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***I
REPORT

on the proposal for a directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC

(COM(2023)0192 – C9-0143/2023 – 2023/0132(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Pernille Weiss

Rapporteur for the opinion of the associated committee pursuant to Rule 57 of the Rules of Procedure:
Adrián Vázquez Lázara, Committee on Legal Affairs

Symbols for procedures

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

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

Amendments to a draft act

Amendments by Parliament set out in two columns

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

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

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.
By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC

(COM(2023)0192 – C9-0143/2023 – 2023/0132(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2023)0192),

– having regard to Article 294(2) and Article 114(1) 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 (C9-0143/2023),

– 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 letter from the Committee on Legal Affairs,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety (A9-0140/2024),

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;

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

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

Amendment 1
Proposal for a directive
Recital 2

Text proposed by the Commission	*Amendment*
(2) The most recent comprehensive revision took place between 2001 and 2004 while targeted revisions on post-authorisation monitoring (pharmacovigilance) and on falsified medicines were adopted subsequently. In the almost 20 years since the last comprehensive revision, the pharmaceutical sector has changed and has become more globalised, both in terms of development and manufacture. Moreover, science and technology have evolved at a rapid pace. However, there continues to be unmet medical needs, i.e. diseases without or only with suboptimal treatments. Moreover, some patients may not benefit from innovation because medicines may be unaffordable or not placed on the market in the Member State concerned. There is also a greater awareness of the environmental impact of medicines. More recently, the COVID-19 pandemic has stress tested the framework.	(2) The most recent comprehensive revision took place between 2001 and 2004 while targeted revisions on post-authorisation monitoring (pharmacovigilance) and on falsified medicines were adopted subsequently. In the almost 20 years since the last comprehensive revision, the pharmaceutical sector has changed and has become more globalised, both in terms of development and manufacture. Moreover, science and technology have evolved at a rapid pace. However, there continues to be unmet medical needs, i.e. diseases without or only with suboptimal ***or highly burdensome*** treatments***, or with treatments targeting only sub-populations of a disease***. Moreover, some patients may not benefit from innovation because medicines may be unaffordable or not placed on the market in the Member State concerned. There is also a greater awareness of the environmental impact of medicines. More recently, the COVID-19 pandemic has stress tested the framework.

Amendment 2
Proposal for a directive
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) This Directive 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 diseases burdens of, humans and animals. In addition, pollution from active pharmaceutical ingredients negatively affects the quality of waters and ecosystems, posing risks to public health globally.

Amendment 3
Proposal for a directive
Recital 3

Text proposed by the Commission	*Amendment*
(3) This revision is part of the implementation of the Pharmaceutical strategy for Europe and aims to promote innovation, in particular for unmet medical needs, while reducing regulatory burden and the environmental impact of medicines; ensure access to innovative and established medicines for patients, with special attention to enhancing security of supply and addressing risks of shortages, taking into account the challenges of the smaller markets of the Union; and create a balanced and competitive system that keeps medicines affordable for health systems while rewarding innovation.	(3) This revision is part of the implementation of the Pharmaceutical strategy for Europe and aims to promote innovation, in particular for unmet medical needs, while reducing regulatory burden and the environmental impact of medicines; ***create an attractive environment for research, development and manufacturing of medicines in the Union;*** ensure access***, including affordability,*** to innovative and established medicines for patients, with special attention to enhancing security of supply and addressing risks of shortages, taking into account the challenges of the smaller markets of the Union; and create a balanced and competitive system that keeps medicines affordable for health systems ***and patients*** while rewarding innovation.

Amendment 4
Proposal for a directive
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) In parallel with this revision, the Union should strengthen the European pharmaceutical ecosystem to accelerate research and development of a new

	medicinal product and support innovation through the establishment of public-private partnerships, the multiplication of university hospital institutes, centres of excellence and bioclusters.

Amendment 5
Proposal for a directive
Recital 3 b (new)

Text proposed by the Commission	*Amendment*
	(3b) A range of Union programmes can be used to fund pharmaceutical research projects, such as Horizon Europe, InvestEU, EU4Health, cohesion policy and the Digital Europe Programme. The Union should also prioritise in its research agenda participation in cross-country collaboration enabling transnational research to meet public health needs.

Amendment 6
Proposal for a directive
Recital 4

Text proposed by the Commission	*Amendment*
(4) This revision focuses on provisions relevant to achieve its specific objectives; therefore it covers all but provisions concerning falsified medicines, homeopathic and traditional herbal medicines. Nevertheless, for the sake of clarity, it is necessary to replace Directive 2001/83/EC of the European Parliament and of the Council[38] with a new Directive. The provisions on falsified medicines, homeopathic ***medicines*** and traditional herbal medicines are therefore maintained in this Directive without changing their substance compared to previous harmonisations. However, in view of the changes in the governance of the Agency, the Herbal Committee is replaced by a	(4) This revision focuses on provisions relevant to achieve its specific objectives; therefore it covers all but provisions concerning falsified medicines, homeopathic ***products*** and traditional herbal medicines. Nevertheless, for the sake of clarity, it is necessary to replace Directive 2001/83/EC of the European Parliament and of the Council[38] with a new Directive. The provisions on falsified medicines, homeopathic ***products*** and traditional herbal medicines are therefore maintained in this Directive without changing their substance compared to previous harmonisations. However, in view of the changes in the governance of the Agency, the Herbal Committee is replaced

working group.

[38] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

by a working group.

[38] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

Amendment 7
Proposal for a directive
Recital 6

Text proposed by the Commission	*Amendment*
(6) The regulatory framework for medicinal products use should also take into account the needs of the undertakings in the pharmaceutical sector and trade in medicinal products within the Union, without jeopardising the quality, safety and efficacy of medicinal products.	(6) The regulatory framework for medicinal products ***for human*** use should also take into account the needs of the undertakings in the pharmaceutical sector and trade in medicinal products within the Union, without jeopardising the quality, safety and efficacy of medicinal products.

Amendment 8
Proposal for a directive
Recital 8

Text proposed by the Commission	*Amendment*
(8) This revision maintains the level of harmonisation that has been achieved. Where necessary and appropriate, it further reduces the remaining disparities, by laying down rules on the supervision and control of medicinal products and the rights and duties incumbent upon the competent authorities of the Member States with a view to ensuring compliance with legal requirements. In the light of experience gained on the application of the Union pharmaceutical legislation and the evaluation of its functioning, the regulatory framework need to be adapted to scientific and technological progress, the current market conditions and economic reality within the Union. Scientific and technological developments induce	(8) This revision maintains the level of harmonisation that has been achieved. Where necessary and appropriate, it further reduces the remaining disparities, by laying down rules on the supervision and control of medicinal products and the rights and duties incumbent upon the competent authorities of the Member States with a view to ensuring compliance with legal requirements. In the light of experience gained on the application of the Union pharmaceutical legislation and the evaluation of its functioning, the regulatory framework need to be adapted to scientific and technological progress, the current market conditions and economic reality within the Union. Scientific and technological developments induce

innovation and development of medicinal products, including for therapeutic areas where there is still unmet medical need. To harness these developments, the Union pharmaceutical framework should be adapted to meet scientific developments such as genomics, accommodate cutting edge medicinal products, e.g. personalised medicinal products and technological transformation such as data analytics, digital tools and the use of artificial intelligence. These adaptations also contribute to competitiveness of the Union pharmaceutical industry.	innovation and development of medicinal products, including for therapeutic areas where there is still unmet medical need. To harness these developments, the Union pharmaceutical framework should be adapted to meet scientific developments such as genomics, accommodate cutting edge medicinal products, e.g. personalised medicinal products***, novel health treatments*** and technological transformation such as data analytics, digital tools and the use of artificial intelligence. These adaptations also contribute to competitiveness of the Union pharmaceutical industry.

Amendment 9
Proposal for a directive
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) This Directive should aim to enhance the Union's open strategic autonomy with regard to its public health objectives. Increasing the number of EU-based clinical trials and the local production of active pharmaceutical ingredients would support a more resilient and sustainable European health ecosystem.

Amendment 10
Proposal for a directive
Recital 9

Text proposed by the Commission	*Amendment*
(9) Medicinal products for rare diseases and for children, should be subject to the same conditions as any other medicinal product concerning their quality, safety and efficacy, for example for what concerns the marketing authorisation procedures, quality and the pharmacovigilance requirements. However, specific requirements also apply	(9) Medicinal products for rare diseases and for children, should be subject to the same conditions as any other medicinal product concerning their quality, safety and efficacy, for example for what concerns the marketing authorisation procedures, quality and the pharmacovigilance requirements. However, specific requirements also apply

to them considering their unique characteristics. Such requirements, which are currently defined in separate legislations, should be integrated in general pharmaceutical legal framework in order to ensure clarity and coherency of all the measures applicable to these medicinal products. Furthermore, as some medicinal products authorised for use in children are authorised by the Member States, specific provisions should be integrated in this Directive.

to them considering their unique characteristics. Such requirements, which are currently defined in separate legislations, should be integrated in general pharmaceutical legal framework in order to ensure clarity and coherency of all the measures applicable to these medicinal products. Furthermore, as some medicinal products authorised for use in children are authorised by the Member States, specific provisions should be integrated in this Directive. ***Effort should be made to address problems encountered which concern medicinal products for children, such as the failure to timely accomplish paediatric clinical studies and to obtain data required for marketing authorisation, which results in significant delay in the approval of medicinal products for children compared to adults.***

Amendment 11
Proposal for a directive
Recital 11

Text proposed by the Commission	*Amendment*
(11) The Directive should work in synergy with the Regulation to enable innovation and promote competitiveness of the Union pharmaceutical industry, in particular SMEs. In this respect a balanced system of incentives is proposed that rewards innovation especially in areas of unmet medical need ***and*** innovation that reaches patients and improves access across the Union. To make the regulatory system more efficient and innovation-friendly the Directive also aims at reducing administrative burden and simplifying procedures for undertakings.	(11) The Directive should work in synergy with the Regulation to enable innovation and promote competitiveness of the Union pharmaceutical industry, in particular ***of*** SMEs. In this respect a balanced system of incentives is proposed that rewards innovation especially in areas of unmet medical need***,*** innovation that reaches patients and improves access across ***the Union and innovation that stems from development in*** the Union. To make the regulatory system more efficient and innovation-friendly the Directive also aims at reducing administrative burden and simplifying procedures for undertakings.

Amendment 12
Proposal for a directive
Recital 11 a (new)

Text proposed by the Commission	*Amendment*
	(11a) This Directive should be consistent with the Union's objectives with regard to promotion of research, innovation, digitalisation, trade, international development and industrial competitiveness.

Amendment 13
Proposal for a directive
Recital 12

Text proposed by the Commission	*Amendment*
(12) The definitions and scope of Directive 2001/83/EC should be clarified in order to achieve high standards for the quality, safety and efficacy of medicinal products and to address potential regulatory gaps, without changing the overall scope, due to scientific and technological developments, e.g. low-volume products, bedside-manufacturing or personalised medicinal products that do not involve an industrial manufacturing process.	(12) The definitions and scope of Directive 2001/83/EC should be clarified in order to achieve high standards for the quality, safety and efficacy of medicinal products and to address potential regulatory gaps, without changing the overall scope ***or affecting national competences in that regard***, due to scientific and technological developments, e.g. low-volume products, bedside-manufacturing or personalised medicinal products that do not involve an industrial manufacturing process.

Amendment 14
Proposal for a directive
Recital 13

Text proposed by the Commission	*Amendment*
(13) To avoid the duplication of requirements for medicinal products in this Directive and in the Regulation, the general standards in regards to quality, safety ***and*** efficacy of medicinal products laid down in this Directive shall be applicable to medicinal products covered by national marketing authorisation and also to medicinal products covered by centralised marketing authorisation. Therefore, the requirements for an application for	(13) To avoid the duplication of requirements for medicinal products in this Directive and in the Regulation, the general standards in regards to quality, safety**,** efficacy ***and environmental risk*** of medicinal products laid down in this Directive shall be applicable to medicinal products covered by national marketing authorisation and also to medicinal products covered by centralised marketing authorisation. Therefore, the requirements

medicinal product are valid for both, also the rules on prescription status, product information, regulatory protection and rules on manufacturing, supply, advertising, supervision and other national requirements shall be applicable to medicinal products covered by centralised marketing authorisation.

for an application for medicinal product are valid for both, also the rules on prescription status, product information, regulatory protection and rules on manufacturing, supply, advertising, supervision and other national requirements shall be applicable to medicinal products covered by centralised marketing authorisation.

Amendment 15
Proposal for a directive
Recital 15

Text proposed by the Commission	*Amendment*
(15) In order to take account both of the emergence of new therapies and of the growing number of so-called 'borderline' products between the medicinal product sector and other sectors, certain definitions and derogations should be modified, so as to avoid any doubt as to the applicable legislation. With the same objective of clarifying situations when a product fully falls within the definition of a medicinal product and also meet the definition of other regulated products, the ***rules*** for medicinal products under this Directive apply. Furthermore, to ensure the clarity of applicable rules, it is also appropriate to improve the consistency of the terminology of the pharmaceutical legislation and clearly indicate the products excluded from the scope of this Directive.	(15) In order to take account both of the emergence of new therapies and of the growing number of so-called 'borderline' products between the medicinal product sector and other sectors, certain definitions and derogations should be modified, so as to avoid any doubt as to the applicable legislation. ***In cases where there is still a lack of clarity of the regulatory status of a product, the competent authorities or 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 that regulatory status. The Commission and the Member States should facilitate the cooperation between the Agency, national competent authorities 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. With the same objective of clarifying situations when a product fully falls within the definition of a medicinal product and also meet the definition of other regulated products, the for medicinal products under this Directive apply. Furthermore, to ensure the clarity of applicable rules, it is also appropriate to improve the consistency of the terminology of the pharmaceutical legislation and clearly indicate the products excluded from the scope of this Directive.

[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 16
Proposal for a directive
Recital 18

Text proposed by the Commission	*Amendment*
(18) Advanced therapy medicinal products that are prepared on a non-routine basis according to specific quality standards, and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient, should be excluded from the scope of this Directive whilst at the same time ensuring that relevant Union rules related to quality and safety are not undermined ('hospital exemption'). Experience has shown that there are great differences in the application of hospital exemption among Member States. To improve the application of hospital exemption this Directive introduces measures for collection, reporting of data as well as	(18) Advanced therapy medicinal products that are prepared on a non-routine basis according to specific quality standards, and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner ***and hospital pharmacist***, in order to comply with an individual medical prescription for a custom-made product for an individual patient, should be excluded from the scope of this Directive whilst at the same time ensuring that relevant Union rules related to quality and safety are not undermined ('hospital exemption'). Experience has shown that there are great differences in the application of hospital exemption among Member States***.*** To improve ***and harmonise*** the application of hospital exemption this Directive introduces

review of these data yearly by the competent authorities and their publication by the Agency in a repository. Furthermore, the Agency should provide a report on the implementation of hospital exemption on the basis of contributions from Member States in order to examine whether an adapted framework should be established for certain less complex ATMPs ***that have been developed and used under the hospital exemption***. When an authorisation for the manufacturing and use of an ATMP under hospital exemption is revoked because of safety concerns, the relevant competent authorities shall inform the competent authorities of other Member States.	measures for collection, reporting of data as well as review of these data yearly by the competent authorities and their publication by the Agency in a repository. Furthermore, the Agency should provide a report on the implementation of hospital exemption on the basis of contributions from Member States in order to examine whether an adapted framework should be established for certain less complex ATMPs. When an authorisation for the manufacturing and use of an ATMP under hospital exemption is revoked because of safety concerns, the relevant competent authorities shall inform the competent authorities of other Member States. ***Competent authorities should support academic institutions and other non-profit entities through the requirements of the hospital exemption clause.***

Amendment 17
Proposal for a directive
Recital 18 a (new)

Text proposed by the Commission	*Amendment*
	(18a) The Agency should establish a programme with the objective to guide academic and other not-for-profit entities through the centralised marketing authorisation procedure. That programme should be able to draw on results of the Agency's pilot programme for enhanced support to academic and non-profit developers of advanced therapy medicinal products, which started in September 2022.

Amendment 18
Proposal for a directive
Recital 20

Text proposed by the Commission	*Amendment*
(20) In the interest of public health, a medicinal product should only be allowed	(20) In the interest of public health, a medicinal product should only be allowed

to be placed on the market in the Union when the marketing authorisation has been granted to the medicinal product, and its quality, safety ***and*** efficacy have been demonstrated. However, exemption should be provided from this requirement in situations characterised by an urgent need to administer a medicinal product to address the specific needs of a patient, or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation that could cause harm. In particular, to fulfil special needs, Member States should be allowed to exclude from the provisions of this Directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under their direct personal responsibility. Member States should be also allowed to temporarily authorise the distribution of an unauthorised medicinal product in response to a suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm.	to be placed on the market in the Union when the marketing authorisation has been granted to the medicinal product, and its quality, safety**,** efficacy ***and environmental risk*** have been demonstrated. However, exemption should be provided from this requirement in situations characterised by an urgent need to administer a medicinal product to address the specific needs of a patient, or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation that could cause harm. In particular, to fulfil special needs, Member States should be allowed to exclude from the provisions of this Directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under their direct personal responsibility. Member States should be also allowed to temporarily authorise the distribution of an unauthorised medicinal product in response to a suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm.

Amendment 19
Proposal for a directive
Recital 22 a (new)

Text proposed by the Commission	*Amendment*
	(22a) Particular attention should be given to the composition of clinical trials to ensure gender-based equity and comprehensive clinical data.

Amendment 20
Proposal for a directive
Recital 24

Text proposed by the Commission	*Amendment*
(24) It is therefore necessary to	(24) It is therefore necessary to

introduce a requirement for new medicinal products or when developing paediatric indications of already authorised products covered by a patent or a supplementary protection certificate to present either the results of studies in the paediatric population in accordance with an agreed paediatric investigation plan or proof of having obtained a waiver or deferral, at the time of filing a marketing authorisation application or an application for a new therapeutic indication, new pharmaceutical form or new route of administration. However, in order to avoid exposing children to unnecessary clinical trials or due to the nature of the medicinal products, that requirement should not apply to generics or similar biological medicinal products and medicinal products authorised through the well-established medicinal use procedure, nor to homeopathic ***medicinal*** products and traditional herbal medicinal products authorised through the simplified registration procedures of this Directive.

introduce a requirement for new medicinal products or when developing paediatric indications of already authorised products covered by a patent or a supplementary protection certificate to present either the results of studies in the paediatric population in accordance with an agreed paediatric investigation plan or proof of having obtained a waiver or deferral, at the time of filing a marketing authorisation application or an application for a new therapeutic indication, new pharmaceutical form or new route of administration. However, in order to avoid exposing children to unnecessary clinical trials or due to the nature of the medicinal products, that requirement should not apply to generics or similar biological medicinal products and medicinal products authorised through the well-established medicinal use procedure, nor to homeopathic products and traditional herbal medicinal products authorised through the simplified registration procedures of this Directive.

Amendment 21
Proposal for a directive
Recital 27

Text proposed by the Commission	*Amendment*
(27) Certain particulars and documentation that are normally to be submitted with an application for a marketing authorisation should not be required if a medicinal product is a generic medicinal product or a similar biological medicinal product (biosimilar) that is authorised or has been authorised in the Union. Both generic and biosimilar medicinal products are important to ensure access of medicinal products to a wider patient population and create a competitive internal market. In a joint statement authorities of the Member States confirmed that the experience with approved biosimilar medicinal products over the past 15 years has shown that in terms of	(27) Certain particulars and documentation that are normally to be submitted with an application for a marketing authorisation should not be required if a medicinal product is a generic medicinal product or a similar biological medicinal product (biosimilar) that is authorised or has been authorised in the Union. Both generic and biosimilar medicinal products are important to ensure access of medicinal products to a wider patient population ***at more affordable prices*** and create a competitive internal market. In a joint statement authorities of the Member States confirmed that the experience with approved biosimilar medicinal products over the past 15 years

efficacy, safety and immunogenicity they are comparable to their reference medicinal product and are therefore interchangeable and can be used instead of its reference product (or vice versa) or replaced by another biosimilar of the same reference product.

has shown that in terms of efficacy, safety and immunogenicity they are comparable to their reference medicinal product and are therefore interchangeable and can be used instead of its reference product (or vice versa) or replaced by another biosimilar of the same reference product.

Amendment 22
Proposal for a directive
Recital 30

Text proposed by the Commission	*Amendment*
(30) Regulatory decision-making on the development, authorisation and supervision of medicines may be supported by access and analysis of health data, including real world data i.e. health data generated outside of clinical studies**,** where appropriate. The competent authorities should be able to use such data, including via the European Health Data Space interoperable infrastructure.	(30) Regulatory decision-making on the development, authorisation and supervision of medicines may be supported by access and analysis of health data, including real world data i.e. health data generated outside of clinical studies where appropriate. The competent authorities should be able to use such data, including via the European Health Data Space interoperable infrastructure. ***Data generated via in silico methods, such as computational modelling and simulation, molecular modelling, mechanistic modelling, digital twin and artificial intelligence, where appropriate, could also be used to support regulatory decision making.***

Amendment 23
Proposal for a directive
Recital 31

Text proposed by the Commission	*Amendment*
(31) Directive 2010/63/EU of the European Parliament and of the Council[43] 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 animals, which provides essential information on the quality, safety and efficacy of a medicinal product, should	(31) Directive 2010/63/EU of the European Parliament and of the Council[43] 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 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 EMA and 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 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.

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 ***only used as necessary and be*** optimised in order to provide the most satisfactory results whilst using the minimum number of animals***. The marketing authorisation applicant should not carry out animal tests where scientifically satisfactory non-animal testing methods are available. Where scientifically satisfactory non-animal testing methods are not available, applicants that use animal testing should ensure that the principle of replacement, reduction and refinement of animal testing for scientific purposes has been applied with regard to any animal study conducted for the purpose of supporting the application***. The procedures of such testing should be designed to avoid causing pain, suffering, distress or lasting harm to animals and should follow the available EMA and 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 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 ***grouping and*** read-across***, aquatic egg*** models ***as well as invertebrate species***.

[43] 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).

[43] 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 24
Proposal for a directive

Recital 32

Text proposed by the Commission	*Amendment*
(32) 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.	(32) 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 25
Proposal for a directive
Recital 34 a (new)

Text proposed by the Commission	*Amendment*
	(34a) Where the environmental risk assessment is incomplete or insufficiently substantiated for a medicinal product authorised before 30 October 2005, it should be possible for the national marketing authorisation to be revoked. However, due consideration to avoid restricting patient access to such medicinal products should be given before any decision is taken on revocation.

Amendment 26
Proposal for a directive
Recital 44

Text proposed by the Commission	*Amendment*
(44) As regards access to medicinal products, previous amendments to the Union pharmaceutical legislation have addressed this issue by providing for accelerated assessment of marketing	(44) As regards access to medicinal products, previous amendments to the Union pharmaceutical legislation have addressed this issue by providing for accelerated assessment of 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 medicinal products. Patient access to medicinal products depends on many factors. Marketing authorisation holders are not obliged to market a medicinal product in all Member States; they may decide not to market their medicinal products in, or withdraw them from, one or more Member States. National pricing and reimbursement policies, the size of the population, the organisation of health systems and national administrative procedures are other factors influencing market launch and patient access.	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***, ***some public health priorities are still unaddressed and*** these medicinal products do not always reach the patient and patients in the Union still have different levels of access to medicinal products. Patient access to medicinal products depends on many factors. Marketing authorisation holders are not obliged to market a medicinal product in all Member States; they may decide not to market their medicinal products in, or withdraw them from, one or more Member States ***often due to commercial reasons***. National pricing and reimbursement policies, the size of the population, the organisation of health systems and national administrative procedures are other factors influencing market launch and patient access. ***In addition, a complex regulatory environment and associated administrative burden can prevent SMEs, research institutes and academic institutions from developing promising innovative treatments and from applying for conditional market authorization.***

Amendment 27
Proposal for a directive
Recital 44 a (new)

Text proposed by the Commission	*Amendment*
	(44a) In order to increase the availability of medicines and contribute to reducing access inequalities within the Union, the marketing authorisation holders of medicinal products should submit an application for pricing and reimbursement in Member States upon request.

