Council of the European Union

Brussels, 2 July 2024
(OR. en)

11753/24

Interinstitutional File: 2023/0131(COD)

CODEC 1623
SAN 435
PHARM 109
MI 654
COMPET 740
VETER 91
ENV 739
RECH 337
PI 110
PE 190

INFORMATION NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 - Outcome of the European Parliament's first reading (Brussels, 10 to 11 April 2024)

I. INTRODUCTION

The rapporteur, Tiemo WÖLKEN (S&D, DE), presented a report on the above proposal for a Regulation on behalf of the Committee on the Environment, Public Health and Food Safety (ENVI) which contained 367 amendments (amendments 1 to 367) to the proposal.

In addition, the ID group tabled nine amendments (amendments 368 to 376), The Left group tabled two amendments (amendments 377 and 378), and a number of MEPs from different political groups tabled one amendment (amendment 379).

II. VOTE

When it voted on 10 April 2024, the plenary of the European Parliament adopted amendments 1 to 367 to the proposal for a Regulation. No other amendments were adopted.

The Commission's proposal as thus amended constitutes the Parliament's first-reading position which is contained in its legislative resolution as set out in the Annex hereto.

P9_TA(2024)0221

Union procedures for the authorisation and supervision of medicinal products for human use and rules governing the European Medicines Agency

European Parliament legislative resolution of 10 April 2024 on the proposal for a regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (COM(2023)0193 – C9-0144/2023 – 2023/0131(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2023)0193),

– having regard to Article 294(2) and Article 114 and Article 168(4), point (c), of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0144/2023),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 25 October 2023[1],

– after consulting the Committee of the Regions,

– having regard to Rule 59 of its Rules of Procedure,

– having regard to the opinion of the Committee on Industry, Research and Energy,

– having regard to the letters from the Committee on Budgets and the Committee on Agriculture and Rural Development,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety (A9-0141/2024),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

[1] OJ C, C/2024/879, 6.2.2024, ELI: http://data.europa.eu/eli/C/2024/879/oj

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Amendment 1
Proposal for a regulation
Recital -1 (new)

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

Amendment 2
Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) This Regulation should contribute to the implementation of the One Health Approach, stressing the well-established interconnectedness between human, animal and ecosystem health, and the need to include those three dimensions when addressing public health threats. Environmental stress and degradation, including biodiversity loss, contribute to the transmission of diseases between, and the disease burden of, humans and animals. In addition, pollution from active pharmaceutical ingredients negatively affects the quality of waters and ecosystems, causes antimicrobial resistance to increase rapidly, posing risks to public health globally.

Amendment 3
Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) The Pharmaceutical Strategy for Europe marks a turning point with the	(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.	addition of further key objectives and by ***aiming to create an attractive environment for research, development and production of medicinal products in the Union, along with*** a modern framework that makes innovative and established medicinal products available to patients and healthcare systems at affordable prices, while ***strengthening the fight against shortages of medicinal products and*** ensuring security of supply and addressing environmental concerns.

Amendment 4
Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) To supplement the measures to address shortages of medicinal products, the communication of the Commission of 24 October 2023 entitled 'Addressing medicine shortages in the EU' aims to address critical shortages of medicines and strengthen security of supply in the Union by, among other things, introducing the launch of a European voluntary solidarity mechanism for medicines allowing Member States to redistribute their available stock in the event of shortages.

Amendment 5
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 European Parliament*** have called for revised mechanisms and incentives for development of medicinal products tailored to the level of unmet medical need, while ensuring ***that the process is transparent,*** patient access and availability ***as well as***

affordability of medicinal products in all Member States.

Amendment 6
Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) Previous amendments to the Union pharmaceutical legislation have addressed access to medicinal products by providing for accelerated assessment for marketing authorisation applications or by allowing conditional marketing authorisation for medicinal products for unmet medical need. While these measures accelerated the authorisation of innovative and promising therapies, these medicinal products do not always reach the patient and patients in the Union still have different levels of access to medicines.	(4) Previous amendments to the Union pharmaceutical legislation have addressed access to medicinal products by providing for accelerated assessment for marketing authorisation applications or by allowing conditional marketing authorisation for medicinal products for unmet medical need. While these measures accelerated the authorisation of innovative and promising therapies ***in some areas, and many unaddressed public health priorities remain***, these medicinal products do not always reach the patient and patients in the Union still have different levels of access to medicines.

Amendment 7
Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) The COVID-19 pandemic ***has spotlighted*** critical issues which require a reform of the Union pharmaceuticals framework to strengthen its resilience and to ensure that it serves the people under all circumstances.	(5) The COVID-19 pandemic ***further underlined*** critical issues***,*** which require a reform of the Union pharmaceuticals framework to strengthen its resilience***, while improving the availability of medicinal products*** and to ensure that it ***corresponds to public health needs and*** serves the people under all circumstances.

Amendment 8
Proposal for a regulation
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) The COVID-19 pandemic also highlighted disparities in terms of the capacity of health systems, national immunisation infrastructure, shortages and preparation. In addition to the

	measures in this Regulation, Member States should strengthen their national immunisation programmes, ensuring their population is better sufficiently protected against infectious diseases and strengthening pandemic preparedness and response.

Amendment 9
Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(6) ***For the sake of clarity,*** it is necessary to replace Regulation (EC) No 726/2004 of the European Parliament and of the Council[38] with a new Regulation.	(6) It is ***therefore*** necessary to replace Regulation (EC) No 726/2004 of the European Parliament and of the Council[38] with a new Regulation.
[38] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).	[38] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

Amendment 10
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.

Amendment 11
Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) The structure and operation of the various bodies making up the Agency should be designed in such a way as to take	(12) The structure and operation of the various bodies making up the Agency should be designed in such a way as to take

into account the need to constantly renew scientific expertise, the need for cooperation between Union and national bodies, the need for adequate involvement of civil society, and the future enlargement of the Union. The various bodies of the Agency should establish and develop appropriate contacts with the parties concerned, in particular with representatives of patients and healthcare professionals.	into account the need to constantly renew scientific expertise, the need for cooperation between Union and national bodies, the need for adequate involvement of civil society, and the future enlargement of the Union. The various bodies of the Agency should establish and develop appropriate contacts with the parties concerned, in particular with representatives of patients***, consumers*** and healthcare professionals.

Amendment 12
Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) The chief task of the Agency should be to provide Union institutions and Member States with the best possible scientific opinions to enable them to exercise the powers of authorisation and supervision of medicinal products conferred on them by Union legal acts in the field of medicinal products. Marketing authorisation should be granted by the Commission only after a single scientific evaluation procedure addressing the quality, safety and efficacy of high-technology medicinal products has been conducted by the Agency, applying the highest possible standards.	(13) The chief task of the Agency should be to provide Union institutions and Member States with the best possible scientific opinions to enable them to exercise the powers of authorisation and supervision of medicinal products conferred on them by Union legal acts in the field of medicinal products. Marketing authorisation should be granted by the Commission only after a single scientific evaluation procedure addressing the quality, safety and efficacy of high-technology medicinal products has been conducted by the Agency, applying the highest possible standards ***and the completion of an environmental risk assessment***.

Amendment 13
Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) The Agency's budget should be composed of fees and charges paid by the private sector and contributions from the Union budget to implement Union policies and contributions paid from third countries.	(15) The Agency's budget should be ***transparent and*** composed of fees and charges paid by the private sector and contributions from the Union budget to implement Union policies and contributions paid from third countries. ***Although the majority of its funding comes from fees, the Agency is a public authority. It is of utmost importance to***

	safeguard its integrity and independence in order to maintain public trust in the Union regulatory framework.

Amendment 14
Proposal for a regulation
Recital 18 a (new)

Text proposed by the Commission	*Amendment*
	(18a) The Agency should set transparent criteria for the appointment of patients' and healthcare professionals' representatives to the Committee for Medicinal Products for Human Use and the Pharmacovigilance Risk Assessment Committee in order to ensure there is a well-balanced representation of medical specialties and diseases amongst appointed members and alternates, and there are robust rules on the prevention of conflicts of interests. Declaration of direct or indirect financial or other interests in the pharmaceutical or other medical industry which could affect the impartiality of appointed stakeholders should be an integral part of the selection process and subsequently should be made publicly available.

Amendment 15
Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(19) Scientific advice for future applicants seeking a marketing authorisation should be provided more generally and in greater depth. Similarly, structures allowing the development of advice for companies, in particular small and medium-sized enterprises ('SMEs'), should be put in place.	(19) Scientific advice for future applicants seeking a marketing authorisation should be provided more generally and in greater depth ***and should be adapted to the specificities of the medicinal product concerned***. Similarly, structures allowing the development of advice for companies, in particular small and medium-sized enterprises ('SMEs') ***and not-for-profit entities***, should be put in place. ***The Agency should also promote open and public exchanges about latest scientific developments and updates of scientific guidelines.***

Amendment 16
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 ***and certain combinations products of medicinal products and medical devices, as well as medicinal products in exclusive use with medical devices*** that have the potential to significantly address patients' unmet medical needs should benefit from early and enhanced scientific support***, including through supporting patient-relevant in vitro and in silico technologies which are key to the development of those products***. Such support will ultimately help patients benefit from new therapies as early as possible.

Amendment 17
Proposal for a regulation
Recital 20 a (new)

Text proposed by the Commission	*Amendment*
	(20a) Next to unmet medical needs already recognised in the pediatric, antimicrobial, oncological, rare, and neurodegenerative diseases, attention should also be given to unmet medical needs in the mental health sphere and treatments therein.

Amendment 18
Proposal for a regulation
Recital 21 a (new)

Text proposed by the Commission	*Amendment*
	(21a) Based on the European Ombudsman's decision in its strategic inquiry OI/7/2017/KR of 17 July 2019 on how the European Medicines Agency engages with medicine developers in the period leading up to applications for authorisations to market new medicines in the Union, the Agency should enhance the transparency of scientific advice. In addition, staff and experts from national

	competent authorities providing scientific advice should, to the extent possible, not be involved in a subsequent evaluation of a marketing authorisation application for the same products. However, in duly justified cases, such as where the indication of a medicinal product concerns a rare disease, that expert should be able to carry out a subsequent evaluation of the same product, provided that that is duly documented.

Amendment 19
Proposal for a regulation
Recital 25

Text proposed by the Commission	*Amendment*
(25) In certain cases, shortcomings in Member States' system of supervision and related enforcement activities could risk to substantially hinder the achievement of the objectives of this Regulation and those of revised Directive 2001/83/EC which could even lead to the emergence of risks to public health. To address these challenges, harmonised inspection standards should be ensured through the establishment of a joint audit programme within the Agency. This joint audit programme will also further harmonise the interpretation of good manufacturing and distribution practices on the basis of Union legislative requirements. Moreover, it will support further mutual recognition of inspection outcomes between Member States and with strategic partners. Within the joint audit programme, the competent authorities are subject to regular audits conducted by other Member States to maintain an equivalent and harmonised quality system and to ensure an appropriate implementation of relevant good manufacturing and distribution practices into national laws and equivalence with other EEA inspectorates.	(25) In certain cases, shortcomings in Member States' system of supervision and related enforcement activities could risk to substantially hinder the achievement of the objectives of this Regulation and those of revised Directive 2001/83/EC which could even lead to the emergence of risks to public health ***or to the environment***. To address these challenges, harmonised inspection standards should be ensured through the establishment of a joint audit programme within the Agency. This joint audit programme will also further harmonise the interpretation of good manufacturing and distribution practices on the basis of Union legislative requirements. Moreover, it will support further mutual recognition of inspection outcomes between Member States and with strategic partners. Within the joint audit programme, the competent authorities are subject to regular audits conducted by other Member States to maintain an equivalent and harmonised quality system and to ensure an appropriate implementation of relevant good manufacturing and distribution practices into national laws and equivalence with other EEA inspectorates.

Amendment 20
Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission	*Amendment*
	(26a) Pharmaceutical research plays a decisive role in the continuing improvement in public health and in ensuring the Union's competitiveness. Medicinal products, in particular those that are the result of long, costly research will not continue to be developed in the Union unless they are covered by favourable rules that provide for sufficient protection to encourage such research. However, it is difficult to establish a direct link between these favourable rules and Union competitiveness. Such rules, while making Union markets more attractive, are agnostic to the medicines' geographical origin and authorised medicines from third countries are equally eligible to receive Union incentives, just as Union-based innovative companies can equally benefit from incentives in third countries.

Amendment 21
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, of research in different subpopulations, repurposing and optimisation and*** 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.

Amendment 22
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 an advisory mechanism would address, as early as possible, questions related to borderline cases with other areas such as ***in particular*** substances of human origin, cosmetics or medical devices, which may arise as science develops. To ensure that recommendations given by the Agency take into account the views of equivalent advisory mechanisms in other legal frameworks, the Agency should consult the relevant advisory or regulatory bodies. ***Where there is a doubt about whether the regulatory status of a particular product under development, which could potentially fall under the mandatory scope of the centralised procedure, meets the scientific criteria to be a medicinal product, the Agency and the relevant advisory bodies responsible for other regulatory frameworks, namely medical devices and substances of human origin should engage in consultations. In such cases, the compendium referred to in Regulation (EU) 2024/... of the European Parliament and of the Council[1a][SoHO Regulation] should be consulted, where relevant. If after consulting the compendium, there remains doubt about the regulatory status the relevant bodies should further consult to determine the regulatory status. The Commission should facilitate the cooperation between the Agency and advisory bodies established by other Union legislation. The opinions and the recommendations of the Agency and the relevant advisory bodies on the regulatory status of the product should be made publicly available after the***

consultations have taken place.

[1a] Regulation (EU) 2024/... of the European Parliament and of the Council of ... on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L, ...).

Amendment 23
Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*
(31) To increase transparency of scientific assessments and all other activities, a European medicines web-portal should be created and maintained by the Agency.	(31) To increase transparency of scientific assessments and all other activities, a ***user-friendly*** European medicines web-portal should be created and maintained by the Agency. ***The portal should provide information for all centrally authorised medicinal products, inter alia on safety, efficacy, environmental risk, patient populations, and where relevant information on antimicrobial resistance, shortages, and pending obligations for marketing authorisation holders. Sufficient budgetary resources should be allocated to the Agency to ensure its transparency obligations and commitments are appropriately implemented.***

Amendment 24
Proposal for a regulation
Recital 31 a (new)

Text proposed by the Commission	*Amendment*
	(31a) The Union Register of medicinal products lists all medicinal products for human and veterinary use as well as orphan medicinal products that have received a marketing authorisation by the Commission through the centralised procedure. The information provided in the Union Register can be used to search for pertinent information on the

	medicinal product in question, including the active substance, the international non-proprietary name, the anatomical therapeutic chemical (ATC), the indications of the medicinal product, information on the authorisation and any post-authorisation requirements as well as applicable regulatory protection periods.

Amendment 25
Proposal for a regulation
Recital 33 a (new)

Text proposed by the Commission	*Amendment*
	(33a) To ensure the adequate expertise and evaluation of the environmental risk assessments of pharmaceutical substances, the Agency should establish a new ad hoc Environmental Risk Assessment working party. That working party should be involved where necessary depending on the application for a marketing authorisation. The working party should have the scientific knowledge necessary to characterise and assess the risks, and the mitigation measures for such risks, related to the manufacture, use and disposal of medicinal products. The working party should contribute towards the implementation of the One Health Approach and closing the gap between pharmaceutical and environmental assessment.

Amendment 26
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, in relation to*** their evaluation duties***, by*** 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.

Amendment 27
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***, ad hoc working groups,*** 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***, 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 publicly available.***

Amendment 28
Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) To allow for a more informative decision making and for exchange of information and pooling of knowledge on general issues of scientific or technical nature related to the tasks of the Agency regarding medicinal products for human use, in particular to scientific guidelines on unmet medical needs and the design of clinical trials, or other studies and the generation of evidence along the life cycle of medicinal product, the Agency should be able to have recourse to a consultation process of authorities or bodies active along the life cycle of medicinal products. These authorities could be, as appropriate, representatives from Heads of Medicines Agencies, the Clinical Trial Coordination and Advisory Group, the SoHO Coordination Board, the Coordination Group on Health Technology Assessment, Medical Devices Coordination Group, medical devices national competent authorities, national competent authorities for pricing and reimbursement of medicines, national insurance funds or healthcare payers. The Agency should also be able to extend the consultation mechanism to consumers, patients, healthcare professionals, industry, associations representing payers, or other stakeholders, as relevant.	(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. ***Additionally, to improve regulatory certainty and cross-sectoral cooperation the Commission should, on an annual basis, or more frequently where deemed necessary, organise joint meetings with the advisory bodies established under other Union legislation to assess emerging trends and questions on the regulatory status of products and find agreement on common regulatory status principles.*** 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 ***and their caregivers***, healthcare professionals***, academia***, industry, associations representing payers, or other stakeholders, as relevant.

Amendment 29
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 be able, exceptionally, to prohibit the use in their territory of medicinal products for human use. ***Member States should provide justification for such prohibition of use to the Commission and the Agency.***

Amendment 30
Proposal for a regulation
Recital 43 a (new)

Text proposed by the Commission	*Amendment*
	(43a) The Union is required, pursuant to Article 208 of the Treaty on the Functioning of the European Union (TFEU), to take account of development objectives in policies that are likely to have an impact on low- and middle-income countries. Union pharmaceutical legislation has a role to play in the realisation of global public health objectives by promoting the development of efficacious, safe, accessible, and affordable innovations for antimicrobial resistance, poverty-related, emerging and re-emerging health threats, and neglected diseases, and other conditions of global public health interest. The Commission should continue to encourage research, development and innovation in areas of major global health interest, in line with its international commitments.

Amendment 31
Proposal for a regulation
Recital 45 a (new)

Text proposed by the Commission	*Amendment*
	(45a) The Agency should pay particular attention to the composition of clinical trials to ensure gender based equity and

comprehensive clinical data.

Amendment 32
Proposal for a regulation
Recital 46

Text proposed by the Commission	*Amendment*
(46) Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes[49] lays down provisions on the protection of animals used for scientific purposes based on the principles of replacement, reduction and refinement. Any study involving the use of live animals, which provides essential information on the quality, safety and efficacy of a medicinal product, should take into account those principles of replacement, reduction and refinement, where they concern the care and use of live animals for scientific purposes, and should be optimised in order to provide the most satisfactory results whilst using the minimum number of animals. The procedures of such testing should be designed to avoid causing pain, suffering, distress or lasting harm to animals and should follow the available Agency and the International Committee for Harmonisation (ICH) guidelines. In particular, the marketing authorisation applicant and the marketing authorisation holder should take into account the principles laid down in Directive 2010/63/EU, ***including, where possible, use of*** new approach methodologies in place of animal testing. These can include but are not limited to: in vitro models, such as microphysiological systems including organ-on-chips, (2D and 3D) cell culture models, organoids and human stem cells-based models; in silico tools or read-across models.	(46) Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes[49] lays down provisions on the protection of animals used for scientific purposes based on the principles of replacement, reduction and refinement. Any study involving the use of live animals, which provides essential information on the quality, safety and efficacy of a medicinal product, should take into account those principles of replacement, reduction and refinement, where they concern the care and use of live animals for scientific purposes, and should be optimised in order to provide the most satisfactory results whilst using the minimum number of animals. The procedures of such testing should be ***only used where necessary and be*** designed to avoid causing pain, suffering, distress or lasting harm to animals and should follow the available Agency and the International Committee for Harmonisation (ICH) guidelines. In particular, the marketing authorisation applicant and the marketing authorisation holder should take into account the principles laid down in Directive 2010/63/EU, ***giving priority to*** new approach methodologies ***(NAMs)*** in place of animal testing. These can include but are not limited to: in vitro models, such as microphysiological systems including organ-on-chips, (2D and 3D) cell culture models, organoids and human stem cells-based models; in silico tools***, in chemico technologies and any combination thereof*** or read-across***, aquatic egg*** models ***as well as invertebrate species***. ***Ultimately, efforts should be made to fully replace procedures on live animals for scientific purposes. The Agency should in its annual report highlight key observations***

	and best practices in the replacement, reduction and refinement of animal testing submitted by applicants.
[49] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).	[49] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

Amendment 33
Proposal for a regulation
Recital 47

Text proposed by the Commission	*Amendment*
(47) Procedures should be in place to facilitate joint animal testing, wherever possible, in order to avoid unnecessary ***duplication of*** testing using live animals covered by Directive 2010/63/EU. Marketing authorisation applicants and marketing authorisation holders should make all efforts to reuse animal study results and make the results obtained from animal studies publicly available. For abridged applications marketing authorisation applicants should refer to the relevant studies conducted for the reference medicinal product.	(47) Procedures should be in place to facilitate joint animal testing, wherever possible, in order to avoid unnecessary testing using live animals covered by Directive 2010/63/EU. Marketing authorisation applicants and marketing authorisation holders should make all efforts to reuse animal study results and make the results obtained from animal studies publicly available. For abridged applications marketing authorisation applicants should refer to the relevant studies conducted for the reference medicinal product.

