, without giving the possibility to deviate from scientific criteria for orphan designation that have been applied so far.

Amendment 295
Massimiliano Salini, Aldo Patriciello

Proposal for a regulation
Article 63 – paragraph 2

Text proposed by the Commission	*Amendment*
2. By way of derogation from paragraph 1, point (a), and on the basis of a recommendation from the Agency, when the requirements specified in paragraph 1, point (a), are not appropriate due to the specific characteristics of certain conditions or any other scientific reasons, the Commission is empowered to adopt delegated acts in accordance with Article 175 in order to supplement paragraph 1, point (a), by setting specific criteria for certain conditions.	***deleted***

Or. en

Amendment 296
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a regulation
Article 63 – paragraph 2

Text proposed by the Commission	*Amendment*
2. By way of derogation from paragraph 1, point (a), and on the basis of a recommendation from the Agency, when the requirements specified in paragraph 1, point (a), are not appropriate due to the specific characteristics of certain conditions or any other scientific reasons, the Commission is empowered to adopt delegated acts in accordance with Article 175 in order to supplement paragraph 1, point (a), by setting specific criteria for certain conditions.	***deleted***

Or. en

Amendment 297
Pernille Weiss

Proposal for a regulation
Article 63 – paragraph 2

Text proposed by the Commission	*Amendment*
2. By way of derogation from paragraph 1, point (a), and on the basis of a recommendation from the Agency, when the requirements specified in paragraph 1, point (a), are not appropriate due to the specific characteristics of certain conditions or any other scientific reasons, the Commission is empowered to adopt delegated acts in accordance with Article 175 in order to supplement paragraph 1, point (a), by setting specific criteria for certain conditions.	***deleted***

Or. en

Justification

Deletion proposed to preserve the predictability of criteria for designation.

Amendment 298
Pernille Weiss

Proposal for a regulation
Article 63 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission shall adopt the necessary provisions for implementing this Article by means of implementing acts in accordance with the procedure laid down in Article 173(2) ***in order to further specify the requirements referred to in paragraph 1***.	3. The Commission shall adopt the necessary provisions for implementing this Article by means of implementing acts in accordance with the procedure laid down in Article 173(2).

Or. en

Justification

See amendment to Article 63 – paragraph 2.

Amendment 299
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a regulation
Article 64 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The orphan ***medicine*** sponsor shall submit an application for the designation of the orphan medicinal product to the Agency at any stage of the development of the medicinal product before the application for marketing authorisation referred to in Articles 5 and 6 is submitted.	1. The orphan ***medicinal product*** sponsor shall submit an application for the designation of the orphan medicinal product to the Agency at any stage of the development of the medicinal product before the application for marketing authorisation referred to in Articles 5 and 6 is submitted.

Or. en

Amendment 300
Massimiliano Salini, Aldo Patriciello

Proposal for a regulation
Article 64 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The orphan ***medicine*** sponsor shall submit an application for the designation of the orphan medicinal product to the Agency at any stage of the development of the medicinal product before the application for marketing authorisation referred to in Articles 5 and 6 is submitted.	1. The orphan ***medicinal product*** sponsor shall submit an application for the designation of the orphan medicinal product to the Agency at any stage of the development of the medicinal product before the application for marketing authorisation referred to in Articles 5 and 6 is submitted.

Or. en

Amendment 301
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a regulation
Article 64 – paragraph 2 – subparagraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The application of the orphan ***medicine sponsor*** shall be accompanied by the following particulars and documentation:	The application ***for the designation*** of the orphan ***medicinal product*** shall be accompanied by the following particulars and documentation:

Or. en

Amendment 302
Massimiliano Salini, Aldo Patriciello

Proposal for a regulation
Article 64 – paragraph 2 – subparagraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The application ***of*** the orphan ***medicine sponsor*** shall be accompanied by the following particulars and documentation:	The application ***for*** the orphan ***medicinal product designation*** shall be accompanied by the following particulars and documentation:

Or. en

Amendment 303
Massimiliano Salini, Aldo Patriciello

Proposal for a regulation
Article 64 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency shall, in consultation with the Member States, the Commission and interested parties, draw up detailed guidelines on the required procedure, format and content of applications for designation and for the transfer of the orphan designation pursuant to Article 65.	3. ***The Agency shall confirm the application's validity and share its preliminary scientific findings with the applicant. The applicant shall be requested to provide their comments on these preliminary conclusions.*** The Agency shall, in consultation with the Member States, the Commission and interested parties, draw up detailed guidelines on the required procedure, format and content of applications for designation and for the transfer of the orphan designation pursuant to Article 65.