Amendment 28
Proposal for a directive
Recital 45

Text proposed by the Commission	*Amendment*
(45) Addressing unequal patient access and affordability of medicinal products has become a key priority of the Pharmaceutical Strategy for Europe, as also highlighted by Council conclusions[45] and a resolution of the European Parliament[46]. Member States called for revised mechanisms and incentives for development of medicinal products tailored to the level of unmet medical need, while ensuring health system sustainability, patient access and availability of affordable medicinal products in all Member States.	(45) Addressing unequal patient access and affordability of medicinal products has become a key priority of the Pharmaceutical Strategy for Europe, as also highlighted by Council conclusions[45] and a resolution of the European Parliament[46]. Member States called for revised mechanisms and incentives for development of medicinal products tailored to the level of unmet medical need, while ensuring health system sustainability, patient access and availability of affordable medicinal products in all Member States. ***Monitoring and evaluating access to medicinal products at Union level is important to understand the results achieved through incentives.***
[45] Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States, (OJ C, C/269, 23.07.2016, p. 31). Council Conclusions on Access to medicines and medical devices for a Stronger and Resilient EU, (2021/C 269 I/02).	[45] Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States, (OJ C, C/269, 23.07.2016, p. 31). Council Conclusions on Access to medicines and medical devices for a Stronger and Resilient EU, (2021/C 269 I/02).
[46] European Parliament resolution of 2 March 2017 on EU options for improving access to medicine (2016/2057(INI)) Shortages of medicines, 2020/2071(INI).	[46] European Parliament resolution of 2 March 2017 on EU options for improving access to medicine (2016/2057(INI)) Shortages of medicines, 2020/2071(INI).

Amendment 29
Proposal for a directive
Recital 46 a (new)

Text proposed by the Commission	*Amendment*
	(46a) Member States apply diverse procedures and measures in the pricing and reimbursement of medicinal products. Those procedures and measures significantly affect access to medicinal

	products, especially with regard to the speed at which access is achieved. Likewise, Member States apply specific procedures and measures pertaining to the promotion of competition from generic and biosimilar medicinal products. Having regard to Member State competences, and recognising the disparities which can be observed in access to medicinal products across the Union, the exchange of best practice among national competent authorities in that area should be given greater priority. In that regard, the Commission should play a distinct role in facilitating the exchange of best practices.

Amendment 30
Proposal for a directive
Recital 47

Text proposed by the Commission	*Amendment*
(47) To ensure dialogue among all actors in the medicines lifecycle, discussions on policy issues related to the application of the rules related to prolongation of regulatory data protection ***for market launch*** shall take place in the Pharmaceutical Committee. The Commission may invite bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 or national bodies responsible for pricing and reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.	(47) To ensure dialogue among all actors in the medicines lifecycle, discussions on policy issues related to the application of the rules related to prolongation of regulatory data protection shall take place in the Pharmaceutical Committee. The Commission may invite bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 or national bodies responsible for pricing and reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.

Amendment 31
Proposal for a directive
Recital 48

Text proposed by the Commission	*Amendment*
(48) While pricing and reimbursement decisions are a Member State competence, the Pharmaceutical Strategy for Europe	(48) While pricing and reimbursement decisions are a Member State competence, the Pharmaceutical Strategy for Europe

announced actions to support cooperation of Member States to improve affordability. The Commission has transformed the group of National Competent Authorities on Pricing and Reimbursement and public healthcare payers (NCAPR) from an ad-hoc forum to a continuous voluntary cooperation with the aim to exchange information and best practices on pricing, payment and procurement policies to improve the affordability and cost-effectiveness of medicines and health system's sustainability. The Commission is committed to stepping up this cooperation and further supporting information exchange among national authorities, including on public procurement of medicines, while fully respecting the competences of Member States in this area. The Commission may also invite NCAPR members to participate in deliberations of the Pharmaceutical Committee on topics that may have an impact on pricing or reimbursement policies, such as the market launch incentive.

announced actions to support cooperation of Member States to improve affordability***. While the price paid within a given Member State reflects the preference of a national health system, more coordination on pricing and procurement could contribute to more equal and timely access to medicinal products, including for Member States with lower purchasing power. The Commission can support initiatives such as the Beneluxa Initiative on Pharmaceutical Policy and the Valletta Declaration***. The Commission has transformed the group of National Competent Authorities on Pricing and Reimbursement and public healthcare payers (NCAPR) from an ad-hoc forum to a continuous voluntary cooperation with the aim to exchange information and best practices on pricing, payment and procurement policies to improve the affordability and cost-effectiveness of medicines and health system's sustainability. The Commission is committed to stepping up this cooperation and further supporting information exchange among national authorities, including on public procurement of medicines, while fully respecting the competences of Member States in this area. The Commission ***should issue guidance on how to best implement 'most economically advantageous tender' ('MEAT' criteria) in public procurement, which aims to ensure the best value for money rather than looking at the lowest price criteria alone. The Commission*** may also invite NCAPR members to participate in deliberations of the Pharmaceutical Committee on topics that may have an impact on pricing or reimbursement policies, such as the market launch incentive. ***Joint procurement should aim not to have detrimental impact on access to medicinal products for countries that do not take part in the tender process concerned.***

Amendment 32
Proposal for a directive
Recital 49

Text proposed by the Commission	*Amendment*
(49) Joint procurement, whether within a country or across countries, can improve access, affordability, and security of supply of medicines, in particular for smaller countries. Member States interested in joint procurement of medicines can make use of Directive 2014/24/EU[47] , which sets out purchasing procedures for public buyers, the Joint Procurement Agreement[48] and the proposed revised Financial Regulation[49] . Upon request from the Member States the Commission may support interested Member States by facilitating coordination to enable access to medicines for patients in the Union as well as information exchange, in particular for medicines for rare and chronic diseases.	(49) Joint procurement, whether within a country or across countries, can improve access, affordability, and security of supply of medicines, in particular for smaller countries. Member States interested in joint procurement of medicines can make use of Directive 2014/24/EU[47] , which sets out purchasing procedures for public buyers, the Joint Procurement Agreement[48] and the proposed revised Financial Regulation[49] . Upon request from the Member States the Commission may support interested Member States by facilitating coordination to enable access to medicines for patients in the Union as well as information exchange, in particular for medicines for rare and chronic diseases. ***In the event of joint procurement of medicinal products as a medical countermeasure in cases of serious cross-border threats to health, Regulation (EU) 2022/2371 of the European Parliament and of the Council[49a] applies.***
[47] 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).	[47] 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).
[48] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU.	[48] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU.
[49] COM/2022/223 final.	[49] COM/2022/223 final.
	[49a] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU.

Amendment 33
Proposal for a directive
Recital 50

Text proposed by the Commission	*Amendment*
(50) The establishment of a criteria-based definition of 'unmet medical need' is required to incentivise the development of medicinal products in therapeutic areas that are currently underserved. To ensure that the concept of unmet medical need reflects scientific and technological developments and current knowledge in underserved diseases, the Commission should specify ***and update using implementing acts,*** the criteria of satisfactory method of diagnosis, prevention or treatment, 'remaining high morbidity or mortality', 'relevant patient population' following scientific assessment by the Agency. The Agency will seek input from a broad range of authorities or bodies active along the lifecycle of medicinal products in the framework of the consultation process established under the [revised Regulation (EC) No 726/2004] and also take into account scientific initiatives at EU level or between Member States related to analysing unmet medical needs, burden of disease and priority setting for research and development. The criteria for 'unmet medical need' can be subsequently used by Member States to identify specific therapeutic areas of interest.	(50) The establishment of a criteria-based definition of 'unmet medical need' is required to incentivise the development of medicinal products in therapeutic areas that are currently underserved. To ensure that the concept of unmet medical need reflects scientific and technological developments and current knowledge in underserved diseases, ***and prevents extensions of data protection that would not be in line with this objective due to unclear interpretation of 'unmet medical need',*** the Commission should specify the criteria of satisfactory method of diagnosis, prevention or treatment, 'remaining high morbidity or mortality', 'relevant patient population' following scientific assessment by the Agency. The Agency will seek input from a broad range of authorities or bodies active along the lifecycle of medicinal products in the framework of the consultation process established under the [revised Regulation (EC) No 726/2004] and also take into account scientific initiatives at EU level or between Member States related to analysing unmet medical needs, burden of disease and priority setting for research and development. The ***Agency should also seek input from other relevant stakeholders, including relevant patient populations. The*** criteria for 'unmet medical need' can be subsequently used by Member States to identify specific therapeutic areas of interest***, but does not need to have any automatic effect on Member States' decisions on pricing and reimbursement of medicinal products which should take into account factors, in particular the Health Technology Assessment, other than the definition established under this Directive***.

Amendment 34
Proposal for a directive
Recital 50 a (new)

Text proposed by the Commission	*Amendment*
	(50a) The concept of morbidity in the definition of 'unmet medical need' should encompass a multiplicity of factors. Morbidity should be understood to include aspects of quality of life of patients, a high burden of disease and treatment and the inability to perform daily life activities. The assessment of 'unmet medical need' should therefore take into account relevant patient experience data.

Amendment 35
Proposal for a directive
Recital 51 a (new)

Text proposed by the Commission	*Amendment*
	(51a) Repurposing of off-patent medicinal products to develop new therapeutic options should be supported as it can expand access in an affordable manner, providing significant benefits to patients;

Amendment 36
Proposal for a directive
Recital 52

Text proposed by the Commission	*Amendment*
(52) For the ***initial*** marketing authorisation application for medicinal products containing a new active substance, the submission of clinical trials that include as a comparator an evidence-based existing treatment should be incentivised, in order to foster the generation of comparative clinical evidence that is relevant and can	(52) For the marketing authorisation application for medicinal products containing a new active substance, the submission of clinical trials that include as a comparator an evidence-based existing treatment should be incentivised, in order to foster the generation of comparative clinical evidence that is relevant and can accordingly support subsequent health

accordingly support subsequent health technology assessments and decisions on pricing and reimbursement by Member States.	technology assessments and decisions on pricing and reimbursement by Member States. ***National competent authorities and the Agency should promote, where possible, the use of comparative studies that compare the new active substance to the existing treatment when giving regulatory advice prior to granting a marketing authorisation for medicinal products.***

Amendment 37
Proposal for a directive
Recital 53

Text proposed by the Commission	*Amendment*
(53) A marketing authorisation holder should ensure the appropriate and continuous supply of a medicinal product throughout its lifetime ***irrespective of whether that medicinal product is covered by a supply incentive or not***.	(53) A marketing authorisation holder should***, within its responsibilities,*** ensure the appropriate and continuous supply of a medicinal product throughout its lifetime.

Amendment 38
Proposal for a directive
Recital 54

Text proposed by the Commission	*Amendment*
(54) Micro, small and medium-sized enterprises ('SMEs'), not-for-profit entities or entities with limited experience in the Union system should benefit from additional time to ***market*** a medicinal product in the Member States where the marketing authorisation is valid ***for the purposes of receiving additional regulatory data protection***.	(54) Micro, small and medium-sized enterprises ('SMEs'), not-for-profit entities or entities with limited experience in the Union system should benefit from additional time to ***submit an application for pricing and reimbursement for*** a medicinal product in the Member States where the marketing authorisation is valid***, and where a Member State has requested it***.

Amendment 39
Proposal for a directive
Recital 55

Text proposed by the Commission	*Amendment*
(55) ***When applying the provisions on market launch incentives,*** marketing authorisation holders and Member States should do their utmost to achieve a mutually agreed supply of medicinal products in accordance with the needs of the Member State concerned, without unduly delaying or hindering the other party from enjoying its rights under this Directive.	(55) Marketing authorisation holders and Member States should do their utmost to achieve a mutually agreed supply of medicinal products in accordance with the needs of the Member State concerned, without unduly delaying or hindering the other party from enjoying its rights under this Directive.

Amendment 40
Proposal for a directive
Recital 56

Text proposed by the Commission	*Amendment*
(56) Member States have the possibility to waive the condition of launch in their territory for the purpose of the prolongation of data protection for market launch. This can be done through a statement of non-objection to prolong the period of regulatory data protection. This is expected to be the case particularly in situations where launch in a particular Member State is materially impossible or because there are special reasons why a Member State wishes that launch take place later.	***deleted***

Amendment 41
Proposal for a directive
Recital 57

Text proposed by the Commission	*Amendment*
(57) The ***issuing of documentation from*** the Member States ***as regards the prolongation of data protection for the purpose of supply of medicinal products in all Member States where a marketing authorisation is valid, in particular the waiver to the conditions for such prolongation,*** does not affect at any time	(57) The ***application for pricing and reimbursement in*** the Member States does not affect at any time the powers of the Member States as regards the supply, setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes.

the powers of the Member States as regards the supply, setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes. ***Member States do not waive the possibility to request release or supply of the product concerned at any time before, during or after the prolongation of the data protection period.***

Amendment 42
Proposal for a directive
Recital 58

Text proposed by the Commission	*Amendment*
(58) An alternative way of demonstrating supply relates to the inclusion of medicinal products in a positive list of medicinal products covered by the national health insurance system in accordance with Directive 89/105/EEC. The related negotiations between companies and the Member State should be conducted in good faith.	(58) An alternative way of demonstrating supply relates to the inclusion of medicinal products in a positive list of medicinal products covered by the national health insurance system in accordance with ***Council*** Directive 89/105/EEC. The related negotiations between companies and the Member State should be conducted in good faith***, and all parties should adhere to the deadlines set out in Directive 89/105/EEC***[1a].
	[1a] Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ L 40, 11.2.1989, p. 8).

Amendment 43
Proposal for a directive
Recital 58 a (new)

Text proposed by the Commission	*Amendment*
	(58a) Cross-border healthcare is an important pathway for patients to access medicinal products that might otherwise not be available to them. To support

	access to medicinal products, in particular in the case of small patient populations, such as for paediatric or rare diseases, which are often disadvantaged when it comes to access to medicinal products, or where the administration of a medicinal product requires special competences or infrastructure, the full implementation of Directive 2011/24/EU of the European Parliament and of the Council[1a] should be supported. It is important to consider in that regard all alternative paths to making available medicinal products to patients. Competent authorities of the Member States should therefore utilise the NCAPR to exchange and share best practice regarding the implementation of cross-border access agreements and negotiations.
	[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).

Amendment 44
Proposal for a directive
Recital 59

Text proposed by the Commission	*Amendment*
(59) A Member State that considers that the conditions of supply have not been met for its territory should provide a reasoned statement of non-compliance at the latest in the Standing Committee on Medicinal Products for Human Use procedure of the variation linked to the provision of the relevant incentive.	***deleted***

Amendment 45
Proposal for a directive
Recital 61

Text proposed by the Commission	*Amendment*
(61) When a compulsory licence has been granted by a relevant authority in the Union ***to tackle a public health emergency***, regulatory data protection may, if still in force, prevent the effective use of the compulsory licence as they impede the authorisation of generic medicinal products, and thus access to the medicinal products needed to address the crisis. For this reason, data and market protection should be suspended ***when a compulsory licence has been issued to tackle a public health emergency***. Such a suspension of the regulatory data protection should be allowed only in relation to the compulsory licence granted and its beneficiary. The suspension shall comply with the objective, the territorial scope, the duration and the subject matter of the granted compulsory licence.	(61) When a compulsory licence has been granted ***under conditions laid down in Union law and in compliance with international agreements*** by a relevant authority in the Union, regulatory data protection may, if still in force, prevent the effective use of the compulsory licence as they impede the authorisation of generic medicinal products, and thus access to the medicinal products needed to address the crisis. For this reason, data and market protection should be suspended. Such a suspension of the regulatory data protection should be allowed only in relation to the compulsory licence granted and its beneficiary. The suspension shall comply with the objective, the territorial scope, the duration and the subject matter of the granted compulsory licence.

Amendment 46
Proposal for a directive
Recital 62

Text proposed by the Commission	*Amendment*
(62) The suspension of the regulatory data protection should be granted only for the duration of the compulsory licence. A ‘suspension‘ of data and market protection in ***cases of public health emergency*** shall mean that data and market protection shall produce no effect in relation to the particular licensee of the compulsory licence while that compulsory licence is in effect. When the compulsory licence ends, the data and market protection shall resume their effect. The suspension should not result in an extension of the original duration.	(62) The suspension of the regulatory data protection should be granted only for the duration of the compulsory licence ***in the Member States where the compulsory licence has been granted***. A ‘suspension‘ of data and market protection in ***accordance with a compulsory licence granted by a relevant authority in the Union under conditions laid down in Union law and in compliance with international agreements*** shall mean that data and market protection shall produce no effect in relation to the particular licensee of the compulsory licence while that compulsory licence is in effect. When the compulsory licence ends, the data and market protection shall resume their effect. The suspension should not result in an

extension of the original duration.

Amendment 47
Proposal for a directive
Recital 64

Text proposed by the Commission	*Amendment*
(64) It will allow, inter alia, to conduct studies to support pricing and reimbursement as well as the manufacture or purchase of patent protected active substances for the purpose of seeking marketing authorisations during that period, contributing to the market entry of generics and biosimilars on day one of loss of the patent or SPC protection.	(64) It will allow ***all necessary steps to support timely access to generic medicinal products***, inter alia, to conduct studies to support pricing and reimbursement as well as the manufacture or purchase of patent protected active substances for the purpose of seeking marketing authorisations during that period, contributing to the ***timely market entry of medicinal products, in particular the*** market entry of generics and biosimilars on day one of loss of the patent or SPC protection.

Amendment 48
Proposal for a directive
Recital 65

Text proposed by the Commission	*Amendment*
(65) The competent authorities should refuse the validation for an application for a marketing authorisation referring to data of a reference medicinal product only on the basis of the grounds set out in this Directive. The same applies to any decision to grant, vary, suspend, restrict or revoke the marketing authorisation. The competent authorities cannot base their decision on any other grounds. In particular, those decisions cannot be based on the patent or SPC status of the reference medicinal product.	(65) ***The timely availability of generic and biosimilar medicinal products were highlighted as priorities in the conclusions of the Council on strengthening the balance in the pharmaceutical systems in the European Union and its Member States[1a]. in the conclusions of the Council on Access to medicines and medical devices for a Stronger and Resilient EU[1b] and in the resolution of the European Parliament of 2 March 2017 on EU options for improving access to medicines[1c]*** **.**The competent authorities should refuse the validation for an application for a marketing authorisation referring to data of a reference medicinal product only on the basis of the grounds set out in this Directive. The same applies to any decision to grant, vary, suspend, restrict or revoke

the marketing authorisation. The competent authorities cannot base their decision on any other grounds. In particular, those decisions cannot be based on the patent or SPC status of the reference medicinal product. ***It is therefore appropriate to explicitly prohibit that practice.***

[1a] OJ C 269, 23.7.2016, p. 31.

[1b] OJ C 269 I, 7.7.2021, p. 3.

[1c] OJ C, 263, 25.7.2018, p. 4.

Amendment 49
Proposal for a directive
Recital 65 a (new)

Text proposed by the Commission	*Amendment*
	(65a) The One Health Approach is needed in order to address antimicrobial resistance, one of the most significant, current health threats. It is estimated that more than 35 000 people in the Union/European Economic Area and more than 1,2 million people globally die each year as a direct consequence of an infection due to bacteria resistant to antibiotics[1a]. High levels of cooperation are required across sectors and globally. This Directive puts in place coordinated action in order to ensure prevention and minimisation of environmental risks throughout the supply chain, use and disposal, awareness raising among patients, consumers and healthcare professionals and prudent and responsible use of antimicrobials.

[1a] Murray, C.J.L., Ikuta, K.S., Sharara, F., et al. 'Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis', Lancet, Vol. 399, No 10325, pp. 629-655.

Amendment 50
Proposal for a directive
Recital 66

Text proposed by the Commission	*Amendment*
(66) In order to address the challenge of antimicrobial resistance, antimicrobials should be packaged in quantities that are appropriate for the therapy cycle relevant for that product and national rules on antimicrobial subject to prescription ensure that they are dispensed in a way that corresponds to the quantities described by the prescription.	(66) In order to address the challenge of antimicrobial resistance, antimicrobials should be packaged in quantities that are appropriate for the therapy cycle relevant for that product***, including where possible the per unit dispensing,*** and national rules on antimicrobial subject to prescription ensure that they are dispensed in a way that corresponds to the quantities described by the prescription. ***Dispensing the exact number of units needed could help address antimicrobial resistance as well as environmental impact.***

Amendment 51
Proposal for a directive
Recital 67

Text proposed by the Commission	*Amendment*
(67) The provision of information to healthcare professionals and to patients on the appropriate use, storage and disposal of antimicrobials is a joint responsibility of marketing authorisation holders and of Member States ***who*** should ensure appropriate collection system for all medicinal products.	(67) The provision of information to healthcare professionals and to patients on the appropriate use, storage and disposal of antimicrobials is a joint responsibility of marketing authorisation holders and of Member States***. Member States*** should ensure appropriate collection ***and disposal*** system for all medicinal products.

Amendment 52
Proposal for a directive
Recital 67 a (new)

Text proposed by the Commission	*Amendment*
	(67a) Pharmacists and other health care professionals should play a role in antimicrobial stewardship, including advising on the prudent use of antibiotics and other antimicrobials, as well as their

correct disposal.

Amendment 53
Proposal for a directive
Recital 68

Text proposed by the Commission	*Amendment*
(68) While this Directive restricts the use of antimicrobials by setting ***certain categories of*** antimicrobials under prescription status, due to the growing antimicrobial resistance in the Union, competent authorities of the Member States should consider further measures ***for example*** expanding the prescription status of antimicrobials or the mandatory use of diagnostic tests before prescription. Competent authorities of the Member States should consider such further measures according to the level of antimicrobial resistance in their territory and the needs of patients.	(68) While this Directive restricts the use of antimicrobials by setting ***antibiotics and*** antimicrobials ***wich have an identified risk of resistance*** under prescription status, due to the growing antimicrobial resistance in the Union, competent authorities of the Member States should consider further ***a number of*** measures***, including*** expanding the prescription status of antimicrobials***, restricting the use of certain antimicrobials to the use in hospitals, mandatory training of healthcare professionals on the environmental impact of medicines use and stewardship regarding the use of antimicrobials,*** or the mandatory use of diagnostic tests before prescription. ***Member States should also ensure that measures are in place to safeguard the prescription for antibiotic products from influence by any form of economic incentive provided directly or indirectly to persons who prescribe medicinal products, given the risks associated with antimicrobial resistanceand for avoiding risks to the environment, in line with the European Union Strategic Approach to Pharmaceuticals in the Environment. Additionally, the combined use of several antimicrobial active substances may represent a particular risk with respect to the development of antimicrobial resistance. Such combined use should therefore only be prescribed in exceptional cases where the benefit-risk balance of the combination is favorable.*** Competent authorities of the Member States ***should promote the availability of rapid diagnostic tests in the Member States and*** should consider such further

measures according to the level of antimicrobial resistance in their territory and the needs of patients.

Amendment 54
Proposal for a directive
Recital 69

Text proposed by the Commission	*Amendment*
(69) The pollution of waters and soils with pharmaceutical residues is an emerging environmental problem, and there is scientific evidence that the presence of those substances in the environment from their manufacturing, use and disposal poses a risk to the environment and public health. The evaluation of the legislation showed that strengthening of existing measures to reduce the impact of medicinal products' lifecycle on the environment and public health is required. Measures under this ***Regulation*** complement the main environmental legislation, in particular the Water Framework Directive (2000/60/EC[50]), the Environmental Quality Standard Directive (2008/105/EC[51]) the Groundwater Directive (2006/118/EC[52]), the Urban Wastewater Treatment Directive (91/271/EEC[53]), the Drinking Water Directive (2020/2184[54]) ***and*** the Industrial Emissions Directive (2010/75/EU[55]).	(69) The pollution of waters and soils with pharmaceutical residues is an emerging environmental problem, and there is scientific evidence that the presence of those substances in the environment from their manufacturing, use and disposal poses a risk to the environment and public health. The evaluation of the legislation showed that strengthening of existing measures to reduce the impact of medicinal products' lifecycle on the environment and public health is required. Measures under this ***Directive*** complement the main environmental legislation, in particular the Water Framework Directive (2000/60/EC[50]), the Environmental Quality Standard Directive (2008/105/EC[51]) the Groundwater Directive (2006/118/EC[52]), the Urban Wastewater Treatment Directive (91/271/EEC[53]), the Drinking Water Directive (2020/2184[54])***,*** the Industrial Emissions Directive (2010/75/EU[55]) ***and the Waste Framework Directive (2008/98/EC[55a])***.
[50] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).	[50] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).
[51] Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing	[51] Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing

Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84).

[52] Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19).

[53] Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment (OJ L 135, 30.5.1991, p. 40).

[54] Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast) (OJ L 435, 23.12.2020, p. 1).

[55] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (recast) (OJ L 334, 17.12.2010, p. 17).

Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84).

[52] Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19).

[53] Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment (OJ L 135, 30.5.1991, p. 40).

[54] Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast) (OJ L 435, 23.12.2020, p. 1).

[55] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (recast) (OJ L 334, 17.12.2010, p. 17).

[55a] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).

Amendment 55
Proposal for a directive
Recital 69 a (new)

Text proposed by the Commission	*Amendment*
	(69a) Emissions of active substances during manufacturing can be a threat to the environment and public health. Therefore, environmental risks should be assessed and addressed through the entire lifecycle of medicinal products, starting from manufacturing, through use and to

disposal.