Amendment 34
Proposal for a regulation
Recital 51 a (new)

Text proposed by the Commission	*Amendment*
	(51a) As a matter of good practice, marketing authorisations should be granted based on comparative clinical trials on patients who are representative of the population that is to be treated with the product. In addition, patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) should be an integral part of clinical data submitted with the marketing authorisation application in order to assess the quality of care and the impact

of the treatments on patients.

Amendment 35
Proposal for a regulation
Recital 53 a (new)

Text proposed by the Commission	*Amendment*
	(53a) Several care pathways should be explored to make therapies available in all Member States, including by advancing provisions for access to cross border care, such as Directive 2011/24/EU[1a] and Regulation (EC) No 883/2004[1b] of the European Parliament and of the Council. This is particularly important for the advanced therapy medicinal products, as their unique characteristics result in significant infrastructural complexities and system barriers, which can substantially limit their continuous supply.
	[1a] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).
	[1b] Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems (OJ L 166 30.4.2004, p. 1).

Amendment 36
Proposal for a regulation
Recital 54

Text proposed by the Commission	*Amendment*
(54) [revised Directive 2001/83/EC] permits Member States to temporarily allow the use and supply of unauthorised medicinal products for public health reasons or individual patient needs and that includes medicinal products to be authorised under this Regulation. It is also necessary, that Member States are allowed	(54) [revised Directive 2001/83/EC] permits Member States to temporarily allow the use and supply of unauthorised medicinal products for public health reasons or individual patient needs and that includes medicinal products to be authorised under this Regulation. It is also necessary, that Member States are allowed

under this Regulation to make a medicinal product available for compassionate use prior to its marketing authorisation. In those exceptional and urgent situations, where there is a lack of a suitable authorised medicinal product, the need to protect public health or the health of individual patients must prevail over other considerations, in particular the need to obtain a marketing authorisation and consequently, to have available complete information about the risks posed by the medicinal product, including any risks to the environment from medicinal products containing or consisting of genetically modified organisms (GMOs). To avoid delays in making these products available or uncertainties as regards their status in certain Member States, it is appropriate, in those exceptional and urgent situations, that for a medicinal product containing or consisting of GMOs, an environmental risk assessment or consent in accordance with Directive 2001/18/EC or Directive 2009/41/EC of the European Parliament and of the Council[52] should not be a prerequisite. Nevertheless, in these cases, Member States should implement appropriate measures to minimise foreseeable negative environmental impacts resulting from the intended or unintended release of the medicinal products containing or consisting of GMOs into the environment.	under this Regulation to make a medicinal product available for compassionate use prior to its marketing authorisation. In those exceptional and urgent situations, where there is a lack of a suitable authorised medicinal product, the need to protect public health or the health of individual patients must prevail over other considerations, in particular the need to obtain a marketing authorisation and consequently, to have available complete information about the risks posed by the medicinal product, including any risks to the environment from medicinal products containing or consisting of genetically modified organisms (GMOs). To avoid delays in making these products available or uncertainties as regards their status in certain Member States, it is appropriate, in those exceptional and urgent situations, that for a medicinal product containing or consisting of GMOs, an environmental risk assessment or consent in accordance with Directive 2001/18/EC or Directive 2009/41/EC of the European Parliament and of the Council[52] should not be a prerequisite. Nevertheless, in these cases, Member States should implement appropriate measures ***in line with the precautionary principle*** to minimise foreseeable negative environmental impacts resulting from the intended or unintended release of the medicinal products containing or consisting of GMOs into the environment ***and agree on an appropriate timeline for the delivery of the environmental risk data***.
[52] Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (Recast) (OJ L 125, 21.5.2009, p. 75).	[52] Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (Recast) (OJ L 125, 21.5.2009, p. 75).

Amendment 37
Proposal for a regulation
Recital 57 a (new)

Text proposed by the Commission	*Amendment*

	(57a) Given the underserved needs in the area of mental health, the revision should contribute to increased access to treatments, and the development of novel treatments, for patients who need them most.

Amendment 38
Proposal for a regulation
Recital 57 b (new)

Text proposed by the Commission	*Amendment*
	(57b) The Commission should support the use of early access pilot programmes to treat patients with complex comorbidities, including physical and mental health conditions who are often excluded from clinical trials. Allowing this would support evidence gathering on the safety and efficacy of these treatments. Such programmes should provide treatment experience for healthcare providers and generate valuable real-world data to inform future authorisations of these treatments.

Amendment 39
Proposal for a regulation
Recital 58

Text proposed by the Commission	*Amendment*
(58) There is the possibility under certain circumstances for marketing authorisations to be granted, subject to specific obligations or conditions, on a conditional basis or under exceptional circumstances. The legislation should allow under similar circumstances for medicinal products with a standard marketing authorisation for new indications to be authorised on a conditional basis or under exceptional circumstances. The medicinal products authorised on a conditional basis or under exceptional circumstances should in principle satisfy the requirements for a standard marketing authorisation with the exception of the specific derogations or conditions outlined in the relevant conditional or exceptional marketing	(58) There is the possibility under certain ***duly justified*** circumstances for marketing authorisations to be granted, subject to specific obligations or conditions, on a conditional basis or under exceptional circumstances. The legislation should allow under similar circumstances for medicinal products with a standard marketing authorisation for new indications to be authorised on a conditional basis or under exceptional circumstances. The medicinal products authorised on a conditional basis or under exceptional circumstances should in principle satisfy the requirements for a standard marketing authorisation with the exception of the specific derogations or conditions outlined in the relevant

authorisation and shall be subject to specific review of the fulfilment of the imposed specific conditions or obligations. It is also understood that the grounds for refusal of a marketing authorisation shall apply mutatis mutandis for such cases.	conditional or exceptional marketing authorisation and shall be subject to specific review of the fulfilment of the imposed specific conditions or obligations. It is also understood that the grounds for refusal of a marketing authorisation shall apply mutatis mutandis for such cases.

Amendment 40
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 data generated via in silico methods, such as computational modelling and simulation, digital molecular representation and mechanistic modelling, digital twin technology and 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***, including results of studies conducted via in silico methods,*** to fulfil its mandate, without compromising privacy rights***. The Agency should put in place sufficient, effective and specific technical and organisational measures to safeguard the fundamental rights and interests of data subjects in line with Regulations (EU) 2016/679[1a] and (EU) 2018/1725[1b] of the European Parliament and of the Council***. Where necessary the Agency may cooperate with the competent authorities of the Member States towards this objective.

[1a] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

[1b] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

Amendment 41
Proposal for a regulation
Recital 65

Text proposed by the Commission	*Amendment*
(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.	(65) In the preparation of scientific advice and in duly justified cases, the Agency should 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. ***In addition to providing scientific advice, the Agency should ensure that scientific guidelines are updated and promote an open and public discussion on latest scientific developments.***

Amendment 42
Proposal for a regulation
Recital 67

Text proposed by the Commission	*Amendment*
(67) The Agency, in consultation with the Member States and the Commission, should set the scientific selection criteria	(67) The Agency, in consultation with the Member States and the Commission, should set the scientific selection criteria

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

Amendment 43
Proposal for a regulation
Recital 68 a (new)

Text proposed by the Commission	*Amendment*
	(68a) There is still a lack of sufficiently detailed and comparable data at Union level to determine the trends and identify possible risk factors that could lead to the development of further measures to limit the risk from antimicrobial resistance and to monitor the effect of measures already introduced. Therefore it is important to collect data on the sales and use of antimicrobials, and data on antimicrobial resistant organisms found in animals, humans and food. To ensure that the information collected can be used effectively, appropriate rules should be laid down concerning the collection and the exchange of data. The Member States should be responsible for collecting data on the use of antimicrobials under the coordination of the Agency.

Amendment 44
Proposal for a regulation
Recital 76

Text proposed by the Commission	*Amendment*
(76) It is considered appropriate to also have the possibility for the Commission to grant temporary emergency marketing authorisations to address public health emergencies. Temporary emergency	(76) It is considered appropriate to also have the possibility for the Commission to grant temporary emergency marketing authorisations**,** to address public health emergencies. Temporary emergency

marketing authorisations may be granted provided that, having regard to the circumstances of the public health emergency, the benefit of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent to the fact that additional comprehensive quality, non-clinical, clinical data may still be required. A temporary emergency marketing authorisation should be valid only during the public health emergency. The Commission should be given the possibility to vary, suspend or revoke such marketing authorisations in order to protect public health or when the marketing authorisation holder has not complied with the conditions and obligations set out in the temporary emergency marketing authorisation.	marketing authorisations may be granted provided that, having regard to the circumstances of the public health emergency, the benefit of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent to the fact that additional comprehensive quality, non-clinical, clinical data may still be required. A temporary emergency marketing authorisation should be valid only during the public health emergency. The Commission should be given the possibility to vary, suspend or revoke such marketing authorisations in order to protect public health or when the marketing authorisation holder has not complied with the conditions and obligations set out in the temporary emergency marketing authorisation ***or when a standard or conditional marketing authorisation has been granted for the relevant indication***.

Amendment 45
Proposal for a regulation
Recital 76 a (new)

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

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

Amendment 46
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 ***whereby antimicrobial research and development (R&D) is hampered by the low commercial value of the antimicrobial medicinal product market.*** It is therefore necessary to ***maintain the efficacy of existing antimicrobials for as long as possible and to*** consider ***a number of*** new measures to promote the development of priority antimicrobials that are effective against antimicrobial resistance and to support undertakings, often SMEs, ***and not-for-profit entities*** which choose to invest in this area. ***It is equally necessary to support research and development of novel antimicrobials through the different phases of antimicrobial development, in particular through market entry rewards and milestone reward payments. Additionally, the establishment of subscription models which delink the volume of antimicrobial sales from the reward received, in particular through voluntary joint procurement, can help overcome such market failures. Such measures should facilitate the development of alternative treatments, such as bacteriophages, which are effective against multi-drug resistant bacteria and can be used as an alternative treatment or together with antibiotics. However, addressing anti-microbial resistance will not be possible by relying on 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.

Amendment 47
Proposal for a regulation
Recital 77 a (new)

Text proposed by the Commission	*Amendment*
	(77a) Reluctance to invest in the development of antimicrobials exists in part because the development of antimicrobials is costly and many developers, often SMEs, cannot afford to proceed to the next stage of development. Additionally, when an antimicrobial is developed, the market is naturally limited by virtue of the need to use antimicrobials prudently. Therefore, it is necessary to consider further Union level action to support the development of antimicrobials and address existing market failures. Accordingly, a milestone payment reward scheme, complemented by a subscription model voluntary joint procurement scheme, should be developed to ensure that a market exists for developers that delink volumes sold from payment received.

Amendment 48
Proposal for a regulation
Recital 77 b (new)

Text proposed by the Commission	*Amendment*
	(77b) Milestone payments are an early-stage financial reward granted upon achieving certain R&D objectives prior to market approval, for example successful completion of phase I. While such mechanisms would serve primarily to provide access to existing antimicrobials, they could also support new antimicrobials in the development phase. A subscription model consists of a series of financial payments to an antibiotic developer for successfully obtaining regulatory approval for an antibiotic that

meets specific pre-defined criteria. A subscription model scheme through voluntary joint procurement agreements should alleviate concerns for developers by ensuring there is a market for the antimicrobial when developed.

Amendment 49
Proposal for a regulation
Recital 78 a (new)

Text proposed by the Commission	*Amendment*
	(78a) To effectively address major ongoing and upcoming public health challenges, in particular antimicrobial resistance, while also building on existing resources, the Health Emergency Preparedness and Response Authority ('HERA' or the 'Authority') should be established as a separate structure under the legal personality of the European Centre for Disease Prevention and Control (ECDC), which was established by Regulation (EC) No 851/2004 of the European Parliament and of the Council[1a]. The Authority should be responsible for creating, coordinating and implementing the long-term European portfolio of biomedical research and development agenda for medical countermeasures against current and emerging public health threats, as well as providing tools to ensure Union-wide access to those products, including tools to support the production, procurement, stockpiling and distribution capacity for medical countermeasures and other priority medical products in the Union. The Authority will play a crucial role in addressing health threats globally. The Authority should primarily focus on the fight against the most urgent health threats, including antimicrobial resistance and shortages of medicinal products. However, in the future as its capacity increases, the Authority should expand the scope of its mission, specifically to tackle other areas of unmet medical need such as rare and neglected diseases. The Authority should have adequate resources

	to fulfil its mandate.
	[1a] Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1).

Amendment 50
Proposal for a regulation
Recital 78 b (new)

Text proposed by the Commission	*Amendment*
	(78b) In addition to the growing threat of antimicrobial resistance, there are other market failures present in the pharmaceutical sector for which further action at Union level is required to meet the public health needs of Union citizens. In particular, there is misalignment between R&D priorities and the public health needs of Union citizens. The market failures in the Union have, in certain instances, resulted in no treatments being available for rare diseases and unequal access to medicinal products, and have led to shortages. This Regulation should therefore address those market failures through providing for a modulated approach to market exclusivities and increased transparency concerning R&D expenditure to better deliver on the objectives of affordability, accessibility and availability of medicinal products in the Union.

Amendment 51
Proposal for a regulation
Recital 78 c (new)

Text proposed by the Commission	*Amendment*
	(78c) Joint procurement, whether within a country or involving more than one country, can improve access to, affordability, and security of supply of medicinal products. Member States interested in joint procurement of

medicinal products should be able to request the Commission to facilitate joint procurement of centrally authorised medicinal products at Union level conducted pursuant to Directive 2014/24/EU of the European Parliament and of the Council[1a].

[1a] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65).

Amendment 52
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.	(79) ***As an alternative, for developers who have not availed of market entry rewards and milestone payment schemes,*** the creation of a voucher rewarding the development of priority antimicrobials through an additional ***period*** 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. ***Additionally, the monetary value paid for the transfer of the voucher should be transferred to the Authority, which should distribute the corresponding amount, in yearly instalments, to the marketing authorisation holder, in order to ensure manufacturing capacity and supply of the priority antimicrobial for which the voucher was created.***

Amendment 53
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 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 ***and indirect*** support given to the medicinal product ***in accordance with Article 57 of [revised Directive 2001/83/EC]***.

Amendment 54
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.	(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 ***and any indirect financial support in accordance with Article 57 of [revised Directive 2001/83/EC]***.

Amendment 55
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.	(82) A transfer of a voucher for a priority antimicrobial may be conducted by sale ***and may only be transferred once***. 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.

Amendment 56
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.	(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. ***Additionally, by ... [five years from the date of entry into force of this Regulation], the Commission should provide an evaluation report on the effectiveness of both the milestone payment reward schemes and the transferable data exclusivity vouchers in the development of priority antimicrobials.***

Amendment 57
Proposal for a regulation
Recital 86

Text proposed by the Commission	*Amendment*
(86) Medicinal products for rare diseases and for children should be subject to the same provisions as any other medicinal product concerning their quality, safety and efficacy, for example for what concerns the marketing authorisation procedures, the pharmacovigilance and quality requirements. However, specific requirements also apply to them. Such requirements, which are currently defined in separate legislations, should be integrated in this Regulation in order to ensure clarity and coherency of all the measures applicable to these medicinal products.	(86) Medicinal products for rare diseases and for children should be subject to the same provisions as any other medicinal product concerning their quality, safety**,** and efficacy ***and environmental risk***, for example for what concerns the marketing authorisation procedures, the pharmacovigilance and quality requirements. However, specific requirements also apply to them. Such requirements, which are currently defined in separate legislations, should be integrated in this Regulation in order to ensure clarity and coherency of all the measures applicable to these medicinal products.

Amendment 58
Proposal for a regulation
Recital 88

Text proposed by the Commission	*Amendment*
(88) Regulation (EC) No 141/2000 of the European Parliament and of the Council[55] has proved to be successful in boosting developments of orphan medicinal products in the Union; therefore an action at Union level remains preferable to uncoordinated measures by the Member States which may result in distortions of competition and barriers to intra-Union trade.	(88) Regulation (EC) No 141/2000 of the European Parliament and of the Council[55] has proved to be successful in boosting developments of orphan medicinal products in the Union***, even though more progress needs to be done, as 95 % of rare diseases are still without authorised treatment and the treatments available for 5 % of rare diseases are not necessarily transformative or curative***; therefore an action at Union level remains preferable to uncoordinated measures by the Member States which may result in distortions of competition and barriers to intra-Union trade. ***The Union should build on its success, driving and ensuring a similar degree of innovation under this Regulation.***
[55] Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1).	[55] Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1).

Amendment 59

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, 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.	(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. ***Nevertheless, medicinal products should still be able to lose the orphan status in cases where the population criterion is no longer met.***

Amendment 60
Proposal for a regulation
Recital 92

Text proposed by the Commission	*Amendment*
(92) With the aim to better identify only those diseases which are rare, the Commission should be empowered to supplement the designation criteria by a delegated act if they are not appropriate for certain conditions due to scientific reasons and on the recommendation of the Agency. In addition, the designation criteria require implementing measures to be adopted by the Commission.	***deleted***

Amendment 61
Proposal for a regulation
Recital 92 a (new)

Text proposed by the Commission	*Amendment*
	(92a) What qualifies as a significant benefit in a patient population can change over time. Therefore, while ensuring predictability, the Agency should also take

	into account any scientific developments and guidance when assessing whether medicinal products meet the significant benefit criteria.

Amendment 62
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 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.	(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, ***should also*** 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.

Amendment 63
Proposal for a regulation
Recital 95

Text proposed by the Commission	*Amendment*
(95) In order to incite faster authorisation of designated orphan medicinal products, the validity of orphan designation has been set at seven years, with the possibility of extension by the Agency under certain	(95) In order to incite faster authorisation of designated orphan medicinal products, the validity of orphan designation has been set at seven years, with the possibility of extension by the Agency under certain

specified conditions; the orphan designation may be withdrawn at the request of the orphan medicine sponsor.	specified conditions; the orphan designation may be withdrawn at the request of the orphan medicine sponsor***, who should be able to provide a reasoned justification for the withdrawal request***. ***The Agency should make the reasoned justification for the withdrawal request, when provided by the sponsor, publicly available.***

Amendment 64
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.	***deleted***

Amendment 65
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).

Amendment 66
Proposal for a regulation
Recital 105 a (new)

Text proposed by the Commission	*Amendment*
	(105a) The Agency should refuse the validation of an application for a marketing authorisation referring to data for a reference medicinal product only on the basis of the grounds set out in this

	Regulation and [revised Directive 2001/83/EC]. The same should apply to any decision to grant, vary, suspend, restrict or revoke the marketing authorisation. The Agency cannot base its decision on any other grounds. In particular, those decisions cannot be based on the patent or supplementary protection certificate status of the reference medicinal product.

Amendment 67
Proposal for a regulation
Recital 105 b (new)

Text proposed by the Commission	*Amendment*
	(105b) One of the overarching goals of this Regulation is to help to meet the medical needs of patients with rare diseases, to improve the affordability of orphan medicinal products and 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 those goals, people living with a rare disease continue to face common challenges that are numerous 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 Union added value in 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 complement this Regulation by developing a dedicated framework for rare diseases to bridge relevant legislation, policies and programmes, and support national strategies with a view to better meeting the unmet needs of people living with rare diseases and of their carers. That framework should be needs-driven and goals-based, and developed in consultation with the Member States and patient organisations as well as, where

relevant, other interested parties.

Amendment 68
Proposal for a regulation
Recital 112

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

Amendment 69
Proposal for a regulation
Recital 126

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

Amendment 70
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	(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.	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 cases, the Agency should consult with the marketing authorisation applicant or marketing authorisation holder, before undertaking any such update.***

Amendment 71
Proposal for a regulation
Recital 132 a (new)

Text proposed by the Commission	*Amendment*
	(132a) To better facilitate patient' access to innovative medicinal products, it is appropriate to establish common rules for the testing and authorisation of innovative medicinal products and innovative technologies related to such products for which, due to their exceptional nature or characteristics, the Union regulatory framework for medicinal products is not expected to be adapted.

Amendment 72
Proposal for a regulation
Recital 132 b (new)

Text proposed by the Commission	*Amendment*
	(132b) On duly justified grounds, regulatory sandboxes should be able to be set up when it is not possible to develop the medicinal product or category of

	medicinal products in compliance with the requirements applicable to medicinal products due to scientific or regulatory challenges arising from characteristics or methods related to the medicinal product, and those characteristics or methods positively and distinctively contribute to the quality, safety or efficacy of the medicinal product or category of medicinal products, or significantly improve patient access to treatment.

Amendment 73
Proposal for a regulation
Recital 132 c (new)

Text proposed by the Commission	*Amendment*
	(132c) The objectives of providing for the possibility of establishing regulatory sandboxes under this Regulation are the following: 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 for which the current regulatory framework is not adapted, as agreed with the competent authorities, and to identify possible future adaptations of the legal framework for the authorisation of medicinal products in the Union.