Or. en

Amendment 304
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a regulation
Article 64 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency shall, in consultation with the Member States, the Commission and interested parties, draw up detailed guidelines on the required procedure, format and content of applications for designation and for the transfer of the orphan designation pursuant to Article 65.	3. ***The Agency shall verify the validity of the application and share its draft scientific conclusions with the applicant. The applicant shall be invited to provide their observations on the draft conclusions.*** The Agency shall, in consultation with the Member States, the Commission and interested parties, draw up detailed guidelines on the required procedure, format and content of applications for designation and for the transfer of the orphan designation pursuant

to Article 65.

Or. en

Amendment 305
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a regulation
Article 64 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency shall adopt a decision granting or refusing the orphan designation based on the criteria referred to in Article 63(1) ***or in the relevant delegated acts adopted in accordance with Article 63(2)*** within 90 days of the receipt of a valid application. The application is considered valid if it includes all the particulars and documentation referred to in paragraph 2.	The Agency shall adopt a decision granting or refusing the orphan designation based on the criteria referred to in Article 63(1) within 90 days of the receipt of a valid application. The application is considered valid if it includes all the particulars and documentation referred to in paragraph 2.
	Within the timelines for adoption of a decision foreseen in [subparagraph 1], the Agency shall transmit its scientific conclusions to the applicant.
	Within 30 days of receipt of the scientific conclusions, the sponsor may submit to the Agency a written request, citing detailed grounds, for a re-examination.
	Within 30 days following receipt of a request for re-examination, the Agency shall confirm or revise its previous scientific conclusions. Where the Agency considers it necessary, it may consult the Committee for Medicinal Products for Human Use or the appropriate working parties when re-examining the above mentioned scientific conclusions. If, within the 30-day period referred to in [6th subparagraph], the applicant does not request re-examination, the scientific conclusions shall become definitive.
	The Agency shall adopt a decision within a period not exceeding 10 days following the date on which the scientific conclusions have become definitive

Or. en

Amendment 306
Massimiliano Salini, Aldo Patriciello

Proposal for a regulation
Article 64 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency shall adopt a decision granting or refusing the orphan designation based on the criteria referred to in Article 63(1) ***or in the relevant delegated acts adopted in accordance with Article 63(2)*** within 90 days of the receipt of a valid application. ***The application is considered valid if it includes all the particulars and documentation*** referred to in ***paragraph 2***.	The Agency shall adopt a decision granting or refusing the orphan designation based on the criteria referred to in Article 63(1) within 90 days of the receipt of a valid application.
	The Agency shall deliver its scientific findings to the applicant within the specified timeframes outlined for adoption of a decision in [subparagraph 1].
	After receiving the scientific conclusions, the sponsor has a 30-day window in which they may submit a written request to the Agency, providing specific reasons, for a re-evaluation.
	Following a request for re-evaluation, the Agency shall either confirm or modify its initial scientific findings within 30 days. If necessary, the Agency may consult the Committee for Medicinal Products for Human Use or relevant working parties during the re-evaluation process. If, within the 30-day period referred to in ***[6th subparagraph], the applicant decides not to request a re-evaluation, the scientific conclusions shall become definitive***.
	Once the scientific conclusions become definitive, the Agency shall reach a decision within 10 days.

Or. en

Amendment 307
Pernille Weiss

Proposal for a regulation
Article 64 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency shall adopt a decision granting or refusing the orphan designation based on the criteria referred to in Article 63(1) ***or in the relevant delegated acts adopted in accordance with Article 63(2)*** within 90 days of the receipt of a valid application. The application is considered valid if it includes all the particulars and documentation referred to in paragraph 2.	The Agency shall adopt a decision granting or refusing the orphan designation based on the criteria referred to in Article 63(1) within 90 days of the receipt of a valid application. The application is considered valid if it includes all the particulars and documentation referred to in paragraph 2.