Amendment 56
Proposal for a directive
Recital 69 b (new)

Text proposed by the Commission	*Amendment*
	(69b) Unitary packaging of medicinal products, in particular in hospital pharmacies, where this packaged and distributed in bulk could result in a decrease of packaging materials used and thereby contribute to environmental footprint of medicinal products, including its waste. It can also contribute to mitigating medicine shortages and antimicrobial resistance. The use of single dose unit containing all relevant information, in hospital environment, could furthermore represent an improvement in the risk of medication errors and therefore increase patient protection. Member States should promote the use of unit dose pre-cut blisters in hospital environment and, progressively, in dispensing pharmacies, when necessary.

Amendment 57
Proposal for a directive
Recital 69 c (new)

Text proposed by the Commission	*Amendment*
	(69c) The use of pharmaceuticals in human and veterinary medicinal products, including antimicrobials, has increased their concentrations in many environmental reservoirs such as soils, sediments and waterbodies in the past 20 years, and the environmental concentration is likely to increase further as the population grows and ages. The discharge of pharmaceuticals into the environment can not only harm ecosystems and wildlife, but can also

undermine the effectiveness of those same pharmaceuticals. The chemical and metabolic stability of certain pharmaceuticals means that up to 90 % of their active substances are released into the environment in their original form after use.

Amendment 58
Proposal for a directive
Recital 70 a (new)

Text proposed by the Commission	*Amendment*
	(70a) In exceptional cases where the ERA is incomplete due to missing data and this can be duly justified and substantiated by the marketing authorisation holder, it should still be possible, for reasons in the interest of public health, for the medicinal product to be placed on the market with certain post-authorisation conditions and obligations. Where a medicinal product has been authorised and the ERA is incomplete due to missing data, the marketing authorisation holder should submit the completed ERA in the timeline agreed with the authorities and deliver upon any other post-authorisation obligations.

Amendment 59
Proposal for a directive
Recital 71

Text proposed by the Commission	*Amendment*
(71) Marketing authorisation applicants should take into account environmental risk assessment procedures of other EU legal frameworks that may apply to chemicals dependent on their use. Further to this Regulation, there are four main other frameworks: (i) Industrial chemicals (REACH, (Regulation (EC) No 1907/2006); (ii) Biocides (Regulation (EC) No 528/2012); (iii) Pesticides (Regulation	(71) Marketing authorisation applicants should take into account environmental risk assessment procedures of other EU legal frameworks that may apply to chemicals dependent on their use. Further to this Regulation, there are four main other frameworks: (i) Industrial chemicals (REACH, (Regulation (EC) No 1907/2006); (ii) Biocides (Regulation (EC) No 528/2012); (iii) Pesticides (Regulation

(EC) No 1107/2009); and (iv) Veterinary medicines (Regulation (EU) 2019/6)). As a part of the Green Deal, the Commission has proposed a 'one-substance one-assessment' (OS-OA) approach for chemicals[56] , in order to increase the efficiency of the registration system, reduce costs and unnecessary animal testing.

(EC) No 1107/2009); and (iv) Veterinary medicines (Regulation (EU) 2019/6)). As a part of the Green Deal, the Commission has proposed a 'one-substance one-assessment' (OS-OA) approach for chemicals[56] , in order to increase the efficiency of the registration system, reduce costs and unnecessary animal testing. ***The ERA covers the risks associated with production. Compliance with relevant Union and Member State legislation in terms of environmental protection at the stage of manufacturing should generally be considered as a relevant risk mitigation measure in terms of production. This should also apply for production in third countries with a level of environmental protection equivalent to that of the Union. More environmentally friendly pharmaceuticals would contribute positively to human health.***

[56] Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal, Brussels (2019), COM(2019) 640 final.

[56] Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal, Brussels (2019), COM(2019) 640 final.

Amendment 60
Proposal for a directive
Recital 72

Text proposed by the Commission

(72) The emissions and discharges of antimicrobials to the environment from manufacturing sites may lead to antimicrobial resistance ("AMR"), which is a global concern regardless where the emissions and discharges take place. Therefore, the ERA scope should be extended to cover the risk of AMR selection during the entire life cycle of antimicrobials, including manufacturing.

Amendment

(72) The emissions and discharges of antimicrobials to the environment from manufacturing sites may lead to antimicrobial resistance ("AMR"), which is a global concern regardless where the emissions and discharges take place. Therefore, the ERA scope should be extended to cover the risk of AMR selection during the entire life cycle of antimicrobials, including manufacturing. ***At the date of adoption of this Directive,***

for the purpose of the ERA, there is not a scientifically agreed method to measure antimicrobial resistance other than for antibiotic resistance. The Commission should therefore issue, after consulting the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC) and the European Environment Agency (EEA), guidelines on how to conduct ERAs for AMR selection for microbials other than bacteria.

Amendment 61
Proposal for a directive
Recital 74 a (new)

Text proposed by the Commission	*Amendment*
	(74a) According to the Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters[1a], the public has a right to obtain information on environmental matters, including on the ERA of a pharmaceutical product.
	[1a] OJ L 124, 17.5.2005, p. 4.

Amendment 62
Proposal for a directive
Recital 93

Text proposed by the Commission	*Amendment*
(93) To optimise the use of resources for both applicants for marketing authorisation and competent authorities and avoid duplication of assessment of chemical active substances of medicinal products, marketing authorisation applicants should be able to rely on an active substance master file certificate or a monograph of the European Pharmacopeia, instead of submitting the relevant data as required in	(93) To optimise the use of resources for both applicants for marketing authorisation and competent authorities and avoid duplication of assessment of chemical active substances of medicinal products ***which includes cell and gene therapies***, marketing authorisation applicants should be able to rely on an active substance master file certificate or a monograph of the European Pharmacopeia, instead of

accordance with Annex II. An active substance master file certificate may be granted by the Agency when the relevant data on the active substance concerned is not already covered by a monograph of the European Pharmacopeia or by another active substance master file certificate. The Commission should be empowered to establish the procedure for the single assessment of an active substance master file. To further optimise the use of resources, the Commission should be empowered to allow use a certification scheme also for additional quality master files i.e. for active substances other than chemical active substances, or for other substances present or used in the manufacture of a medicinal product, required in accordance with Annex II, e.g. in case of novel excipients, adjuvants, radiopharmaceutical precursors and active substance intermediates, when the intermediate is a chemical active substance by itself or used in conjugation with a biological substance.

submitting the relevant data as required in accordance with Annex II. An active substance master file certificate may be granted by the Agency when the relevant data on the active substance concerned is not already covered by a monograph of the European Pharmacopeia or by another active substance master file certificate. The Commission should be empowered to establish the procedure for the single assessment of an active substance master file. To further optimise the use of resources, the Commission should be empowered to allow use ***of*** a certification scheme also for additional ***master files, including*** quality master files***,*** i.e. for active substances other than chemical active substances, or for other substances present or used in the manufacture of a medicinal product, required in accordance with Annex II, e.g. in case of novel excipients, adjuvants, ***raw materials, viral vectors and other starting materials, growth media,*** radiopharmaceutical precursors and active substance intermediates, when the intermediate is a chemical active substance by itself or used in conjugation with a biological substance***, as well as for raw materials and starting materials used for manufacturing of cell therapy and gene therapy***.

Amendment 63
Proposal for a directive
Recital 101

Text proposed by the Commission	*Amendment*
(101) The increasing use of electronic networks for communication of information on adverse reactions to medicinal products marketed in the Union is intended to allow competent authorities to share the information at the same time.	(101) The increasing use of electronic networks for communication of information on adverse reactions to medicinal products marketed in the Union is intended to allow competent authorities to share the information at the same time. ***In that regard, Member States should seek to inform directly those stakeholders who report adverse reactions in case there exists any update on the safety profile of***

the medicinal products.

Amendment 64
Proposal for a directive
Recital 109

Text proposed by the Commission	*Amendment*
(109) There may be cases where manufacturing or testing steps of medicinal products need to take place in sites close to patients, for example advanced therapy medicinal products with short shelf-life. In such cases, these manufacturing or testing steps may need to be decentralised to multiple sites to reach patients across the Union. When the manufacturing or testing steps are decentralised, they should be carried out under the responsibility of the qualified person of an authorised central site. The decentralised sites should not require a separate manufacturing authorisation from the one granted to the relevant central site but should be registered by the competent authority of the Member State in which the decentralised site is established. In the case of medicinal products containing, consisting or derived from autologous SoHO, the decentralised sites have to be registered as a SoHO entity as defined in and pursuant to [SoHO Regulation] for the activities of donor review and eligibility assessment, donor testing and collection, or just for collection in the case of products manufactured for autologous use.	(109) There may be cases where manufacturing or testing steps of medicinal products need to take place in sites close to patients, for example advanced therapy medicinal products with short shelf-life. In such cases, these manufacturing or testing steps may need to be decentralised to multiple sites to reach patients across the Union. When the manufacturing or testing steps are decentralised, they should be carried out under the responsibility of the qualified person of an authorised central site***. Additionally, in order to ensure the smooth functioning of decentralised sites under this framework with the activities relevant for other Union legal frameworks, competent authorities of Member States supervising the decentralised site should coordinate their acitivities and supervisory tasks with the relevant authorities responsible for the supervision of the manufacturing or testing activities under other Union acts***. The decentralised sites should not require a separate manufacturing authorisation from the one granted to the relevant central site but should be registered by the competent authority of the Member State in which the decentralised site is established. In the case of medicinal products containing, consisting or derived from autologous SoHO, the decentralised sites have to be registered as a SoHO entity as defined in and pursuant to [SoHO Regulation] for the activities of donor review and eligibility assessment, donor testing and collection, or just for collection in the case of products manufactured for autologous use.

Amendment 65
Proposal for a directive
Recital 123 a (new)

Text proposed by the Commission	*Amendment*
	(123a) Pharmacists and other health care professionals have an important role in primary care, particularly to compound, dispense and sell medicinal products that patients need, to provide advice on their proper use and possible adverse effects and to support patients suffering of acute and chronic illnesses. In a hospital environment, hospital pharmacists set up pharmaceutical consultations and designate personalised pharmaceutical plans, in cooperation with other health professionals, patients and carers. Hospital pharmacists and community pharmacists could play a significant role in the use of electronic package leaflets, as well as for understanding the information contained in paper leaflets.

Amendment 66
Proposal for a directive
Recital 124

Text proposed by the Commission	*Amendment*
(124) Rules should be laid down as to how the labelling and package leaflets are to be presented.	(124) Rules should be laid down as to how the labelling and package leaflets are to be presented. ***The package leaflet should be easily legible, clearly comprehensible by users, including especially the target patient groups, and indelible. Patient leaflets are in the category of consultative reading which means that relevant information should be found without reading the whole leaflet. For readability and legibility, the package leaflet can benefit from a typographic hierarchy and a legible typeface. Design choices should primarily serve function and readability, rather than aesthetics.***

Amendment 67
Proposal for a directive
Recital 125

Text proposed by the Commission	*Amendment*
(125) The provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information.	(125) ***Sharing accurate information with the general public in order to promote trust in science and the regulatory system and supporting health literacy of patients and consumers is crucial. Where relevant, competent authorities should also share up to date information with healthcare professionals, including pharmacists, and the scientific community.*** The provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information.

Amendment 68
Proposal for a directive
Recital 127

Text proposed by the Commission	*Amendment*
(127) The use of electronic and technological possibilities other than paper package leaflets can facilitate access to medicinal products, medicinal products distribution and should always guarantee equal or better quality of information to all patients compared to the paper form of product information.	(127) The use of electronic and technological possibilities other than paper package leaflets***, which is complementary to the paper leaflets which are crucial for patients with limited digital health literacy,*** can facilitate access to medicinal products, medicinal products distribution and should always guarantee equal or better quality of information to all patients compared to the paper form of product information. ***Ensuring the protection of personal data in accordance with Regulation (EU) 2016/679 and prevention of the identification, profiling or tracking of individuals is necessary in that regard.***

Amendment 69
Proposal for a directive

Recital 128

Text proposed by the Commission	*Amendment*
(128) Member States have varying levels of digital literacy and internet access. In addition, patient and healthcare professional needs may differ. It is therefore necessary that Member States have a discretion on the adoption of measures enabling the electronic provision of product information while ensuring that no patient is left behind, taking into account the needs of different age categories and the different levels of digital literacy in the population, and making sure that product information is easily accessible to all patients. ***Member States*** should ***progressively allow the possibility for*** electronic product information***, while ensuring*** full compliance with the rules on protection of personal data, and adhere to harmonised standards developed at EU level.	(128) Member States have varying levels of digital literacy and internet access. In addition, patient and healthcare professional needs may differ. It is therefore necessary that Member States have a discretion on the adoption of measures enabling the electronic provision of product information while ensuring that no patient is left behind, taking into account the needs of different age categories and the different levels of digital literacy in the population, and making sure that product information is easily accessible to all patients. ***A package leaflet*** should ***be made available electronically and be included in paper format, except where the Member State, following a consultation, decides to make only the*** electronic product information ***available. Electronic product information should be available in*** full compliance with the rules on protection of personal data, and adhere to harmonised standards developed at EU level. ***The information in digital format should be easily accessible to all patients. Based on the findings from hospital pilots, the obligation to provide a paper leaflet should not be applied for medicinal products which are not intended for self-administration by the patient.***

Amendment 70
Proposal for a directive
Recital 129

Text proposed by the Commission	*Amendment*
(129) ***Where*** Member States ***decide that*** the package leaflet ***should be made*** available ***in principle only*** electronically, ***they*** should also ensure that a paper version of the package leaflet is to be made available on demand and without additonal cost to patients. They should also ensure	(129) Member States ***should make*** the package leaflet available ***electronically and in paper format, except where the Member State decides to make only the electronic product information available. Where the package leaflet is only available*** electronically, ***Member States***

that the information in digital format is easily accessible to all patients, for instance by including in the outer packaging of the product a digitally readable barcode, which would direct the patient to the electronic version of the package leaflet.	should also ensure that a paper version of the package leaflet is to be made available on demand and without additonal cost to patients. They should also ensure that the information in digital format is easily accessible to all patients, for instance by including in the outer packaging of the product a digitally readable barcode, which would direct the patient to the electronic version of the package leaflet.

Amendment 71
Proposal for a directive
Recital 130

Text proposed by the Commission	*Amendment*
(130) The use of multi-language packages can be a tool for access to medicinal products, in particular for small markets and in public health emergencies. Where multi-language packages are used, Member States may allow the use on the labelling and package leaflet of an official language of the Union that is commonly understood in the Member States where the multi-language package is marketed.	(130) The use of multi-language packages can be a tool for access to medicinal products, in particular for small markets and in public health emergencies. Where multi-language packages are used, Member States may allow the use on the labelling and package leaflet of an official language of the Union that is commonly understood in the Member States where the multi-language package is marketed. ***While electronic medicinal product information can facilitate the redistribution of packages between Member States, language requirements on labels can remain a challenge. The granting of an exemption to the requirement for an official language, as well as the obligation to use the international non-proprietary name for medicinal products not intended for self-administration by the patient, in addition to providing electronic product information, could improve the availability of medicinal products and enable easier redistribution between Member States.***

Amendment 72
Proposal for a directive
Recital 131

Text proposed by the Commission	*Amendment*
(131) To ensure a high level of transparency of public support to the research and development of medicinal products, the reporting of public contribution for the development of a particular medicinal product should be a requirement for all medicines. Given however the practical difficulty to identify how indirect public funding instruments, such as tax advantages, have supported a particular product, the reporting obligation should only concern the direct public financial support, such as direct grants or contracts. Therefore, the provisions of this Directive ensure, without prejudice to the rules on the protection of confidential and personal data, transparency regarding ***any direct*** financial support received from any public authority or public body to carry out any activities for the research and development of medicinal products.	(131) To ensure a high level of transparency of public support to the research and development of medicinal products, the reporting of public contribution for the development of a particular medicinal product should be a requirement for all medicines. Given however the practical difficulty to identify ***in third countries*** how indirect public funding instruments, such as tax advantages, have supported a particular product, the reporting obligation ***on financial support from entities outside of the Union*** should only concern the direct public financial support, such as direct grants or contracts. Therefore, the provisions of this Directive ensure, without prejudice to the rules on the protection of confidential and personal data, transparency regarding financial support received from any public authority or public body ***or philanthropic or non-for profit organisation or fund*** to carry out any activities for the research and development of medicinal products.

Amendment 73
Proposal for a directive
Recital 135 a (new)

Text proposed by the Commission	*Amendment*
	(135a) Clear, impartial and independent information from healthcare professional to the public about a medicinal product and its correct use can play an important role in informing citizens and combatting misinformation, in particular during health emergencies such as the COVID-19 pandemic. Member States should ensure that the ability of healthcare professionals to share clear, impartial and independent information, whether in a direct conversation with a patient or in broader communication, should not be

hindered.

Amendment 74
Proposal for a directive
Recital 136

Text proposed by the Commission	*Amendment*
(136) Advertising of medicinal products should aim at disseminating objective and unbiased information about the medicinal product. For that purpose, it is expressly forbidden highlight negatively another medicinal product or to suggest that advertised medicinal product might be safer or more effective than another medicinal product. Comparison of medicinal products should only be allowed if such information is listed in the summary of product characteristics of the medicinal product being advertised. This prohibition covers any medicinal product, also biosimilars, and therefore it would be misleading to refer in the advertising, that a biosimilar medicinal product would not be interchangeable with the original biological medicinal product or another biosimilar from the same original biological medicinal product. Additional strict rules about negative and comparative advertising of competitor medicinal products will prohibit claims that can mislead persons qualified to prescribe, administer or supply them.	(136) Advertising of medicinal products should aim at disseminating objective and unbiased information about the medicinal product. For that purpose, it is expressly forbidden highlight negatively another medicinal product or to suggest that advertised medicinal product might be safer or more effective than another medicinal product. Comparison of medicinal products should only be allowed if such information is listed in the summary of product characteristics ***for the relevant indications and patient population*** of the medicinal product being advertised. This prohibition covers any medicinal product, also biosimilars, and therefore it would be misleading to refer in the advertising, that a biosimilar medicinal product would not be interchangeable with the original biological medicinal product or another biosimilar from the same original biological medicinal product. Additional strict rules about negative and comparative advertising of competitor medicinal products will prohibit claims that can mislead persons qualified to prescribe, administer or supply them.

Amendment 75
Proposal for a directive
Recital 138 a (new)

Text proposed by the Commission	*Amendment*
	(138a) Because of the global reach of social media, patients and consumers are increasingly exposed to the promotional practices of using celebrities to advertise medicinal products. The Commission

	should assess the exposure and impact of pharmaceutical advertising and promotions online, and adopt specific rules to regulate such advertising and promotional practices.

Amendment 76
Proposal for a directive
Recital 139 a (new)

Text proposed by the Commission	*Amendment*
	(139a) Even minimal inducement can result in biased decisions with regard to prescription behaviour by physicians. Therefore, to avoid conflict of interest, Member States should maintain a transparency register of transfer of value regarding advertising activities which target persons qualified to prescribe medicinal products. The Commission should establish a web portal to list all national registers of transfers of value to persons qualified to prescribe medicinal products.

Amendment 77
Proposal for a directive
Recital 145

Text proposed by the Commission	*Amendment*
(145) In order to ensure uniform conditions for the implementation of this ***Regulation***, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[66] .	(145) In order to ensure uniform conditions for the implementation of this ***Directive***, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[66] .
[66] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of	[66] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of

implementing powers (OJ L 55, 28.2.2011, p. 13).

implementing powers (OJ L 55, 28.2.2011, p. 13).

Amendment 78
Proposal for a directive
Recital 149

Text proposed by the Commission	*Amendment*
(149) In order to supplement or amend certain non-essential elements of this Directive, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of specifying the procedure for examination of application of active substance master file certificate, the publication of such certificates, the procedure for changes to the active substance master file and its certificate, access to the active substance master file and its assessment report; specifying additional ***quality*** master files to provide information on a constituent of a medicinal product, the procedure for examination of application of a quality master file certificate, the publication of such certificates, the procedure for changes to the ***quality*** master file and its certificate, and access to the ***quality*** master file and its assessment report; determining the situations in which post-authorisation efficacy studies may be required; specifying the categories of medicinal products to which a marketing authorisation subject to specific obligations could be granted and specifying the procedures and requirements for granting such a marketing authorisation and for its renewal; specifying exemptions to variation and the categories in which variations should be classified and establishing procedures for the examination of applications for variations to the terms of marketing authorisations as well as specifying conditions and procedures for cooperation with third countries and international organisations	(149) In order to supplement or amend certain non-essential elements of this Directive, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of specifying the procedure for examination of application of active substance master file certificate, the publication of such certificates, the procedure for changes to the active substance master file and its certificate, access to the active substance master file and its assessment report; specifying additional master files to provide information on a constituent of a medicinal product, the procedure for examination of application of a quality master file certificate ***or a platform technology master file certificate***, the publication of such certificates, the procedure for changes to the master file and its certificate, and access to the master file and its assessment report; determining the situations in which post-authorisation efficacy studies may be required; specifying the categories of medicinal products to which a marketing authorisation subject to specific obligations could be granted and specifying the procedures and requirements for granting such a marketing authorisation and for its renewal; specifying exemptions to variation and the categories in which variations should be classified and establishing procedures for the examination of applications for variations to the terms of marketing authorisations as well as specifying conditions and procedures for cooperation with third countries and international organisations

for examination of applications for such variations. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[67] . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

[67] OJ L 123, 12.5.2016, p. 1.

for examination of applications for such variations. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[67] . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

[67] OJ L 123, 12.5.2016, p. 1.

Amendment 79
Proposal for a directive
Article 1 – paragraph 2

Text proposed by the Commission	*Amendment*
2. This Directive shall apply to medicinal products for human use intended to be placed on the market.	2. This Directive shall apply to medicinal products for human use intended to be placed on the market ***in Member States***.

Amendment 80
Proposal for a directive
Article 1 – paragraph 4 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	In cases where, taking into account all its characteristics, questions arise as to the regulatory status of a substance or a product, the competent authority or, in the case of a centralised marketing authorisation the Agency shall consult other relevant advisory and regulatory bodies with a view to reaching a decision on the regulatory status f the substance or

	a product concerned. In any decision on such question, the competent authority or the Agency shall make publicly available the views of other authorities or bodies consulted.

Amendment 81
Proposal for a directive
Article 1 – paragraph 5 – point b

Text proposed by the Commission	*Amendment*
(b) medicinal product prepared in a pharmacy in accordance with a pharmacopoeia and intended to be supplied directly to the patients served by the pharmacy in question ('officinal formula');	(b) medicinal product prepared in a pharmacy in accordance with a pharmacopoeia and intended to be supplied directly to the patients served by the pharmacy in question ***or to another pharmacy which intends to supply the medicinal product directly to the patient*** ('officinal formula');

Amendment 82
Proposal for a directive
Article 1 – paragraph 5 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) medicinal product prepared in advance, in duly justified cases, by the pharmaceutical department of a hospital ('hospital formula'), supplied on medical prescription to one or several patients by the hospital's pharmaceutical department.

Amendment 83
Proposal for a directive
Article 1 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Medicinal products referred to in paragraph 5, ***point*** (a), may be prepared in duly justified cases in advance by a pharmacy serving a hospital, on the basis of the estimated medical prescriptions within that hospital for the following seven	6. Medicinal products referred to in paragraph 5, ***points*** (a) ***and (b)***, may be prepared in duly justified cases in advance by a pharmacy serving a hospital, on the basis of the estimated medical prescriptions within that hospital for the following seven

days.	days***, or when duly justified based on the stability of the medicinal product within a different time limit***.

Amendment 84
Proposal for a directive
Article 1 – paragraph 7

Text proposed by the Commission	*Amendment*
7. Member States shall take the necessary measures to develop the production and use of medicinal products derived from substances of human origin coming from voluntary unpaid donations.	7. Member States shall take the necessary measures to develop the production and use of medicinal products derived from substances of human origin coming from voluntary unpaid donations ***in accordance with Regulation (EU) 2024/... [SoHO Regulation].***

Amendment 85

Proposal for a directive
Article 1 – paragraph 10 – point a

Text proposed by the Commission	*Amendment*
(a) the sale, supply or use of medicinal products as contraceptives or abortifacients;	***deleted***

Amendment 86
Proposal for a directive
Article 2 – paragraph 1

Text proposed by the Commission	*Amendment*
1. By way of derogation from Article 1(1), only this Article shall apply to advanced therapy medicinal products prepared ***on*** a non-routine basis in accordance with the requirements set in paragraph 3 and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product ***for*** an individual	1. By way of derogation from Article 1(1), only this Article shall apply to advanced therapy medicinal products prepared a non-routine basis in accordance with the requirements set in paragraph 3 and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner ***and***, ***where relevant, a hospital pharmacist. To satisfy the criteria of 'non-routine basis', the exemption shall be***

patient (‘advanced therapy medicinal products prepared under hospital exemption’).

made only in order to comply with an individual medical prescription for a custom-made product ***to meet the special need of*** an individual patient (‘advanced therapy medicinal products prepared under hospital exemption’).