Amendment 74
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	(133) Regulatory sandboxes can provide the opportunity for advancing regulation through proactive regulatory learning, enabling regulators to gain better regulatory knowledge and to find the best means to regulate innovations based on real-world evidence, especially at a very early stage of development of a medicinal product, which can be particularly important in the face of high uncertainty

and disruptive challenges, as well as when preparing new policies. Regulatory sandboxes provide a structured context for experimentation, enable where appropriate in a real-world environment the testing of innovative technologies, products, services or approaches – at the moment especially in the context of digitalisation or the use of artificial intelligence and machine learning in the life cycle of medicinal products from drug discovery, development to the administration of medicinal products – for a limited time and in a limited part of a sector or area under regulatory supervision ensuring that appropriate safeguards are in place. In its conclusions of 23 December 2020 the Council has encouraged the Commission to consider the use of regulatory sandboxes on a case-by-case basis when drafting and reviewing legislation.	and disruptive challenges, as well as when preparing new policies. ***SMEs and startups should also have the possibility of utilising*** regulatory sandboxes ***whereby they can, as relevant, contribute with their knowhow and experience. Regulatory sandboxes can*** provide ***controlled frameworks which, by providing*** a structured context for experimentation, enable where appropriate in a real-world environment the testing of innovative technologies, products, services or approaches – at the moment especially in the context of digitalisation or the use of artificial intelligence and machine learning in the life cycle of medicinal products from drug discovery, development to the administration of medicinal products – for a limited time and in a limited part of a sector or area under regulatory supervision ensuring that appropriate safeguards are in place. ***They allow the authorities tasked with implementing and enforcing the legislation to exercise on a case-by-case basis a degree of flexibility in relation to testing innovative medicinal products, for the benefit of bringing such products to patients without compromising the standards of quality, safety and efficacy. The regulatory sandbox should in principle allow the Agency to assess if an adapted framework for the medicinal product in question is appropriate and should be developed. Given that the regulatory sandbox should not continue indefinitely, upon its completion the medicinal product in question should, if appropriate, be regulated through an adapted framework.*** In its conclusions of 23 December 2020 the Council has encouraged the Commission to consider the use of regulatory sandboxes on a case-by-case basis when drafting and reviewing legislation.

Amendment 75
Proposal for a regulation
Recital 134

Text proposed by the Commission	*Amendment*

(134) In the area of medicinal products, a high level of protection of inter alia citizens, consumers, health, as well as legal certainty, a level playing field and fair competition always need to be ensured and existing levels of protection need to be respected.	(134) In the area of medicinal products, a high level of protection of inter alia citizens, consumers, health***, the environment***, as well as legal certainty, a level playing field and fair competition always need to be ensured and existing levels of protection need to be respected. ***Whenever possible, priority should be given to the use of non-animal approaches.***

Amendment 76
Proposal for a regulation
Recital 135

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

Amendment 77
Proposal for a regulation
Recital 135 a (new)

Text proposed by the Commission	*Amendment*
	(135a) The Union market for medicinal products remains fragmented, despite the Union having a single market and being the second largest market for pharmaceuticals in the world. The organisation of healthcare systems is a national competence of Member States and that allows for decisions to be made

closer to the patient, but also brings divergences in both pricing and patient access. Better and closer coordination between national authorities opens the door to a more efficient and effective supply of medicinal products throughout the Union.

Amendment 78
Proposal for a regulation
Recital 135 b (new)

Text proposed by the Commission	*Amendment*
	(135b) More often than in the past, Member States experience critical shortages of certain antimicrobials, endangering the health of patients and risking the development of antimicrobial resistance. Those critical shortages are the result of changing infection patterns, which strongly increases demand. On the supply side, the long lead times needed to boost production makes it difficult to respond quickly. This experience underlines the need for a dedicated effort from all actors to address the issue of critical shortages.

Amendment 79
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	(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. Member States should collect data on the impact of***

prevent shortages. The Agency should provide guidance to marketing authorisation holders on approaches to streamline the implementation of those plans.	***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***. 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.

Amendment 80
Proposal for a regulation
Recital 137

Text proposed by the Commission	*Amendment*
(137) To achieve a better security of supply for medicinal products in the internal market and to contribute thereby to a high level of public health protection, it is appropriate to approximate the rules on monitoring and reporting of actual or potential shortages of medicinal products, including the procedures and the respective roles and obligations of concerned entities in this Regulation. It is important to ensure continued supply of medicinal products, which is often taken for granted across Europe. This is especially true for the most critical medicinal products which are essential to ensure the continuity of care, the provision of quality healthcare and guarantee a high level of public health protection in Europe.	(137) To achieve a better security of supply for medicinal products in the internal market and to contribute thereby to a high level of public health protection, it is appropriate to approximate the rules on monitoring and reporting of actual or potential shortages of medicinal products, including the procedures and the respective roles and obligations of concerned entities in this Regulation***, while allowing Member States to adopt or maintain legislation ensuring a higher degree of protection against shortages of medicinal products***. It is important to ensure continued supply of medicinal products, which is often taken for granted across Europe. This is especially true for the most critical medicinal products which are essential to ensure the continuity of care, the provision of quality healthcare and guarantee a high level of public health protection in Europe. ***To combat certain shortages, medicinal products prepared for individual patients in a pharmacy according to a medical***

prescription 'magistral formula', or according to the pharmacopoeia and intended to be supplied directly to patients served by the pharmacy 'officinal formula', should be able to be used.

Amendment 81
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	(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. ***Information on such shortages should be made available on the European medicines web-portal provided for in this Regulation.*** 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 the estimated duration of the shortage and available alternatives, and*** manage those critical shortages, whether the medicinal product concerned by the critical shortage is covered by a centralised marketing authorisation or a national marketing authorisation. Marketing authorisation holders and other relevant entities***, importers, manufacturers and suppliers,*** must provide the relevant information to inform the monitoring. Wholesale distributors and other persons or legal entities, including patient organisations or health care professionals ***and consumers and other persons or legal entities that are authorised or entitled to supply medicinal products to the public***, may also report a shortage of a given medicinal product marketed in the Member

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.	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. ***Where appropriate, those security of supply measures should also comprise the use of regulatory flexibilities such as on packaging and labelling requirements. However, such flexibility should not undermine high quality and safety standards.*** Implementing acts can be adopted by the Commission to ensure that appropriate measures, including the establishment or maintenance of contingency stocks, are taken by marketing authorisation holders, wholesale distributors or other relevant entities.
[56] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1).	[56] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1).

Amendment 82
Proposal for a regulation
Recital 138 a (new)

Text proposed by the Commission	*Amendment*
	(138a) Wholesalers are usually a key supply link between marketing authorisation holders and the users of medicinal products, and in those cases, in order to estimate demand, the quantity requested in wholesale orders should be considered.

Amendment 83
Proposal for a regulation
Recital 138 b (new)

Text proposed by the Commission	*Amendment*
	(138b) It is necessary to avoid that measures planned or taken in one Member State to prevent or mitigate a shortage at national level when responding to the legitimate needs of its citizens increase the risk of shortages in another Member State.

Amendment 84
Proposal for a regulation
Recital 139 a (new)

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

Amendment 85
Proposal for a regulation
Recital 140

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

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

Amendment 86
Proposal for a regulation
Recital 149

Text proposed by the Commission	*Amendment*

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

Amendment 87
Proposal for a regulation
Recital 155

Text proposed by the Commission	*Amendment*
(155) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, the rights of the child, respect for private and family life, the protection of personal data and the freedom of art and science.	(155) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, the rights of the child, respect for private and family life, the protection of personal data and the freedom of art and science. ***Similarly, this Regulation aims to ensure a high level of protection of the environment in accordance with Article 192(1) TFEU.***

Amendment 88
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*** 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.

Amendment 89
Proposal for a regulation
Article 2 – paragraph 2 – point 7

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

Amendment 90
Proposal for a regulation
Article 2 – paragraph 2 – point 8 – point a

Text proposed by the Commission	*Amendment*
(a) greater efficacy than an authorised medicinal orphan medicinal product in a ***substantial*** part of the target population;	(a) greater efficacy than an authorised medicinal orphan medicinal product in a ***relevant*** part of the target population;

Amendment 91
Proposal for a regulation
Article 2 – paragraph 2 – point 8 – point b

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

Amendment 92
Proposal for a regulation
Article 2 – paragraph 2 – point 10

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

supervision.

Amendment 93
Proposal for a regulation
Article 2 – paragraph 2 – point 12

Text proposed by the Commission	*Amendment*
(12) 'shortage' means a situation in which the supply of a medicinal product that is authorised and placed on the market in a Member State does not meet the demand for that medicinal product in that Member State.	(12) 'shortage' means a situation in which the supply of a medicinal product that is authorised and placed on the market in a Member State does not meet the demand for that medicinal product in that Member State ***whatever the cause***.

Amendment 94
Proposal for a regulation
Article 2 – paragraph 2 – point 14 a (new)

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

Amendment 95
Proposal for a regulation
Article 2 – paragraph 2 – point 14 b (new)

Text proposed by the Commission	*Amendment*
	(14b) 'supply' means the total volume of stock of a given medicinal product that is placed on the market by a marketing authorisation holder or a manufacturer;

Amendment 96
Proposal for a regulation
Article 5 – paragraph 5

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

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

Amendment 97
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***; and***
	(b) the use of identified versions of the summary of product characteristics as referred to in Article 62 of [revised Directive 2001/83/EC] in situations where elements of the product information are still covered by patent law or supplementary protection certificates for medicinal products.
[66] Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade	[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).	mark (OJ L 154, 16.6.2017, p. 1).

Amendment 98
Proposal for a regulation
Article 6 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
For medicinal products that are likely to offer an exceptional therapeutic advancement in the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the Union, the Agency may, following the advice of the Committee for Medicinal Products for Human Use regarding the maturity of the data related to the development, offer to the applicant a phased review of complete data packages for individual modules of particulars and documentation as referred to in paragraph 1.	For medicinal products that are likely to offer an exceptional therapeutic advancement in the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition ***or that are expected to be of major interest from the point of view of public health or intended for conditions with no authorised alternatives*** in the Union, the Agency may, following the advice of the Committee for Medicinal Products for Human Use regarding the maturity of the data related to the development, offer to the applicant a phased review of complete data packages for individual modules of particulars and documentation as referred to in paragraph 1.

Amendment 99
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. ***The Agency shall in its annual report highlight key observations and best practices in the replacement, reduction and refinement of animal testing submitted by applicants.***

Amendment 100
Proposal for a regulation
Article 7 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Without prejudice to Article 22 of [revised Directive 2001/83/EC], the	1. Without prejudice to Article 22 of [revised Directive 2001/83/EC], the

marketing authorisation application of a medicinal product for human use containing or consisting of genetically modified organisms as defined in Article 2(2) of Directive 2001/18/EC shall be accompanied by an environmental risk assessment identifying and evaluating potential adverse effects of the genetically modified organisms on human health and the environment.	marketing authorisation application of a medicinal product for human use containing or consisting of genetically modified organisms as defined in Article 2(2) of Directive 2001/18/EC shall be accompanied by an environmental risk assessment identifying and evaluating potential adverse effects of the genetically modified organisms on human ***and animal*** health**,** and the environment.

Amendment 101
Proposal for a regulation
Article 8 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) identification and characterisation of hazards for the environment, animals and for human health;	(b) identification and characterisation of hazards for the environment, animals and for human health ***throughout the lifecycle of the medicinal product, including manufacturing***; ***for the purpose of this point, 'hazards for human health' include 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;***

Amendment 102
Proposal for a regulation
Article 8 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) risk minimisation strategies proposed to address identified risks including specific containment measures to limit contact with the medicinal product.	(e) risk minimisation ***and mitigation*** strategies proposed to address identified risks including specific containment measures to limit contact with the medicinal product.

Amendment 103
Proposal for a regulation
Article 9 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
The Committee for Medicinal Products for Human Use shall assess the environmental risk assessment.	The Committee for Medicinal Products for Human Use shall assess the environmental risk assessment***, and where necessary consult the ad-hoc Environmental Risk***

	Assessment working party referred to in Article 150.

Amendment 104
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. Details on the consultation procedure shall be published by the Agency at the latest by [OJ:12 months after the date of entry into force of this Regulation].

Amendment 105
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 withdrawn ***by default***.

Amendment 106
Proposal for a regulation
Article 12 – paragraph 4 – point g

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

Amendment 107
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;

Amendment 108
Proposal for a regulation
Article 12 – paragraph 4 – point i

Text proposed by the Commission	*Amendment*
(i) in case of medicinal products for which there is ***substantial*** uncertainty as to the surrogate endpoint relation to the expected health outcome, where appropriate and relevant for the benefit-risk balance, a post-authorisation obligation to substantiate the clinical benefit***;***	(i) in case of medicinal products for which there is ***a detailed justification submitted to the Agency as to the grounds of*** uncertainty as to the surrogate endpoint relation to the expected health outcome, where appropriate and relevant for the benefit-risk balance, ***with specific attention given to new active substances and therapeutic indications,*** a post-authorisation obligation to substantiate the

clinical benefit*:*

Amendment 109
Proposal for a regulation
Article 12 – paragraph 4 – point j a (new)

Text proposed by the Commission	*Amendment*
	(ja) where appropriate, any justified reasoning for granting marketing authorisation pursuant to Article 18, 19 and 30 of this Regulation;

Amendment 110
Proposal for a regulation
Article 12 – paragraph 4 – point m a (new)

Text proposed by the Commission	*Amendment*
	(ma) a stewardship and access plan in accordance with Article 17(1), point (a), 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;

Amendment 111
Proposal for a regulation
Article 12 – paragraph 4 – point m b (new)

Text proposed by the Commission	*Amendment*
	(mb) where applicable, reasoning 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.

Amendment 112
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	Where the draft decision differs from the opinion of the Agency, the Commission shall provide a detailed explanation of the

reasons for the differences.	reasons for the differences ***and make that information publicly available***.

Amendment 113
Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 6

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

Amendment 114
Proposal for a regulation
Article 13 – paragraph 4

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

Amendment 115
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 environmental risk assessment is incomplete or insufficiently substantiated by the applicant or if the risks identified in the environmental risk assessment have not been sufficiently addressed by the ***risk mitigation measures proposed by the*** applicant ***in accordance with Article 22(3) of [revised Directive 2001/83/EC]***;

Amendment 116
Proposal for a regulation
Article 16 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency shall immediately publish the	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.	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 ***following a notification to relevant patient organisations***. ***The Agency shall ensure that European public assessment report summaries are readable, clear and comprehensible.***

Amendment 117
Proposal for a regulation
Article 16 – paragraph 3 – subparagraph 2 – indent 2

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

Amendment 118
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.

Amendment 119
Proposal for a regulation
Article 18 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. In exceptional circumstances where, in an application under Article 6 of [revised Directive 2001/83/EC] for a marketing authorisation of a medicinal	1. In exceptional circumstances where, in an application under Article 6 of [revised Directive 2001/83/EC] for a marketing authorisation of a medicinal

product or a new therapeutic indication of an existing marketing authorisation under this Regulation, an applicant is unable to provide comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use, the Commission may, by derogation to Article 6, grant an authorisation under Article 13, subject to specific conditions, where the following requirements are met:	product or a new therapeutic indication**,** of an existing marketing authorisation under this Regulation, an applicant is unable to provide comprehensive data on the efficacy and safety of***, and, where missing, on the environmental risk posed by,*** the medicinal product under normal conditions of use, the Commission may, by derogation to Article 6, grant an authorisation under Article 13, subject to specific conditions, where the following requirements are met:

Amendment 120
Proposal for a regulation
Article 18 – paragraph 2 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	Where specific conditions referred to in paragraph 1, point (c), of this Article are not fulfilled within the timeframe given by the Agency or the marketing authorisation holder does not provide duly justified reasons for not fulfilling the conditions, the Commission may suspend, revoke or vary the marketing authorisation by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 173(2).

Amendment 121
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***, in particular for ongoing or new studies as referred to in paragraph 4,*** and, where appropriate the time limit for compliance shall be specified in the conditions to the marketing authorisation. Those specific obligations shall be reviewed annually by the Agency for the first three years after granting the authorisation and every two years

thereafter.

Amendment 122
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 that the benefit-risk balance is favourable.

Amendment 123
Proposal for a regulation
Article 19 – paragraph 7 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Where the specific obligations referred to in paragraph 3 are not complied with within the timeframe stipulated by the Agency or the marketing authorisation holder does not provide duly justified reasons for not complying with the obligations, the Commission may suspend, revoke or vary the marketing authorisation by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 173(2).

Amendment 124
Proposal for a regulation
Article 19 – paragraph 8 – point b

Text proposed by the Commission	*Amendment*
(b) the procedures and requirements for granting a conditional marketing authorisation, for its renewal, ***and*** for adding a new conditional therapeutic indication to an existing marketing authorisation.	(b) the procedures and requirements for granting a conditional marketing authorisation, for its renewal, for adding a new conditional therapeutic indication to an existing marketing authorisation***, and for the withdrawal, suspension or revocation of the conditional marketing***

authorisation.

Amendment 125
Proposal for a regulation
Article 19 – paragraph 8 a (new)

Text proposed by the Commission	*Amendment*
	8a. The Agency shall publish in the database referred to in Article 138(1), second subparagraph, point (n), the list of conditional marketing authorisations, together with the following information:
	(a) specific obligations to be complied with by the marketing authorisation holder;
	(b) timelines for compliance with specific obligations;
	(c) any delays by the marketing authorisation holder regarding the compliance with specific obligations and the reasons for such delays;
	(d) any actions on the conditional marketing authorisation taken in accordance with Article 56.

Amendment 126
Proposal for a regulation
Article 20 – paragraph 1 – subparagraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) conducts a post-authorisation treatment optimisation study where the optimal usage of an authorised medicinal product has not been previously established.

Amendment 127
Proposal for a regulation
Article 20 – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
Where the Agency considers that any of the post-authorisations studies referred to in points (a) to ***(c)*** is necessary, it shall inform the marketing authorisation holder thereof in writing, stating the grounds for	Where the Agency considers that any of the post-authorisations studies referred to in ***the first subparagraph,*** points (a) to ***(ca),*** is necessary, it shall inform the marketing authorisation holder thereof in

its assessment and shall include the objectives and timeframe for submission and conduct of the study.	writing, stating the grounds for its assessment and shall include the objectives and timeframe for submission and conduct of the study.

Amendment 128
Proposal for a regulation
Article 20 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Where the opinion of the Agency confirms the need for any of the post-authorisation studies referred to in paragraph 1, points (a) to ***(c)***, to be carried out, the Commission shall vary the marketing authorisation, by means of implementing acts, adopted pursuant to Article 13 to include the obligation as a condition of the marketing authorisation unless the Commission returns the opinion to the Agency for further consideration. For obligations under paragraph 1, points (a) and (b), the marketing authorisation holder shall update the risk management system accordingly.	4. Where the opinion of the Agency confirms the need for any of the post-authorisation studies referred to in paragraph 1, ***first subparagraph,*** points (a) to ***(ca)***, to be carried out, the Commission shall vary the marketing authorisation, by means of implementing acts, adopted pursuant to Article 13 to include the obligation as a condition of the marketing authorisation unless the Commission returns the opinion to the Agency for further consideration. For obligations under paragraph 1, points (a) and (b), the marketing authorisation holder shall update the risk management system accordingly.

Amendment 129
Proposal for a regulation
Article 24 – paragraph 1 – subparagraph 1

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

Amendment 130
Proposal for a regulation
Article 24 – paragraph 1 – subparagraph 2 – point f a (new)

Text proposed by the Commission	*Amendment*

(fa) commercial reasons.

Amendment 131
Proposal for a regulation
Article 24 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. In the cases referred to in paragraph 1, second subparagraph, point (f), the Agency shall immediately inform the Commission. The Commission shall in turn inform the relevant national and Union authorities. Where relevant, national authorities shall forward the information to drinking water and wastewater operators.

Amendment 132
Proposal for a regulation
Article 24 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The Agency may decide to extend obligations set out in paragraph 4 in justified cases to a specific non-critical medicinal product on a case-by-case basis.

Amendment 133
Proposal for a regulation
Article 24 – paragraph 4 b (new)

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

Amendment 134
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 ***without undue delay*** withdraw the initial or duplicate marketing authorisation.