Or. en

Justification

See amendment to Article 63 – paragraph 2.

Amendment 308
Nicola Danti

Proposal for a regulation
Article 64 – paragraph 4 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	Where the opinion of the Agency is that the application does not satisfy the criteria, the Agency shall forthwith inform the sponsor. Within 30 days of receipt of the draft opinion, the sponsor may submit detailed grounds for re-examination. Within 30 days following receipt of a request for re-examination, the Agency shall confirm or revise its previous conclusions.

Or. en

Justification

A mechanism for re-examination is already foreseen in the existing orphan medicinal

products Regulation. It is proposed to reintroduce it here

Amendment 309
Massimiliano Salini, Aldo Patriciello

Proposal for a regulation
Article 66 – paragraph 1

Text proposed by the Commission	*Amendment*
1. An orphan designation shall be valid for seven years. During this period, the orphan medicine sponsor shall be eligible for incentives referred to in Article 68.	***deleted***

Or. en

Amendment 310
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a regulation
Article 66 – paragraph 1

Text proposed by the Commission	*Amendment*
1. An orphan designation shall be valid for seven years. During this period, the orphan medicine sponsor shall be eligible for incentives referred to in Article 68.	***deleted***

Or. en

Amendment 311
Nicola Danti

Proposal for a regulation
Article 66 – paragraph 1

Text proposed by the Commission	*Amendment*
1. An orphan designation shall be valid for seven years. During this period, the orphan medicine sponsor shall be	***deleted***

eligible for incentives referred to in Article 68.

Or. en

Justification

Introducing a limited validity to the Orphan Designation will only add undue regulatory burden and further uncertainty to the development process of OMPs

Amendment 312
Massimiliano Salini, Aldo Patriciello

Proposal for a regulation
Article 66 – paragraph 2

Text proposed by the Commission	*Amendment*
2. By way of derogation from paragraph 1, on the basis of a justified request of the orphan medicine sponsor, the Agency may extend the validity, where the orphan medicine sponsor can provide evidence that the relevant studies supporting the use of the designated orphan medicinal product in the applied conditions are ongoing and promising with regard to the filing of a future application. Such an extension shall be limited in time, taking into account the expected remaining time needed to file an application for marketing authorisation.	***deleted***

Or. en

Amendment 313
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a regulation
Article 66 – paragraph 2

Text proposed by the Commission	*Amendment*
2. By way of derogation from paragraph 1, on the basis of a justified request of the orphan medicine sponsor,	***deleted***

the Agency may extend the validity, where the orphan medicine sponsor can provide evidence that the relevant studies supporting the use of the designated orphan medicinal product in the applied conditions are ongoing and promising with regard to the filing of a future application. Such an extension shall be limited in time, taking into account the expected remaining time needed to file an application for marketing authorisation.

Or. en

Amendment 314
Nicola Danti

Proposal for a regulation
Article 66 – paragraph 2

Text proposed by the Commission	*Amendment*
2. By way of derogation from paragraph 1, on the basis of a justified request of the orphan medicine sponsor, the Agency may extend the validity, where the orphan medicine sponsor can provide evidence that the relevant studies supporting the use of the designated orphan medicinal product in the applied conditions are ongoing and promising with regard to the filing of a future application. Such an extension shall be limited in time, taking into account the expected remaining time needed to file an application for marketing authorisation.	***deleted***

Or. en

Justification

Introducing a limited validity to the Orphan Designation will only add undue regulatory burden and further uncertainty to the development process of OMPs

Amendment 315
Massimiliano Salini, Aldo Patriciello

Proposal for a regulation
Article 66 – paragraph 3

Text proposed by the Commission	*Amendment*
3. By way of derogation from paragraph 1, where an orphan designation is valid at the time when a marketing authorisation for an orphan medicinal product has been submitted in accordance with Article 5, the orphan designation shall remain valid until a decision is adopted by the Commission in accordance with Article 13(2).	***deleted***