Amendment 87
Proposal for a directive
Article 2 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
The application for a hospital exemption approval shall be submitted to the competent authority of the Member State where the hospital is located.	The application for a hospital exemption approval shall be submitted to the competent authority of the Member State where the hospital is located. ***The application shall include evidence on quality, safety and expected efficacy of the advanced therapy medicinal products prepared under hospital exemption.***

Amendment 88
Proposal for a directive
Article 2 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States shall ensure that advanced therapy medicinal products prepared under hospital exemption comply with the ***requirements*** equivalent to the good manufacturing practices and traceability for advanced therapy medicinal products referred to in Articles 5 and 15 of Regulation (EC) No 1394/2007[69] respectively, and with pharmacovigilance requirements equivalent to those provided for at Union level pursuant to [revised Regulation (EC) No 726/2004].	3. Member States shall ensure that advanced therapy medicinal products prepared under hospital exemption comply with the ***good pharmacy preparation practices that are adapted to hospital processes while still*** equivalent to the good manufacturing practices and traceability for advanced therapy medicinal products referred to in Articles 5 and 15 of Regulation (EC) No 1394/2007 ***of the European Parliament and of the Council***[69] respectively, and with pharmacovigilance requirements equivalent to those provided for at Union level pursuant to [revised Regulation (EC) No 726/2004]. ***This shall include site inspections as well as traceability and pharmacovigilance plans and the evaluation of the preclinical and clinical***

data generated by the applicant.

[69] 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. 1).

[69] 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. 1).

Amendment 89
Proposal for a directive
Article 2 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall ensure that data on the use, safety and the efficacy of advanced therapy medicinal products prepared under hospital exemption is collected and reported by the hospital exemption approval holder to the competent authority of the Member State at least annually. The competent authority of the Member State shall review such data and shall verify the compliance of advanced therapy medicinal products prepared under hospital exemption with the requirements referred to in paragraph 3.	4. Member States shall ensure that data on the use, safety and the efficacy of advanced therapy medicinal products prepared under hospital exemption***, as well as any relevant data from patient follow-up for a sufficient period of time after the administration of the advanced therapy medicinal product,*** is collected and reported by the hospital exemption approval holder to the competent authority of the Member State at least annually***. The data shall be collected and reported in a structured and standardised way that enables robust, reliable and comparable results and conclusions***. The competent authority of the Member State shall review such data and shall verify the compliance of advanced therapy medicinal products prepared under hospital exemption with the requirements referred to in paragraph 3. ***Competent authorities shall ensure that scientific and regulatory advice is provided to non-profit and academic institutions in order to ensure appropriate reporting mechanisms.***

Amendment 90
Proposal for a directive
Article 2 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The competent authority of the Member State shall transmit the data related to the use, safety and efficacy of an advanced therapy medicinal product prepared under the hospital exemption approval to the Agency annually. The Agency shall, in collaboration with the competent authorities of Member States and the Commission, set up and maintain a repository of that data.	6. The competent authority of the Member State shall transmit the data related to the use, safety and efficacy of an advanced therapy medicinal product prepared under the hospital exemption approval to the Agency annually. The Agency shall, in collaboration with the competent authorities of Member States and the Commission, set up and maintain ***via regular updates*** a repository of that data ***as well as of information on the authorisation, suspension or withdrawal of hospital exemption approvals, which shall be updated regularly***. ***The repository shall be publicly available except for personal data and commercially confidentail information.***

Amendment 91
Proposal for a directive
Article 2 – paragraph 7 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) details of the application for the approval of hospital exemption referred to in paragraph 1, second subparagraph, including the evidence on quality, safety and efficacy of the advance therapy medicinal products prepared under hospital exemption for the approval and the subsequent changes;	***deleted***

Amendment 92
Proposal for a directive
Article 2 – paragraph 7 – subparagraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) the modalities of guidance for academic and other not-for-profit entities through the requirements of the hospital exemption clause.

Amendment 93
Proposal for a directive
Article 2 – paragraph 7 – subparagraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) the modalities for preparation and use of advanced therapy medicinal products under hospital exemption on a non-routine basis.	***deleted***

Amendment 94
Proposal for a directive
Article 2 – paragraph 7 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	By ... [24 months from the date of entry into force of this Directive], the Commission shall adopt delegated acts in accordance with Article 215 to supplement this Directive by establishing:
	(a) details of the application for the approval of hospital exemption referred to in paragraph 1, second subparagraph, including the evidence on quality, safety and efficacy of the advance therapy medicinal products prepared under hospital exemption for the approval and the subsequent changes;
	(b) the modalities for harmonised implementation of the preparation and use of advanced therapy medicinal products under hospital exemption on a non-routine basis.

Amendment 95
Proposal for a directive
Article 2 – paragraph 8

Text proposed by the Commission	*Amendment*
8. The Agency shall provide to the Commission a report on the experience acquired with the hospital exemption approvals on the basis of contributions	8. The Agency shall provide to the Commission a report on the experience acquired with the hospital exemption approvals on the basis of contributions

from Member States and the data referred to in paragraph 4. The first report shall be provided three years after [OP please insert the date =18 months after the date of entering into force of this Directive] and then every five years thereafter.	from Member States and the data referred to in paragraph 4. The ***report shall be made publicly available. The*** first report shall be provided three years after [OP please insert the date =18 months after the date of entering into force of this Directive] and then every five years thereafter.

Amendment 96
Proposal for a directive
Article 2 – paragraph 8 a (new)

Text proposed by the Commission	*Amendment*
	8a. By way of derogation from paragraph 1, Member States may authorise the cross-border exchange of advanced therapy medicinal products prepared under hospital exemption in justified cases of medical need and in the absence of other solutions for the individual patient. A second medical practitioner and a hospital pharmacist in the receiving Member State shall be designated for the exclusive professional responsibility of the use and collection of follow-up data for the advanced therapy medicinal product. Information about the cross-border exchange shall be submitted to the competent authorities of both Member States, and shall be shared in the public repository referred to in paragraph 6 by the competent authority of the Member State of origin of the advanced therapy medicinal product.

Amendment 97
Proposal for a directive
Article 3 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
A Member State may, in order to fulfil special needs, exclude from the scope of this Directive medicinal products supplied in response to a bona fide unsolicited order, prepared in accordance with the	A Member State may, in order to fulfil special needs, exclude from the scope of this Directive medicinal products supplied in response to a bona fide unsolicited order, prepared in accordance with the

specifications of an authorised healthcare professional and for use by an individual patient under their direct personal responsibility. However, in such case Member States shall encourage healthcare professionals and patients to report data on the safety of the use of such products to the competent authority of the Member State in accordance with Article 97.	specifications of an authorised healthcare professional and for use by an individual patient under their direct personal responsibility***, or prepared in accordance with the specifications of a competent authority***. However, in such case Member States shall encourage ***and establish channels for*** healthcare professionals and patients to report data on the safety of the use of such products to the competent authority of the Member State in accordance with Article 97.

Amendment 98
Proposal for a directive
Article 4 – paragraph 1 – point 11

Text proposed by the Commission	*Amendment*
(11) 'non-clinical' means a study or a test conducted in vitro, in silico, or in chemico, or a non-human in vivo test related to the investigation of the safety and efficacy of a medicinal product. Such test may include simple and complex human cell-based assays, microphysiological systems including organ-on-chip, computer modelling, other non-human or human biology-based test methods, and animal-based tests;	(11) 'non-clinical' means a study or a test conducted in vitro***, ex vivo***, in silico, or in chemico, or a non-human in vivo test related to the investigation of the safety and efficacy of a medicinal product. Such test may include simple and complex human cell-based assays, microphysiological systems including organ-on-chip, computer modelling ***and other in silico methods***, other non-human or human biology-based test methods, ***including aquatic egg models as well as invertebrate species,*** and animal-based tests;

Amendment 99
Proposal for a directive
Article 4 – paragraph 1 – point 22

Text proposed by the Commission	*Amendment*
(22) 'antimicrobial' means any medicinal product with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals ***and*** antifungals;	(22) 'antimicrobial' means any medicinal product with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals***,*** antifungals ***and antiprotozoals***;

Amendment 100
Proposal for a directive
Article 4 – paragraph 1 – point 26

Text proposed by the Commission	*Amendment*
(26) 'combination of a medicinal product with a product other than a medical device' means a combination of a medicinal product with a product other than a medical device (as defined by Regulation (EU) 2017/745***)*** and where the two are intended for use in the given combination in accordance with the summary of product characteristics;	(26) 'combination of a medicinal product with a product other than a medical device' means a combination of a medicinal product with a product other than a medical device (as defined by Regulation (EU) 2017/745 ***and Regulation (EU) 2017/746 of the European Parliament and of the Council***[1a]) and where the two are intended for use in the given combination in accordance with the summary of product characteristics;
	[1a] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117 5.5.2017, p. 176).

Amendment 101
Proposal for a directive
Article 4 – paragraph 1 – point 29 – introductory part

Text proposed by the Commission	*Amendment*
(29) ***'***gene therapy medicinal product***'*** means a medicinal product***, except vaccines against infectious diseases, that contains or consists of:***	(29) ***"***gene therapy medicinal product***"*** means a ***type 1 or type 2*** medicinal product***;***
(a) a substance or a combination of substances intended to edit the host genome in a sequence-specific manner or that contain or consists of cells subjected to such modification; or	
(b) a recombinant or synthetic nucleic acid used in or administered to human beings with a view to regulating, replacing or adding a genetic sequence that	

mediates its effect by transcription or translation of the transferred genetic materials or that contain or consists of cells subjected to these modifications;

Amendment 102
Proposal for a directive
Article 4 – paragraph 1 – point 29 a (new)

Text proposed by the Commission	*Amendment*
	(29a) "type 1 gene therapy medicinal product" means a medicinal product that contains or consists of a substance or a combination of substances that edit the host genome in a sequence-specific manner or that contain or consists of cells subjected to such modification;

Amendment 103
Proposal for a directive
Article 4 – paragraph 1 – point 29 b (new)

Text proposed by the Commission	*Amendment*
	(29b) "type 2 gene therapy medicinal product" means a medicinal product, except a vaccine against infectious disease that contains or consists of a recombinant or synthetic nucleic acid used in or administered to human beings with a view to regulating, replacing or adding a genetic sequence that mediates its effect by transcription or translation of the transferred genetic materials or that contain or consists of cells subjected to these modifications;

Amendment 104
Proposal for a directive
Article 4 – paragraph 1 – point 30 a (new)

Text proposed by the Commission	*Amendment*
	(30a) 'platform technology' means a technology or collection of technologies

	that is comprehensive, well-characterised, reproducible and used to support the development, manufacturing process, quality control, or testing of medicinal products or their components that rely on prior knowledge and are established under the same underlying scientific principles

Amendment 105
Proposal for a directive
Article 4 – paragraph 1 – point 30 b (new)

Text proposed by the Commission	*Amendment*
	(30b) 'platform technology master file' means a document, prepared by the owner of the platform technology, that contains data of a platform technology for which the underlying scientific principles, under which the platform technology is established, have reasonable scientific certainty to remain unchanged across medicinal products and to apply regardless of components added to the platform for a medicinal product;

Amendment 106
Proposal for a directive
Article 4 – paragraph 1 – point 31 – point a

Text proposed by the Commission	*Amendment*
(a) a method involving an industrial process which includes pooling of donations; or	(a) a method involving an industrial process which includes pooling of donations***, for purposes beyond processing of substances of human origin for concentrates or pathogen inactivation***; or

Amendment 107
Proposal for a directive
Article 4 – paragraph 1 – point 33

Text proposed by the Commission	*Amendment*
(33) 'environmental risk assessment'	(33) 'environmental risk assessment'

means the evaluation of the risks to the environment, or risks to public health, posed by the release of the medicinal product in the environment from the use and disposal of the medicinal product and the identification of risk prevention, limitation and mitigation measures. For medicinal product with an antimicrobial mode of action, the ERA also encompasses an evaluation of the risk for antimicrobial resistance selection in the environment due to the manufacturing, use and disposal of that medicinal product;	means the evaluation of the risks to the environment, or risks to public health, posed by the release of the medicinal product in the environment from the ***manufacturing,*** use and disposal of the medicinal product and the identification of risk prevention, limitation and mitigation measures. For medicinal product with an antimicrobial mode of action, the ERA also encompasses an evaluation of the risk for antimicrobial resistance selection in the environment due to the manufacturing, use and disposal of that medicinal product;

Amendment 108
Proposal for a directive
Article 4 – paragraph 1 – point 34

Text proposed by the Commission	*Amendment*
(34) 'antimicrobial resistance' means the ability of a micro-organism to survive or to grow in the presence of a concentration of an antimicrobial agent that is usually sufficient to inhibit or kill that micro-organism;	(34) 'antimicrobial resistance' means the ability of a micro-organism to survive or to grow in the presence of a concentration of an antimicrobial agent that is usually ***or was previously*** sufficient to inhibit or kill that micro-organism;

Amendment 109
Proposal for a directive
Article 4 – paragraph 1 – point 62

Text proposed by the Commission	*Amendment*
(62) 'homeopathic ***medicinal*** product' means a medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States;	(62) 'homeopathic product' means a medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States;

Amendment 110
Proposal for a directive
Article 4 – paragraph 1 – point 70

Text proposed by the Commission	*Amendment*
(70) 'public service obligation' means to ***guarantee*** permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question.	(70) 'public service obligation' means to ***ensure*** permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question.

Amendment 111
Proposal for a directive
Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend the definitions in paragraph 1, points (2) to (6), (8), (14), (16) to (***31***)***,*** in the light of technical and scientific progress and taking into account definitions agreed at Union and international level without extending the scope of the definitions.	2. The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend the definitions in paragraph 1, points (2) to (6), (8), (14), (16) to (***28***) ***and (30)*** in the light of technical and scientific progress and taking into account definitions agreed at Union and international level without extending the scope of the definitions.

Amendment 112
Proposal for a directive
Article 6 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. A marketing authorisation may be granted for a medicinal product on the basis of an active substance master file, an additional quality master file or a platform technology master file where such a file exists and is referred to in the application.

Amendment 113
Proposal for a directive
Article 6 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The risk management system referred to in Annex I shall be proportionate to the identified risks and the potential risks of the medicinal product, and the need for post-authorisation safety data.	4. The risk management system referred to in Annex I shall be proportionate to the identified risks and the potential risks ***to human health or the environment*** of the medicinal product, and the need for post-authorisation safety data.

Amendment 114
Proposal for a directive
Article 6 – paragraph 5 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	In the absence of a paediatric investigation plan in accordance with the first subparagraph point (a), or where in this regard a comparative study has not been carried out, a justification shall be submitted and where relevant also evidence shall be obtained from post-marketing long-term studies.

Amendment 115
Proposal for a directive
Article 6 – paragraph 7 – subparagraph 2

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

Amendment 116
Proposal for a directive
Article 10 – paragraph 1

Text proposed by the Commission	*Amendment*
In cases where the medicinal product does not fall within the definition of a generic medicinal product or has changes in strength, pharmaceutical form, route of administration or therapeutic indications, compared to the reference medicinal product, the results of the appropriate non-clinical tests or clinical studies shall be provided to the competent authorities to the extent necessary to establish a scientific bridge to the data relied upon in the marketing authorisation for the reference medicinal product, and to demonstrate the safety and efficacy profile of the hybrid medicinal product.	In cases where the medicinal product does not fall within the definition of a generic medicinal product or has changes in strength, pharmaceutical form, route of administration or therapeutic indications, compared to the reference medicinal product, the results of the appropriate non-clinical tests or clinical studies shall be provided to the competent authorities to the extent necessary to establish a scientific bridge to the data relied upon in the marketing authorisation for the reference medicinal product, and to demonstrate the safety and efficacy profile of the hybrid medicinal product. ***The Agency shall adopt guidelines on the appropriate tests and clinical studies for marketing authorisation of hybrid medicinal products.***

Amendment 117
Proposal for a directive
Article 12 – paragraph 1

Text proposed by the Commission	*Amendment*
In cases where a biosimilar medicinal product has changes in strength, pharmaceutical form, route of administration or therapeutic indications, compared to the reference biological medicinal product (‘bio-hybrid’), the results of the appropriate non-clinical tests or clinical studies shall be provided to the competent authorities to the extent necessary to establish a scientific bridge to the data relied upon in the marketing authorisation for the reference biological medicinal product, and to demonstrate the safety or efficacy profile of the biosimilar medicinal product.	In cases where a biosimilar medicinal product has changes in strength, pharmaceutical form, route of administration or therapeutic indications, compared to the reference biological medicinal product (‘bio-hybrid’), the results of the appropriate non-clinical tests or clinical studies shall be provided to the competent authorities to the extent necessary to establish a scientific bridge to the data relied upon in the marketing authorisation for the reference biological medicinal product, and to demonstrate the safety or efficacy profile of the biosimilar medicinal product. ***The Agency shall adopt guidelines on the appropriate tests and***

	clinical studies for marketing authorisation of bio-hybrid medicinal products.

Amendment 118
Proposal for a directive
Article 13 – paragraph 1

Text proposed by the Commission	*Amendment*
In cases where no reference medicinal product is or has been authorised for the active substance of the medicinal product concerned, the applicant shall, by way of derogation from Article 6(2), not be required to provide the results of non-clinical tests or clinical studies if the applicant can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Union ***for*** the same therapeutic use and route of administration and for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex II. In that event, the test and trial results shall be replaced by appropriate bibliographic data in the form of scientific literature.	In cases where no reference medicinal product is or has been authorised for the active substance of the medicinal product concerned, the applicant shall, by way of derogation from Article 6(2), not be required to provide the results of non-clinical tests or clinical studies if the applicant can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Union the same therapeutic use and route of administration and for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex II. In that event, the test and trial results shall be replaced by appropriate bibliographic data in the form of scientific literature. ***A justification shall be provided with regard to the relevance of that literature for the medicinal product.***

Amendment 119
Proposal for a directive
Article 15 – title

Text proposed by the Commission	*Amendment*
Fixed dose combination medicinal product, platform ***technologies*** and multi-medicinal product packages	Fixed dose combination medicinal product, platform ***marketing authorisation*** and multi-medicinal product packages

Amendment 120
Proposal for a directive
Article 15 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
Where justified for therapeutic purposes, a marketing authorisation may***, in exceptional circumstances,*** be granted for a medicinal product comprised of a fixed component and a variable component that is pre-defined in order to, where appropriate, target different variants of an infectious agent or, where necessary, to tailor the medicinal product to characteristics of an individual patient or a group of patients ('platform ***technology***').	Where justified for therapeutic purposes, a marketing authorisation may be granted for a medicinal product comprised of a fixed component and a variable component that is pre-defined in order to, where appropriate, target different variants of an infectious agent or, where necessary, to tailor the medicinal product to characteristics of an individual patient or a group of patients ('platform ***marketing authorisation***').

Amendment 121
Proposal for a directive
Article 16 – paragraph 1

Text proposed by the Commission	*Amendment*
1. A marketing authorisation shall be required for radionuclide generators, kits, and radionuclide precursors, unless they are used as starting material, active substance or intermediate of radiopharmaceuticals covered by a marketing authorisation under Article 5(1).	1. A marketing authorisation shall be required for radionuclide generators, kits ***for radiopharmaceutical preparations ('kits')***, and radionuclide precursors, unless they are used as starting material, active substance or intermediate of radiopharmaceuticals covered by a marketing authorisation under Article 5(1).

Amendment 122
Proposal for a directive
Article 17 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) an antimicrobial stewardship plan as referred to in Annex I;	(a) an antimicrobial stewardship ***and access*** plan as referred to in Annex I;

Amendment 123
Proposal for a directive
Article 17 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*

	1a. The competent authority of the Member State shall, following the granting of a marketing authorisation, make publicly available the documents referred to in paragraph 1.

Amendment 124
Proposal for a directive
Article 17 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The competent authority ***may*** impose obligations on the marketing authorisation holder if it finds the risk mitigation measures contained in the antimicrobial stewardship plan unsatisfactory.	2. The competent authority ***shall review the information submitted in accordance with paragraph 1 point (b). The competent authority shall*** impose obligations on the marketing authorisation holder if it finds the risk mitigation measures contained in the antimicrobial stewardship ***and access*** plan unsatisfactory.

Amendment 125
Proposal for a directive
Article 17 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The marketing authorisation holder shall ensure that the pack size of the antimicrobial corresponds to the usual posology and duration of treatment.	3. ***The marketing authorisation holder shall ensure, wherever possible, that the antimicrobial may be dispensed per unit in a number corresponding to the quantities corresponding to the duration of treatment. If an antimicrobial cannot be dispensed per unit,*** the marketing authorisation holder shall ensure that the pack size of the antimicrobial corresponds to the usual posology and duration of treatment.

Amendment 126
Proposal for a directive
Article 18 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*

As part of the assessment, in accordance with Article 29, of the integral combination of a medicinal product and a medical device the competent authorities shall assess the benefit-risk balance of the integral combination of a medicinal product and a medical device, taking into account the suitability of the use of the medicinal product together with the medical device.	As part of the assessment, in accordance with Article 29, of the integral combination of a medicinal product and a medical device the competent authorities shall assess the benefit-risk balance of the integral combination of a medicinal product and a medical device, taking into account the suitability of the use of the medicinal product together with the medical device***, where relevant particularly for paediatric patients, including aspects such as storage, assembly, cleanliness, and the technique required for application or intake***.

Amendment 127
Proposal for a directive
Article 22 – paragraph 1

Text proposed by the Commission	*Amendment*
1. When preparing the environmental risk assessment ('ERA') to be submitted pursuant to Article 6(2), the applicant shall take into account the scientific guidelines on the environmental risk assessment of medicinal products for human use as referred to in paragraph ***6***, or provide the reasons for any divergence from the scientific guidelines to the Agency or, as appropriate to the competent authority of the Member State concerned, in a timely manner. Where available, the applicant shall take into account existing ERAs performed under other Union legislation.	1. When preparing the environmental risk assessment ('ERA') to be submitted pursuant to Article 6(2), the applicant shall take into account the scientific guidelines on the environmental risk assessment of medicinal products for human use as referred to in paragraph ***5***, or provide the ***duly justified*** reasons for any divergence from the scientific guidelines to the Agency or, as appropriate to the competent authority of the Member State concerned, in a timely manner. Where available, the applicant shall take into account existing ERAs performed under other Union legislation.

Amendment 128
Proposal for a directive
Article 22 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The applicant shall also include in the ERA risk mitigation measures to avoid or where it is not possible, limit emissions to air, water and soil of pollutants listed in	3. The applicant shall also include in the ERA risk mitigation measures to avoid or where it is not possible, limit emissions to air, water and soil of pollutants listed in

Directive 2000/60/EC, Directive 2006/118/EC, Directive 2008/105/EC and Directive 2010/75/EU. The applicant shall provide detailed explanation that the proposed mitigation measures are appropriate and sufficient to address the identified risks to the environment.	Directive 2000/60/EC, Directive 2006/118/EC, Directive 2008/105/EC and Directive 2010/75/EU ***during the manufacturing, use and disposal of the medicinal product***. The applicant shall provide detailed explanation that the proposed mitigation measures are appropriate and sufficient to address the identified risks to the environment. ***Where necessary, the applicant shall also include information on available techniques and on the techniques that will be used to reduce the discharges and emissions of the medicinal product, in particular those occurring in manufacturing effluents before those effluents leave the manufacturing sites.***

Amendment 129
Proposal for a directive
Article 22 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The ERA for antimicrobials shall include an evaluation of the risk for antimicrobial resistance selection in the environment due to the entire manufacturing supply chain inside and outside the Union, use and disposal of the antimicrobial taking into account, where relevant, the existing international standards that have established predicted no effect concentration (PNECs) specific for antibiotics.	4. The ERA for antimicrobials shall include an evaluation of the risk for antimicrobial resistance selection in the environment due to the entire manufacturing supply chain inside and outside the Union, use and disposal***, including by healthcare professionals and patients,*** of the antimicrobial taking into account, where relevant, the existing international standards that have established predicted no effect concentration (PNECs) specific for antibiotics.

Amendment 130
Proposal for a directive
Article 22 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. By ... [12 months from the date of entry into force of this Directive], the Commission shall, after having consulted

	the Agency, the EEA, and the ECDC, issue guidelines on how to conduct the ERA for antimicrobials other than antibiotics.