Amendment 135
Proposal for a regulation
Article 26 – paragraph 2

Text proposed by the Commission	*Amendment*
2. For the purposes of this Article, 'compassionate use' shall mean making a medicinal product belonging to the categories referred to in Article 3, paragraphs 1 and 2 available for compassionate reasons to a group of patients with a chronically or seriously debilitating disease or whose disease is considered to be life-threatening, and who cannot be treated satisfactorily by an authorised medicinal product. The medicinal product concerned must either be the subject of an application for a marketing authorisation in accordance with Article 6 or the submission of such application is imminent, or it must be undergoing clinical trials in the same indication.	2. For the purposes of this Article, 'compassionate use' shall mean making a medicinal product belonging to the categories referred to in Article 3, paragraphs 1 and 2 available for compassionate reasons to a ***single or*** group of patients with a chronically or seriously debilitating disease or whose disease is considered to be life-threatening***, treatment resistant, or causing psychological distress or patients in palliative care***, and who cannot be treated satisfactorily by an authorised medicinal product. The medicinal product concerned must either be the subject of an application for a marketing authorisation in accordance with Article 6 or the submission of such application is imminent, or it must be undergoing clinical trials in the same indication.

Amendment 136
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***.

Amendment 137
Proposal for a regulation
Article 26 – paragraph 4 – subparagraph 2

Text proposed by the Commission	*Amendment*

In the preparation of the opinion, the Committee for Medicinal Products for Human Use may request information and data from marketing authorisation holders and from developers and may engage with them in preliminary discussions. The Committee may also make use of health data generated outside of clinical studies, where available, taking into account the reliability of those data.	In the preparation of the opinion, the Committee for Medicinal Products for Human Use may request information and data from marketing authorisation holders and from developers and may engage with them in preliminary discussions. The Committee may also make use of health data generated outside of clinical studies, ***including real world data,*** where available, taking into account the reliability of those data.

Amendment 138
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 the database referred to in Article 138(1), second subparagraph, point (n),*** on its website.

Amendment 139
Proposal for a regulation
Article 26 – paragraph 10

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

Amendment 140
Proposal for a regulation
Article 29 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	The applicable periods of regulatory protection shall be published and updated where appropriate by the Commission in the Union Register of medicinal products.

Amendment 141
Proposal for a regulation

Article 32 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Agency shall ensure that the scientific opinion of the Committee for Medicinal Products for Human Use is given without undue delay, taking into account, the recommendation of the Emergency Task Force referred to in Article 38(1), second subparagraph. For the purpose of issuing its opinion, the Agency may consider any relevant data on the medicinal product concerned.	1. The Agency shall ensure that the scientific opinion of the Committee for Medicinal Products for Human Use is given without undue delay, taking into account, the recommendation of the Emergency Task Force referred to in Article 38(1), second subparagraph. For the purpose of issuing its opinion, the Agency may consider any relevant data on the medicinal product concerned ***in addition to the evidence submitted in the applicant's dossier***.

Amendment 142
Proposal for a regulation
Article 32 – paragraph 2 – subparagraph 1

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

Amendment 143
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. ***The scientific opinion and information on the application for the use of the temporary emergency marketing authorisation shall be made publicly available by the Agency.***

Amendment 144
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***.

Amendment 145
Proposal for a regulation
Article 36 – paragraph 1

Text proposed by the Commission	*Amendment*
The marketing authorisation holder of an authorisation in accordance with Article 33 may submit an application in accordance with Articles 5 and 6 in order to obtain an authorisation in accordance with Articles 13, 16 or 19.	The marketing authorisation holder of an authorisation in accordance with Article 33 may submit an application in accordance with Articles 5 and 6 in order to obtain an authorisation in accordance with Articles 13, 16 or 19 ***based on the pre-agreed deadlines established with the Agency***.

Amendment 146
Proposal for a regulation
Article 37 – paragraph 1

Text proposed by the Commission	*Amendment*
When the temporary marketing authorisation of a medicinal product is suspended or revoked for reasons other than the safety of the medicinal product, or if that temporary emergency marketing authorisation ceases to be valid, Member States may, in exceptional circumstances, allow for a transitional period, the supply of the medicinal product to patients who	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.	are already being treated with it. ***In such cases, the Member State shall inform the Agency about the application of the transitional period. Conditions for manufacturing, use, supply and safety monitoring and the compliance with the related good manufacturing and pharmacovigilance practices shall continue to apply during that period.***

Amendment 147
Proposal for a regulation
Article 39 a (new)

Text proposed by the Commission	*Amendment*
	Article 39a
	Milestone payment reward scheme
	1. An antimicrobial shall be considered a 'priority antimicrobial' if preclinical and clinical data underpin a significant clinical benefit with regard 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.
	2. The Commission, in consultation with the Agency, shall award milestone payments and support to potential priority antimicrobials addressing the priority pathogens referred to in paragraph 1 of this Article. The milestone payments shall be financed through resource matching

by the Commission, including within the framework of Article 12(2), point (b)(i), of Regulation (EU) 2021/695 of the European Parliament and of the Council[1a] and Regulation (EU) 2021/522 of the European Parliament and of the Council [1b].

The Commission shall adopt delegated acts in accordance with Article 175 to supplement this Regulation by setting the criteria for the awarding of milestone payments, including payments for the completion of pre-specified development stages and criteria, taking into account the costs of the development of that stage and the anticipated costs of the next stage of development.

The awarding of milestone payments shall be contingent on legal commitments to use the payments:

(a) to further develop the priority antimicrobial ;

(b) to apply for a marketing authorisation in accordance with this Regulation;

(c) to conduct antimicrobial stewardship and access plans as referred to in Article 17(1), point (a), of [revised Directive 2001/83/EC]; and

(d) where relevant, to apply for the joint procurement agreement referred to in Article 39b.

3. The priority antimicrobial shall also be subject to joint clinical assessment in accordance with Article 7(2), point (a), of Regulation (EU) 2021/2282.

4. A developer who benefits from milestone payments under this Article shall not be eligible to avail of a transferable exclusivity voucher in accordance with Article 40.

[1a] Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon

Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (OJ L 170, 12.5.2021, p. 1).

[1b] Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (OJ L 107, 26.3.2021, p. 1).

Amendment 148
Proposal for a regulation
Article 39 b (new)

Text proposed by the Commission	*Amendment*
	Article 39b
	Subscription model for the joint procurement of antimicrobials
	1. The Commission and any of the Member States may engage, as contracting parties, in a joint procurement procedure conducted pursuant to Article 165(2) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council[1a] with a view to the advance purchase of antimicrobials.
	2. A joint procurement procedure as referred to in paragraph 1 shall be preceded by a joint procurement agreement between the parties determining the practical arrangements governing the subscription model system and other procedures, including the length of the subscription contract and the possibility of parallel procurement.
	3. The joint procurement agreement shall take the form of a multi-year subscription and include the following conditions:
	(a) delinkage or partial delinkage of funding from the volume of sales of the

antimicrobial;

(b) commitment to continuous and sufficient supply in pre-agreed quantities;

(c) commitment to the antimicrobial stewardship and access plans as referred to in Article 17(1), point (a), of [revised Directive 2001/83/EC] ;

(d) commitment to the environmental risk assessment as referred to in Article 22 of [revised Directive 2001/83/EC];

(e) submission of a global access plan to supply third countries in critical need, including through development partners or voluntarily licensing.

4. Participation in the joint procurement procedure shall be open to all Member States and third countries, including the European Free Trade Association States and Union candidate countries, as well as the Principality of Andorra, the Principality of Monaco, the Republic of San Marino and the Vatican City State, by way of derogation from Article 165(2) of Regulation (EU, Euratom) 2018/1046.

5. The Commission shall inform the European Parliament about procedures concerning the joint procurement of antimicrobials and, upon request, grant access to the contracts that are concluded as a result of those procedures, subject to the adequate protection of business secrecy, commercial relations and the interests of the Union. The Commission shall communicate information to the European Parliament regarding sensitive documents in accordance with Article 9(7) of Regulation (EC) No 1049/2001.

[1a] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU)

No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

Amendment 149
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 the 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 ***Article 39a(1)***, under the conditions referred to in paragraph 4 ***of this Article*** based on a scientific assessment by the Agency.

Amendment 150
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 ***a maximum of*** additional 12 months of data protection for one authorised medicinal product.

Amendment 151
Proposal for a regulation
Article 40 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Commission shall adopt delegated acts in in accordance with Article 175 to supplement this Regulation by setting up the eligibility of pathogens for the protection periods referred to in paragraph 2 of this Article in accordance with the WHO priority pathogens list or an equivalent established at Union level, with 12 months of data protection for an authorised product ranked 'critical', 9

	months of data protection for those ranked 'high' and 6 months of data protection for those ranked 'medium'.

Amendment 152
Proposal for a regulation
Article 40 – paragraph 3

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

Amendment 153
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 the*** supply ***of*** the priority antimicrobial in sufficient quantities for the expected needs of the Union market***, as defined in a contract with the Authority***;

Amendment 154
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 ***and indirect financial support in accordance with Article 57 of [revised Directive 2001/83/EC]*** received for research related to the development of the priority antimicrobial***;***

Amendment 155
Proposal for a regulation
Article 40 – paragraph 4 – subparagraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) submit the stewardship and access plan as referred to Article 17(1), point (a), of and Annex I to [revised Directive 2001/83/EC];

Amendment 156
Proposal for a regulation
Article 40 – paragraph 4 – subparagraph 1 – point b b (new)

Text proposed by the Commission	*Amendment*
	(bb) submit a global access plan to supply third countries in critical need, including through development partners or voluntary licensing.

Amendment 157
Proposal for a regulation
Article 40 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The priority antimicrobial shall be added to the list of antimicrobials which are to be reserved for treatment of certain infections in humans and added to the Union list as established by Commission Implementing Regulation (EU) 2022/1255[1a].
	[1a] Commission Implementing Regulation (EU) 2022/1255 of 19 July 2022 designating antimicrobials or groups of

	antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council (OJ L 191, 20.7.2022, p. 58).

Amendment 158
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 may be used to extend the data protection for a period of ***6, 9 or*** 12 months of the priority antimicrobial or another medicinal product authorised in accordance with this Regulation of the same or different marketing authorisation holder.

Amendment 159
Proposal for a regulation
Article 41 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
A voucher shall only be used once and in relation to a single centrally authorised medicinal product and only if that product is within its first four years of regulatory data protection.	A voucher shall only be used once and in relation to a single centrally authorised medicinal product and only if that product is within its first four years of regulatory data protection. ***The voucher shall not be used for a product which already benefited from the maximum regulatory data protection period as set out in Article 81 of [revised Directive 2001/83/EC].***

Amendment 160
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. A voucher may be transferred to another marketing authorisation holder ***once*** and shall not be transferred further.

Amendment 161
Proposal for a regulation
Article 41 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The monetary value paid for the transfer of the voucher shall be directed to the Authority, which shall in yearly instalments transfer the amount to the marketing authorisation holder, in order to ensure the manufacturing capacity and supply of the priority antimicrobial. The Commission shall adopt delegated acts in accordance with Article 175 to supplement this Regulation by setting up the framework for the conditions and functioning of annual instalments.

Amendment 162
Proposal for a regulation
Article 42 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) where it is not used within ***5*** years ***from the date it was granted***.	(b) where it is not used within ***four*** years ***after the conditions set out in Article 41 have been fulfilled by the seller***.

Amendment 163
Proposal for a regulation
Article 42 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. The Commission may revoke the voucher 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. ***To protect the buyer from damage resulting from a possible revocation of a voucher after the transfer, seller and buyer shall make contractual liability arrangements.***

Amendment 164
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 ***immediately from ... [***the date of entry into force of this Regulation] ***and for 15 years*** or until the date when the Commission has granted a

a total of 10 vouchers in accordance with this Chapter, whichever date is the earliest.	total of 10 vouchers in accordance with this Chapter, whichever date is the earliest.

Amendment 165
Proposal for a regulation
Article 43 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	By ... [five years from the date of entry into force of this Regulation], the Commission shall submit an evaluation report to the European Parliament and to the Council containing a scientific assessment measuring the progress with regard to antimicrobial research and development and the effectiveness of the incentives and rewards in this Chapter.

Amendment 166
Proposal for a regulation
Article 45 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency may at any time request the marketing authorisation holder to submit data demonstrating that the benefit-risk balance remains favourable. The marketing authorisation holder shall answer fully and ***promptly*** any such request. The marketing authorisation holder shall also respond fully and within the time limit set ***to*** any request of a competent authority regarding the implementation of any measures previously imposed, including risk minimisation measures.	The Agency may at any time request the marketing authorisation holder to submit data demonstrating that the benefit-risk balance remains favourable. The marketing authorisation holder shall answer fully and ***within the time limit set for*** any such request. The marketing authorisation holder shall also respond fully and within the time limit set any ***such*** request of a competent authority regarding the implementation of any measures previously imposed, including risk minimisation measures.

Amendment 167
Proposal for a regulation
Article 47 – paragraph 1

Text proposed by the Commission	*Amendment*
1. An application for variation of a centralised marketing authorisation by the marketing authorisation holder shall be made electronically in the formats made available by the Agency, unless the variation is an update by the marketing	1. An application for variation of a centralised marketing authorisation by the marketing authorisation holder shall be made electronically in the formats made available by the Agency, unless the variation is an update by the marketing

authorisation holder of their information held in a database.	authorisation holder of their information held in a database. ***The electronic format shall include a baseline sequence in relations to the Common Technical Document (CTD).***

Amendment 168
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.

Amendment 169
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***, including any additional evidence that may be submitted by the marketing authorisation holders for the medicinal products concerned,*** make a scientific evaluation of the benefit-risk of the use of a medicinal product with a new therapeutic indication.

Amendment 170
Proposal for a regulation
Article 48 – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
The opinion of the Agency shall be made publicly available and the competent authorities of the Member States shall be informed.	The opinion of the Agency shall be made publicly available and the competent authorities of the Member States ***and the marketing authorisation holder*** shall be informed.

Amendment 171
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.	***deleted***

Amendment 172
Proposal for a regulation
Article 52 – paragraph 2 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) to lend its assistance by participating in a joint inspection with the supervisory authority of the site. In that case the supervisory authority leads the inspection and the follow up thereof. After completion of the inspection, the supervisory authority grants the relevant ***good manufacturing practice (GMP)*** certificate and enters the certificate in the Union database; or	(a) to lend its assistance by participating in a joint inspection with the supervisory authority of the site ***to assess compliance with good manufacturing practice (GMP) as well as any practices relating to environmental and worker safety***. In that case the supervisory authority leads the inspection and the follow up thereof. After completion of the inspection, the supervisory authority grants the relevant ***GMP*** certificate and enters the certificate in the Union database; or

Amendment 173
Proposal for a regulation
Article 53 – paragraph 2

Text proposed by the Commission	*Amendment*
2. In cooperation with the Agency, the Commission ***may*** adopt detailed guidelines laying down the principles applicable to those international inspection programmes.	2. In cooperation with the Agency, the Commission ***shall*** adopt detailed guidelines laying down the principles applicable to those international inspection programmes. ***The guidelines shall include rules on impartially, independence and conflict of interest of inspectors.***

Amendment 174
Proposal for a regulation
Article 56 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	Where the marketing authorisation holder fails to comply with the obligations in the

	post-authorisation studies laid down in accordance with Article 20, the Commission may adopt a decision to vary, suspend, or revoke that marketing authorisation in accordance with the procedure laid down in Article 13.

Amendment 175
Proposal for a regulation
Article 58 – paragraph 3

Text proposed by the Commission	*Amendment*
3. In the preparation of the scientific advice referred to in paragraph 1 ***and in duly justified cases,*** the Agency may consult authorities established in other Union legal acts as relevant for the provision of the scientific advice in question ***or*** other public bodies established in the Union, as applicable.	3. In the preparation of the scientific advice referred to in paragraph 1 ***of this Article*** the Agency may consult authorities established in other Union legal acts as relevant for the provision of the scientific advice in question***,*** other public bodies established in the Union, ***in particular those listed in Article 162 or other bodies,*** as applicable***, or in duly justified cases public bodies established in third countries***.

Amendment 176
Proposal for a regulation
Article 58 – paragraph 4

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

Amendment 177
Proposal for a regulation
Article 58 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*

	4a. The Agency shall, to the greatest extent possible, ensure that there is a separation between those responsible for providing scientific advice to a given medicinal product developer and those subsequently responsible for the evaluation of the marketing authorisation application for the same medicinal product.
	The Agency shall ensure that at least one of the two rapporteurs for a marketing authorisation application has not 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 and recorded in the summary minutes of the meetings in accordance with Article 147(2).

Amendment 178
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 that, based on preliminary evidence submitted by the developer fulfil ***at least one of*** the following conditions:

Amendment 179
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) 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 provided for in the***

	'WHO priority pathogens list for R&D of new antibiotics', specifically those listed as priority 1 (critical) or priority 2 (high), or taking into account as a priority any equivalent list of priority pathogens adopted at Union level.

Amendment 180
Proposal for a regulation
Article 60 – paragraph 4 a (new)

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

Amendment 181
Proposal for a regulation
Article 61 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
For products under development which may fall within the categories of medicinal products to be authorised by the Union listed in Annex I, a developer or a competent authority of the Member States may submit a duly substantiated request to the Agency for a scientific recommendation with a view to determining on scientific grounds whether the concerned product is potentially a 'medicinal product', including an 'advanced therapy medicinal product' as defined in Article 2 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council[71] .	For products under development which may fall within the categories of medicinal products to be authorised by the Union listed in Annex I, a developer or a competent authority of the Member States may submit a duly substantiated request to the Agency for a scientific recommendation with a view to determining on scientific grounds whether the concerned product is potentially a 'medicinal product', including an 'advanced therapy medicinal product' as defined in Article 2 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council[71]. ***The Agency may rely on the relevant expertise of working parties and pools of experts when making its***

recommendation.

[71] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).

[71] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).

Amendment 182
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 ***and where there is a doubt as to the regulatory status of a product under development***, 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 ***first*** consult ***the compendium referred to in Regulation (EU) 2024/... [SoHO Regulation] and where necessary, conduct joint meetings with*** the Substances of Human Origin (SoHO) Coordination Board as established in ***that*** Regulation.

Amendment 183
Proposal for a regulation
Article 61 – paragraph 2 – subparagraph 3

Text proposed by the Commission	*Amendment*
The Agency shall publish ***summaries of*** the recommendations delivered in accordance with paragraph 1, after deletion of all information of a commercially confidential nature.	The Agency shall publish the recommendations delivered in accordance with paragraph 1, after deletion of all information of a commercially confidential nature.

Amendment 184
Proposal for a regulation
Article 61 – paragraph 2 – subparagraph 3 a (new)

Text proposed by the Commission	*Amendment*
	For transparency purposes, the respective opinions and conclusions of the Agency and the relevant advisory bodies on the regulatory status of the product shall be made publicly available after the consultations and, where applicable, the joint meetings have taken place.

Amendment 185
Proposal for a regulation
Article 62 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
In the case of duly substantiated disagreement with the Agency's recommendation, in accordance with Article 61(2), a Member State may request the Commission to decide whether the product is a product referred to in Article 61(1).	In the case of duly substantiated disagreement with the Agency's ***scientific*** recommendation, in accordance with Article 61(2), a Member State may request the Commission to decide whether the product is a product referred to in Article 61(1).

Amendment 186
Proposal for a regulation
Article 62 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission may ask the Agency for clarifications or refer the recommendation back to the Agency for further consideration where a Member State's substantiated request raises new questions of a scientific or technical nature or on its own initiative.	2. The Commission may ask the Agency ***and the relevant advisory or regulatory bodies involved in the delivery of the scientific recommendation*** for clarifications or refer the recommendation back to the Agency for further consideration where a Member State's substantiated request raises new questions of a scientific or technical nature or on its own initiative.

Amendment 187
Proposal for a regulation
Article 62 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The decision of the Commission referred to in paragraph 1 shall be adopted by means of implementing acts, in accordance with the examination procedure	3. The decision of the Commission referred to in paragraph 1 shall be adopted by means of implementing acts, in accordance with the examination procedure

referred to in Article 173(2), taking into account the scientific recommendation of the Agency.	referred to in Article 173(2), taking into account the scientific recommendation of the Agency ***and other advisory bodies***.

Amendment 188
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***

Amendment 189
Proposal for a regulation
Article 64 – paragraph 2 – subparagraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) justification that the criteria laid down in Article 63(1) ***or in the relevant delegated acts adopted in accordance with Article 63(2)*** are fulfilled and a description of the stage of development, including the expected therapeutic indication.	(d) justification that the criteria laid down in Article 63(1) are fulfilled and a description of the stage of development, including the expected therapeutic indication.

Amendment 190
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	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.

documentation referred to in paragraph 2.

Amendment 191
Proposal for a regulation
Article 65 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) reasons for the transfer of the orphan designation.

Amendment 192
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 may provide a reasoned justification for the withdrawal request, which shall be made publicly available.***

Amendment 193
Proposal for a regulation
Article 67 – paragraph 3 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) where applicable, any request made in accordance with Article 66(2) and any decisions taken in that respect.

Amendment 194
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:

Amendment 195
Proposal for a regulation
Article 68 – paragraph 1 – point a

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

Amendment 196
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 entities not engaged in economic activity*** provided for in framework programmes for research and technological development.