Or. en

Amendment 316
Nicola Danti

Proposal for a regulation
Article 66 – paragraph 3

Text proposed by the Commission	*Amendment*
3. By way of derogation from paragraph 1, where an orphan designation is valid at the time when a marketing authorisation for an orphan medicinal product has been submitted in accordance with Article 5, the orphan designation shall remain valid until a decision is adopted by the Commission in accordance with Article 13(2).	***deleted***

Or. en

Justification

Introducing a limited validity to the Orphan Designation will only add undue regulatory burden and further uncertainty to the development process of OMPs

Amendment 317
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a regulation
Article 66 – paragraph 3

Text proposed by the Commission	*Amendment*
3. By way of derogation from paragraph 1, where an orphan designation is valid at the time when a marketing authorisation for an orphan medicinal product has been submitted in accordance with Article 5, the orphan designation shall remain valid until a decision is adopted by the Commission in accordance with Article 13(2).	***deleted***

Or. en

Amendment 318
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a regulation
Article 66 – paragraph 4

Text proposed by the Commission	*Amendment*
4. An orphan designation ceases to be valid once an orphan medicine sponsor has obtained a marketing authorisation for the relevant medicinal product in accordance with Article 13(2).	4. An orphan designation ceases to be valid once an orphan medicine sponsor has obtained a marketing authorisation for the relevant medicinal product in accordance with Article 13(2). ***An orphan designation shall however remain valid in case the indication of the initial marketing authorisation addresses only a subset of the population affected by the designated orphan condition OR where the orphan medicinal product sponsor can provide evidence that studies supporting the use of the designated orphan medicinal product are planned or ongoing with respect to additional indications within the scope of the designated condition / orphan designation.***

Or. en

Amendment 319

Massimiliano Salini, Aldo Patriciello

Proposal for a regulation
Article 66 – paragraph 4

Text proposed by the Commission	*Amendment*
4. An orphan designation ceases to be valid once an orphan medicine sponsor has obtained a marketing authorisation for the relevant medicinal product in accordance with Article 13(2).	4. An orphan designation ceases to be valid once an orphan medicine sponsor has obtained a marketing authorisation for the relevant medicinal product in accordance with Article 13(2). ***However, when the original marketing authorization only addresses part of the population affected by the designated orphan condition, the orphan designation shall remain valid.***

Or. en

Amendment 320
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Article 66 – paragraph 5

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

Or. en

Amendment 321
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Article 67 – paragraph 3 – point f a (new)

Text proposed by the Commission	*Amendment*
	(f a) where applicable, any request made in accordance with Article 66(2)

and any decisions taken in that respect.

Or. en

Amendment 322
Josianne Cutajar

Proposal for a regulation
Article 68 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The orphan medicine sponsor ***may***, prior to the submission of an application for marketing authorisation, request advice from the Agency on the following:	1. The orphan medicine sponsor ***shall***, prior to the submission of an application for marketing authorisation, request advice from the Agency on the following:

Or. en

Amendment 323
Susana Solís Pérez, Klemen Grošelj

Proposal for a regulation
Article 68 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The orphan medicine sponsor ***may***, prior to the submission of an application for marketing authorisation, request advice from the Agency on the following:	1. The orphan medicine sponsor ***shall***, prior to the submission of an application for marketing authorisation, request advice from the Agency on the following:

Or. en

Amendment 324
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 68 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the conduct of the various tests and	(a) the conduct of the various tests and

trials necessary to demonstrate the quality, safety ***and*** efficacy of the medicinal product, as referred to Article 138(1), second subparagraph, point (p);	trials necessary to demonstrate the quality, safety***,*** efficacy ***and environmental impact*** of the medicinal product, as referred to Article 138(1), second subparagraph, point (p);

Or. en

Amendment 325
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a regulation
Article 68 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Medicinal products designated as orphan medicinal products under the provisions of this Regulation shall be eligible for incentives made available by the Union and by the Member States to support research into, and the development and availability of, orphan medicinal products ***and in particular aid for*** research ***for*** small- and medium-sized undertakings ***provided for in*** framework ***programmes*** for research and technological development.	2. Medicinal products designated as orphan medicinal products under the provisions of this Regulation shall be eligible for incentives made available by the Union and by the Member States to support research into, and the development and availability of, orphan medicinal products***. Notably, this encompasses financial assistance and administrative support for application processes expressly designed to bolster the*** research ***endeavors of*** small- and medium-sized undertakings***, in accordance with the*** framework ***programs*** for research and technological development.