Amendment 131
Proposal for a directive
Article 22 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Agency shall draw up scientific guidelines in accordance with Article 138 of [revised Regulation No (EC) 726/2004], to specify technical details regarding the ERA requirements for medicinal products for human use. Where appropriate, the Agency shall consult the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) ***and the European Environmental Agency (EEA)*** on the drafting of these scientific guidelines.	5. The Agency shall draw up scientific guidelines in accordance with Article 138 of [revised Regulation No (EC) 726/2004], to specify technical details regarding the ERA requirements for medicinal products for human use. Where appropriate, the Agency shall consult the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA)***, the EEA, the ECDC and other relevant stakeholders, including drinking water and wastewater operators,*** on the drafting of these scientific guidelines.

Amendment 132
Proposal for a directive
Article 22 – paragraph 6 – subparagraph 2

Text proposed by the Commission	*Amendment*
For an ERA conducted prior to [OP please insert the date = 18 months after the date of entering into force of this Directive], the competent authority shall request the marketing authorisation holder to update the ERA if missing information has been identified for medicinal products potentially harmful to the environment.	For an ERA conducted prior to [OP please insert the date = 18 months after the date of entering into force of this Directive], the competent authority shall request the marketing authorisation holder to update the ERA ***to include risk mitigation measures as referred to in paragraph 3. The competent authority shall also request the marketing authorisation holder to update the ERA*** if missing information has been identified for medicinal products potentially harmful to the environment.

Amendment 133
Proposal for a directive
Article 22 – paragraph 7

Text proposed by the Commission	*Amendment*
7. For medicinal products referred to in Articles 9 to 12, the applicant may refer to ERA studies conducted for the reference medicinal product when preparing the ERA.	7. For medicinal products referred to in Articles 9 to 12, the applicant may refer to ERA studies conducted for the reference medicinal product when preparing the ERA ***and shall provide any other data and the scientific guidelines as referred to in the paragraph 1 of this Article***.

Amendment 134
Proposal for a directive
Article 22 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	7a. The outcome of the assessment of the ERA, including the data submitted by the marketing authorisation holder, shall be made publicly available by the Agency or, as appropriate, by the competent authority of the Member State.

Amendment 135
Proposal for a directive
Article 22 – paragraph 7 b (new)

Text proposed by the Commission	*Amendment*
	7b. When making public the information on the ERA, including the antimicrobial stewardship and access plan referred to in Article 17, the competent authority shall delete any information of a commercially confidential nature.

Amendment 136
Proposal for a directive
Article 23 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*

By [OP please insert the date = ***30*** months after the date of the entry into force of this Directive] the Agency shall, after consultation with the competent authorities of the Member States, the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environmental Agency (EEA), establish a programme for the ERA to be submitted in accordance with Article 22 of the medicinal products authorised before 30 October 2005 that have not been subject to any ERA and that the Agency has identified as potentially harmful to the environment in accordance with paragraph 2.	By [OP please insert the date = ***24*** months after the date of the entry into force of this Directive] the Agency shall, after consultation with the competent authorities of the Member States***, the ECDC***, the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environmental Agency (EEA), establish a programme for the ERA to be submitted in accordance with Article 22 of the medicinal products authorised before 30 October 2005 that have not been subject to any ERA and that the Agency has identified as potentially harmful to the environment in accordance with paragraph 2.

Amendment 137
Proposal for a directive
Article 23 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Agency shall set the scientific criteria for the identification of the medicinal products as potentially harmful to the environment and for the prioritisation of their ERA, using a risk based approach. For this task, the Agency may request from marketing authorisation holders the submission of relevant data or information.	2. The Agency shall set the scientific criteria for the identification of the medicinal products as potentially harmful to the environment and for the prioritisation of their ERA, using a risk based approach. For this task, the Agency ***shall consult relevant stakeholders, including actors managing residues from medicinal products and their production in the environment and*** may request from marketing authorisation holders the submission of relevant data or information.

Amendment 138
Proposal for a directive
Article 23 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The marketing authorisation holders for medicinal products identified in the programme referred to in paragraph 1 shall submit the ERA to the Agency. The outcome of the assessment of the ERA	3. The marketing authorisation holders for medicinal products identified in the programme referred to in paragraph 1 shall submit the ERA to the Agency. The outcome of the assessment of the ERA

including the data submitted by the marketing authorisation holder shall be made publicly available by the Agency.

including the data ***and a summary of ERA studies and their results as*** submitted by the marketing authorisation holder shall be made publicly available by the Agency.

Amendment 139
Proposal for a directive
Article 24 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Agency shall, in collaboration with the competent authorities of the Member States, set-up an active substance based review system of ERA data ('ERA monographs') for authorised medicinal products. An ERA monograph shall include a comprehensive set of physiochemical data, fate data and effect data based on an assessment of a competent authority.	1. The Agency shall, in collaboration with the competent authorities of the Member States, set-up an active substance based review system of ERA data ('ERA monographs') for authorised medicinal products ***and publicise relevant information about that system***. An ERA monograph shall include a comprehensive set of physiochemical data, fate data and effect data based on an assessment of a competent authority.

Amendment 140
Proposal for a directive
Article 24 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The setting-up of the system of ERA monographs shall be based on a risk-based prioritisation of active substances.	2. The setting-up of the system of ERA monographs shall be based on a risk-based prioritisation of active substances ***and data requirements***.

Amendment 141
Proposal for a directive
Article 24 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Agency in cooperation with the competent authorities of the Member States shall conduct a proof-of-concept pilot of ERA monographs to be completed within ***three years*** after entering into force of this	4. The Agency in cooperation with the competent authorities of the Member States shall conduct a proof-of-concept pilot of ERA monographs to be completed within ***30 months*** after entering into force of this Directive***, while taking into account***

Directive.	***outcomes from relevant Union initiatives with regard to animal testing***.

Amendment 142
Proposal for a directive
Article 26 – paragraph 3 – point b

Text proposed by the Commission	*Amendment*
(b) additional quality master files for which a certificate may be used in order to provide specific information on the quality of a substance present or used in the manufacture of a medicinal product;	(b) additional quality master files for which a certificate may be used in order to provide specific information on the quality of a substance***, preparation or other material*** present or used in the manufacture of a medicinal product***, including cell therapies and gene therapies***;

Amendment 143
Proposal for a directive
Article 26 a (new)

Text proposed by the Commission	*Amendment*
	Article26a
	Additional platform technology master files
	1. Marketing authorisation applicants may, instead of submitting the relevant data related to a platform technology, rely on an additional platform technology master file or an additional platform technology master file certificate granted by the Agency in accordance with this Article ('additional platform technology master file certificate').
	2. Article 25(1) to (5), (7) and (8) shall also apply mutatis mutandis to additional platform technology master file certificates.
	3. To adequately describe the platform technology master file, appropriate information as laid down in scientific guidelines published by the

Agency shall be provided.

4. The Commission is empowered to adopt delegated acts in accordance with Article 215 to supplement this Directive by specifying:

(a) the rules governing the content and format of the application for an additional platform technology master file certificate;

(b) additional platform technology master files for which a certificate may be used in order to provide specific information on the platform technology on the basis of which a substance present or used in the manufacturing of a medicinal product is manufactured;

(c) the rules for the examination of applications for making publicly available of additional platform technology master file certificates;

(d) the rules for introducing changes to the additional platform technology master file and the certificate;

(e) the rules on access for competent authorities of the Member State to the additional platform technology master file and its assessment report;

(f) the rules on access for marketing authorisation applicants and marketing authorisation holders relying on an additional platform technology master file certificate to the additional platform technology master file and to the assessment report. 5. The Agency shall develop and publish scientific guidelines on the requirements for an additional platform technology master file.

6. If requested by the Agency, the manufacturer of a substance present or used in the manufacturing of a medicinal product for which an application for an additional platform technology master file certificate has been submitted or the additional platform technology master file certificate holder shall undergo an

inspection to verify the information contained in the application or the master file.

If the holder of the additional platform technology master file refuses to undergo such an inspection, the Agency may suspend or terminate the application for the additional platform technology master file certificate.

Amendment 144
Proposal for a directive
Article 27 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
If a colour used in medicinal product is removed from the Union list of authorised food additives, on the basis of the scientific opinion of the European Food Safety Authority ('EFSA'), the Agency shall, on the request of the Commission or on its own initiative, without undue delay issue a scientific opinion as regards the use of the colour concerned in medicinal product, taking into account the opinion of the EFSA ***if relevant***. The opinion of the Agency shall be adopted by the Committee for Medicinal Products for Human Use.	If a colour used in medicinal product is removed from the Union list of authorised food additives, on the basis of the scientific opinion of the European Food Safety Authority ('EFSA'), the Agency shall, on the request of the Commission or on its own initiative, without undue delay issue a scientific opinion as regards the use of the colour concerned in medicinal product, taking into account the opinion of the EFSA. The opinion of the Agency shall be adopted by the Committee for Medicinal Products for Human Use.

Amendment 145
Proposal for a directive
Article 27 – paragraph 5

Text proposed by the Commission	*Amendment*
5. If a colour has been removed from the Union list of authorised food additives for reasons that do not require an EFSA opinion, the Commission shall decide on the use of the colour concerned in medicinal products and, where applicable, include it in the list of colours permitted for use in medicinal products referred to in paragraph 3. The Commission ***may***, in such cases, request the opinion from the	5. If a colour has been removed from the Union list of authorised food additives for reasons that do not require an EFSA opinion, the Commission shall decide on the use of the colour concerned in medicinal products and, where applicable, include it in the list of colours permitted for use in medicinal products referred to in paragraph 3. The Commission ***shall***, in such cases, request the opinion from the

Agency.

Agency.

Amendment 146
Proposal for a directive
Article 28 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. The Commission shall submit a report on the application of adapted frameworks to the European Parliament and to the Council. The first report shall be submitted five years from [OP please insert the date =18 months from the date of entry into force of this Directive] and then every five years thereafter.

Amendment 147
Proposal for a directive
Article 29 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the competent authority of the Member State considers that the marketing authorisation application is incomplete, or contains critical deficiencies that may prevent the evaluation of the medicinal product it shall inform the applicant accordingly and shall set a time limit for submitting the missing information and documentation. If the applicant fails to provide the missing information and documentation within the time limit set, the application shall be considered to have been withdrawn.	3. Where the competent authority of the Member State considers that the marketing authorisation application is incomplete, or contains critical deficiencies that may prevent the evaluation of the medicinal product it shall inform the applicant accordingly and shall set a time limit for submitting the missing information and documentation. If the applicant fails to provide the missing information and documentation within the time limit set, the application shall be considered to have been withdrawn ***by default***.

Amendment 148
Proposal for a directive
Article 29 – paragraph 4 – subparagraph 2

Text proposed by the Commission	*Amendment*
The competent authority of the Member State shall summarise the deficiencies in	The competent authority of the Member State shall summarise the deficiencies in

writing. On this basis, the competent authority of the Member State 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 competent authority of the Member State, the application shall be considered as withdrawn.

writing. On this basis, the competent authority of the Member State 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 competent authority of the Member State, the application shall be considered as withdrawn ***by default***.

Amendment 149
Proposal for a directive
Article 29 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. When making public the information on the ERA and the antimicrobial stewardship and access plan referred to in Article 17, the competent authority shall delete any information of a commercially confidential nature.

Amendment 150
Proposal for a directive
Article 34 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The ***applicant*** shall inform ***all*** the competent authorities of all Member States ***of its application at the time of submission***. The competent authority of a Member State may request for justified public health reasons to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the decentralised procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay.	3. The ***competent authority of the reference Member State for the decentralised procedure*** shall inform ***the Coordination group for decentralised and mutual recognition procedures of an application, which shall thereafter notify*** the competent authorities of all Member States. The competent authority of a Member State may request for justified public health reasons to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the decentralised procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the

competent authorities of those Member States entering the procedure with the application without undue delay.

Amendment 151
Proposal for a directive
Article 34 – paragraph 4 – subparagraph 2

Text proposed by the Commission	*Amendment*
The competent authority of the reference Member State for the decentralised procedure shall summarise the deficiencies in writing. On this basis, the competent authority of the reference Member State for the decentralised procedure shall inform the applicant and the competent authorities of the Member States concerned 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 competent authority of the reference Member State for the decentralised procedure, the application shall be considered as withdrawn.	The competent authority of the reference Member State for the decentralised procedure shall summarise the deficiencies in writing. On this basis, the competent authority of the reference Member State for the decentralised procedure shall inform the applicant and the competent authorities of the Member States concerned 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 competent authority of the reference Member State for the decentralised procedure, the application shall be considered as withdrawn ***by default***.

Amendment 152
Proposal for a directive
Article 36 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The ***applicant*** shall inform the competent authorities of all Member States ***of its application at the time of submission***. The competent authority of a Member State may request for justified public health reasons to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the mutual recognition procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the	4. The ***competent authority of the reference Member State for the decentralised procedure*** shall inform ***the Coordination group for decentralised and mutual recognition procedures of an application, which shall thereafter notify*** the competent authorities of all Member States. The competent authority of a Member State may request for justified public health reasons to enter the procedure and shall inform the applicant and the competent authority of the reference

competent authorities of those Member States entering the procedure with the application without undue delay.	Member State for the mutual recognition procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay.

Amendment 153
Proposal for a directive
Article 37 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
The coordination group shall be composed of one representative per Member State appointed for a renewable period of three years. ***Member States may appoint an alternate*** for a renewable period of three years. Members of the coordination group may arrange to be accompanied by experts.	The coordination group shall be composed of one representative per Member State ***and one representative from patients' organisations*** appointed for a renewable period of three years. ***Alternates may be appointed*** for a renewable period of three years. Members of the coordination group may arrange to be accompanied by experts.

Amendment 154
Proposal for a directive
Article 42 – paragraph 1 – subparagraph 5

Text proposed by the Commission	*Amendment*
The Commission shall send the draft decision to the competent authorities of the Member States and the applicant or the marketing authorisation holder.	The Commission shall send the draft decision to the competent authorities of the Member States and the applicant or the marketing authorisation holder ***and make the decision, including the justification, publicly available***.

Amendment 155
Proposal for a directive
Article 43 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The competent authorities of the Member States shall, without undue delay, make publicly available the national marketing authorisation together with the	3. The competent authorities of the Member States shall, without undue delay, make publicly available the national marketing authorisation together with the

summary of product characteristics, the package leaflet as well as any conditions established in accordance with Articles 44, 45 and any obligations imposed subsequently in accordance with Article 87, together with any deadlines for the fulfilment of those conditions and obligations for each medicinal product that they have authorised.	summary of product characteristics, the package leaflet***, the antimicrobial stewardship and access plan and special information requirements referred to in Article 17(1), points (a) and (b),*** as well as any conditions established in accordance with Articles ***17,*** 44, 45 and any obligations imposed subsequently in accordance with Article 87, together with any deadlines for the fulfilment of those conditions and obligations for each medicinal product that they have authorised.

Amendment 156
Proposal for a directive
Article 43 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The competent authority of the Member State may consider and decide upon additional evidence available, independently from the data submitted by the 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.	4. The competent authority of the Member State may consider and decide upon additional evidence available, independently from the data submitted by the 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. ***The competent authority shall inform the marketing authorisation holder of its decision, including the grounds for that decision, without unnecessary delay.***

Amendment 157
Proposal for a directive
Article 44 – paragraph 1 – subparagraph 1 – point g

Text proposed by the Commission	*Amendment*
(g) 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	(g) in case of medicinal products for which***, on duly justified grounds set out in the assessment report,*** there is substantial uncertainty as to the surrogate endpoint relation to the expected health outcome, where appropriate and relevant for the benefit-risk balance, ***with particular***

substantiate the clinical benefit;	***attention to new active substances and therapeutic indications,*** a post-authorisation obligation to substantiate the clinical benefit;

Amendment 158
Proposal for a directive
Article 47 – 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***, and the reason for the incomplete nature of the environmental risk assessment is not duly justified and substantiated*** by the applicant***,*** or if the risks identified in the environmental risk assessment have not been sufficiently addressed by the applicant ***or by the risk mitigation measures included by the applicant, in accordance with Article 22(3)***;

Amendment 159
Proposal for a directive
Article 47 – paragraph 1 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) For medicinal products where the reference medicinal product received its first marketing authorisation before 30 October 2005, the national marketing authorisation may be refused if the view is taken that the environmental risk assessment is incomplete or insufficiently substantiated and those medicinal products can be identified as potentially harmful to the environment.

Amendment 160
Proposal for a directive
Article 49 – paragraph 2

Text proposed by the Commission	*Amendment*
2. If the application complies with all the measures contained in the agreed completed paediatric investigation plan and if the summary of product characteristics reflects the results of studies conducted in compliance with that agreed paediatric investigation plan, the competent authority of the Member State shall include within the marketing authorisation a statement indicating compliance of the application with the agreed completed paediatric investigation plan.	2. If the application complies with all the measures contained in the agreed completed paediatric investigation plan and if the summary of product characteristics reflects the results of studies conducted in compliance with that agreed paediatric investigation plan, the competent authority of the Member State shall include within the marketing authorisation a statement indicating compliance of the application with the agreed completed paediatric investigation plan. ***The competent authority shall make the conclusions of the assessment regarding compliance with the agreed completed paediatric investigation plan publicly available.***

Amendment 161
Proposal for a directive
Article 51 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) is an antimicrobial; or	(e) is an ***antibiotic or any other*** antimicrobial ***for which there is an identified risk of antimicrobial resistance***; or

Amendment 162
Proposal for a directive
Article 51 – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
(f) contains an active substance which are persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, or persistent, mobile and toxic, or very persistent and very mobile for which medical prescription is required as risk minimisation measure with regard to the environment, unless the use of the medicinal product and the patient safety require otherwise.	(f) contains an active substance***, adjuvants or any other ingredients or constituent parts*** which are persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, or persistent, mobile and toxic, or very persistent and very mobile for which medical prescription is required as risk minimisation measure with regard to the environment, unless the use of the medicinal product and the patient safety

require otherwise.

Amendment 163
Proposal for a directive
Article 51 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The Commission shall adopt implementing acts to add further antimicrobial products that shall be subject to prescription status where the Agency has identified a risk of antimicrobial resistance. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).

Amendment 164
Proposal for a directive
Article 51 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States may set additional conditions on the prescription of antimicrobials, restrict the validity of medical prescription and limit the quantities prescribed to the amount required for the treatment or therapy concerned or submitting certain antimicrobial medicinal products to special medical prescription or restricted prescription.	2. Member States may set additional conditions on the prescription of antimicrobials, restrict the validity of medical prescription and limit the quantities prescribed to the amount required for the treatment or therapy concerned ***by authorising the use of pre-cut blister units*** or submitting certain antimicrobial medicinal products to special medical prescription or restricted prescription.

Amendment 165
Proposal for a directive
Article 51 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. A prescription for antibiotic products shall be subject to the following conditions:

	(a) be limited to the amount required for the treatment or therapy concerned;
	(b) only be prescribed for a limited duration to cover the period of risk when used as prophylaxis;
	(c) in the event that a diagnostic test has not been performed, a justification shall be required.

Amendment 166
Proposal for a directive
Article 51 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. Member States shall, wherever possible, provide per unit prescription and dispensing for the treatment or therapy concerned.

Amendment 167
Proposal for a directive
Article 51 – paragraph 4 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) the risk of antimicrobial resistance, including any mitigating measures in that regard, from use of the medicinal product

Amendment 168
Proposal for a directive
Article 51 – paragraph 5 – point b

Text proposed by the Commission	*Amendment*
(b) other circumstances of use that it has specified.	***deleted***

Amendment 169
Proposal for a directive
Article 57 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The marketing authorisation holder shall declare to the public any direct financial support received from any public authority or publicly funded body**,** in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support.	1. The marketing authorisation holder shall declare to the public any direct financial support received from any public authority***, publicly funded body or philanthropic or not-for-profit organisation or fund, irrespective of its geographic location, and any indirect financial support received from any public authority*** or publicly funded body ***of the Union or its Member States*** in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support.

Amendment 170
Proposal for a directive
Article 57 – paragraph 2 – point a – point ii

Text proposed by the Commission	*Amendment*
(ii) the ***public authority or publicly funded body*** that provided the financial support referred to in point (i);	(ii) the ***entity*** that provided the financial support referred to in point (i);

Amendment 171
Proposal for a directive
Article 57 – paragraph 2 – point a – point iii a (new)

Text proposed by the Commission	*Amendment*
	(iiia) where relevant, any independent legal entity from which it obtained a licence in relation to, or acquired the medicinal product in its previous phases of development, and at which stage of the research and development process. The marketing authorisation holder shall, to the extent possible, include in the report information on funding received as referred to paragraph 1 specific to the relevant medicinal product.

Amendment 172
Proposal for a directive
Article 57 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Commission ***may*** adopt implementing acts to lay down the principles and format for the information to be reported pursuant to paragraph 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).	6. The Commission ***shall*** adopt implementing acts to lay down the principles and format for the information to be reported pursuant to paragraph 2***, by [12 months from the date of entry into force of this Directive]***. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).

Amendment 173
Proposal for a directive
Article 57 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. The Agency shall provide on its website the links to the information communicated to the Agency in accordance with paragraphs 2 and 3, sorted, where relevant, by medicinal product and by Member State.

Amendment 174
Proposal for a directive
Article 58 a (new)

Text proposed by the Commission	*Amendment*
	Article58a
	Obligation to submit an application for pricing and reimbursement in all Member States
	1. The marketing authorisation holder shall, upon request by a Member State in which the marketing authorisation is valid, in good faith and within the limits of its responsibilities, submit an application for pricing and reimbursement for the medicinal product

and, where relevant, negotiate. In the case of a positive decision to permit the marketing of the medicinal product in accordance with Directive 89/105/EEC, the obligation in Article 56(3) of this Directive to ensure appropriate and continued supply to cover the needs of patients in that Member State shall apply. The application for pricing and reimbursement for the medicinal product shall be submitted no later than 12 months from the date when the Member State made its request, or within 24 months from that date for any of the following entities:

(i) SMEs;

(ii) entities not engaged in an economic activity ('not-for-profit entity'); and

(iii) undertakings that, by the time of granting the marketing authorisation, have received not more than five centralised marketing authorisations for the undertaking concerned or, in the case of an undertaking belonging to a group, for the group of which it is part, since the establishment of the undertaking or the group, whichever is earliest.

The deadlines set out in the first subparagraph of this paragraph shall be prolonged by six months following the notification of the marketing authorisation holder to the competent authority. The marketing authorisation holder shall in such cases state the reasons for the delay. The marketing authorisation holder shall notify that it complied with the obligations set out in the first subparagraph of this paragraph through the EU Access to Medicines Notification System provided for in Article 58b.

2. For the purposes of paragraph 1 of this Article, Member States shall make either their request or a notification that their request will be made at a later date within one year of the granting of a

marketing authorisation. This shall be notified in the EU Access to Medicines Notification System provided for in Article 58b of this Directive, and for a notification that a request will be made at a later date be accompanied by a justification. Following the filing for pricing and reimbursement by the marketing authorisation holder, Directive 89/105/EEC shall apply. Where a Member State has not complied with the time limits laid down in Directive 89/105/EEC, the obligation on the marketing authorisation holder set out in this Article shall be considered to be fulfilled in that Member State.

3. By way of derogation from paragraph 1, the marketing authorisation holder for a designated orphan medicinal product or for an advanced therapy medicinal product may choose instead to comply with the obligations set out in paragraph 1 only in the Member States where the relevant patient population has been identified.

4. Following agreement between a Member State and a marketing authorisation holder, timelines that are different from those set out in paragraphs 1 and 2 may apply. A Member State may choose, after making a request in accordance with paragraph 1, to issue a product-specific waiver after which the obligation to submit an application shall be considered to be complied with in that Member State.

5. The Commission shall adopt delegated acts in accordance with Article 215 to supplement this Directive by specifying criteria for the exemption of medicinal products from the obligations set out in this Article based on the nature of the medicinal product or its market. The delegated acts shall provide clarity to developers regarding the application of exemptions, and set out requirements related to impartiality and transparency in

decisions of the implementing acts referred to in this Article. After consultation with the Agency, the Commission shall adopt, by means of implementing acts, a list of medicinal products to be exempted from the obligations set out in this Article. The inclusion of a medicinal product in that list shall, where relevant, take into account circumstances related to regulatory and reimbursement procedures pertaining to particular medicinal products, or to the administration of a medicinal product in most Member States being impracticable. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).

6. Where a marketing authorisation is transferred to a different legal entity before the end of the period referred to in paragraph 1, the obligations shall be transferred to the new marketing authorisation holder.

7. The Commission shall, by means of implementing acts, establish a conciliation mechanism to facilitate discussions between applicants and Member States to resolve potential disputes related to the process for submission of applications for pricing and reimbursement and with respect to the timelines set out in Directive 89/105/EEC. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2). In the event of continued disagreement between an applicant and a Member State regarding compliance with the obligations set out in this Article, the Commission shall be empowered to issue a legally binding decision following an opinion of the Agency.