Amendment 197
Proposal for a regulation
Article 69 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
In addition, the applicant shall demonstrate that the medicinal product has been granted an orphan designation and that the criteria set out in Article 63(1) ***or in the relevant delegated acts adopted in accordance with Article 63(2)*** are fulfilled for the therapeutic indication sought.	In addition, the applicant shall demonstrate that the medicinal product has been granted an orphan designation and that the criteria set out in Article 63(1) are fulfilled for the therapeutic indication sought.

Amendment 198
Proposal for a regulation
Article 69 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Committee for Medicinal Products for Human Use shall assess whether the	The Committee for Medicinal Products for Human Use shall assess whether the

medicinal product fulfils the requirements set out in Article 63(1) ***or in the relevant delegated acts adopted in accordance with Article 63(2)***. In the situation referred in paragraph 2, subparagraph 2, that Committee shall also assess whether the medicinal product addresses a high unmet medical need as specified in Article 70(1).	medicinal product fulfils the requirements set out in Article 63(1). In the situation referred in paragraph 2, subparagraph 2, that Committee shall also assess whether the medicinal product addresses a high unmet medical need as specified in Article 70(1).

Amendment 199
Proposal for a regulation
Article 69 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The orphan marketing authorisation shall cover only those therapeutic indications, which fulfil the requirements set out in Article 63(1) ***or in the relevant delegated acts adopted in accordance with Article 63(2)*** at the time when the orphan marketing authorisation is granted.	4. The orphan marketing authorisation shall cover only those therapeutic indications, which fulfil the requirements set out in Article 63(1) at the time when the orphan marketing authorisation is granted.

Amendment 200
Proposal for a regulation
Article 69 – paragraph 6

Text proposed by the Commission	*Amendment*
6. An applicant may submit an application for a separate marketing authorisation for other indications which do not fulfil the requirements set out in Article 63(1) ***or in the relevant delegated acts adopted in accordance with Article 63(2)***.	6. An applicant may submit an application for a separate marketing authorisation for other indications which do not fulfil the requirements set out in Article 63(1).

Amendment 201
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***	(a) there is no medicinal product authorised in the Union for such condition***; or***

exceptional therapeutic advancement;

Amendment 202
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 a medicinal product is authorised for such condition, in addition to having a significant benefit, it will bring exceptional therapeutic advancement and*** the use of the orphan medicinal product results in a meaningful reduction in disease morbidity or mortality for the relevant patient population.

Amendment 203
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.

Amendment 204
Proposal for a regulation
Article 71 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) ***ten*** years for orphan medicinal products addressing a high unmet medical need as referred to in Article 70;	(b) ***eleven*** years for orphan medicinal products addressing a high unmet medical need as referred to in Article 70;

Amendment 205
Proposal for a regulation
Article 71 – paragraph 2 – point c

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

Amendment 206
Proposal for a regulation
Article 71 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The submission, validation and assessment of the application for the marketing authorisation and granting the marketing authorisation for a generic or biosimilar product to the reference medicinal product ***for which market exclusivity has expired***, shall not be prevented by the market exclusivity of a similar product to the reference medicinal product.	5. The submission, validation and assessment of the application for the marketing authorisation and granting the marketing authorisation for a generic or biosimilar product to the reference medicinal product, shall not be prevented by the market exclusivity of a similar product to the reference medicinal product.

Amendment 207
Proposal for a regulation
Article 71 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The market exclusivity of the orphan medicinal product shall not prevent the submission, validation ***and*** assessment of an application for a marketing authorisation for a similar medicinal product, including generics and biosimilars, where the remainder of the duration of the market exclusivity is less than two years.	6. The market exclusivity of the orphan medicinal product shall not prevent the submission, validation***,*** assessment of an application for***, or the granting of,*** a marketing authorisation for a similar medicinal product, including generics and biosimilars, where the remainder of the duration of the ***initial*** market exclusivity is less than two years.

Amendment 208
Proposal for a regulation
Article 72 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The periods of market exclusivity referred to in Article 71, paragraph 2, points (a) and (b), shall be prolonged by 12 months, where the orphan marketing authorisation holder can demonstrate that the conditions referred to in Article 81(2), point (a), and Article 82(1) [of revised Directive 2001/83/EC] are fulfilled. ***The procedures set out in Articles 82(2) to (5) [of revised Directive 2001/83/EC] shall accordingly apply to the prolongation of***	***deleted***

market exclusivity.

Amendment 209
Proposal for a regulation
Article 73 a (new)

Text proposed by the Commission	*Amendment*
	Article73a
	Joint procurement of centrally authorised medicinal products
	1. Upon request from the Member States, the Commission shall facilitate joint procurement of centrally authorised medicinal products at Union level on Member States' behalf.
	2. The Commission is empowered to adopt delegated acts in accordance with Article 175 to supplement this Regulation by further defining the conditions and procedures for joint procurement of centrally authorised medicinal products.

Amendment 210
Proposal for a regulation
Article 73 b (new)

Text proposed by the Commission	*Amendment*
	Article73b
	Union Framework for Rare Diseases
	By ... [24 months from the date of entry into force of this Regulation], the Commission shall, following a consultation with the Member States, patient organisations and other relevant stakeholders, propose a needs-driven and goals-based Union Framework for Rare Diseases with a view to better framing and coordinating Union policies and programmes, and supporting Member States in the elaboration of national strategies to better meet the unmet needs of people living with rare diseases, and their carers.

Amendment 211
Proposal for a regulation

Article 74 – paragraph 2 – subparagraph 1 – point b

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

Amendment 212
Proposal for a regulation
Article 74 – paragraph 3

Text proposed by the Commission	*Amendment*
3. When it is not possible, on the basis of scientifically justified reasons, to have a complete paediatric development plan in accordance with the timing given in Article 76(1) an applicant may submit a justified request to the Agency to utilise the procedure mentioned in paragraph 2. The Agency has 20 days to accept or refuse the request and shall immediately inform the applicant and state the reasons for refusal.	3. When it is not possible, on the basis of scientifically justified reasons, to have a complete paediatric development plan in accordance with the timing given in Article 76(1) an applicant may submit a ***duly*** justified request to the Agency to utilise the procedure mentioned in paragraph 2. The Agency has 20 days to accept or refuse the request and shall immediately inform the applicant and state the reasons for refusal.

Amendment 213
Proposal for a regulation
Article 75 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) that the disease or condition for which the specific medicinal product or class is intended occurs only in adult populations, unless when the product is directed at a molecular target ***that*** on the basis of existing scientific data, is responsible for a different disease or condition in the same therapeutic area in children than the one for which the specific medicinal product or class of medicinal products is intended for in the adult population;	(b) that the disease or condition for which the specific medicinal product or class is intended occurs only in adult populations, unless when the product is directed at a molecular target ***or due to its mechanism of action*** on the basis of existing scientific data, is responsible for a different disease or condition in the same therapeutic area in children than the one for which the specific medicinal product or class of medicinal products is intended for in the adult population;

Amendment 214
Proposal for a regulation
Article 75 – paragraph 3

Text proposed by the Commission	*Amendment*

3. On the basis of the experience acquired as a result of the operation of this Article or of scientific knowledge the Commission is empowered to adopt delegated acts in accordance with Article 175 to amend the grounds for granting a waiver detailed in paragraph 1.	***deleted***

Amendment 215
Proposal for a regulation
Article 75 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The Agency shall, after consultation with the Commission and relevant interested parties, draw up guidelines for the application of this Article.

Amendment 216
Proposal for a regulation
Article 81 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The length of the deferral shall be specified in a decision of the Agency and shall not exceed five years.	3. The length of the deferral shall be specified in a decision of the Agency and shall ***be substantiated by scientific and technical grounds or by considerations pertaining to public health and*** not exceed five years.

Amendment 217
Proposal for a regulation
Article 84 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The procedure provided for in paragraph 1 of this Article shall also apply when the applicant updates the elements of an initial paediatric investigation plan submitted in accordance with Article 74(2).

Amendment 218
Proposal for a regulation
Article 84 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
If, following the decision agreeing the paediatric investigation plan referred to in Article 77, paragraphs 1, 2 and 4, or on the basis of the updated paediatric investigation plan received in accordance with Article 77(3), the Agency, on the base of new scientific information available, considers that the agreed plan or any of its elements are no longer appropriate, it shall request the applicant ***to*** propose changes to the paediatric investigation plan.	If, following the decision agreeing the paediatric investigation plan referred to in Article 77, paragraphs 1, 2 and 4, or on the basis of the updated paediatric investigation plan received in accordance with Article 77(3), the Agency, on the base of new scientific information available, considers that the agreed plan or any of its elements are no longer appropriate, it shall request***, based on detailed scientific grounds, that*** the applicant propose changes to the paediatric investigation plan.

Amendment 219
Proposal for a regulation
Article 84 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Within the timelines for adoption of a decision provided for in Articles 77, 78, 80, 81, 82 and 84, the Agency shall transmit its scientific conclusions to the applicant.

Amendment 220
Proposal for a regulation
Article 84 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. Where marketing authorisation applicants or marketing authorisation holders disagree with the scientific conclusions, they may respond within 20 days of receipt of those conclusions by providing detailed grounds and evidence for re-examination.
	The Agency shall assess the request for re-examination and may request more information from the marketing authorisation applicant or marketing authorisation holder in this process.
	Within 30 days of receipt of a request for re-examination, the Agency shall confirm its scientific conclusions or commence a

re-examination where deemed justified.

Amendment 221
Proposal for a regulation
Article 88 – paragraph 1

Text proposed by the Commission	*Amendment*
Where a paediatric investigation plan, agreed in accordance with the provisions of Article 77, paragraphs 1, 2 and 4, is discontinued, the applicant shall notify the Agency of its intention to discontinue the conduct of the paediatric investigation plan and provide the reasons for such discontinuation no less than six months before the discontinuation.	Where a paediatric investigation plan, agreed in accordance with the provisions of Article 77, paragraphs 1, 2 and 4, is discontinued, the applicant shall notify the Agency of its intention to discontinue the conduct of the paediatric investigation plan and provide the reasons for such discontinuation no less than six months before the discontinuation ***or as soon as possible***.

Amendment 222
Proposal for a regulation
Article 91 – paragraph 3

Text proposed by the Commission	*Amendment*
3. When products are authorised in accordance with the provisions of this Regulation, the Commission may update the summary of product characteristics and package leaflet, and may vary the marketing authorisation accordingly.	3. When products are authorised in accordance with the provisions of this Regulation, the Commission may update the summary of product characteristics and package leaflet, and may vary the marketing authorisation accordingly***, including regarding information on dosage accuracy***.

Amendment 223
Proposal for a regulation
Article 101 – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
The Eudravigilance database shall contain information on suspected adverse reactions in human beings arising from use of the medicinal product within the terms of the marketing authorisation as well as from uses outside the terms of the marketing authorisation, and on those occurring in the course of post-authorisation studies with the medicinal product or associated with occupational exposure.	The Eudravigilance database shall contain information on suspected adverse reactions in human beings arising from use of the medicinal product within the terms of the marketing authorisation as well as from uses outside the terms of the marketing authorisation, ***including errors in relation to medication,*** and on those occurring in the course of post-authorisation studies with the medicinal product or associated

with occupational exposure.

Amendment 224
Proposal for a regulation
Article 101 – paragraph 2 – subparagraph 5

Text proposed by the Commission	*Amendment*
The Agency shall ensure that healthcare professionals and the public have appropriate levels of access to the Eudravigilance database, and that personal data is protected. The Agency shall work together with all stakeholders, including research institutions, healthcare professionals, and patient and consumer organisations, in order to define the 'appropriate level of access' for healthcare professionals and the public to the Eudravigilance database.	The Agency shall ensure that healthcare professionals and the public have appropriate levels of access to the Eudravigilance database, and that personal data is protected ***in line with Union data protection and privacy law***. The Agency shall work together with all stakeholders, including research institutions, healthcare professionals, and patient and consumer organisations, in order to define the 'appropriate level of access' for healthcare professionals and the public to the Eudravigilance database.

Amendment 225
Proposal for a regulation
Article 101 – paragraph 2 – subparagraph 6

Text proposed by the Commission	*Amendment*
The data held on the Eudravigilance database shall be made publicly available in an aggregated format together with an explanation of how to interpret the data.	The data held on the Eudravigilance database shall be made publicly available in an aggregated ***and anonymised*** format together with an explanation of how to interpret the data.

Amendment 226
Proposal for a regulation
Article 101 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The periodic safety update reports shall, in addition, be made publicly available in the web-portal referred to in Article 138(1), second subparagraph, point (n).

Amendment 227
Proposal for a regulation
Article 104 – paragraph 1 – subparagraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a European medicines web-portal for the dissemination of information on medicinal products authorised or to be authorised in the Union. By means of that portal, the Agency shall make public the following:	The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a European medicines web-portal for the dissemination of information on medicinal products authorised or to be authorised in the Union. ***The dedicated web-portal shall be set up in accordance with Directive (EU) 2016/2102 of the European Parliament and of the Council[1a].*** By means of that portal, the Agency shall make public the following:
	[1a] Directive (EU) 2016/2102 of the European Parliament and of the Council of 26 October 2016 on the accessibility of the websites and mobile applications of public sector bodies (OJ L 327, 2.12.2016, p. 1).

Amendment 228
Proposal for a regulation
Article 104 – paragraph 1 – subparagraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) ***a summary of*** the risk management plans for medicinal products authorised in accordance with this Regulation;	(c) the risk management plans for medicinal products authorised in accordance with this Regulation ***and the accompanying summaries of the risk management plans***;

Amendment 229
Proposal for a regulation
Article 104 – paragraph 1 – subparagraph 1 – point h

Text proposed by the Commission	*Amendment*
(h) the initiation of the procedure provided for in Article 41(2), and Articles 114, 115 and 116 of [revised Directive 2001/83/EC], the active substances or medicinal products concerned and the issue being addressed, any public hearings pursuant to that procedure and information on how to submit information and to participate in public hearings;	(h) the initiation of the procedure provided for in Article 41(2) ***of this Regulation***, and Articles 114, 115 and 116 of [revised Directive 2001/83/EC], the active substances or medicinal products concerned and the issue being addressed, any public hearings pursuant to that procedure and information on how to submit information and to participate in

public hearings;

Amendment 230
Proposal for a regulation
Article 104 – paragraph 1 – subparagraph 1 – point i

Text proposed by the Commission	*Amendment*
(i) conclusions of assessments, recommendations, opinions, approvals and decisions taken by the Agency and its Committees under this Regulation and [revised Directive 2001/83/EC]***, unless it is required that this information is made public by the Agency by other means;***	(i) conclusions of assessments***, obligations for post-marketing studies***, recommendations, opinions, approvals and decisions taken by the Agency and its Committees under this Regulation and [revised Directive 2001/83/EC]**.**

Amendment 231
Proposal for a regulation
Article 104 – paragraph 1 – subparagraph 1 – point j

Text proposed by the Commission	*Amendment*
(j) conclusions of assessments, recommendations, opinions, approvals and decisions taken by the coordination group, the competent authorities of the Member States and the Commission in the framework of the procedures set out in Articles 16, 106, 107 and 108 of this Regulation and of Chapter IX, Sections 3 and 7 of [revised Directive 2001/83/EC].	(j) conclusions of assessments, recommendations, opinions, approvals***, obligations deriving from the conditional marketing authorisations*** and decisions taken by the coordination group, the competent authorities of the Member States and the Commission in the framework of the procedures set out in Articles 16, 106, 107 and 108 of this Regulation and of Chapter IX, Sections 3 and 7 of [revised Directive 2001/83/EC].

Amendment 232
Proposal for a regulation
Article 104 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
The ***summaries*** referred to in point (c) shall include a description of any additional risk minimisation measures.	The ***risk management plans*** referred to in point (c) shall include a description of any additional risk minimisation measures ***and distribution or implementation plans***.

Amendment 233
Proposal for a regulation
Article 104 – paragraph 2

Text proposed by the Commission	*Amendment*
2. In the development and review of the web portal, the Agency shall consult relevant stakeholders, including patient and consumer groups, healthcare professionals and industry representatives.	2. In the development and review of the web portal, the Agency shall consult relevant stakeholders, including patient and consumer groups, healthcare professionals***, not-for-profit entities*** and industry representatives.

Amendment 234
Proposal for a regulation
Article 104 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a register of environmental risk assessment studies conducted for the purpose of supporting an environmental risk assessment for medicinal products authorised in the Union***, unless such information is made public in the Union by different means***.	The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a register of environmental risk assessment studies conducted for the purpose of supporting an environmental risk assessment for medicinal products authorised in the Union.

Amendment 235
Proposal for a regulation
Article 104 – paragraph 3 – subparagraph 2

Text proposed by the Commission	*Amendment*
Information in such register shall be publicly available, unless restrictions are necessary to protect commercially confidential information. For the purpose of setting up such register, the Agency ***may*** request marketing authorisation holders and competent authorities to submit results of any such study already completed for products authorised in the Union within [OP please add the date = 24 months after the date of application of this Regulation].	Information in such register shall be publicly available ***and easily accessible on the Agency's website***, ***and shall include, as a minimum, the information reported in accordance with Section 1.6 of Annex II to [revised Directive 2001/83/EC],*** unless restrictions are necessary to protect commercially confidential information. For the purpose of setting up such register, the Agency ***shall, where not already received,*** request marketing authorisation holders and competent authorities to submit results of any such study already completed for products authorised in the Union within [OP please add the date = 24 months after the date of application of this Regulation].

Amendment 236
Proposal for a regulation

Article 105 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency shall, in consultation with the Commission, Member States and ***interested*** parties, draw up a detailed guide regarding the monitoring of medical literature and the entry of relevant information into the Eudravigilance database.	3. The Agency shall, in consultation with the Commission, Member States and ***their relevant authorities, as well as other relevant*** parties***, including experts from academia***, draw up a detailed guide regarding the monitoring of medical literature and the entry of relevant information into the Eudravigilance database.

Amendment 237
Proposal for a regulation
Article 109 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Agency and the ***European Monitoring Centre for*** Drugs ***and Drug Addiction*** shall exchange information that they receive on the abuse of medicinal products including information related to illicit drugs.	2. The Agency and the ***Union*** Drugs ***Agency*** shall exchange information that they receive on the abuse of medicinal products including information related to illicit drugs.

Amendment 238
Proposal for a regulation
Article 111 – paragraph 1

Text proposed by the Commission	*Amendment*
The Agency and the Member States shall cooperate to continuously develop pharmacovigilance systems capable of achieving high standards of public health protection for all medicinal products, regardless of the routes of marketing authorisation, including the use of collaborative approaches, to maximise use of resources available within the Union.	The Agency and the Member States shall cooperate to continuously develop pharmacovigilance systems***, including those that record adverse events including medication errors, processes and standards for medication safety,*** capable of achieving high standards of public health protection for all medicinal products, regardless of the routes of marketing authorisation, including the use of collaborative approaches, to maximise use of resources available within the Union.

Amendment 239
Proposal for a regulation
Article 113 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The Commission may set up a regulatory sandbox pursuant to a specific sandbox plan, based on a recommendation of the Agency and pursuant to the procedure set out in paragraphs 4 to 7, where all the following conditions are met*:*	1. The Commission may set up ***on a case-by-case basis*** a regulatory sandbox pursuant to a specific sandbox plan, based on a recommendation of the Agency and pursuant to the procedure set out in paragraphs 4 to 7, where all the following conditions are met***;***

Amendment 240
Proposal for a regulation
Article 113 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency shall monitor the field of emerging medicinal products and may request information and data from marketing authorisation holders, developers, independent experts and researchers, and representatives of healthcare professionals and of patients and may engage with them in preliminary discussions.	3. The Agency shall monitor the field of emerging medicinal products and may request information and data from marketing authorisation holders, developers, independent experts and researchers, and representatives of healthcare professionals and of patients and may engage with them in preliminary discussions***, where appropriate referring to the consultation mechanism provided for in Article 162***.

Amendment 241
Proposal for a regulation
Article 113 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
Where the Agency considers it appropriate to set up a regulatory sandbox for medicinal products which are likely to fall under the scope of this Regulation, it shall provide a recommendation to the Commission. The Agency shall list eligible products or category of products in that recommendation and shall include the sandbox plan referred to in paragraph 1.	Where the Agency considers it appropriate to set up a regulatory sandbox for medicinal products which are likely to fall under the scope of this Regulation ***but for which there is an absence of existing adapted rules for development and authorisation***, it shall provide a recommendation to the Commission. The Agency shall list eligible products or category of products in that recommendation and shall include the sandbox plan referred to in paragraph 1.

Amendment 242
Proposal for a regulation
Article 113 – paragraph 5

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

Amendment 243
Proposal for a regulation
Article 113 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Commission shall***, by means of implementing acts, take*** a decision on the set up of a regulatory sandbox taking into account the recommendation of the Agency and the sandbox plan pursuant to paragraph 4. ***Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 173(2).***	6. The Commission shall ***adopt delegated acts in accordance with Article 175 to supplement this Regulation by taking*** a decision on the set up of a regulatory sandbox taking into account the recommendation of the Agency and the sandbox plan pursuant to paragraph 4.