Or. en

Amendment 326
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 68 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Medicinal products designated as orphan medicinal products under the	2. Medicinal products designated as orphan medicinal products under the

provisions of this Regulation shall be eligible for incentives made available by the Union and by the Member States to support research into, and the development and availability of, orphan medicinal products and in particular aid for research for small- and medium-sized undertakings provided for in framework programmes for research and technological development.	provisions of this Regulation shall be eligible for incentives made available by the Union and by the Member States to support research into, and the development and availability of, orphan medicinal products and in particular aid for research for small- and medium-sized undertakings ***and entities not engaged in economic activities*** provided for in framework programmes for research and technological development.

Or. en

Amendment 327
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Article 68 – paragraph 2

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

Or. en

Amendment 328
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a regulation
Article 68 – paragraph 2 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*

For the purpose of paragraph 2, this Regulation and [revised Directive 2001/83/EC] as a whole, the Commission shall by ... [18 months after the date of entry into force of this Directive] adopt delegated acts in accordance with Article 215 to supplement this Directive by laying down the criteria to qualify as a micro, small and medium-sized enterprise, taking into account the specificities of enterprises of this sector within the Union.

Or. en

Amendment 329
Pernille Weiss

Proposal for a regulation
Article 68 – paragraph 2 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	For the purpose of paragraph 2, the definitions set out in Article 58a paragraph 1 of [revised Directive 2001/83/EC] shall apply.

Or. en

Justification

See amendment in Article 58a of the draft report on the revised Directive 2001/83/EC.

Amendment 330
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a regulation
Article 70

Text proposed by the Commission	*Amendment*
Article 70	***deleted***
Orphan medicinal products addressing a high unmet medical need	

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

(a) there is no medicinal product authorised in the Union for such condition orwhere, despite medicinal products being authorised for such condition in the Union, the applicant demonstrates that the orphan medicinal product, in addition to having a significant benefit, will bring exceptional therapeutic advancement;

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

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

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

Or. en

Amendment 331
Susana Solís Pérez, Nicola Danti

Proposal for a regulation
Article 70

Text proposed by the Commission	*Amendment*
Article 70	***deleted***
Orphan medicinal products addressing a high unmet medical need	
1. An orphan medicinal product shall be considered as addressing a high unmet medical need where it fulfils the following	

requirements:

(a) there is no medicinal product authorised in the Union for such condition orwhere, despite medicinal products being authorised for such condition in the Union, the applicant demonstrates that the orphan medicinal product, in addition to having a significant benefit, will bring exceptional therapeutic advancement;

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

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

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

Or. en

Amendment 332
Pernille Weiss

Proposal for a regulation
Article 70 – title

Text proposed by the Commission	*Amendment*
Orphan medicinal products ***addressing a high unmet medical need***	***Breakthrough Designated*** Orphan medicinal products

Or. en

Amendment 333
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
1. An orphan medicinal product shall be ***considered as addressing a high unmet medical need*** where it ***fulfils*** the following requirements:	1. An orphan medicinal product shall be ***designated as a breakthrough orphan medicinal product*** where it ***can be demonstrated at the moment of designation that the one of*** the following requirements ***are met***:

Or. en

Amendment 334
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
(a) there ***is no medicinal product*** authorised in the Union ***for such condition orwhere, despite medicinal products being authorised for such condition in the Union, the applicant demonstrates that the orphan medicinal product, in addition to having a significant benefit, will bring exceptional therapeutic advancement***;	(a) there ***exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been*** authorised in the Union***, or***;