8. This Article shall not prevent a marketing authorisation holder from submitting an application for pricing and reimbursement and placing a medicinal

product on the market of a Member State without a Member State having made a request in accordance with paragraph 1.

Amendment 175
Proposal for a directive
Article 58 b (new)

Text proposed by the Commission	*Amendment*
	Article58b
	EU Access to Medicines Notification System
	1. The Commission shall set up and maintain an electronic notification system for the notification of compliance with the obligations set out in Article 58a (the 'EU Access to Medicines Notification System'). The EU Access to Medicines Notification System shall be interoperable with other relevant Union-wide data repositories for medicinal products.
	2. The marketing authorisation holder shall use the EU Access to Medicines Notification System to notify their compliance with the obligations set out in Article 58a. In the Member States where the marketing authorisation is valid, the national competent authority shall use the EU Access to Medicines Notification System to indicate that the marketing authorisation holder has fulfilled its obligations set out in Article 58a.
	3. By ... [3 years from the date of entry into force of this Directive], the Commission shall adopt implementing acts to establish technical and organisational requirements. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).
	4. By ... [5 years from the date of entry into force of this Directive], the Commission shall assess the feasibility of

	extending the EU Access to Medicines Notification System to other areas of the process for pricing of medicinal products as set out in Directive 89/105/EEC and, if appropriate, adopt implementing acts to establish this extended system. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2) of this Directive. Anonymised data, aggregated to Member State level, from the EU Access to Medicines Notification System may be made public for the purpose of reporting on access in Article 86a.

Amendment 176
Proposal for a directive
Article 63 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States may decide that the package leaflet shall be made available in paper format or electronically***, or both***. In the absence of such specific rules in a Member State, a package leaflet in paper format ***shall be included*** in the packaging of a medicinal product. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients.	3. Member States may decide that ***for individual medicinal products, categories of medicinal products or for all medicinal products,*** the package leaflet shall be made available ***both*** in paper format ***and electronically*** or electronically ***only. In the latter case, the decision shall be made only following a consultation of patients, carers and other relevant stakeholders***. In the absence of such specific rules in a Member State, a package leaflet ***shall be made available electronically and be included*** in paper format in the packaging of a medicinal product. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients ***as well as written and designed in a clear and understandable way***.

Amendment 177
Proposal for a directive
Article 63 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. If a Member State has decided that the package leaflet is only to be made available electronically, patients shall be made aware of their right to a printed copy of the package leaflet.

Amendment 178
Proposal for a directive
Article 63 – paragraph 3 b (new)

Text proposed by the Commission	*Amendment*
	3b. If a Member State decides that the package leaflet shall be made available electronically, a paper package leaflet in addition to the electronic format may be made available on a voluntary basis by the marketing authorisation holder in addition to the electronic package leaflet.

Amendment 179
Proposal for a directive
Article 63 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. By way of derogation from paragraph 3, where the medicinal product is intended for dispensation and administration by a qualified healthcare professionals rather than for self-administration by the patient, the package leaflet may be made available only electronically.

Amendment 180
Proposal for a directive
Article 63 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend paragraph 3 by making mandatory the electronic version of the package leaflet. That delegated act shall also establish the patient's right to a printed copy of the package leaflet upon request and free of charge. The delegation of powers shall apply as of [OP please insert the date = five years following 18 months after the date of entering into force of this Directive].	***deleted***

Amendment 181
Proposal for a directive
Article 63 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies.	6. ***By ... [12 months from the date of entry into force of this Directive],*** the Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies.

Amendment 182
Proposal for a directive
Article 63 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. The Agency shall make available a system to accommodate the electronic product information after consultation with Member States and the relevant stakeholders. The system shall be available at the latest by [24 months from the date of entry into force of this Directive].

Amendment 183
Proposal for a directive
Article 63 – paragraph 7

Text proposed by the Commission	*Amendment*
7. ***Where*** the package leaflet ***is made available*** electronically, the individual right to privacy shall be ensured. Any technology giving access to the information shall not allow the identification or tracking of individuals, nor shall it be used for commercial purposes.	7. ***When accessing*** the package leaflet electronically, the individual right to privacy shall be ensured. Any technology giving access to the information shall ***ensure the protection of personal data in accordance with Regulation (EU) 2016/679 and Directive 2002/58/EC and shall*** not allow the identification***, profiling*** or tracking of individuals, nor shall it be used for commercial purposes ***including for advertising or marketing activities***.

Amendment 184
Proposal for a directive
Article 64 – paragraph 3

Text proposed by the Commission	*Amendment*
3. ***The package leaflet shall reflect the results of consultations*** with target patient groups to ensure that ***it*** is legible, clear and easy to use.	3. ***Following a consultation*** with target patient groups ***and other relevant stakeholders, the Commission shall adopt guidelines*** to ensure that ***the package leaflet*** is legible, clear and easy to use.

Amendment 185
Proposal for a directive
Article 66 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The particulars laid down in Annex IV shall appear on immediate packagings other than those referred to in the paragraphs 2 and 3.	1. The particulars laid down in Annex IV shall appear on immediate packagings other than those referred to in the paragraphs 2 and 3 ***and shall allow, at the request of the national competent authorities, single dispensation, particularly in the event of a shortage or major public health issue***.

Amendment 186
Proposal for a directive
Article 66 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Each single dose of the blister pack shall include the following labelling particulars:
	(a) the name of the medicinal product followed by its strength and pharmaceutical form;
	(b) a data matrix code in which the following information is encoded: (i) the Global Trading Index Number (GTIN)
	(ii) the expiry date;
	(iii) the batch number.

Amendment 187
Proposal for a directive
Article 67 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
Medicinal products not subject to prescription shall not bear the safety features referred to in Annex IV, unless, by way of exception, they have been listed in accordance with the procedure referred to in paragraph 2, second subparagraph, point (b).	Medicinal products not subject to prescription shall not bear the safety features referred to in Annex IV, unless, by way of exception, they have been listed in accordance with the procedure referred to in paragraph 2, second subparagraph, point (b)***, or where the marketing authorisation holder chooses to do so voluntarily***.

Amendment 188
Proposal for a directive
Article 67 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	7a. For the purpose of patient safety, Member States may decide that medicinal products imported or distributed in parallel shall be repackaged in new outer packaging.

Amendment 189
Proposal for a directive
Article 69 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The marketing authorisation holder shall ensure availability of educational material to healthcare professionals***,*** ***including through medical sales representatives as referred to in Article 175(1), point (c)***, regarding the appropriate use of diagnostic tools, testing or other diagnostic approaches related to antimicrobial-resistant pathogens, that may inform on the use of the antimicrobial.	1. The marketing authorisation holder shall ensure availability of educational material to healthcare professionals, regarding the appropriate use of diagnostic tools, testing or other diagnostic approaches related to antimicrobial-resistant pathogens, that may inform on the use of the antimicrobial. ***Any informational material shall be compatible with the summary of product characteristics.***

Amendment 190
Proposal for a directive
Article 69 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
Member States ***may decide*** that the awareness card ***shall be*** made available in paper format or ***electronically, or both. In the absence of such specific rules in a Member State, an awareness card*** in paper format ***shall be included*** in the packaging of an antimicrobial.	Member States ***shall ensure*** that the awareness card ***is*** made available in paper format or ***both*** in paper format ***and electronically*** in the packaging of an antimicrobial.

Amendment 191
Proposal for a directive
Article 69 – paragraph 3 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Members States shall introduce appropriate disposal systems for antimicrobials in the community setting, and inform the general public on the correct disposal methods for antimicrobial.

Amendment 192

Proposal for a directive
Article 69 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The Commission may adopt implementing acts laying down further standards for the awareness card after consulting the Agency. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).

Amendment 193
Proposal for a directive
Article 73 – paragraph 1

Text proposed by the Commission	*Amendment*
The outer packaging and the package leaflet may include symbols or pictograms designed to clarify certain information set out in Articles 64(1) ***and*** 65 and other information compatible with the summary of product characteristics that is useful for the patient, to the exclusion of any element of a promotional nature.	The outer ***packaging, the immediate*** packaging and the package leaflet may include symbols or pictograms designed to clarify certain information set out in Articles 64(1)***,*** 65 ***and 69*** and other information compatible with the summary of product characteristics that is useful for the patient, to the exclusion of any element of a promotional nature.

Amendment 194
Proposal for a directive
Article 74 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The competent authorities of the Member State may also grant a full or partial exemption to the obligation that the labelling and the package leaflet must be in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State. For the purpose of multi-language packages, Member States may allow the use on the labelling and package leaflet of an official	4. The competent authorities of the Member State may also grant a full or partial exemption to the obligation that the labelling and the package leaflet must be in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State. ***Where a competent authority grants a full or partial exemption to the language requirements that apply to the label or***

language of the Union that is commonly understood in the Member States where the multi-language package is marketed.	***package leaflet, the patients' right to a printed copy in the official language or official languages of the Member State shall be guaranteed upon request and free of charge.*** For the purpose of multi-language packages, Member States may allow the use on the labelling and package leaflet of an official language of the Union that is commonly understood in the Member States where the multi-language package is marketed.

Amendment 195
Proposal for a directive
Article 77 – paragraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) the wording on prudent use and safe disposal of antimicrobials;

Amendment 196
Proposal for a directive
Article 80 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The period referred in paragraph 2 of this Article shall be extended by an additional period of one year, where the marketing authorisation holder obtains, during the data protection period referred to in Article 81, an authorisation for an additional therapeutic indication, provided that significant clinical benefit in comparison with existing therapies has been demonstrated by the marketing authorisation holder with supporting data. That extension may only be granted once.

Amendment 197
Proposal for a directive
Article 80 – paragraph 4

Text proposed by the Commission	*Amendment*
4. By way of derogation from ***the*** paragraphs 1 and 2, when a compulsory licence has been granted by a relevant authority in the Union to a party ***to address a public health emergency***, the data and market protection shall be suspended with regard to that party insofar as the compulsory licence requires, and during the duration period of the compulsory licence.	4. By way of derogation from paragraphs 1 and 2, when a compulsory licence has been granted by a relevant ***Member State*** authority in the Union ***under conditions laid down in Union law and in compliance with international agreements*** to a party, the data and market protection shall be suspended with regard to that party insofar as the compulsory licence requires, and during the duration period of the compulsory licence ***in the Member State(s) where the compulsory license has been granted***.

Amendment 198
Proposal for a directive
Article 80 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The marketing authorisation holder for the medicinal product for which a compulsory licence has been granted shall be informed of the decision without delay.

Amendment 199
Proposal for a directive
Article 81 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The regulatory data protection period shall be ***six*** years from the date when the marketing authorisation for that medicinal product was granted in accordance with Article 6(2). For marketing authorisations that belong to the same global marketing authorisation the period of data protection shall start from the date when the initial marketing authorisation was granted in the Union.	1. The regulatory data protection period shall be ***seven*** years ***and six months*** from the date when the marketing authorisation for that medicinal product was granted in accordance with Article 6(2). For marketing authorisations that belong to the same global marketing authorisation the period of data protection shall start from the date when the initial marketing authorisation was granted in the Union.

Amendment 200
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) 24 months, where the marketing authorisation holder demonstrates that the conditions referred to in Article 82(1) are fulfilled within two years, from the date when the marketing authorisation was granted or, within three years from that date for any of the following entities:	***deleted***
(i) SMEs within the meaning of Commission Recommendation 2003/361/EC;	
(ii) entities not engaged in an economic activity ('not-for-profit entity'); and	
(iii) undertakings that, by the time of granting of a marketing authorisation, have received not more than five centralised marketing authorisations for the undertaking concerned or, in the case of an undertaking belonging to a group, for the group of which it is part, since the establishment of the undertaking or the group, whichever is earliest.	

Amendment 201
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) ***six*** months, where the marketing authorisation applicant demonstrates at the time of the initial marketing authorisation application that the medicinal product addresses an unmet medical need as referred to in Article 83;	(b) ***12*** months, where the marketing authorisation applicant demonstrates at the time of the initial marketing authorisation application that the medicinal product addresses an unmet medical need as referred to in Article 83;

Amendment 202
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) six months, where the marketing authorisation holder demonstrates that a significant share of research and development, including preclinical and clinical, related to the medicinal product has been done within the Union and at least in part in collaboration with public entities, including university hospital institutes, centres of excellence or bioclusters located in the Union.

Amendment 203
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) 12 months, where the marketing authorisation holder obtains, during the data protection period, an authorisation for an additional therapeutic indication for which the marketing authorisation holder has demonstrated, with supporting data, a significant clinical benefit in comparison with existing therapies.	***deleted***

Amendment 204
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 3

Text proposed by the Commission	*Amendment*
The prolongation referred to in the first subparagraph, point (d), may only be granted once.	***deleted***

Amendment 205
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 3 a (new)

Text proposed by the Commission	*Amendment*
	By ... [12 months from the date of entry into force of this Directive], the

	Commission shall adopt delegated acts in accordance with Article 215 to supplement this Directive by setting out the procedural aspects and criteria related to the first subparagraph, point (ca), of this paragraph.

Amendment 206
Proposal for a directive
Article 81 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The regulatory protection referred to in paragraphs 1 and 2 shall not exceed eight years and six months.

Amendment 207
Proposal for a directive
Article 82

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

Amendment 208
Proposal for a directive
Article 83 – 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*** of [revised Regulation (EC) No 726/2004].	3. Where the Agency adopts scientific guidelines for the application of this Article it shall consult the Commission and the authorities or bodies ***and the stakeholders*** referred to in Article ***162(1) and (2), respectively,*** of [revised Regulation (EC) No 726/2004].

Amendment 209
Proposal for a directive
Article 85 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*

Patent rights, or supplementary protection certificates under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted] shall not be regarded as infringed when ***a reference medicinal product is used*** for the ***purposes*** of:	Patent rights, or supplementary protection certificates under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted] shall not be regarded as infringed when ***necessary studies, trials and other activities are conducted*** for the ***purpose*** of:

Amendment 210
Proposal for a directive
Article 85 – paragraph 1 – point a – introductory part

Text proposed by the Commission	*Amendment*
(a) studies, trials and other activities conducted to generate data for an application, for:	***deleted***

Amendment 211
Proposal for a directive
Article 85 – paragraph 1 – point a – point i

Text proposed by the Commission	*Amendment*
(i) a marketing authorisation ***of generic, biosimilar, hybrid or bio-hybrid medicinal products and for*** subsequent variations;	(i) ***obtaining*** a marketing authorisation ***and*** subsequent variations;

Amendment 212
Proposal for a directive
Article 85 – paragraph 1 – point a – point ii

Text proposed by the Commission	*Amendment*
(ii) health technology assessment as defined in Regulation (EU) 2021/2282;	(ii) ***conducting a*** health technology assessment as defined in Regulation (EU) 2021/2282;

Amendment 213
Proposal for a directive
Article 85 – paragraph 1 – point a – point iii

Text proposed by the Commission	*Amendment*

(iii) pricing and reimbursement**.**	(iii) ***obtaining*** pricing and reimbursement ***approval; and***

Amendment 214
Proposal for a directive
Article 85 – paragraph 1 – point a – point iii a (new)

Text proposed by the Commission	*Amendment*
	(iiia) the subsequent practical requirements associated with such activities.

Amendment 215
Proposal for a directive
Article 85 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the activities conducted exclusively for the purposes set out in ***point (a), may*** cover the submission of the application for a marketing authorisation and the offer, manufacture, sale, supply, storage, import, use and purchase of patented medicinal products or processes, including by third party suppliers and service providers.	The activities conducted exclusively for the purposes set out in ***the first paragraph, shall*** cover ***as relevant*** the submission of the application for a marketing authorisation and the offer, manufacture, sale, supply, storage, import, use and purchase of patented medicinal products or processes, including by third party suppliers and service providers.

Amendment 216
Proposal for a directive
Article 85 a (new)

Text proposed by the Commission	*Amendment*
	Article 85a
	Non-interference of intellectual property rights
	1. Member States shall consider the procedures and decisions referred to in Article 85 as regulatory or administrative procedures which, as such, are independent from the enforcement of intellectual property rights.

	2. The protection of intellectual property rights shall not be a valid ground to refuse, suspend, delay, withdraw or revoke decisions referred to in Article 85.
	3. Paragraphs 1 and 2 shall apply without prejudice to the Union and national legislation relating to the protection of intellectual property.

Amendment 217
Proposal for a directive
Article 86 a (new)

Text proposed by the Commission	*Amendment*
	Article 86a
	Reporting on access to medicinal products
	The Commission, in collaboration with the Member States, shall develop indicators to measure access to medicinal products within the Union. Those indicators shall be evidence-based, measurable, and regularly reviewed to reflect the evolving healthcare landscape within the Union.
	The Commission shall publish a report assessing access to medicinal products and barriers to improving such access in each Member State and at aggregated Union level. The report shall be publically available.
	Based on the report, the Commission shall create a dedicated website with easily accessible information on the access indicators and access to medicinal products in the Union, intended for the general public and relevant stakeholders.
	The report shall be drawn up for the first time by [the date of the end of the second year from the date of entry into force of this Directive] and every five years thereafter.

Amendment 218

Proposal for a directive
Article 87 – paragraph 1 – subparagraph 1 – point c – paragraph 1

Text proposed by the Commission	*Amendment*
(c) to conduct a post-authorisation environmental risk assessment study, collection of monitoring data or information on use, if there are concerns about the risks to the environment or public health, including antimicrobial resistance, due to an authorised medicinal product, or related active substance.	(c) to conduct a post-authorisation environmental risk assessment study, collection of monitoring data or information on use, if there are concerns about the risks to the environment or public health, including antimicrobial resistance, due to an authorised medicinal product, or related active substance***; where the post-authorisation environmental risk assessment study concerns an antimicrobial, it shall include relevant and comparable data on the volume of sales and the use per types of antimicrobial medicinal products; the Agency shall cooperate with Member States and with other Union agencies to analyse those data and shall publish an annual report; the Agency shall take into account those data when adopting any relevant guidelines and recommendations***.

Amendment 219
Proposal for a directive
Article 87 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
The imposition of such an obligation shall be duly justified, notified in writing, and shall include the objectives and timeframe for submission and conduct of the study.	The imposition of such an obligation shall be duly justified, notified in writing, and shall include the objectives and timeframe for submission and conduct of the study. ***Information on imposed post-authorisation studies shall be noted in the product's European Public Assessment Report and a database of the competent authority.***

Amendment 220
Proposal for a directive
Article 92 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The procedures for examination of applications for variations shall be proportionate to the risk and impact involved. Those procedures shall range from procedures that allow implementation only after approval based on a complete scientific assessment to procedures that allow immediate implementation and subsequent notification by the marketing authorisation holder to the competent authority. Such procedures may also include updates by the marketing authorisation holder of their information held in a database.	3. The procedures for examination of applications for variations shall be proportionate to the risk and impact involved. Those procedures shall range from procedures that allow implementation only after approval based on a complete scientific assessment to procedures that allow immediate implementation and subsequent notification by the marketing authorisation holder to the competent authority. Such procedures may also include updates by the marketing authorisation holder of their information held in a database. ***Where deemed justified by the Agency, accelerated assessment procedures shall also be envisaged for variations which are of major interest from the point of view of public health.***

Amendment 221
Proposal for a directive
Article 94 – paragraph 1

Text proposed by the Commission	*Amendment*
1. On the basis of relevant paediatric clinical studies received in accordance with Article 45(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council[76] , the competent authorities of the Member States may vary the marketing authorisation of the medicinal product concerned accordingly and update the summary of product characteristics and package leaflet of the medicinal product concerned. The competent authorities shall exchange information regarding the studies submitted and, as appropriate, their implications for any marketing authorisations concerned.	1. On the basis of relevant paediatric clinical studies received in accordance with Article 45(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council[76] , the competent authorities of the Member States may***, following a consultation of the marketing authorisation holder,*** vary the marketing authorisation of the medicinal product concerned accordingly and update the summary of product characteristics and package leaflet of the medicinal product concerned. The competent authorities shall exchange information regarding the studies submitted and, as appropriate, their implications for any marketing authorisations concerned.
[76] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of	[76] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of

12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).	12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).

Amendment 222
Proposal for a directive
Article 96 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Member States shall operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks and their participation in the Union pharmacovigilance activities.	Member States shall operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks and their participation in the Union pharmacovigilance activities ***including the pharmacovigilance of the post-authorisation safety and efficacy long-term studies in children, including where relevant data from the off-label use of the product***.

Amendment 223
Proposal for a directive
Article 97 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) facilitate the protection of patients in relation to adverse events through the development and implementation of plans for safe administration and handling of medicinal products, which may include the use of digital medication safety systems in hospitals and ambulatory care settings.

Amendment 224
Proposal for a directive
Article 102 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) the outcome of the assessment of the ERA, including the data submitted by

the marketing authorisation holder, in accordance with Article 22(7a) and Article 29(4a);

Amendment 225
Proposal for a directive
Article 102 – paragraph 1 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) where relevant, information related to antimicrobials, in accordance with Article 17(2) and Article 29(4a);

Amendment 226
Proposal for a directive
Article 102 – paragraph 1 – point d b (new)

Text proposed by the Commission	*Amendment*
	(db) where relevant, the awareness card with information on antimicrobial resistance and the appropriate use and disposal of antimicrobials;

Amendment 227
Proposal for a directive
Article 102 – paragraph 1 – point d c (new)

Text proposed by the Commission	*Amendment*
	(dc) periodic safety update reports;

Amendment 228
Proposal for a directive
Article 102 – paragraph 1 – point d d (new)

Text proposed by the Commission	*Amendment*
	(dd) information on the shortage status of medicinal products as referred to in Article 121(1), point (b), of [revised Regulation (EC) No 726/2004];

Amendment 229
Proposal for a directive
Article 105 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Marketing authorisation holders shall not refuse to consider reports of suspected adverse reactions received electronically or by any other appropriate means from patients or healthcare professionals.	2. Marketing authorisation holders shall not refuse to consider reports of suspected adverse reactions received electronically or by any other appropriate means from patients***, carers or other relevant persons, such as family members,*** or healthcare professionals.

Amendment 230
Proposal for a directive
Article 106 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Each Member State shall record all suspected adverse reactions that occur in its territory and that are brought to its attention from healthcare professionals and patients. This shall include all authorised medicinal products and medicinal products used in accordance with Article 3, paragraphs 1 or 2. Member States shall involve patients and healthcare professionals, as appropriate, in the follow-up of any reports they receive in order to comply with Article 97(1), points (c) and (e).	Each Member State shall record all suspected adverse reactions that occur in its territory and that are brought to its attention from healthcare professionals and patients. This shall include all authorised medicinal products and medicinal products used in accordance with Article 3, paragraphs 1 or 2. Member States shall involve patients and healthcare professionals, as appropriate, in the follow-up of any reports they receive in order to comply with Article 97(1), points (c) and (e)***, and shall seek to inform directly those stakeholders that reported a suspected adverse drug reaction on decisions taken in relation to the safety of the medicinal product***.

Amendment 231
Proposal for a directive
Article 106 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Member States shall ensure that reports of suspected adverse reactions arising from an error associated with the	5. Member States shall ensure that reports of suspected adverse reactions arising from an error***, including those***

use of a medicinal product that are brought to their attention are made available to the Eudravigilance database and to any authorities, bodies, organisations or institutions, responsible for patient safety within that Member State concerned. They shall also ensure that the authorities responsible for medicinal products within that Member State are informed of any suspected adverse reactions brought to the attention of any other authority within that Member State. These reports shall be appropriately identified in the forms referred to in Article 102 of [revised Regulation (EC) No 726/2004]**.**	associated with the use***, administration, and dispensation*** of a medicinal product***, by professionals,*** that are brought to their attention are made available to the Eudravigilance database and to any authorities, bodies, organisations or institutions, responsible for patient safety within that Member State concerned. They shall also ensure that the authorities responsible for medicinal products within that Member State are informed of any suspected adverse reactions brought to the attention of any other authority within that Member State. These reports shall be appropriately identified in the forms referred to in Article 102 of [revised Regulation (EC) No 726/2004]

Amendment 232
Proposal for a directive
Article 106 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. Reports of adverse reactions arising from incorrect administration or dispensation of a medicinal product shall be available in the Eudravigilance database and shall be included in periodic safety update reports. Where relevant, Member States shall take corrective action to achieve high standards of medication safety in healthcare settings after consultation of healthcare professionals and other relevant stakeholders.

Amendment 233
Proposal for a directive
Article 107 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The Agency or the national competent authorities, as appropriate, shall make publicly available the reports referred to in paragraph 1, points (a) and

(b).