Amendment 244
Proposal for a regulation
Article 113 – paragraph 8 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) it is appropriate to protect public health.	(b) it is appropriate to protect public health ***or the environment***.

Amendment 245
Proposal for a regulation
Article 113 – paragraph 9

Text proposed by the Commission	*Amendment*
9. Where after the Decision to establish the regulatory sandbox in accordance with paragraph 6, risks to health are identified but these risks can be fully mitigated by the adoption of supplementary conditions, the Commission may, after consultation of the Agency, amend its decision by means of implementing acts. ***The Commission may also prolong the duration of a regulatory sandbox by means of implementing acts.*** Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 173(2).	9. Where after the Decision to establish the regulatory sandbox in accordance with paragraph 6, risks to health are identified but these risks can be fully mitigated by the adoption of supplementary conditions, the Commission may, after consultation of the Agency, amend its decision by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 173(2). ***The Commission is empowered to adopt delegated acts in accordance with Article 175 to supplement this Regulation by, on the basis of duly justified reasoning and evidence from the Agency, prolonging the duration of a regulatory sandbox.***

Amendment 246
Proposal for a regulation
Article 114 – paragraph 2

Text proposed by the Commission	*Amendment*
2. A medicinal product developed as part of a regulatory sandbox may be placed on the market only when authorised in accordance with this Regulation. The initial validity of such authorisation shall not exceed the duration of the regulatory sandbox. The authorisation may be prolonged at the request of the marketing authorisation holder.	2. A medicinal product developed as part of a regulatory sandbox may be placed on the market only when authorised in accordance with this Regulation. The initial validity of such authorisation shall not exceed the duration of the regulatory sandbox. The authorisation may***, upon a justified recommendation by the Agency,*** be prolonged at the request of the marketing authorisation holder.

Amendment 247
Proposal for a regulation
Article 114 – paragraph 3

Text proposed by the Commission	*Amendment*
3. In duly justified cases, the marketing authorisation of a medicinal product developed under the regulatory sandbox may include derogations from the	3. In duly justified cases, the marketing authorisation of a medicinal product developed under the regulatory sandbox may include derogations from the

requirements set out in this Regulation and [revised Directive 2001/83/EC]. Those derogations may entail adapted, enhanced, waived or deferred requirements. Each derogation shall be limited to what is apt and strictly necessary to attain the objectives pursued, duly justified and specified in the conditions to the marketing authorisation.	requirements set out in this Regulation and [revised Directive 2001/83/EC]***. Any derogation from the requirements in context of the sandbox shall ensure that the level of patient safety and protection of public health and ethical principles are upheld***. Those derogations may entail adapted, enhanced, waived or deferred requirements. Each derogation shall be limited to what is apt and strictly necessary to attain the objectives pursued, duly justified and specified in the conditions to the marketing authorisation.

Amendment 248
Proposal for a regulation
Article 115 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
Where such mitigation is not possible or proves to be ineffective, the development and testing process shall be suspended without delay until an effective mitigation takes place.	Where such mitigation is not possible or proves to be ineffective, the development and testing process shall be suspended without delay until an effective mitigation takes place. ***If no effective mitigation plan can be provided, the Agency shall end the sandbox without undue delay.***

Amendment 249
Proposal for a regulation
Article 115 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Agency with input from Member States shall submit annual reports to the Commission on the results from the implementation of a regulatory sandbox, including good practices, lessons learnt and recommendations on their setup and, where relevant, on the application of this Regulation and other Union legal acts supervised within the sandbox. These reports shall be made publicly available by the Commission.	4. The Agency with input from Member States shall submit annual reports to the Commission on the results from the implementation of a regulatory sandbox, including ***a breakdown on the number of sandboxes granted, trends on medicinal products eligible for a regulatory sandbox,*** good practices, ***difficulties encountered,*** lessons learnt***, reflections on possible future adaptations to the regulatory framework*** and recommendations on their setup and, where relevant, on the application of this Regulation and other Union legal acts supervised within the sandbox. These reports ***as well as lay summaries*** shall be made publicly available by the

Commission.

Amendment 250
Proposal for a regulation
Article 116 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The marketing authorisation holder of a medicinal product in possession of a centralised marketing authorisation or a national marketing authorisation ('the marketing authorisation holder') shall notify the competent authority of the Member State where the medicinal product has been placed on the market and, in addition, the Agency for a medicinal product covered by a centralised marketing authorisation (these are referred to in this Chapter as 'the competent authority concerned') of the following:	1. The marketing authorisation holder of a medicinal product in possession of a centralised marketing authorisation or a national marketing authorisation ('the marketing authorisation holder') shall notify ***and explain the reasons to*** the competent authority of the Member State where the medicinal product has been placed on the market and, in addition, the Agency for a medicinal product covered by a centralised marketing authorisation (these are referred to in this Chapter as 'the competent authority concerned') of the following:

Amendment 251
Proposal for a regulation
Article 116 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) its decision to temporarily suspend the marketing of a medicinal product in that Member State no less than six months before the start of the temporary suspension of supply of that medicinal product into the market of a given Member State by the marketing authorisation holder;	(c) its decision to temporarily suspend the marketing of a medicinal product in that Member State ***as soon as possible and*** no less than six months before the start of the temporary suspension of supply of that medicinal product into the market of a given Member State by the marketing authorisation holder;

Amendment 252
Proposal for a regulation
Article 116 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) a temporary disruption in supply of a medicinal product in a given Member State, of an expected duration of in excess of two weeks or, based on the demand forecast of the marketing authorisation holder no less than six months before the start of such temporary disruption of	(d) a ***foreseeable*** temporary disruption in supply of a medicinal product in a given Member State, of an expected duration of in excess of two weeks or, based on the demand forecast of the marketing authorisation holder ***and national competent authorities, where available, as***

supply or, if this is not possible and where duly justified, as soon as they become aware of such temporary disruption, to allow the Member State to monitor any potential or actual shortage in accordance with Article 118(1).	***soon as possible and*** no less than six months before the start of such temporary disruption of supply or, if this is not possible and ***unforeseeable*** where duly justified, as soon as they become aware of such temporary disruption, to allow the Member State to monitor any potential or actual shortage in accordance with Article 118(1).

Amendment 253
Proposal for a regulation
Article 117 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The marketing authorisation holder as defined in Article 116(1) shall have in place and keep up to date a shortage prevention plan, for any medicinal product placed on the market. To put in place the shortage prevention plan, the marketing authorisation holder shall include the minimum set of information set out in Part V of Annex IV and take into account the guidance drawn up by the Agency according to paragraph 2.	1. ***By ... [18 months from the date of entry into force of this Regulation],*** the marketing authorisation holder as defined in Article 116(1) shall have in place and keep up to date a shortage prevention plan, for any medicinal product placed on the market. To put in place the shortage prevention plan, the marketing authorisation holder shall include the minimum set of information set out in Part V of Annex IV and take into account the guidance drawn up by the Agency according to paragraph 2. ***The shortage prevention plan shall be made available upon request by the Agency or the competent authority of the Member State where the medicinal product has been placed on the market.***

Amendment 254
Proposal for a regulation
Article 117 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Agency, in collaboration with the working party referred to in Article 121(1)***, point (c), shall*** draw up guidance to marketing authorisation holders as defined in Article 116(1) to put in place the shortage prevention plan.	2. The Agency ***shall***, in collaboration with the working party referred to in Article 121(1) ***and after consultation with the Healthcare Professionals' Working Party (HPWP) and the Patients' and Consumers' Working Party (PCWP),*** draw up guidance to marketing authorisation holders as defined in Article 116(1) to put in place the shortage prevention plan.

Amendment 255
Proposal for a regulation
Article 118 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Based on the reports referred to in Articles 120(1) and 121(1), point (c), information referred to in Articles 119, 120(2) and 121 and the notification made pursuant to Article 116(1), points (a) to (d), the competent authority concerned as referred to in Article 116(1) shall continuously monitor any potential or actual shortage of those medicinal products.	Based on the reports referred to in Articles 120(1) and 121(1), point (c), information referred to in Articles 119, 120(2) and 121 and the notification made pursuant to Article 116(1), points (a) to (d), the competent authority concerned as referred to in Article 116(1) shall continuously monitor any potential or actual shortage of those medicinal products ***through their national IT surveillance systems or data bases and send the information to the Agency without undue delay***.

Amendment 256
Proposal for a regulation
Article 118 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. On the basis of the information provided pursuant to Article 121(2), point (f), the Agency shall monitor and assess any actions planned or taken by a Member State to mitigate a shortage at national level with regard to their impact on the availability and supply of medicinal products at Union level.

Amendment 257
Proposal for a regulation
Article 118 – paragraph 2

Text proposed by the Commission	*Amendment*
2. For the purposes of paragraph 1, the competent authority concerned as defined in Article 116(1) may request any additional information from the marketing authorisation holder as defined in Article 116(1). In particular, it may request the marketing authorisation holder to submit a shortage mitigation plan in accordance with Article 119(2), a risk assessment of impact of suspension, cessation or withdrawal in accordance with Article	2. For the purposes of paragraph 1, the competent authority concerned as defined in Article 116(1) may request any additional information from the marketing authorisation holder as defined in Article 116(1). In particular, it may request the marketing authorisation holder to submit a shortage mitigation plan in accordance with Article 119(2), a risk assessment of impact of suspension, cessation or withdrawal in accordance with Article

119(3), or the shortage prevention plan referred to in Article 117. The competent authority concerned ***may*** set a deadline for the submission of the information requested.	119(3), or the shortage prevention plan referred to in Article 117. The competent authority concerned ***shall*** set a deadline for the submission of the information requested.

Amendment 258
Proposal for a regulation
Article 120 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Wholesale distributors and other persons or legal entities that are authorised or entitled to supply medicinal products authorised to be placed on the market of a Member State pursuant to Article 5 of [revised Directive 2001/83/EC] to the public ***may*** report a shortage of a given medicinal product marketed in the Member State concerned to the competent authority in that Member State.	1. Wholesale distributors and other persons or legal entities that are authorised or entitled to supply medicinal products authorised to be placed on the market of a Member State pursuant to Article 5 of [revised Directive 2001/83/EC] to the public ***shall*** report a shortage of a given medicinal product marketed in the Member State concerned to the competent authority in that Member State. ***In addition, wholesale distributors shall submit regular information on the available stocks of the medicinal products they supply to the competent authority.***

Amendment 259
Proposal for a regulation
Article 120 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. When a marketing authorisation holder notifies a temporary disruption in supply of a medicinal product, wholesale distributors as well as other persons or legal entities that are authorised or entitled to supply medicinal products shall provide information upon request in a timely manner to the Agency, the competent authority in a Member State and the relevant marketing authorisation holder on the reasons for the temporary disruption in supply of the product in a Member State.

Amendment 260
Proposal for a regulation
Article 121 – paragraph 1 – point -a (new)

Text proposed by the Commission	*Amendment*
	(-a) collect and assess the information on potential and actual shortages provided by marketing authorisation holders, importers, manufacturers and suppliers of medicinal products or active substances, wholesale distributors, healthcare professionals, patients and consumers, and other persons or legal entities that are authorised or entitled to supply medicinal products to the public;

Amendment 261
Proposal for a regulation
Article 121 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) publish information on actual shortages of medicinal products, ***in cases in which*** that competent authority has assessed the shortage**,** on a publicly available website;	(b) publish information ***and provide regular updates*** on actual shortages of medicinal products, that competent authority has assessed the shortage on a publicly available ***and user-friendly*** website ***and ensure such information, including regarding available alternatives, has been actively communicated to representatives of healthcare professionals and patients***; ***competent authorities shall as soon as possible inform the Agency of any measure planned or taken at national level to mitigate the shortage or expected shortage.***

Amendment 262
Proposal for a regulation
Article 121 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) create a system allowing patients to report shortages of medicinal products and request pharmacies supplying hospitals and hospital pharmacies to electronically communicate data on available stock of the medicinal product concerned, in order to avert or mitigate an imminent or existing supply shortage relevant to the supply of a medicinal

	product.

Amendment 263
Proposal for a regulation
Article 121 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) address recommendations to health professionals on the alternative medicinal products to use to pursue treatments in the event of shortages;

Amendment 264
Proposal for a regulation
Article 121 – paragraph 1 – point c b (new)

Text proposed by the Commission	*Amendment*
	(cb) consider the use of appropriate regulatory measures to mitigate the shortage.

Amendment 265
Proposal for a regulation
Article 121 – paragraph 2 – point f

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

Amendment 266
Proposal for a regulation
Article 121 – paragraph 2 a (new)

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

Amendment 267
Proposal for a regulation
Article 121 – paragraph 5 – point a

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

Amendment 268
Proposal for a regulation
Article 121 – paragraph 5 – point d

Text proposed by the Commission	*Amendment*
(d) inform the Agency of any actions foreseen or taken by that Member State in accordance with points (b) and (c) and report on any other actions taken to mitigate or resolve the critical shortage in the Member State, as well as the results of these actions.	(d) inform the Agency of any actions foreseen or taken by that Member State in accordance with points (b) and (c) and report on any other actions taken to mitigate or resolve the critical shortage in the Member State, as well as the results of these actions***, without undue delay***.

Amendment 269
Proposal for a regulation
Article 121 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Member States may request that the MSSG provide further recommendations, referred to in Article 123(4).	6. The Member States may request that the MSSG provide further recommendations, referred to in Article 123(4). ***Where Member States take an alternative course of action which is not in line with the recommendations of the MSSG at national level, they shall communicate the reasons for doing so to the MSSG in a timely manner.***

Amendment 270
Proposal for a regulation
Article 121 a (new)

Text proposed by the Commission	*Amendment*
	Article 121a

	National websites on medicines shortages
	The website referred to in Article 121(1), point (b), shall include at least the following information:
	(a) trade name of the medicinal product and international non-proprietary name, for interoperability purposes;
	(b) the therapeutic indication for the medicinal product of which there is a shortage;
	(c) reasons for the shortages and mitigation measures taken to address the shortages;
	(d) the start and expected end dates of the shortage;
	(e) other relevant information for healthcare professionals and patients, including information about therapeutic alternatives available.

Amendment 271
Proposal for a regulation
Article 122 – paragraph 1

Text proposed by the Commission	*Amendment*
1. For the purposes of Article 118(1), the Agency may request additional information from the competent authority of the Member State, through the working party referred to in Article 121(1), point (c). The Agency may set a deadline for the submission of the information requested.	1. For the purposes of Article 118(1) ***and (1a)***, the Agency may request additional information from the competent authority of the Member State, through the working party referred to in Article 121(1), point (c). The Agency may set a deadline for the submission of the information requested.

Amendment 272
Proposal for a regulation
Article 122 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. For the purpose of Article 118(1a) and based on the information provided pursuant to Article 121(1), point (cb), and Article 121(2), the Agency shall assess the actions planned or taken by a Member State to mitigate a shortage at national level with regard to any potential or actual

	negative impacts of those actions on the availability and security of supply in another Member State and at Union level. The Agency shall inform the Member State concerned and the MSSG, as well as the Member States potentially or actually impacted, of its assessment in a timely manner through the single point of contact working party referred to in Article 3(6) of Regulation (EU) 2022/123. The Agency shall also inform the Commission of its assessment.

Amendment 273
Proposal for a regulation
Article 122 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. For the purpose of identifying the medicinal products for which the shortage cannot be resolved without Union coordination pursuant to paragraph 2, the Agency may consult market authorisation holders and other relevant stakeholders.

Amendment 274
Proposal for a regulation
Article 122 – paragraph 4 – introductory part

Text proposed by the Commission	*Amendment*
4. For the purposes of fulfilling the tasks referred to in Articles 118(1), 123 and 124, the Agency shall ensure the following, in consultation with the working party referred to in Article 121(1), point (c):	4. For the purposes of fulfilling the tasks referred to in Articles 118(1), 123 and 124, the Agency shall ensure the following, in consultation with the working party referred to in Article 121(1), point (c)***, and in consultation with the Patients' and Consumers' Working Party (PCWP) and the Healthcare Professionals' Working Party (HCPWP) and other relevant stakeholders***:

Amendment 275
Proposal for a regulation
Article 122 – paragraph 6

Text proposed by the Commission	*Amendment*
6. For the purposes of implementing this Regulation, the Agency shall expand	6. For the purposes of implementing this Regulation, the Agency shall expand

the scope of the ESMP. The Agency shall ensure that***, where relevant,*** data is interoperable between the ESMP***,*** Member States' IT systems and other relevant IT systems and databases, without duplication of reporting.	the scope of the ESMP. The Agency shall ensure that data is interoperable between the ESMP ***and*** Member States' IT systems and***, where relevant, with*** other relevant IT systems and databases, without duplication of reporting.

Amendment 276
Proposal for a regulation
Article 123 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The MSSG shall review the status of the critical shortage whenever necessary and shall update the list when it considers that a medicinal product needs to be added or that the critical shortage has been resolved based on the report pursuant to Article 122(5).	2. The MSSG shall review the status of the critical shortage whenever necessary and shall update the list when it considers that a medicinal product needs to be added or that the critical shortage has been resolved based on the report pursuant to Article 122(5). ***The MSSG may recommend monitoring forecasts of supply and demand for medicinal products for human use in the Union and monitoring of available stocks in the whole supply chain.***

Amendment 277
Proposal for a regulation
Article 123 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The MSSG ***may*** provide recommendations on measures to resolve or to mitigate the critical shortage***,*** in accordance with the methods referred to in Article 122(4), point (d), to relevant marketing authorisation holders, the Member States, the Commission, the representatives of healthcare professionals or other entities.	4. The MSSG ***shall, without undue delay,*** provide recommendations on measures to resolve or to mitigate the critical shortage in accordance with the methods referred to in Article 122(4), point (d), to relevant marketing authorisation holders, the Member States, the Commission, the representatives of healthcare professionals or other entities.

Amendment 278
Proposal for a regulation
Article 123 – paragraph 4 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Member States, within the MSSG, may decide to activate the 'Voluntary

	Solidarity Mechanism for medicines' to:
	(a) notify a critical shortage of a medicinal product at national level to other Member States and the Commission;
	(b) identify, with the support of the Agency, the availabilities of the medicinal product in other Member States;
	(c) organise, with the support of the Agency, meetings with the issuing Member States, the donating party and other relevant parties to discuss operational requirements;
	(d) request the activation of the Union Civil Protection Mechanism to coordinate and logistically support the voluntary transfer of medicinal products.

Amendment 279
Proposal for a regulation
Article 124 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
For the purposes of this paragraph, the Agency ***may*** set a deadline for the submission of the information requested.	For the purposes of this paragraph, the Agency ***shall*** set a deadline for the submission of the information requested.

Amendment 280
Proposal for a regulation
Article 124 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency shall establish within its web-portal referred to in Article 104 a publicly available webpage that provides information on actual critical shortages of medicinal products ***in cases in which*** the Agency ***has assessed the shortage and has provided*** recommendations to healthcare professionals and patients. This webpage shall also provide references to the lists of actual shortages published by the competent authorities of the Member State pursuant to Article 121(1), point (b).	3. The Agency shall establish within its web-portal referred to in Article 104 a publicly available ***and user-friendly*** webpage that provides information on ***all*** actual critical shortages of medicinal products***, including the reasons for the shortages. After assessing the shortages,*** the Agency ***shall provide*** recommendations to healthcare professionals and patients***. The webpage shall include the information referred to in Article 121a in addition to the list of Member States affected by each shortage***. This webpage shall also provide references to the lists of actual shortages published by

	the competent authorities of the Member State pursuant to Article 121(1), point (b)***, the ESMP and include, to the extent possible, information from other relevant sources and databases identified by the Agency and include reference to alternative treatment options or products and appropriate communication***.

Amendment 281
Proposal for a regulation
Article 125 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) provide any additional information that the Agency may request;	(a) provide any additional information that the Agency may request***, including regular information on the available stocks of medicinal products***;

Amendment 282
Proposal for a regulation
Article 125 – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
(f) inform the Agency of the end date of the critical shortage**.**	(f) inform the Agency of the end date of the critical shortage ***without undue delay;***

Amendment 283
Proposal for a regulation
Article 126 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Commission shall take the appropriate steps to address any concerns raised by the assessment of the Agency referred to in Article 122(1a).

Amendment 284
Proposal for a regulation
Article 127 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The competent authority of the Member State shall identify critical medicinal products in that Member State, using the methodology set out in Article	1. The competent authority of the Member State shall***, after consultation with healthcare professionals and patient organisations,*** identify critical medicinal

130(1), point (a).	products in that Member State, using the methodology set out in Article 130(1), point (a).