Or. en

Amendment 335
Ville Niinistö
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
(a) there is no medicinal product authorised in the Union for such condition ***orwhere***, despite medicinal products being authorised for such condition in the Union,	(a) there is no medicinal product authorised in the Union for such condition ***or where***, despite medicinal products being authorised for such condition in the Union,

the applicant demonstrates that the orphan medicinal product, in addition to having a significant benefit, will bring exceptional therapeutic advancement;	the applicant demonstrates that the orphan medicinal product, in addition to having a significant benefit, will bring exceptional therapeutic advancement; ***and***

Or. en

Amendment 336
Josianne Cutajar

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

Text proposed by the Commission	*Amendment*
(a) there is no medicinal product authorised in the Union for such condition orwhere, despite medicinal products being authorised for such condition in the Union, the applicant demonstrates that the orphan medicinal product, in addition to having a significant benefit, will bring ***exceptional*** therapeutic advancement;	(a) there is no medicinal product authorised in the Union for such condition orwhere, despite medicinal products being authorised for such condition in the Union, the applicant demonstrates that the orphan medicinal product, in addition to having a significant benefit, will bring therapeutic advancement;

Or. en

Amendment 337
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
(b) ***the use of*** the orphan medicinal product results in ***a*** meaningful reduction in disease morbidity or mortality for the relevant ***patient*** population.	(b) ***where, despite medicinal products being authorised for such condition in the Union, the applicant demonstrates that*** the orphan medicinal product ***uses a new and unique mechanism of action and the use of the medicinal product*** results in meaningful ***prevention of or*** reduction in disease morbidity or mortality ***or a major contribution to patient care*** for the relevant population.

Or. en

Amendment 338
Ville Niinistö
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
(b) the use of the orphan medicinal product results in a ***meaningful*** reduction in disease morbidity or mortality for the relevant patient population.	(b) the use of the orphan medicinal product results in a ***substantial*** reduction in disease morbidity or mortality for the relevant patient population.

Or. en

Amendment 339
Josianne Cutajar

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

Text proposed by the Commission	*Amendment*
(b) the use of the orphan medicinal product results in a ***meaningful*** reduction in disease morbidity or mortality for the relevant patient population.	(b) the use of the orphan medicinal product results in a reduction in disease morbidity or mortality for the relevant patient population.

Or. en

Amendment 340
Pernille Weiss

Proposal for a regulation
Article 70 – paragraph 2

Text proposed by the Commission	*Amendment*
2. A medicinal product for which an application has been submitted in accordance with Article 13 of [revised Directive 2001/83/EC] shall not be considered as addressing a high unmet	***deleted***

medical need.

Or. en

Amendment 341
Pernille Weiss

Proposal for a regulation
Article 70 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the Agency adopts scientific guidelines for the application of this Article, it shall consult the Commission and the authorities or bodies referred to in Article 162.	3. Where the Agency adopts scientific guidelines for the application of this Article, it shall consult the Commission and the authorities or bodies***, as well as the stakeholders such as representatives of patients' organisations in the relevant disease areas, healthcare professionals, orphan medicinal product sponsors, representatives of pharmaceutical industry and other relevant stakeholders*** referred to in Article 162.

Or. en

Amendment 342
Laura Ballarín Cereza, Nicolás González Casares

Proposal for a regulation
Article 70 – paragraph 3

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

Or. en

Amendment 343
Laura Ballarín Cereza, Nicolás González Casares

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

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

Or. en

Amendment 344
Pietro Fiocchi, Elisabetta De Blasis

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

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

Or. en

Amendment 345
Ville Niinistö
on behalf of the Verts/ALE Group

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

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

Or. en

Amendment 346
Pernille Weiss

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

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

Or. en

Amendment 347
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

Text proposed by the Commission	*Amendment*
(a) ***nine*** years for orphan medicinal products other than those referred to in points (b) and (c);	(a) ***12*** years for orphan medicinal products other than those referred to in points (b) and (c);

Or. en

Amendment 348
Pilar del Castillo Vera

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

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

Or. en

Amendment 349
Andreas Glück

Proposal for a regulation

Article 71 – paragraph 2 – point a

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

Or. en