Amendment 234
Proposal for a directive
Article 123 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The Agency shall, in cooperation with competent authorities of the Member States and other interested parties, draw up:	The Agency shall, in cooperation with competent authorities of the Member States and other interested parties, ***including those referred to in Article 162 of [revised Regulation (EC) No 726/2004],*** draw up:

Amendment 235
Proposal for a directive
Article 123 – paragraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) guidance for national competent authorities on the effective inclusion of patients and healthcare professionals in the data collection and communication of the risks of medicinal products within the pharmacovigilance activities;

Amendment 236
Proposal for a directive
Chapter X – title

Text proposed by the Commission	*Amendment*
Homeopathic ***medicinal*** products and traditional herbal medicinal products	Homeopathic products and traditional herbal medicinal products

Amendment 237
Proposal for a directive
Article 125 – title

Text proposed by the Commission	*Amendment*
Registration or authorisation of homeopathic ***medicinal*** products	Registration or authorisation of homeopathic products

Amendment 238
Proposal for a directive
Article 125 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that homeopathic ***medicinal*** products manufactured and placed on the market in the Union are registered in accordance with Articles 126 and 127 or authorised in accordance with Article 133(1), except where such homeopathic ***medicinal*** products are covered by a registration or authorisation granted in accordance with national legislation on or before 31 December 1993. In case of registrations, Chapter III, Sections 3 and 4, and Article 38, paragraphs 1, 2 and 3 shall apply.	1. Member States shall ensure that homeopathic products manufactured and placed on the market in the Union are registered in accordance with Articles 126 and 127 or authorised in accordance with Article 133(1), except where such homeopathic products are covered by a registration or authorisation granted in accordance with national legislation on or before 31 December 1993. In case of registrations, Chapter III, Sections 3 and 4, and Article 38, paragraphs 1, 2 and 3 shall apply.

Amendment 239
Proposal for a directive
Article 125 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall establish a simplified registration procedure referred to in Article 126 for the homeopathic ***medicinal*** products.	2. Member States shall establish a simplified registration procedure referred to in Article 126 for the homeopathic products.

Amendment 240
Proposal for a directive
Article 126 – title

Text proposed by the Commission	*Amendment*
Simplified registration procedure for homeopathic ***medicinal*** products	Simplified registration procedure for homeopathic products

Amendment 241
Proposal for a directive
Article 126 – paragraph 1 – subparagraph 1 – introductory part

Text proposed by the Commission	*Amendment*
Homeopathic ***medicinal*** products that satisfy all of the following conditions may be subject to a simplified registration procedure:	Homeopathic products that satisfy all of the following conditions may be subject to a simplified registration procedure:

Amendment 242
Proposal for a directive
Article 126 – paragraph 1 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) no specific therapeutic indication appears on the labelling of the ***medicinal*** product or in any information relating thereto;	(b) no specific therapeutic indication appears on the labelling of the ***homeopathic*** product or in any information relating thereto;

Amendment 243
Proposal for a directive
Article 126 – paragraph 1 – subparagraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) there is a sufficient degree of dilution to guarantee the safety of the ***medicinal*** product***.***	(c) there is a sufficient degree of dilution to guarantee the safety of the ***homeopathic*** product

Amendment 244
Proposal for a directive
Article 126 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
For the purposes of point (c), the ***medicinal*** product may not contain either more than one part per 10000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active substances whose presence in an allopathic ***medicinal*** product results in the obligation to submit a doctor's prescription.	For the purposes of point (c), the ***homeopathic*** product may not contain either more than one part per 10000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active substances whose presence in an allopathic ***homeopathic*** product results in the obligation to submit a doctor's prescription.

Amendment 245
Proposal for a directive
Article 126 – paragraph 1 – subparagraph 4

Text proposed by the Commission	*Amendment*
At the time of registration, Member States shall determine the prescription status for the dispensing of the homeopathic ***medicinal*** product.	At the time of registration, Member States shall determine the prescription status for the dispensing of the homeopathic product.

Amendment 246
Proposal for a directive
Article 126 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The criteria and rules of procedure provided for in Article 1(10), point (c), Article 30, Chapter III, Section 6, Articles 191, 195 and 204 shall apply by analogy to the simplified registration procedure for homeopathic ***medicinal*** products, with the exception of the proof of therapeutic efficacy.	2. The criteria and rules of procedure provided for in Article 1(10), point (c), Article 30, Chapter III, Section 6, Articles 191, 195 and 204 shall apply by analogy to the simplified registration procedure for homeopathic products, with the exception of the proof of therapeutic efficacy.

Amendment 247
Proposal for a directive
Article 127 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
An application a simplified registration may cover a series of homeopathic ***medicinal*** products derived from the same homeopathic stock or stocks. The following shall be included with the application in order to demonstrate, in particular, the pharmaceutical quality and the batch-to-batch homogeneity of the homeopathic ***medicinal*** products concerned:	An application a simplified registration may cover a series of homeopathic products derived from the same homeopathic stock or stocks. The following shall be included with the application in order to demonstrate, in particular, the pharmaceutical quality and the batch-to-batch homogeneity of the homeopathic products concerned:

Amendment 248
Proposal for a directive
Article 127 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) the manufacturing authorisation for the homeopathic ***medicinal*** product concerned;	(d) the manufacturing authorisation for the homeopathic product concerned;

Amendment 249
Proposal for a directive
Article 127 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) the copies of any registrations or authorisations obtained for the same homeopathic ***medicinal*** product in other Member States;	(e) the copies of any registrations or authorisations obtained for the same homeopathic product in other Member States;

Amendment 250
Proposal for a directive
Article 127 – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
(f) one or more mock-ups of the outer packaging and the immediate packaging of the homeopathic ***medicinal*** products to be registered;	(f) one or more mock-ups of the outer packaging and the immediate packaging of the homeopathic products to be registered;

Amendment 251
Proposal for a directive
Article 127 – paragraph 1 – point g

Text proposed by the Commission	*Amendment*
(g) the data concerning the stability of the homeopathic ***medicinal*** product.	(g) the data concerning the stability of the homeopathic product.

Amendment 252
Proposal for a directive
Article 128 – title

Text proposed by the Commission	*Amendment*
Application of decentralised and mutual	Application of decentralised and mutual

recognition procedures to homeopathic ***medicinal*** products	recognition procedures to homeopathic products

Amendment 253
Proposal for a directive
Article 128 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Article 38, paragraphs 4 and 6, Articles 39 to 42 and 95 shall not apply to the homeopathic ***medicinal*** products referred to in Article 126.	1. Article 38, paragraphs 4 and 6, Articles 39 to 42 and 95 shall not apply to the homeopathic products referred to in Article 126.

Amendment 254
Proposal for a directive
Article 128 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Chapter III, Sections 3 to 5, shall not apply to the homeopathic ***medicinal*** products referred to in Article 133(2).	2. Chapter III, Sections 3 to 5, shall not apply to the homeopathic products referred to in Article 133(2).

Amendment 255
Proposal for a directive
Article 129 – title

Text proposed by the Commission	*Amendment*
Labelling of homeopathic ***medicinal*** products	Labelling of homeopathic products

Amendment 256
Proposal for a directive
Article 129 – paragraph 1

Text proposed by the Commission	*Amendment*
Homeopathic ***medicinal*** products, with the exception those referred to in Article 126(1), shall be labelled in accordance with the provisions of Chapter VI and shall be identified by a reference on their labels, in clear and legible form, to their	Homeopathic products, with the exception those referred to in Article 126(1), shall be labelled in accordance with the provisions of Chapter VI and shall be identified by a reference on their labels, in clear and

homeopathic nature.	legible form, to their homeopathic nature.

Amendment 257
Proposal for a directive
Article 130 – title

Text proposed by the Commission	*Amendment*
Specific requirements for labelling of certain homeopathic ***medicinal*** products	Specific requirements for labelling of certain homeopathic products

Amendment 258
Proposal for a directive
Article 130 – paragraph 1 – subparagraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The labelling and, where appropriate, the package insert for homeopathic ***medicinal*** products referred to in Article 126(1) in addition to the clear mention of the words 'homeopathic ***medicinal*** product', shall bear the following, and no other, information:	The labelling and, where appropriate, the package insert for homeopathic products referred to in Article 126(1) in addition to the clear mention of the words 'homeopathic product', shall bear the following, and no other, information:

Amendment 259
Proposal for a directive
Article 130 – paragraph 1 – subparagraph 1 – point k

Text proposed by the Commission	*Amendment*
(k) 'homeopathic ***medicinal*** product without approved therapeutic indications';	(k) 'homeopathic product without approved therapeutic indications';

Amendment 260
Proposal for a directive
Article 130 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
As regards the first subparagraph, point (a), if the homeopathic ***medicinal*** product is composed of two or more stocks, the scientific names of the stocks on the labelling may be supplemented by an	As regards the first subparagraph, point (a), if the homeopathic product is composed of two or more stocks, the scientific names of the stocks on the labelling may be

invented name.	supplemented by an invented name.

Amendment 261
Proposal for a directive
Article 130 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) the price of the homeopathic ***medicinal*** product;	(a) the price of the homeopathic product;

Amendment 262
Proposal for a directive
Article 131 – title

Text proposed by the Commission	*Amendment*
Advertising of homeopathic ***medicinal*** products	Advertising of homeopathic products

Amendment 263
Proposal for a directive
Article 131 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Chapter XIII shall apply to homeopathic ***medicinal*** products.	1. Chapter XIII shall apply to homeopathic products.

Amendment 264
Proposal for a directive
Article 131 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
By derogation from paragraph 1, Article 176(1) shall not apply to ***medicinal*** products referred to in Article 126(1).	By derogation from paragraph 1, Article 176(1) shall not apply to ***homeopathic*** products referred to in Article 126(1).

Amendment 265
Proposal for a directive
Article 131 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
However, only the information specified in Article 130(1) may be used in the advertising of such homeopathic ***medicinal*** products.	However, only the information specified in Article 130(1) may be used in the advertising of such homeopathic products.

Amendment 266
Proposal for a directive
Article 132 – title

Text proposed by the Commission	*Amendment*
Exchange of information on homeopathic ***medicinal*** products	Exchange of information on homeopathic products

Amendment 267
Proposal for a directive
Article 132 – paragraph 1

Text proposed by the Commission	*Amendment*
Member States shall communicate to each other all the information necessary to guarantee the quality and safety of homeopathic ***medicinal*** products manufactured and marketed within the Union, and in particular the information referred to in Articles 202 and 203.	Member States shall communicate to each other all the information necessary to guarantee the quality and safety of homeopathic products manufactured and marketed within the Union, and in particular the information referred to in Articles 202 and 203.

Amendment 268
Proposal for a directive
Article 133 – title

Text proposed by the Commission	*Amendment*
Other requirements for homeopathic ***medicinal*** products	Other requirements for homeopathic products

Amendment 269
Proposal for a directive
Article 133 – paragraph 1

Text proposed by the Commission	*Amendment*

1. Homeopathic ***medicinal*** products other than those referred to in Article 126(1) shall be granted a marketing authorisation in accordance with Articles 6 and 9 to 14 and labelled in accordance with Chapter VI.	1. Homeopathic products other than those referred to in Article 126(1) shall be granted a marketing authorisation in accordance with Articles 6 and 9 to 14 and labelled in accordance with Chapter VI.

Amendment 270
Proposal for a directive
Article 133 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
A Member State may introduce or retain in its territory specific rules for the non-clinical tests and clinical studies of homeopathic ***medicinal*** products other than those referred to in Article 126(1), in accordance with the principles and characteristics of homeopathy as practised in that Member State.	A Member State may introduce or retain in its territory specific rules for the non-clinical tests and clinical studies of homeopathic products other than those referred to in Article 126(1), in accordance with the principles and characteristics of homeopathy as practised in that Member State.

Amendment 271
Proposal for a directive
Article 133 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Chapter IX shall apply to homeopathic ***medicinal*** products, with the exception of those referred to in Article 126(1). Chapter XI, Chapter XII, Section 1, and Chapter XIV shall apply to homeopathic ***medicinal*** products.	3. Chapter IX shall apply to homeopathic products, with the exception of those referred to in Article 126(1). Chapter XI, Chapter XII, Section 1, and Chapter XIV shall apply to homeopathic products.

Amendment 272
Proposal for a directive
Article 140 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the user should consult a doctor or a qualified healthcare practitioner if the symptoms persist during the use of the traditional herbal medicinal product or if adverse effects ***not mentioned in the***	(b) the user should consult a doctor or a qualified healthcare practitioner if the symptoms persist during the use of the traditional herbal medicinal product or if

package leaflet occur***.***	adverse effects occur***; and***

Amendment 273
Proposal for a directive
Article 140 – paragraph 2 – subparagraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) the user consult a doctor or a qualified healthcare practitioner for information about possible contraindications or pharmacological interactions with other medications.

Amendment 274
Proposal for a directive
Article 140 – paragraph 3

Text proposed by the Commission	*Amendment*
3. In addition to the requirements set out in Chapter XIII, any advertisement for a traditional herbal medicinal product registered under this Section shall contain the following statement: Traditional herbal medicinal product for use in specified therapeutic indication(s) exclusively based upon long-standing use.	3. In addition to the requirements set out in Chapter XIII, any advertisement for a traditional herbal medicinal product registered under this Section shall contain the following statement: Traditional herbal medicinal product for use in specified therapeutic indication(s) exclusively based upon long-standing use. ***For more information, consult a healthcare professional.***

Amendment 275
Proposal for a directive
Article 142 – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
(a) preparation, dividing up, changes in packaging or presentation where these processes are carried out, solely for retail supply, by pharmacists in dispensing pharmacies or by persons legally authorised in the Member States to carry out such processes; or	(a) preparation, dividing up, changes in packaging or presentation where these processes are carried out, solely for retail ***and hospital*** supply, by pharmacists in dispensing pharmacies or by persons legally authorised in the Member States to carry out such processes; or

Amendment 276
Proposal for a directive
Article 147 – paragraph 1 – subparagraph 1 – point j a (new)

Text proposed by the Commission	*Amendment*
	(ja) use an appropriate wastewater treatment system;

Amendment 277
Proposal for a directive
Article 147 – paragraph 1 – subparagraph 1 – point j b (new)

Text proposed by the Commission	*Amendment*
	(jb) comply with relevant risk mitigation measures identified in accordance with Article 22.

Amendment 278
Proposal for a directive
Article 148 – paragraph 9

Text proposed by the Commission	*Amendment*
9. Where relevant, competent authorities of the Member State supervising the central and decentralised sites ***may*** liaise with the competent authority of the Member State responsible for the supervision of the marketing authorisation.	9. Where relevant, competent authorities of the Member State supervising the central and decentralised sites ***shall*** liaise with the competent authority of the Member State responsible for the supervision of the marketing authorisation.

Amendment 279
Proposal for a directive
Article 160 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The Commission ***may*** adopt ***implementing*** acts in accordance with Article ***214(2)*** to supplement this Directive by specifying:	The Commission ***is empowered to*** adopt ***delegated*** acts in accordance with Article ***215*** to supplement this Directive by specifying:

Amendment 280

Proposal for a directive
Article 160 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) measures to reduce the negative impact on the environment posed by the manufacturing of medicinal products.

Amendment 281
Proposal for a directive
Article 163 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The competent authority of the Member State concerned shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to an authorisation to engage in activity as a wholesaler in medicinal products ("wholesale distribution authorisation"). The wholesale distribution authorisation shall indicate the premises, the medicinal products and the wholesale distribution operations for which it is valid.	1. The competent authority of the Member State concerned shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to an authorisation to engage in activity as a wholesaler in medicinal products ("wholesale distribution authorisation"). The wholesale distribution authorisation shall indicate the premises, the ***categories of*** medicinal products and the wholesale distribution operations for which it is valid.

Amendment 282
Proposal for a directive
Article 166 – paragraph 1 – point m

Text proposed by the Commission	*Amendment*
(m) cooperate with marketing authorisation holders and competent authorities of the Member States on the security of supply.	(m) cooperate with ***all relevant stakeholders, including*** marketing authorisation holders and competent authorities of the Member States on the security of supply.

Amendment 283
Proposal for a directive
Article 168 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*

1. For all supplies of medicinal products to a person authorised or entitled to supply medicinal products to the public in the Member State concerned, the authorised wholesaler ***must enclose*** a document that makes it possible to ascertain the following:	1. For all supplies of medicinal products to a person authorised or entitled to supply medicinal products to the public in the Member State concerned, the authorised wholesaler ***shall provide*** a document***, which may be submitted in electronic format,*** that makes it possible to ascertain the following:

Amendment 284
Proposal for a directive
Article 172 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the natural or legal person offering the medicinal products is authorised or entitled to supply medicinal products to the public, also at a distance, in accordance with national legislation of the Member State in which that person is established;	(a) the natural or legal person offering the medicinal products is authorised or entitled to supply medicinal products to the public, also at a distance, in accordance with national legislation of the Member State in which that person is established ***and complies, where applicable, with the conditions referred to in paragraph 2 of this Article***;

Amendment 285
Proposal for a directive
Article 175 – paragraph 1 – subparagraph 2 – point e

Text proposed by the Commission	*Amendment*
(e) the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind***, except when their intrinsic value is minimal***;	(e) the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind;

Amendment 286
Proposal for a directive
Article 176 – paragraph 3 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) shall not induce to an excessive or abusive use of the medicinal product.

Amendment 287
Proposal for a directive
Article 176 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Any form of advertising that aims to highlight negatively another medicinal product shall be prohibited. Advertising that suggests that a medicinal product is safer or more effective than another medicinal product shall also be prohibited, unless demonstrated and supported by the summary of product characteristics.	4. Any form of advertising that aims to highlight negatively another medicinal product shall be prohibited. Advertising that suggests that a medicinal product is safer or more effective than another medicinal product shall also be prohibited, unless demonstrated and supported by the summary of product characteristics ***for the relevant indications and patient population***.

Amendment 288
Proposal for a directive
Article 177 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) are antibiotics or antimicrobials for which there is an identified risk of antimicrobial resistance as referred to in Article 51(1a).

Amendment 289
Proposal for a directive
Article 177 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Medicinal products may be advertised to the general public where, by virtue of their composition and purpose, they are intended and designed for use without the intervention of a ***medical practitioner*** for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary.	2. Medicinal products may be advertised to the general public where, by virtue of their composition and purpose, they are intended and designed for use without the intervention of a ***healthcare professional*** for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary.

Amendment 290
Proposal for a directive
Article 177 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The prohibition contained in paragraph 1 shall not apply to vaccination campaigns ***carried out by the industry and*** approved by the competent authorities of the Member States.	4. The prohibition contained in paragraph 1 shall not apply to vaccination campaigns approved by the competent authorities of the Member States.

Amendment 291
Proposal for a directive
Article 178 – paragraph 1 – point b – point ii

Text proposed by the Commission	*Amendment*
(ii) the information necessary for correct use of the medicinal product;	(ii) the information necessary for correct use ***and disposal*** of the medicinal product;

Amendment 292
Proposal for a directive
Article 178 – paragraph 1 – point b – point iii

Text proposed by the Commission	*Amendment*
(iii) an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be.	(iii) an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be***, and to consult a medical practitioner or a pharmacist for additional information***.

Amendment 293
Proposal for a directive
Article 178 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Commission shall adopt delegated acts in accordance with Article 215 to supplement this Directive by specifying requirements in relation to direct and indirect advertising of

	medicinal products through social media and other media platforms and product placements by celebrities and influencers.

Amendment 294
Proposal for a directive
Article 179 – paragraph 1 – point h

Text proposed by the Commission	*Amendment*
(h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;	(h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural ***or not chemical***;

Amendment 295
Proposal for a directive
Article 183 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons ***unless they are inexpensive and relevant to the practice of medicine or pharmacy***.	1. Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons.

Amendment 296
Proposal for a directive
Article 185 – paragraph 1 – point g

Text proposed by the Commission	*Amendment*
(g) no samples of medicinal products containing substances classified as psychotropic or narcotic within the meaning of international conventions may be supplied.	(g) no samples of medicinal products containing substances classified as ***antibiotic,*** psychotropic or narcotic within the meaning of international conventions may be supplied.

Amendment 297
Proposal for a directive
Article 186 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that there are adequate and effective methods to monitor the advertising of medicinal products. Such methods***, which may*** be based on a system of prior vetting, shall in any event include legal provisions under which persons or organisations regarded under national law as having a legitimate interest in prohibiting any advertisement inconsistent with this Chapter, may take legal action against such advertisement, or bring such advertisement before the competent authority of the Member State either to decide on complaints or to initiate appropriate legal proceedings.	1. Member States shall ensure that there are adequate and effective methods to monitor the advertising of medicinal products. ***At least for advertisements targeted at the general public,*** such methods ***shall*** be based on a system of prior vetting, ***and*** shall in any event include legal provisions under which persons or organisations regarded under national law as having a legitimate interest in prohibiting any advertisement inconsistent with this Chapter, may take legal action against such advertisement, or bring such advertisement before the competent authority of the Member State either to decide on complaints or to initiate appropriate legal proceedings.

Amendment 298
Proposal for a directive
Article 186 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Member States shall set up and maintain a national transparency register of transfers of value regarding the advertising activities referred to in Articles 175, 177, 180 and 182 to 185, targeting persons qualified to prescribe medicinal products. The Commission shall publish on its website a list referring to all national registries.

Amendment 299
Proposal for a directive
Article 186 – paragraph 4 b (new)

Text proposed by the Commission	*Amendment*
	4b. The national registries referred to in paragraph 4a of this Article shall include at least the following information:

(a) the name of the marketing authorisation holder;

(b) the name of a person qualified to prescribe medicinal products;

(c) the medicinal product concerned;

(d) the type of advertising activity, referred to in Article 175(1), second subparagraph, points (b) to (g) and Article 184;

(e) the monetary value.

Amendment 300
Proposal for a directive
Article 186 – paragraph 4 c (new)

Text proposed by the Commission	*Amendment*
	4c. Marketing authorisation holders shall use the national transparency register referred to in paragraph 4a to submit the information referred to in paragraph 4b in relation to each person qualified to prescribe medicinal products in the Member State where such activity takes place.

Amendment 301
Proposal for a directive
Article 186 – paragraph 5

Text proposed by the Commission	*Amendment*
5. ***The*** paragraphs 1 to ***4*** shall not exclude the voluntary control of advertising of medicinal products by self-regulatory bodies ***and recourse to such bodies, if proceedings before such bodies are possible in addition to the judicial or administrative proceedings referred to in paragraph 1***.	5. Paragraphs 1 to ***4c*** shall not exclude the voluntary control of advertising of medicinal products by self-regulatory bodies.

Amendment 302
Proposal for a directive
Article 187 – paragraph 2 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) report activities in national registries, as laid down in Article 186 (4c).

Amendment 303
Proposal for a directive
Article 188 – paragraph 5 – introductory part

Text proposed by the Commission	*Amendment*
5. Where the competent authority of the Member State considers it necessary, in particular where there are grounds for suspecting non-compliance with the rules of this Directive, including with the principles of good manufacturing practice and good distribution practices, referred to in Articles 160 and 161, it may have its official representatives carry out the measures referred to in paragraph 1, second subparagraph at the premises or on the activities of:	5. Where the competent authority of the Member State considers it necessary, in particular where there are grounds for suspecting non-compliance with the rules of this Directive, including with the principles of good manufacturing practice and good distribution practices, referred to in Articles 160 and 161, ***or based on a risk assessment,*** it may have its official representatives carry out the measures referred to in paragraph 1, second subparagraph at the premises or on the activities of:

Amendment 304
Proposal for a directive
Article 188 – paragraph 5 – point d

Text proposed by the Commission	*Amendment*
(d) distributors of medicinal products or active substances located in third countries;	(d) distributors of medicinal products or ***manufacturers or distributors of*** active substances located in third countries;

Amendment 305
Proposal for a directive
Article 188 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. The Agency shall draw up guidelines on the use of the Union database.

Amendment 306
Proposal for a directive
Article 193 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where, in the interests of public health, the laws of a Member State so provide, the competent authorities of the Member State may require the marketing authorisation holder for medicinal products derived from human blood or human plasma to submit samples from each batch of the bulk or the medicinal product for testing by an Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose before being released into free circulation, unless the competent authorities of another Member State have previously examined the batch in question and declared it to be in conformity with the approved specifications. Member States shall ensure that any such examination is completed within 60 days of the receipt of the samples.	2. Where, in the interests of public health, the laws of a Member State so provide, the competent authorities of the Member State may require the marketing authorisation holder for medicinal products derived from human blood or human plasma to submit samples from each batch of the bulk or the medicinal product for testing by an Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose before being released into free circulation, unless the competent authorities of another Member State have previously examined the batch in question and declared it to be in conformity with the approved specifications. ***In such a case the declaration of conformity issued by another Member State shall be recognised.*** Member States shall ensure that any such examination is completed within 60 days of the receipt of the samples.