Amendment 285
Proposal for a regulation
Article 128 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The marketing authorisation as defined in Article 116(1) ***authorisation*** shall be responsible for providing correct, not misleading, and complete information as requested by the competent authority concerned as defined in Article 116(1) and shall have the duty to cooperate and to disclose on their own motion any relevant information without undue delay to that competent authority and to update the information as soon as that information becomes available.	2. The marketing authorisation ***holder*** as defined in Article 116(1) shall be responsible for providing correct, not misleading, and complete information as requested by the competent authority concerned as defined in Article 116(1) and shall have the duty to cooperate and to disclose on their own motion any relevant information without undue delay to that competent authority and to update the information as soon as that information becomes available.

Amendment 286
Proposal for a regulation
Article 129 – paragraph 1

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

Amendment 287
Proposal for a regulation
Article 130 – paragraph 1 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) develop a common methodology to identify critical medicinal products, including the evaluation of vulnerabilities with respect to the supply chain of those medicines, in consultation***, where appropriate,*** with relevant stakeholders;	(a) develop a common methodology to identify critical medicinal products, including the evaluation of vulnerabilities ***and the availability of appropriate alternatives*** with respect to the supply chain of those medicines, in consultation with ***the Patients' and Consumers' Working Party (PCWP) and the Healthcare Professionals' Working Party (HCPWP), as well as other*** relevant stakeholders;

Amendment 288
Proposal for a regulation
Article 130 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the marketing authorisation holder of the medicinal product, including the shortage prevention plan, referred to in Article 117;	(b) the marketing authorisation holder of the medicinal product, including the shortage prevention ***and mitigation*** plan, referred to in Article 117 ***and Article 119(2)***;

Amendment 289
Proposal for a regulation
Article 130 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Following the adoption of the Union list of critical medicinal products in accordance with Article 131, the Agency shall ***report to the MSSG on*** any relevant information received from the marketing authorisation holder pursuant to Article 133 and the competent authority of the Member State in accordance with Article 127, paragraphs 7 and 8.	5. Following the adoption of the Union list of critical medicinal products in accordance with Article 131, the Agency shall ***assess*** any relevant information received from the marketing authorisation holder pursuant to Article 133 and the competent authority of the Member State in accordance with Article 127, paragraphs 7 and 8 ***and report on that information to the MSSG***.

Amendment 290
Proposal for a regulation
Article 130 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*

	6a. Following the request by a Member State to use the Voluntary Solidarity Mechanism referred to in Article 132(1a), the Agency shall provide assistance to the MSSG and may:
	(a) confirm that the conditions are met to launch the Voluntary Solidarity Mechanism;
	(b) notify the members of the MSSG of the launch of the Voluntary Solidarity Mechanism;
	(c) request from the members of the MSSG relevant information within a specific time limit;
	(d) put the issuing country in contact with those Member States able to support them;
	(e) organise meetings with the issuing Member States, the donating party and other relevant concerned parties;
	(f) request the activation of the Union Civil Protection Mechanism to coordinate and logistically support the voluntary transfer of medicinal products.

Amendment 291
Proposal for a regulation
Article 131 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Following the reporting referred to in Article 130, paragraph 2, second subparagraph, and Article 130(5), the MSSG shall consult the working party referred to in Article 121(1), point (c). Based on this consultation, the MSSG shall propose a Union list of critical medicinal products authorised to be placed on the market of a Member State pursuant to Article 5 of [revised Directive 2001/83/EC] and for which coordinated Union level action is necessary ("the Union list of critical medicinal products").	1. Following the reporting referred to in Article 130, paragraph 2, second subparagraph, and Article 130(5), the MSSG shall consult the working party referred to in Article 121(1), point (c)***, and the Patients' and Consumers' Working Party (PCWP), the Healthcare Professionals' Working Party (HCPWP) and the Industry Standing Group (ISG)***. Based on this consultation, the MSSG shall propose a Union list of critical medicinal products authorised to be placed on the market of a Member State pursuant to Article 5 of [revised Directive 2001/83/EC] and for which coordinated Union level action is necessary ("the Union list of critical medicinal products").

Amendment 292
Proposal for a regulation
Article 131 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The MSSG ***may*** propose updates to the Union list of critical medicines to the Commission, where necessary.	2. The MSSG ***shall*** propose updates to the Union list of critical medicines to the Commission, where necessary.

Amendment 293
Proposal for a regulation
Article 132 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Following the adoption of the Union list of critical medicinal products pursuant to Article 131(3), in consultation with the Agency and the working party referred to in Article 121(1), point (c), the MSSG may provide recommendations, in accordance with the methods referred to in Article 130(1), point (d), on appropriate security of supply measures to marketing authorisation holders as defined in Article 116(1), the Member States, the Commission or other entities. Such measures may include recommendations on diversification of suppliers ***and*** inventory management.	1. Following the adoption of the Union list of critical medicinal products pursuant to Article 131(3), in consultation with the Agency and the working party referred to in Article 121(1), point (c), the MSSG may provide recommendations, in accordance with the methods referred to in Article 130(1), point (d), on appropriate security of supply measures to marketing authorisation holders as defined in Article 116(1), the Member States, the Commission or other entities. Such measures may include recommendations on ***manufacturing capacity, on reorganisation of manufacturing capacity,*** diversification of suppliers***,*** inventory management***, establishment of minimum safety stock and, if necessary, redistribution of available stock among Member States under the Voluntary Solidarity Mechanism to address urgent needs, as well as pricing and procurement mechanisms and measures and, where appropriate, the use of regulatory flexibilities without lowering safety and efficacy standards***.

Amendment 294
Proposal for a regulation
Article 132 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The MSSG shall coordinate the Voluntary Solidarity Mechanism to allow

	Member States to request assistance in obtaining stocks of a medicinal product during critical shortages. The MSSG shall specify the procedures and criteria to launch the Voluntary Solidarity Mechanism in consultation with the Member States, the Agency and the Commission.

Amendment 295
Proposal for a regulation
Article 132 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. Following the update of the Union list of critical medicinal products, the MSSG shall assess the shortage prevention plan of the medicinal products present on the list.

Amendment 296
Proposal for a regulation
Article 134 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The Commission ***may, where it considers it appropriate and necessary***:	1. The Commission ***shall***:

Amendment 297
Proposal for a regulation
Article 134 – paragraph 1 – point -a (new)

Text proposed by the Commission	*Amendment*
	(-a) take all necessary action within the limits of the powers conferred on it, with a view to mitigating critical shortages of medicinal products;

Amendment 298
Proposal for a regulation
Article 134 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) develop guidelines to ensure that national initiatives on stockpiling are proportionate to the needs and do not

	create undesirable consequences, such as supply shortages, in other Member States;

Amendment 299
Proposal for a regulation
Article 134 – paragraph 1 – point c b (new)

Text proposed by the Commission	*Amendment*
	(cb) develop, within the framework of Directive 2014/24/EU, guidelines to support public procurement practices in the pharmaceutical field, in particular with regard to the implementation of the most economically advantageous tender (MEAT) criteria in order to establish remedies against single-winner, price-only tenders.

Amendment 300
Proposal for a regulation
Article 134 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The Commission shall work with the ECDC on producing reliable forecasts of potential threats and potential shortages.

Amendment 301
Proposal for a regulation
Article 134 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission, taking into consideration the information or the opinion, referred to in paragraph 1, or MSSG recommendations, ***may decide*** to adopt ***an implementing act*** to improve security of supply***. The implementing act*** may impose contingency stock requirements of active pharmaceutical ingredient or finished dosage forms, or other relevant measures required to improve security of supply, on marketing authorisation holders, wholesale distributors or other relevant entities.	2. The Commission, taking into consideration the information or the opinion, referred to in paragraph 1, or MSSG recommendations, ***is empowered*** to adopt ***delegated acts in accordance with Article 175 supplementing this Regulation*** to improve security of supply***, while allowing Member States to adopt or maintain legislation ensuring a higher degree of protection against shortages of medicinal products, in respect of the commitments taken in the framework of the Voluntary Solidarity Mechanism. The delegated acts*** may impose contingency stock requirements of active pharmaceutical ingredient or finished

	dosage forms, or other relevant measures required to improve security of supply, on marketing authorisation holders, wholesale distributors or other relevant entities.

Amendment 302
Proposal for a regulation
Article 134 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The implementing act referred to in paragraph 2 shall be adopted in accordance with the examination procedure referred to in Article 173(2).	***deleted***

Amendment 303
Proposal for a regulation
Article 138 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency shall provide the Member States and the institutions of the Union with the best possible scientific opinion on any question relating to the evaluation of the quality, safety ***and*** efficacy of medicinal products for human use, veterinary medicinal products, which is referred to it in accordance with the Union legal acts relating to medicinal products for human use or veterinary medicinal products.	The Agency shall provide the Member States and the institutions of the Union with the best possible scientific opinion on any question relating to the evaluation of the quality, safety***,*** efficacy ***and environmental risk*** of medicinal products for human use, veterinary medicinal products, which is referred to it in accordance with the Union legal acts relating to medicinal products for human use or veterinary medicinal products.

Amendment 304
Proposal for a regulation
Article 138 – paragraph 1 – subparagraph 2 – introductory part

Text proposed by the Commission	*Amendment*
The Agency, acting particularly through its Committees, shall carry out the following tasks:	The Agency, acting particularly through its Committees ***and working groups***, shall carry out the following tasks:

Amendment 305
Proposal for a regulation
Article 138 – paragraph 1 – subparagraph 2 – point a

Text proposed by the Commission	*Amendment*

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

Amendment 306
Proposal for a regulation
Article 138 – paragraph 1 – subparagraph 2 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) develop, after consulting with relevant national authorities and national bodies responsible for pricing and reimbursement in accordance with Article 162 of this Regulation and the Member State Coordination Group on Health Technology Assessment established by Article 3 of Regulation (EU) 2021/2282, harmonised standards for the design of scientific studies for marketing authorisation holders;

Amendment 307
Proposal for a regulation
Article 138 – paragraph 1 – subparagraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) coordinating the scientific evaluation of the quality, safety and efficacy of veterinary medicinal products, which are subject to Union marketing authorisation procedures in accordance with Regulation (EU) 2019/6 and the performance of other tasks set out in Regulation (EU) 2019/6 and Regulation (EC) 470/2009;	(b) coordinating the scientific evaluation of the quality, safety and efficacy of veterinary medicinal products, which are subject to Union marketing authorisation procedures in accordance with Regulation (EU) 2019/6***, providing advice on methodological aspects relating to the trials for such products and the use of clinical trial results affected for regulatory purposes*** and ***coordinating*** the performance of other tasks set out in Regulation (EU) 2019/6 and Regulation (EC) 470/2009;

Amendment 308
Proposal for a regulation
Article 138 – paragraph 1 – subparagraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) transmitting on request and making	(c) transmitting on request and making

publicly available assessment reports, summaries of product characteristics, labels ***and*** package leaflets for the medicinal products for human use;	publicly available assessment reports, summaries of product characteristics, ***periodic safety update reports,*** labels***,*** package leaflets ***and AMR awareness cards, where applicable,*** for the medicinal products for human use;

Amendment 309
Proposal for a regulation
Article 138 – paragraph 1 – subparagraph 2 – point n

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

Amendment 310
Proposal for a regulation
Article 138 – paragraph 1 – subparagraph 2 – point zc

Text proposed by the Commission	*Amendment*
(zc) establishing a mechanism of consultation of authorities or bodies active along the life cycle of medicinal products for human use for exchange of information and pooling of knowledge on general issues of scientific or technical nature related to the tasks of the Agency;	(zc) establishing a mechanism of consultation of authorities or bodies active along the life cycle of medicinal products for human use for exchange of information and pooling of knowledge on general issues of scientific or technical nature related to the tasks of the Agency***, notably with the SoHO Coordination Board, Medical Devices Coordination Group, the Member State Coordination Group on Health Technology Assessment and national pricing and reimbursement authorities***;

Amendment 311
Proposal for a regulation
Article 138 – paragraph 1 – subparagraph 2 – point ze

Text proposed by the Commission	*Amendment*
(ze) cooperating with EU decentralised agencies and other scientific authorities and bodies established under Union law, notably the European Chemicals Agency, the European Food Safety Authority, the European Centre for Disease Prevention and Control and the European Environment Agency as regards the scientific assessment of relevant substances, exchange of data and information and development of coherent scientific methodologies, including replacing, reducing or refining animal testing, taking into account the specificities of the assessment of medicinal products;	(ze) cooperating with EU decentralised agencies and other scientific authorities and bodies established under Union law, notably the European Chemicals Agency, the European Food Safety Authority, the European Centre for Disease Prevention and Control and the European Environment Agency as regards the scientific assessment of relevant substances, exchange of data and information and development of coherent scientific methodologies, including replacing, reducing or refining animal testing, ***and, where possible, prioritising replacement strategies such as non-animal in vitro and silico approaches,*** taking into account the specificities of the assessment of medicinal products;

Amendment 312
Proposal for a regulation
Article 138 – paragraph 1 – subparagraph 2 – point zl a (new)

Text proposed by the Commission	*Amendment*
	(zla) where scientific guidelines are provided, the Agency shall ensure that such guidelines are kept up-to-date and based on the latest scientific developments.

Amendment 313
Proposal for a regulation
Article 138 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
The database provided for in paragraph 1, point (n), shall include all medicinal products for human use authorised in the Union together with the summaries of product characteristics, the package leaflet ***and*** the information shown on the labelling. Where relevant, it shall include the electronic links to the dedicated	The database provided for in paragraph 1, point (n), shall include all medicinal products for human use authorised in the Union together with the summaries of product characteristics, ***European product assessment reports, periodic safety update reports, where applicable documentation related to scientific advice received,***

webpages where the marketing authorisation holders have reported the information pursuant to Article 40(4), point (b), and Article 57 of [revised Directive 2001/83/EC].	***environmental risk assessment reports,*** the package leaflet***,*** the information shown on the labelling***, awareness cards in the case of antimicrobials, post-marketing obligations related to the medicinal product, shortage prevention and, where relevant, mitigation plans, and information as to in which Member States the medicinal product is placed on the market and other documents deemed relevant by the Agency***. Where relevant, it shall include the electronic links to the dedicated webpages where the marketing authorisation holders have reported the information pursuant to Article 40(4), point (b), and Article 57 of [revised Directive 2001/83/EC].

Amendment 314
Proposal for a regulation
Article 138 – paragraph 2 – subparagraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) marketing authorisation holders shall electronically submit to the Agency information concerning in which Member States the medical products for human use authorised in the Union have been placed on the market.

Amendment 315
Proposal for a regulation
Article 138 – paragraph 2 – subparagraph 3

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

Amendment 316
Proposal for a regulation
Article 142 – paragraph 1 – point l

Text proposed by the Commission	*Amendment*
(l) a Secretariat, which shall provide	(l) a Secretariat, which shall provide

technical, scientific and administrative support to all bodies of the Agency and ensure appropriate coordination between them, and which shall provide technical and administrative support for the coordination group referred to in Article 37 of [revised Directive 2001/83/EC] and ensure appropriate coordination between it and the Committees. It shall also undertake the work required of the Agency under the procedures for the assessment and preparations of decisions for paediatric investigation plans, waivers, deferrals or orphan designations.	technical, scientific and administrative support to all bodies of the Agency and ensure appropriate coordination between them, and which shall provide technical and administrative support for the coordination group referred to in Article 37 of [revised Directive 2001/83/EC] and ensure appropriate coordination between it and the Committees. It shall also ***ensure the implementation of all transparency commitments and*** undertake the work required of the Agency under the procedures for the assessment and preparations of decisions for paediatric investigation plans, waivers, deferrals or orphan designations.

Amendment 317
Proposal for a regulation
Article 143 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
In addition, two representatives of patients' organisations, one representative of doctors' organisations and one representative of veterinarians' organisations, all with voting rights, shall be appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission which includes appreciably more names than there are posts to be filled. The list drawn up by the Commission shall be forwarded to the European Parliament, together with the relevant background documents. As quickly as possible, and at the latest within three months of notification, the European Parliament may submit its views for consideration to the Council, which shall then appoint these representatives to the Management Board.	In addition, two representatives of patients' organisations, one representative of doctors***' organisations, one representative of pharmacists***' organisations and one representative of veterinarians' organisations, all with voting rights, shall be appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission which includes appreciably more names than there are posts to be filled. The list drawn up by the Commission shall be forwarded to the European Parliament, together with the relevant background documents. As quickly as possible, and at the latest within three months of notification, the European Parliament may submit its views for consideration to the Council, which shall then appoint these representatives to the Management Board.

Amendment 318
Proposal for a regulation
Article 143 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
All parties represented in the Management	All parties represented in the Management

Board shall make efforts to limit turnover of their representatives, in order to ensure continuity of the work of the Management Board. All parties shall aim to achieve a balanced representation ***between men and women*** on the Management Board.	Board shall make efforts to limit turnover of their representatives, in order to ensure continuity of the work of the Management Board. All parties shall aim to achieve a ***gender*** balanced representation on the Management Board.

Amendment 319
Proposal for a regulation
Article 143 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The term of office for members and their alternates shall be four years. That term shall be extendable.	4. The term of office for members and their alternates shall be four years. That term shall be extendable ***once consecutively***.

Amendment 320
Proposal for a regulation
Article 143 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Representatives from patients' organisations serving as members or alternate members on scientific committees shall be eligible for reimbursement of expenses incurred in the execution of their duties as representatives, financed through the Agency budget, in accordance with the financial rules applicable to the Agency.

Amendment 321
Proposal for a regulation
Article 146 – paragraph 8 – subparagraph 1

Text proposed by the Commission	*Amendment*
The scientific committees and any working parties and scientific advisory groups established in accordance with this Article shall in general matters establish contacts, on an advisory basis, with parties concerned with the use of medicinal products for human use, in particular patient and consumer organisations and healthcare professionals' associations. For that purpose working groups of patient and consumer organisations and healthcare	The scientific committees and any working parties and scientific advisory groups established in accordance with this Article shall in general matters establish contacts, on an advisory basis, with parties concerned with the use of medicinal products for human use, in particular patient and consumer organisations***, including paediatric representatives,*** and healthcare professionals' associations. For that purpose working groups of patient and

professionals' associations shall be established by the Agency. They shall ensure a fair representation of healthcare professionals, patients and consumers covering a wide range of experience and disease areas, including orphan, paediatric and geriatric diseases and advanced therapy medicinal products, and a broad geographical range.	consumer organisations and healthcare professionals' associations shall be established by the Agency. They shall ensure a fair representation of healthcare professionals, patients and consumers covering a wide range of experience and disease areas, including orphan, paediatric and geriatric diseases and advanced therapy medicinal products, and a broad geographical range.

Amendment 322
Proposal for a regulation
Article 147 – title

Text proposed by the Commission	*Amendment*
Conflict of interest	***Independence and*** conflict of interest

Amendment 323
Proposal for a regulation
Article 147 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
The Agency's code of conduct shall provide for the implementation of this Article ***with particular reference to the acceptance of gifts***.	The Agency's code of conduct shall provide for the implementation of this Article.

Amendment 324
Proposal for a regulation
Article 147 – paragraph 2

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

concerning that item of the agenda. Such declarations of representatives and the decision of the Commission shall be recorded in the summary minutes of the meeting.

Amendment 325
Proposal for a regulation
Article 147 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Executive Director shall after leaving the service continue to be bound by the duty to behave with integrity and discretion as regards the acceptance of certain appointments or benefits and if intending to engage in an occupational activity, whether gainful or not, within two years of leaving the service shall inform the Management Board for approval. The Management Board shall, in principle, prohibit them, for 12 months after leaving the service, from engaging in lobbying or advocacy vis-à-vis staff of the Union's institutions, bodies, offices and agencies for their business, clients or employers on matters for which they were responsible during their last three years in the service.

Amendment 326
Proposal for a regulation
Article 147 – paragraph 2 b (new)

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

Amendment 327
Proposal for a regulation
Article 147 – paragraph 2 c (new)

Text proposed by the Commission	*Amendment*
	2c. The Agency shall make available the rules of procedure, agendas, minutes and the members of the Management Board, committees, working parties and advisory committees on its website.

Amendment 328
Proposal for a regulation
Article 150 – title

Text proposed by the Commission	*Amendment*
Scientific working parties and scientific advisory groups	Scientific working parties***, ad hoc working groups*** and scientific advisory groups

Amendment 329
Proposal for a regulation
Article 150 – paragraph 2 – subparagraph 3

Text proposed by the Commission	*Amendment*
The Committee ***may*** establish an Environmental Risk Assessment working party and other scientific working parties, as necessary.	The Committee ***shall*** establish an ***ad hoc*** Environmental Risk Assessment working party and other scientific working parties, as necessary.

Amendment 330
Proposal for a regulation
Article 150 – paragraph 3 – subparagraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) fulfilment of conflict of interest requirements referred to in Article 147

Amendment 331
Proposal for a regulation
Article 150 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Representatives of patients, caregivers, clinicians and academia shall be included as members of the working parties as appropriate.

Amendment 332
Proposal for a regulation
Article 150 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. The Agency shall establish the following ad hoc working groups:
	(a) an ad hoc working group on advanced therapy medicinal products;
	(b) an ad hoc working group on orphan medicinal products;
	(c) an ad hoc working group on paediatric medicinal products.

Amendment 333
Proposal for a regulation
Article 151 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
Where necessary, for the nomination of other experts the Agency ***may*** publish a call for expression of interest after endorsement by the Management Board of the necessary criteria and fields of expertise, in particular to ensure a high level of public health and animal protection.	Where necessary, for the nomination of other experts the Agency ***shall*** publish a call for expression of interest after endorsement by the Management Board of the necessary criteria and fields of expertise, in particular to ensure a high level of public health and animal protection.

Amendment 334
Proposal for a regulation
Article 152 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
The person concerned, or their employer, shall be remunerated in accordance with [a scale of fees to be included in the financial arrangements established by ***the Management Board/mechanism under the new fee legislation]***.	The person concerned, or their employer, shall be remunerated in accordance with [a scale of fees to be included in the financial arrangements established by ***Regulation (EU) 2024/568 of the European Parliament and of the Council***[1a].
	[1a] Regulation (EU) 2024/568 of the European Parliament and of the Council of 7 February 2024 on fees and charges payable to the European Medicines Agency, amending Regulations (EU)

	2017/745 and (EU) 2022/123 of the European Parliament and of the Council and repealing Regulation (EU) No 658/2014 of the European Parliament and of the Council and Council Regulation (EC) No 297/95 (OJ L, 2024/568, 14.2.2024, ELI: http://data.europa.eu/eli/reg/2024/568/oj).

Amendment 335
Proposal for a regulation
Article 153 – paragraph 1

Text proposed by the Commission	*Amendment*
At the request of the Commission, the Agency shall, in respect of authorised medicinal products for human use, collect any available information on methods that Member States' competent authorities use to determine the added therapeutic value that any new medicinal product for human use provides.	At the request of the Commission, the Agency shall, in respect of authorised medicinal products for human use, collect any available information on methods that Member States' competent authorities use to determine the added therapeutic value that any new medicinal product for human use provides. ***The Agency shall, in collaboration with patient organisations and healthcare professionals, draw up guidelines for the determination of added therapeutic value.***

Amendment 336
Proposal for a regulation
Article 154 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Activities relating to the assessment of marketing authorisation applications, subsequent variations, pharmacovigilance, to the operation of communications networks and to market surveillance shall be under the permanent control of the Management Board in order to guarantee the independence of the Agency. This shall not preclude the Agency from charging fees to marketing authorisation holders for performing these activities by the Agency on the condition that its independence is strictly guaranteed.	4. Activities relating to the assessment of marketing authorisation applications, subsequent variations, pharmacovigilance, to the operation of communications networks and to market surveillance shall be under the permanent control of the Management Board in order to guarantee the independence of the Agency. This shall not preclude the Agency from charging fees to marketing authorisation holders for performing these activities by the Agency on the condition that its independence is strictly guaranteed ***in accordance with Article 147***.

Amendment 337
Proposal for a regulation
Article 162 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Agency ***may*** extend the consultation process to patients, medicine developers, healthcare professionals, industries or other stakeholders**,** as relevant.	2. The Agency ***shall*** extend the consultation process to patients, medicine developers, healthcare professionals, industries or other stakeholders as relevant.

Amendment 338
Proposal for a regulation
Article 163 – paragraph 1

Text proposed by the Commission	*Amendment*
The Management Board shall, in agreement with the Commission, develop appropriate contacts between the Agency and the representatives of the industry, consumers and patients and the healthcare professions. These contacts may include the participation of observers in certain aspects of the Agency's work, under conditions determined beforehand by the Management Board, in agreement with the Commission.	The Management Board shall, in agreement with the Commission, develop appropriate contacts between the Agency and the representatives of the industry, consumers and patients and the healthcare professions***, including through the Patients' and Consumers' Working Party (PCWP), the Healthcare Professionals' Working Party (HCPWP) and the Industry Standing Group (ISG)***. These contacts may include the participation of observers in certain aspects of the Agency's work, under conditions determined beforehand by the Management Board, in agreement with the Commission.

Amendment 339
Proposal for a regulation
Article 164 – paragraph 5

Text proposed by the Commission	*Amendment*
5. For not-for-profit entities**,** the Commission shall adopt specific provisions clarifying the definitions, establishing waivers, reductions or deferrals of fees, as appropriate, in accordance with the procedure referred to in Article 10 and Article 12 of [revised Regulation (EC) No 297/95].	5. For not-for-profit entities the Commission shall adopt specific provisions clarifying the definitions, establishing waivers, reductions or deferrals of fees, as appropriate, in accordance with the procedure referred to in Article 10 and Article 12 of ***and Annex V to*** [revised Regulation (EC) No 297/95].

Amendment 340
Proposal for a regulation

Article 165 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	Sufficient resources shall be allocated to the Agency to ensure appropriate implementation of its transparency obligations and commitments.

Amendment 341
Proposal for a regulation
Article 166 – paragraph 1

Text proposed by the Commission	*Amendment*
1. To support its public health tasks and in particular the evaluation and monitoring medicinal products or the preparation of regulatory decisions and scientific opinions, the Agency may process personal health data, from sources other than clinical trials, for the purpose of improving the robustness of its scientific assessment or verifying claims of the applicant or marketing authorisation holder in the context of the evaluation or supervision of medicinal product.	1. To support its public health tasks and in particular the evaluation and monitoring medicinal products or the preparation of regulatory decisions and scientific opinions, the Agency may process personal health data, from sources other than clinical trials, ***including real world data*** for the purpose of improving the robustness of its scientific assessment or verifying claims of the applicant or marketing authorisation holder in the context of the evaluation or supervision of medicinal product. ***The Agency shall put in place sufficient, effective and specific technical and organisational measures to safeguard the fundamental rights and interests of data subjects in line with Regulations (EU) 2016/679 and (EU) 2018/1725, including but not limited to clear and targeted data minimisation policies, state-of-the-art anonymisation and pseudonymisation requirements.***

Amendment 342
Proposal for a regulation
Article 166 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Such data shall in particular include personal electronic health data as defined in Regulation (EU) .../... [EHDS Regulation 2022/0140(COD)], data from the Eudravigilance database, clinical data and, where applicable, data from monitoring studies on the use,

	effectiveness and safety of medicinal products intended for treatment, prevention or the diagnosis of disease, including health data provided by public authorities.

Amendment 343
Proposal for a regulation
Article 166 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Agency may consider and decide upon additional evidence available, independently from the data submitted by the marketing authorisation applicant or marketing authorisation holder. On that basis, the summary of product characteristics shall be updated if the additional evidence has an impact on the benefit-risk balance of a medicinal product.	2. The Agency may consider and decide upon additional evidence available, independently from the data submitted by the marketing authorisation applicant or marketing authorisation holder. On that basis, the summary of product characteristics shall be updated if the additional evidence has an impact on the benefit-risk balance of a medicinal product. ***Such update shall only take place after the consultation with the marketing authorisation applicant or marketing authorisation holder concerned. Marketing authorisation applicants and marketing authorisation holders shall have the opportunity to respond within a reasonable timeline set by the Agency. Marketing authorisation applicants and marketing authorisation holders may submit to the Agency questions and shall be offered the opportunity of an explanation to any proposed update to the summary of product characteristics as appropriate. The reasons for the conclusions reached shall be included in the final opinion.***

Amendment 344
Proposal for a regulation
Article 167 – paragraph 2

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

cyber attacks.	***to-date cybersecurity best practices*** for preventing, detecting, mitigating, and responding to cyber attacks.

Amendment 345
Proposal for a regulation
Article 168 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/2001 and Directive (EU) 2019/1937 of the European Parliament and of the Council[85] , and existing national provisions ***and practices in the Member States*** on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the commercially confidential information and trade secrets of natural or legal persons in accordance with Directive (EU) 2016/943 of the European Parliament and of the Council[86] , including intellectual property rights.	1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/2001 and Directive (EU) 2019/1937 of the European Parliament and of the Council[85] , and existing national provisions on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the commercially confidential information and trade secrets of natural or legal persons in accordance with Directive (EU) 2016/943 of the European Parliament and of the Council[86] , including intellectual property rights.
[85] Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union law (OJ L 305, 26.11.2019, p. 17).	[85] Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union law (OJ L 305, 26.11.2019, p. 17).
[86] Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1).	[86] Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1).

Amendment 346
Proposal for a regulation
Article 169 – paragraph 1 – subparagraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) as regards special categories of personal data, is strictly necessary and	(b) as regards special categories of personal data, is strictly necessary and

subject to appropriate safeguards, which may include pseudonymisation.	subject to appropriate safeguards, which may include pseudonymisation ***requirements and techniques, data minimisation measures, specific organisational measures and access controls on a 'need to know' basis and other appropriate measures, confidentiality requirements, and fundamental rights of data subjects as set out in Regulations (EU) 2016/679 and (EU) 2018/1725***.

Amendment 347
Proposal for a regulation
Article 171 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, without delay, notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.	1. ***By ... [12 months from the date of entry into force of this Regulation],*** Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, without delay, notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.

Amendment 348
Proposal for a regulation
Article 172 – paragraph 5 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) the nature, gravity and duration of the infringement and of its consequences, taking into account the scope as well as the number of persons affected and the level of damage suffered by them;

Amendment 349
Proposal for a regulation
Article 172 – paragraph 5 – point b b (new)

Text proposed by the Commission	*Amendment*

(bb) the size and market share of the entity committing the infringement;

Amendment 350
Proposal for a regulation
Article 172 – paragraph 5 – point b c (new)

Text proposed by the Commission	*Amendment*
	(bc) the intentional or negligent character of the infringement;

Amendment 351
Proposal for a regulation
Article 172 – paragraph 5 – point b d (new)

Text proposed by the Commission	*Amendment*
	(bd) any action taken by the infringing party to mitigate the damage caused by the infringement;

Amendment 352
Proposal for a regulation
Article 172 – paragraph 5 – point b e (new)

Text proposed by the Commission	*Amendment*
	(be) the degree of responsibility of the infringing party taking into account technical and organisational measures implemented to prevent the infringement;

Amendment 353
Proposal for a regulation
Article 172 – paragraph 5 – point b f (new)

Text proposed by the Commission	*Amendment*
	(bf) the degree of cooperation with the competent authorities, in order to remedy the infringement and mitigate the possible adverse effects of the infringement;

Amendment 354
Proposal for a regulation
Article 172 – paragraph 5 – point b g (new)

Text proposed by the Commission	*Amendment*
	(bg) the manner in which the infringement became known to the competent authorities, in particular whether, and if so to what extent, the infringing party notified the infringement;

Amendment 355
Proposal for a regulation
Article 172 – paragraph 5 – point b h (new)

Text proposed by the Commission	*Amendment*
	(bh) the risk to public health, including in the case of falsification of medicinal products.

Amendment 356
Proposal for a regulation
Article 175 a (new) – paragraph 1 – point 1

Regulation (EC) No 851/2004

Articles 11a a (new) and 11a b (new)

Text proposed by the Commission	*Amendment*
	Article 175a
	Amendments to Regulation (EC) No 851/2004
	Regulation (EC) No 851/2004 is amended as follows:
	(1) the following articles are inserted:
	'Article 11aa
	European Health Emergency Preparedness and Response Authority
	1. The Health Emergency Preparedness and Response Authority ('HERA' or the 'Authority') is hereby established as a separate structure under the legal personality of the European Centre for Disease Prevention and Control ('ECDC').
	2. The Authority shall be responsible for creating, coordinating and

implementing the long-term European portfolio of biomedical research and development agenda for medical countermeasures against current and emerging public health threats as well as the production, procurement, stockpiling and distribution capacity of medical countermeasures and other priority medical products in the Union.

3. The Authority is represented by the Director of the ECDC.

Article 11ab

Objectives and tasks of the Authority

1. The Authority shall provide the Member States and the Union institutions, bodies, offices and agencies, with the strategic direction and the resources to develop a robust biomedical R&D capacity to address major public health issues.

The Authority shall carry out the following tasks:

(a) setting out a long-term European portfolio of research and development projects in line with public health priorities set by the Commission in consultation with the World Health Organization ('WHO');

(b) setting up and supporting biomedical R&D projects addressing at least the following areas:

(i) the development of priority antimicrobials as defined in Article 40a of [Pharma Regulation];

(ii) the development of medical countermeasures and related technologies;

(c) setting up and management of collaboration with third-party research centres at national and European level, not-for profit entities, academia and industry;

(d) providing strategic advice to the Commission on the allocation of relevant Union grants and other financial sources to ensure appropriate resource allocation

for biomedical R&D;

(e) detecting biological and other health threats soon after they emerge, evaluating their impacts and identifying potential countermeasures;

(f) assessing and addressing vulnerabilities in global supply chains and strategic dependencies related to availability of medical countermeasures and medicinal products in the Union, in coordination with the Medicine Shortages Steering Group and Medical Device Shortages Steering Group, established by Regulation (EU) 2022/123;

(g) addressing market challenges by identifying and ensuring the availability of production sites for priority products in the Union;

(h) facilitating joint procurement and distribution of medical products in Member States;

(i) monitoring compliance with funding and procurement agreements;

(j) establishing a mechanism of consultation and cooperation, in line with the One Health approach, internally within the ECDC and with other Union bodies and agencies, in particular the EMA, the European Food Safety Authority and the European Environment Agency;

(k) contributing to reinforcing the global health emergency preparedness and response architecture.

3. The Commission is empowered to adopt delegated acts to supplement this Regulation by expanding the priority research agenda set out in paragraph 1, second subparagraph, point (b), in order to address other areas of unmet medical need.'

Amendment 357
Proposal for a regulation
Article 175 a (new) – paragraph 1 – point 2

Regulation (EC) No 851/2004

Article 13 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(2) in Article 13, the following point is inserted:
	'(ba) the HERA Board;'

Amendment 358
Proposal for a regulation
Article 175 a (new) – paragraph 1 – point 3

Regulation (EC) No 851/2004

Article 16 – paragraph 2 – point d a (new)

Text proposed by the Commission	*Amendment*
	(3) in Article 16(2), the following point is inserted:
	'(da) ensuring that appropriate scientific, technical and administrative support are provided to the HERA Board;'

Amendment 359
Proposal for a regulation
Article 175 a (new) – paragraph 1 – point 4

Regulation (EC) No 851/2004

Articles 17 a (new) and 17 b (new)

Text proposed by the Commission	*Amendment*
	(4) the following articles are inserted:
	'Article 17a
	HERA Board
	1. The HERA Board shall be composed of one representative from each Member State, two representatives of the Commission and two representatives of the European Parliament, all with voting rights. All HERA Board members shall be appointed for a two-year term, renewable once.

2. In addition, two public health experts shall be appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission. The list drawn up by the Commission shall be forwarded to the European Parliament, together with the relevant background documents. As quickly as possible, and at the latest within three months of notification, the European Parliament may submit its views for consideration to the Council, which shall then appoint those representatives to the HERA Board.

3. The HERA Board shall be co-chaired by the director and an elected representative of a Member State. The members of the HERA Board shall be appointed in such a way as to guarantee the highest levels of specialist qualifications, a broad spectrum of relevant expertise, and an absence of direct or indirect conflict of interest.

4. The term of office for members and their alternates shall be four years. That term may be extendable once consecutively.

5. A representative of the Health Security Committee and a representative of the EMA shall attend the meetings of the HERA Board, as permanent observers. Other relevant Union bodies and agencies may be invited to attend as observers, where relevant.

6. The co-Chairs of the HERA Board may invite relevant stakeholders to attend the HERA Board meetings as observers. Observers shall declare their interests ahead of each meeting.

7. The HERA Board shall adopt its rules of procedure, including regarding the election of a co-Chair and voting procedures.

8. The list of members and alternates, and the rules of procedure of the HERA Board, as well as the agendas and minutes of its meetings shall be made available on the Authority's website.

Article 17b

Tasks of the HERA Board

The HERA Board shall:

(a) adopt the multiannual strategic planning for HERA;

(b) adopt strategic decisions concerning HERA on research and innovation and industrial strategy in the area of antimicrobials and medical countermeasures;

(c) adopt a long-term European portfolio of research and development projects in line with public health priorities set by the Commission in consultation with the WHO;

(d) ensure scientific and technical management of HERA;

(e) assess the performance of the tasks entrusted to HERA;

(f) contribute to the coherence of the Union's crisis preparedness and response management;

(g) contribute to the coordinated action by the Commission and the Member States for the implementation of Regulation (EU) 2022/2371;

(h) contribute to the implementation of the Union's Global Health Strategy, in particular in relation to addressing current and emerging health threats;

(i) adopt opinions and guidance, including on specific response measures for the Member States for the prevention and control of serious cross-border threats to health, including antimicrobial resistance;

(j) adopt proposals for the annual budget of HERA and the monitoring of its implementation.'

Amendment 360
Proposal for a regulation
Article 175 a (new) – paragraph 1 – point 5

Regulation (EC) No 851/2004

Present text	*Amendment*
	(5) Article 19 is replaced by the following:
Article 19	***'***Article 19
Declaration of interest	***Transparency and conflicts*** of interest
1. ***The*** members of the Management Board, ***the*** members of the ***Advisory Forum***, scientific panels ***and*** the director shall undertake to act in the public interest.	1. Members of the Management Board, members of the ***HERA Board***, ***members of the*** scientific panels***, members of the Advisory Forum,*** the director ***and the staff*** shall undertake to act in the public interest ***and in an independent manner. They shall not have any direct or indirect financial or other interests in the pharmaceutical or other medical industry which could affect their impartiality. They shall make an annual declaration of their financial interests and update them annually and whenever necessary. The declaration shall be made available upon request.***
2. The members of the Management Board, the director, the members of the Advisory Forum, as well as external experts participating in scientific panels shall make a declaration of commitment and a declaration of interests indicating either the absence of any interest which might be considered prejudicial to their independence or any direct or indirect interest which might be considered prejudicial to their independence. Those declarations shall be made annually in writing and shall be available to the public.	***2. The ECDC's and Authority's code of conduct shall provide for the implementation of this Article.***
3. The director, the members of the Advisory Forum, as well as external experts participating in scientific panels, shall declare at each meeting any interests which might be considered prejudicial to their independence in relation to the items on the agenda. In such cases these persons have to disqualify themselves from relevant discussions and decisions.	***3. The ECDC and the Authority shall make available the rules of procedure, meeting agendas and minutes, and the members of the structures referred to in paragraph 1 and their declarations of interest on their website.***
	4. Stakeholders invited to meetings at

	the ECDC and the Authority shall declare their interests ahead of the meeting'.

Amendment 361
Proposal for a regulation
Article 181 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	The provisions in Chapter III shall apply from ... [the date of entry into force of this Regulation].

Amendment 362
Proposal for a regulation
Annex II – point 16

Text proposed by the Commission	*Amendment*
(16) the obligation to conduct post-marketing studies, including post-authorisation safety studies ***and*** post-authorisation efficacy studies, and to submit them for review, as provided for in Article 20;	(16) the obligation to conduct post-marketing studies, including post-authorisation safety studies***,*** post-authorisation efficacy ***studies and post-authorisation environmental risk assessment*** studies, and to submit them for review, as provided for in Article 20;

Amendment 363
Proposal for a regulation
Annex II – point 25 a (new)

Text proposed by the Commission	*Amendment*
	(25a) the obligations related to the availability and supply of medicinal products as laid down in Chapter X;

Amendment 364
Proposal for a regulation
Annex II – point 25 b (new)

Text proposed by the Commission	*Amendment*
	(25b) the obligations to report on financial support and research and development costs as laid down in Article 57 of [revised Directive 2001/83/EC].

Amendment 365
Proposal for a regulation

Annex IV – Part III – paragraph 1 – point 2 – point e

Text proposed by the Commission	*Amendment*
(e) Reason for shortage;	(e) Reason for shortage ***providing, where applicable, information on:***
	(i) raw material disruption;
	(ii) API disruption;
	(iii) excipient disruption;
	(iv) production problems;
	(v) quality problems;
	(vi) production capacity;
	(vii) logistics problems;
	(viii) distribution problems;
	(ix) inventory and storage practices;
	(x) increase in demand;
	(xi) commercial reasons; and
	(xii) any other reasons;

Amendment 366
Proposal for a regulation
Annex IV – Part V – paragraph 1 – point 2 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) methodology for establishing the demand forecast;

Amendment 367
Proposal for a regulation
Annex IV – Part V a (new)

Text proposed by the Commission	*Amendment*
	Part Va
	For the purposes of reporting in accordance with Article 118(1) and for the early detection of supply shortages, wholesalers shall provide the following information in a timely manner:
	1. Product availability information:
	Product availabilities shall be reported per warehouse and shall be indexed as

yes/no.

2. Service level information:

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