Amendment 307
Proposal for a directive
Article 194 – title

Text proposed by the Commission	*Amendment*
Processes for the preparation of medicinal products derived from ***human blood or*** human ***plasma***	Processes for the preparation of medicinal products derived from ***substances of*** human ***origin***

Amendment 308
Proposal for a directive
Article 194 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall take all necessary measures to ensure that the manufacturing and purifying processes used in the preparation of medicinal products derived from ***human blood or*** human ***plasma*** are properly validated, attain batch-to-batch consistency and guarantee, insofar as the state of technology permits, the absence of ***specific viral contamination***.	1. Member States shall take all necessary measures to ensure that the manufacturing and purifying processes used in the preparation of medicinal products derived from ***substances of*** human ***origin*** are properly validated, attain batch-to-batch consistency and guarantee, insofar as the state of technology permits, the absence of ***relevant risks for human health, including contaminations***.

Amendment 309
Proposal for a directive
Article 194 – paragraph 2

Text proposed by the Commission	*Amendment*
2. To this end manufacturers shall notify the competent authorities of the Member States of the ***method*** used to ***reduce or eliminate pathogenic viruses liable to be transmitted by medicinal products derived from*** human ***blood or human plasma***. The competent authority of the Member State may submit samples of the bulk or the medicinal product for testing by a State laboratory or a laboratory designated for that purpose, either during the examination of the application pursuant to Article 29, or after a marketing authorisation has been granted.	2. To this end manufacturers shall notify the competent authorities of the Member States of the ***methods*** used to ***ensure the quality and safety of the substances of*** human ***origin, as set out in Regulation (EU) 2024/...[SoHO Regulation]***. The competent authority of the Member State may submit samples of the bulk or the medicinal product for testing by a State laboratory or a laboratory designated for that purpose, either during the examination of the application pursuant to Article 29, or after a marketing authorisation has been granted.

Amendment 310
Proposal for a directive
Article 195 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission may suspend, revoke or vary a marketing authorisation if a serious risk to the environment or public health has been identified and not sufficiently	2. The competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission may suspend, revoke or vary a marketing authorisation if a serious risk to the environment or public health has been identified and not sufficiently

addressed by the marketing authorisation holder.	addressed by the marketing authorisation holder ***and if the risks cannot be mitigated through the grant of the conditions specified in Articles 44(1), first subparagraph, point (h) or 87(1), first subparagraph, point (c) following a decision of suspension or modification***. ***Any such decision shall take into account the clinical benefits of the medicinal product and the needs of patients, including alternative treatments available.***

Amendment 311
Proposal for a directive
Article 196 – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
(f) a serious risk to the environment or to public health via the environment has been identified and not sufficiently addressed by the marketing authorisation holder.	(f) a serious risk to the environment or to public health via the environment has been identified and not sufficiently addressed by the marketing authorisation holder ***through the grant of the conditions specified in Articles 44(1), first subparagraph, point (h), or 87(1), first subparagraph, point (c); any such decision shall also take into account the clinical benefits of the medicinal product and the needs of patients, including alternative treatments available***.

Amendment 312
Proposal for a directive
Article 200 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ensure that adequate financial resources are available to provide the staff and other resources necessary for the competent authorities to carry out the activities required by this Directive and [revised Regulation (EC) No 726/2004].	2. Member States shall ensure that adequate financial resources are available to provide the staff and other resources***, including appropriate digital infrastructure,*** necessary for the competent authorities to carry out the activities required by this Directive and [revised Regulation (EC) No 726/2004].

Amendment 313
Proposal for a directive
Article 200 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
The competent authority of the Member State may process personal health data from sources other than clinical studies to support their public health tasks and, in particular, the evaluation and monitoring to medicinal products, for the purpose of improving the robustness of the scientific assessment or verifying claims of the applicant or marketing authorisation holder.	The competent authority of the Member State may process personal health data from sources other than clinical studies***, including real world data,*** to support their public health tasks and, in particular, the evaluation and monitoring to medicinal products, for the purpose of improving the robustness of the scientific assessment or verifying claims of the applicant or marketing authorisation holder.

Amendment 314
Proposal for a directive
Article 201 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States, in applying this Directive, shall ensure that when questions arise with regard to the regulatory status of a medicinal product, in relation to their link to substances of human origin as referred to in Regulation (EU) No [SoHO Regulation], the competent authorities of the Member States shall consult the relevant authorities established under that Regulation.	1. Member States, in applying this Directive, shall ensure that when questions arise with regard to the regulatory status of a medicinal product, in relation to their link to substances of human origin as referred to in Regulation (EU) No [SoHO Regulation], the competent authorities of the Member States shall consult the ***Agency and the*** relevant authorities established under that Regulation.

Amendment 315
Proposal for a directive
Article 201 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. In order to improve regulatory certainty and cross-sectoral cooperation, the Commission shall, where necessary, organise joint meetings between the Agency and the relevant advisory and regulatory bodies established under other Union legislation to assess, for the

purposes of this Directive, emerging trends and questions on the regulatory status of products and to find agreement on common regulatory status principles. The summaries and conclusions of those joint meetings shall be made publicly available, including the opinions and conclusions of each of the respective bodies.

Amendment 316
Proposal for a directive
Article 206 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. When determining the type and level of penalties to be imposed in the case of infringements, the competent authorities of the Member States shall give due regard to all relevant circumstances of the specific infringement and to the following:
	(a) the nature, gravity and extent of the infringement;
	(b) the repetitive or singular character of the infringement;
	(c) where appropriate, the intentional or negligent character of the infringement;
	(d) any action taken by the infringing party to mitigate or remedy the damage caused;
	(e) the level of cooperation with the competent authorities, in order to remedy the infringement and mitigate the possible adverse effects of the infringement;

Amendment 317
Proposal for a directive
Article 206 – paragraph 2 – point e a (new)

Text proposed by the Commission	*Amendment*

	(ea) non-compliance with the obligations set out in Article 58a shall be subject to the imposition of effective, proportionate and dissuasive financial penalties.

Amendment 318
Proposal for a directive
Article 207 – title

Text proposed by the Commission	*Amendment*
Collection of unused or expired medicinal products	Collection ***and management*** of unused or expired medicinal products

Amendment 319
Proposal for a directive
Article 207 – paragraph 1

Text proposed by the Commission	*Amendment*
Member States shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired.	Member States shall ensure that appropriate collection ***and management*** systems are in place for medicinal products that are unused or have expired ***and that the collected medicinal products are managed properly without any technically avoidable leakage to the environment***.

Amendment 320
Proposal for a directive
Article 207 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. By ... [18 months from the date of entry into force of this Directive], Member States shall draw up national plans including measures designed to:
	(a) monitor the rates of correct and incorrect disposal of unused and expired medicinal products;
	(b) inform the general public about the environmental risks associated with incorrect disposal of medicinal products,

	in particular those that contain substances referred to in Article 22(2);
	(c) inform healthcare professionals about the environmental risks associated with incorrect disposal of unused or expired medicinal products, in particular those that contain substances referred to in Article 22(2);
	(d) increase the rate of correct disposal of unused or expired medicinal products; and
	(e) designate public or private actors, or both, responsible for the collection systems referred to in paragraph 1.

Amendment 321
Proposal for a directive
Article 207 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. Member States shall submit the national plans to the Commission.

Amendment 322
Proposal for a directive
Article 208 – paragraph 1

Text proposed by the Commission	*Amendment*
1. In order to guarantee independence and transparency, the Member States shall ensure that members of staff of the competent authority responsible for granting authorisations, rapporteurs and experts concerned with the authorisation and surveillance of medicinal products have no financial or other interests in the pharmaceutical industry that could affect their impartiality. These persons shall make an annual declaration of their financial interests.	1. In order to guarantee independence and transparency, the Member States shall ensure that members of staff of the competent authority responsible for granting authorisations, rapporteurs and experts concerned with the authorisation and surveillance of medicinal products have no ***direct or indirect*** financial or other interests in the pharmaceutical industry that could affect their impartiality ***and their independence***. These persons shall make an annual declaration of their financial interests ***and update them annually and whenever necessary***. ***The declaration shall be made available upon request.***

Amendment 323
Proposal for a directive
Article 208 – paragraph 2

Text proposed by the Commission	*Amendment*
2. In addition, the Member States shall ensure that the competent authority makes publicly available its rules of procedure and those of its committees, agendas for its meetings and records of its meetings, accompanied by decisions taken, details of votes and explanations of votes, including minority opinions.	2. In addition, the Member States shall ensure that the competent authority makes publicly available its rules of procedure and those of its committees***, including their working groups and expert groups***, agendas for its meetings and records of its meetings, accompanied by decisions taken, details of votes and explanations of votes, including minority opinions.

Amendment 324
Proposal for a directive
Article 214 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The rules of procedure of the Standing Committee on Medicinal Products shall be made publicly available.	4. The rules of procedure***, lists of participating entities of its meetings, agendas for its meetings and records of its meetings, accompanied by decisions taken, and, where applicable, details of votes and explanations of votes, including minority opinions,*** of the Standing Committee on Medicinal Products shall be made publicly available.

Amendment 325
Proposal for a directive
Article 216 – paragraph 1

Text proposed by the Commission	*Amendment*
By [OP please insert the date = 10 years following 18 months after the date of entering into force of this Directive], the Commission shall present a report to the European Parliament and the Council on the application of this Directive, including	By [OP please insert the date = 10 years following 18 months after the date of entering into force of this Directive], the Commission shall present a report to the European Parliament and the Council on the application of this Directive, including

an assessment of the fulfilment of its objectives and the resources required to implement it.	an assessment of the fulfilment of its objectives and the resources required to implement it***, including regarding the revised framework for regulatory data protection periods***.

Amendment 326
Proposal for a directive
Article 216 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. By ...[2 years from the date of entry into force of this Directive], the Commission shall submit a report to the European Parliament and Council evaluating the appropriateness of the framework of homeopathic products, in particular aspects of public health and patient protection. The report shall, where appropriate, be accompanied by a legislative proposal.

Amendment 327
Proposal for a directive
Article 216 a (new)

Text proposed by the Commission	*Amendment*
	Article 216a
	Fostering research on, and innovation and production of, medicinal products in the Union
	1. The Commission shall establish a strategy on fostering research on, and innovation and production of, medicinal products in the Union, based on the results published in the report provided for paragraph 2. Member States shall be encouraged to participate in that strategy.
	2. By... [two years from the date of entry into force of this Directive] the Commission shall present an impact assessment evaluating potential measures to be implemented at Union level and at a

Member State level to foster research on, and innovation and production of, critical medicinal products in the Union. That report shall evaluate the effect of measures such as:

(a) funding and push and pull incentives directed to foster research and innovation in the Union, including public and private funding for preclinical and clinical research and innovation;

(b) public-private partnerships in research and innovation;

(c) regulatory support for public research and innovation entities;

(d) incentives for production of critical medicinal products within the Union.

Any proposed measures shall be in line with the development of the strategic autonomy of the Union regarding medicinal products.

Amendment 328
Proposal for a directive
Annex I – point 21 – point a – introductory part

Text proposed by the Commission	*Amendment*
a) an antimicrobial stewardship plan which shall in particular outline:	a) an antimicrobial stewardship ***and access*** plan which shall in particular outline:

Amendment 329
Proposal for a directive
Annex I – point 21 – point a – point ii a (new)

Text proposed by the Commission	*Amendment*
	(iia) information about measures for a strategy to promote access, including proposed production chain capacity;

Amendment 330

Proposal for a directive
Annex I – point 21 – point a – point ii b (new)

Text proposed by the Commission	*Amendment*
	(iib) information about measures to ensure marketing approvals are received for key territories in a timely manner; and

Amendment 331
Proposal for a directive
Annex I – point 21 – point a – point ii c (new)

Text proposed by the Commission	*Amendment*
	(iic) information about measures to monitor effectiveness of stewardship and access.

Amendment 332
Proposal for a directive
Annex IV – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the name of the medicinal product, including in Braille, followed by its strength and pharmaceutical form, and, if appropriate, whether it is intended for babies, children or adults; where the medicinal product contains up to three active substances, the international non-proprietary name (INN) shall be included, or, if one does not exist, the common name;	(a) the name of the medicinal product, including in Braille, followed by its strength and pharmaceutical form, and, if appropriate, whether it is intended for babies, children or adults; where the medicinal product contains up to three active substances, the international non-proprietary name (INN) shall be included, ***unless it is already part of the name of the medicinal product,*** or, if one does not exist, the common name;

Amendment 333
Proposal for a directive
Annex IV – paragraph 1 – point g a (new)

Text proposed by the Commission	*Amendment*
	(ga) for antimicrobials, a warning that improper use and unsafe disposal of the medicinal product contributes to

antimicrobial resistance;

Amendment 334
Proposal for a directive
Annex IV – paragraph 1 – point j

Text proposed by the Commission	*Amendment*
(j) specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products***,*** ***where appropriate,*** as well as reference to any appropriate collection system in place;	(j) specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products as well as reference to any appropriate collection system in place;

Amendment 335
Proposal for a directive
Annex V – paragraph 1 – point 6 – point f

Text proposed by the Commission	*Amendment*
(f) special precautions for disposal of a ***used*** medicinal product or waste materials derived from such medicinal product***, if appropriate***. In case of antimicrobial medicinal products in addition to the precautions a warning that inappropriate disposal of the medicinal product contributes to antimicrobial resistance***.***	(f) special precautions for disposal of a medicinal product or waste materials derived from such medicinal product ***as well as any designated collection system in place***. In case of antimicrobial medicinal products in addition to the precautions a warning that inappropriate disposal of the medicinal product contributes to antimicrobial resistance***;***

Amendment 336
Proposal for a directive
Annex VI – paragraph 1 – point 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) a key information section reflecting the results of consultations with patients' organisations to ensure that the leaflet is legible, clear and easy to use;

Amendment 337
Proposal for a directive
Annex VI – paragraph 1 – point 4 – point b

Text proposed by the Commission	*Amendment*
(b) the method and, if necessary, route of administration;	(b) the method and, if necessary, route of administration***, and where relevant a description of the measuring or delivery device, as well as the relevant individual steps of medicine preparation and administration***;

Amendment 338
Proposal for a directive
Annex VI – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	The package leaflet may also contain information on the importance of therapeutic adherence and available support for adherence in the Member State.

EXPLANATORY STATEMENT

The Union general pharmaceutical legislation was established in 1965 with the dual objective of safeguarding public health and harmonising the internal market for medicines. The latest proposal of the European Commission for revision of this legislation includes a new Directive and a new Regulation to replace pharmaceutical legislation currently in force, with the overall objectives of promoting innovation, ensuring access to innovative and established medicines for patients, and creating a balanced and competitive system that keeps medicines affordable for health systems while rewarding innovation. Of the 'Pharmaceutical Package', this Directive contains all the requirements for authorisation, monitoring, labelling and regulatory protection, placing on the market and other regulatory procedures for all medicines authorised at EU and national level.

The Rapporteur supports the objectives of the European Commission's proposal and finds that a revision of current Union general pharmaceutical legislation comes at the right time: Europe is increasingly falling behind other regions in pharmaceutical research and development investments, novel technologies challenge the existing legislative framework, and the COVID-19 pandemic demonstrated the need for timely and equitable access to medicines.

Incentivising Innovation
The Rapporteur believes that increasing the number of innovative medicinal products available to Europeans is of crucial benefit to patients and society. In this regard, the Directive must present a framework for rewarding innovation which is attractive to the global pharmaceutical industry, including the wider research-based life-science environment.

Making Europe competitive is an objective which requires a multifactorial solution. However, among the key factors, which is within the scope of this Directive, is the system of incentives and namely the regulatory data protection. Regulatory data protection affects companies' decisions to invest in innovation and to bring scientific innovation to launch on the Union market. In this regard, the Rapporteur finds that the level of regulatory data protection offered on the Union market should be competitive with what is being offered in other markets. Furthermore, there should be certainty and long-term predictability regarding the level of regulatory data protection to be expected, which means that a significant amount of the total regulatory data protection should remain within the 'baseline'.

The Rapporteur agrees with the European Commission's proposal that further incentives on top of an attractive baseline of regulatory data protection may help steer innovation and finds that a definition of unmet medical need should be considered from both the individual patient and societal perspectives. That is, innovation for unmet medical need should be sufficiently incentivised, while the definitions applied for deciding which medicinal products address an unmet medical need should consider the patient perspective centrally. In this regard, the Rapporteur finds that the concept of 'quality of life' of patients should be considered.

Outside of regulatory data protection, the Rapporteur also proposes to increase the reward for completion of a paediatric investigation plan where this is completed for a different disease than the one for which a medicinal product is intended in the adult population.

Access to Medicines
The European Commission has proposed an incentive which will grant a prolongation of data protection if a medicinal product is supplied in accordance with the needs of the Member States concerned within two years from the marketing authorisation (or within three years in the case of SMEs, not-for-profit entities or companies with limited experience in the EU system). The Rapporteur opposes this measure, by which the European Commission intends to promote access to medicinal products. Firstly, because the release and continuous supply of medicinal products is not only within the control of the marketing authorisation holder but also relies on the Member State competent authorities. Thus, it would be disproportionate to place all responsibility, and direct consequences, for a failure to launch only on the marketing authorisation holder. Secondly, linking the failure to comply with the conditionality of supply in every Member State to losing out on regulatory data protection will be to the detriment of innovation, as described above. Finally, the Rapporteur is concerned about how this measure would work in relation to orphan medicinal products and ATMPs.

Rather, the Rapporteur proposes to place an obligation on marketing authorisation holders to submit in every Member State, which requested them to do so, an application for pricing and reimbursement. In case of non-compliance with the obligation, a proportional financial penalty shall be applied by affected Member States. This can promote access to medicinal products across Europe, while ensure predictability in the expectations, as well as in the possible penalties, of marketing authorisation holders. Marketing authorisation holders of orphan medicinal products and ATMPs shall be subject to an adapted obligation, and in special cases the European Commission may exempt specific medicinal products. To further the processes surrounding the obligation, the European Commission shall set up an "EU Access to Medicines Notification System".

Environmental Health
The Rapporteur welcomes the initiative of the European Commission to strengthen measures related to the environmental impact of medicines, and, by extension, the impact on human health of negative environmental impacts. However, these should be proportionate and not unjustly have a negative effect on patients.

Notably, the Rapporteur finds that in case of serious risks to the environment a marketing authorisation may be suspended or varied, but should only be revoked in cases where those risks clearly outweigh the loss of positive therapeutic effect of the medicine. The Rapporteur also asks the Commission to ensure that the proper guidelines for conducting environmental risk assessments for antimicrobials other than antibiotics are in place before obligations in this regard shall apply. When specifying technical details for the environmental risk assessments, all relevant stakeholders shall be consulted. As regards medicines for which a prescription is needed, the Rapporteur wishes to ensure continued patient access to antimicrobials not for systemic use.

The Rapporteur suggests to place extended obligations on the Member States with regard to the appropriate collection and management of unused or expired medicines. In this regard, Member States are asked to draw up national plans, including measures designed to inform the public and healthcare professionals about environmental risks in regard to incorrect disposal of medicines and increase its rate of correct disposal of medicines.

Patient-centred Information

The Rapporteur places emphasis on the importance of properly ensuring accurate information to patients about the medicines they consume. The first objective of package leaflets shall be to meet the needs of patients. Whether the leaflet is in electronic or in paper format, its content must be legible, clear and easy to use. The Rapporteur proposes that the package leaflet shall contain a 'key information section' to support this objective.

The addition by the European Commission of electronic information can, in this regard, benefit some patients. However, where no other position has been taken, the information should be available in the form of both paper leaflets and electronic product information. The decision to make information available only electronically shall lay with each Member State, and in this case, patients shall be made aware of their right to a printed copy. However, where the medicinal product is not intended to be delivered directly to, and administered by, the patient the Commission may take the decision to make only the electronic product information mandatory.

Awareness cards shall be available in paper format, or in both paper format and electronically, to support that this information is duly received by patients. The Rapporteur supports the proposal of the European Commission that Member States may make exemptions to the language requirements of labelling, however, patients should, in this case, still be able to request a copy in the official language of their Member State.

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

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

Entity and/or person
2K/DENMARK
Abbvie
Advanced Accelerator Applications
Association of the European Self-Care Industry (AESGP)
Affordable Medicines Europe
Alexion
Alliance for Regenerative Medicines (ARM)
American Chamber of Commerce to the European Union
Amgen
Astellas Pharma
AstraZeneca
BioMarin
Bristol Myers Squibb
Boehringer Ingelheim
Childhood Cancer International Europe (CCI Europe)
Confederation of Danish Industry (DI)
Deutsche Stiftung Weltbevölkerung (DSW)
European Association of E-Pharmacies (EAEP)
Edwards Lifesciences
European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
European Federation of National Associations of Water Services (EurEau)
European Federation of Pharmaceutical Industries and Associations (EFPIA)
European Healthcare Distribution Association (GIRP)
EuropaBio - The European Association for Bioindustries
European Patients' Forum (EPF)
European Society for Paediatric Oncology (SIOP Europe)
German Medicines Manufacturers' Association (BAH)
Gilead Sciences
GRAKOM
GlaxoSmithKline Pharmaceuticals (GSK)
Intergraf
International Association of Mutual Benefit Societies (AIM)
International Diabetes Federation (IDF)
Johnson & Johnson
Medical Leaflets = Patient Safety (MLPS)
Medicines for Europe
MSD Europe
Novartis

Novo Nordisk
Novo Nordisk Foundation
Pfizer
PTC Therapeutics
Regulatory Institute
Roche
Sanofi
Servier
Standing Committee of European Doctors (CPME)
Stibo Complete
Takeda
Vaccines Europe
Vertex Pharmaceuticals
Viatris

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

22.2.2024

OPINION OF THE COMMITTEE ON INDUSTRY, RESEARCH AND ENERGY

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

on the proposal for a directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC
(COM(2023)0192 – C9-0143/2023 – 2023/0132(COD))

Rapporteur for opinion: Henna Virkkunen

SHORT JUSTIFICATION

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

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

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

Regulatory data protection (RDP)

Medical research and development (R&D) usually takes a long time, costs a lot, and has many uncertainties. To encourage R&D, we need strong rules for intellectual property (IP) and good incentives. The proposed Directive recommends reducing the protection period for regulatory data, which could be extended under certain conditions. In line with the European Council's conclusions in March 2023, the Rapporteur agrees that it's important to strengthen, not weaken, the protection of regulatory data and other incentives in Europe.

Unmet medical needs

The goal of medical advancements is to address Unmet Medical Needs (UMN), which can take various forms and change quickly. Since the UMN concept is important in the pharmaceutical field, having a clear definition is crucial. The Rapporteur is worried that the proposed UMN

definition might hinder progress in preventing, treating, and caring for patients. UMN assessment should consider a wide range of patient outcomes and the benefits for society as a whole.

Bolar exemption

The Bolar exemption currently allows third parties to conduct necessary studies and trials on patented inventions to promote the introduction of generic medicines and biosimilars. The Commission suggests expanding this exemption to include activities like generating data for health assessments and the pricing and reimbursement process. However, this could weaken the protection of intellectual property (IP) rights for pharmaceuticals in the EU, leading to less confidence in the European IP framework and potential harm to EU competitiveness. The Rapporteur recommends limiting the Bolar exemption to activities solely related to obtaining marketing authorization.

Environmental effects

Evaluating and mitigating the environmental footprint is crucial. While environmental considerations are vital, patients' needs and swift access to innovative therapies should remain the primary focus.

Conclusion

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

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

AMENDMENTS

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

Amendment 1
Proposal for a directive
Recital 3

Text proposed by the Commission	*Amendment*
(3) This revision is part of the implementation of the Pharmaceutical strategy for Europe and aims to promote innovation, in particular for unmet medical	(3) This revision is part of the implementation of the Pharmaceutical strategy for Europe and aims to promote innovation, in particular for unmet medical

needs, while reducing regulatory burden and the environmental impact of medicines; ensure access to innovative and established medicines for patients, with special attention to enhancing security of supply and addressing risks of shortages, taking into account the challenges of the smaller markets of the Union; and create a balanced and competitive system that keeps medicines affordable for health systems while rewarding innovation.	needs, ***and establishes a conducive environment for the research, development, and manufacturing of pharmaceuticals within the Union*** while reducing regulatory burden and ***administrative burden as well as*** the environmental impact of medicines; ensure access to innovative and established medicines for patients, with special attention to enhancing security of supply and addressing risks of shortages, taking into account the challenges of the smaller markets of the Union; and create a balanced and competitive system that keeps medicines affordable for health systems while rewarding innovation.

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

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

Amendment 3
Proposal for a directive
Recital 4 b (new)

Text proposed by the Commission	*Amendment*
	(4 b) This Directive acknowledges that fostering a competitive pharmaceutical industry within the EU, bolstering EU-

based clinical trials, and localizing the manufacture of active pharmaceutical ingredients are complementary objectives that enhance the Union's strategic health autonomy while increasing the affordability, accessibility, and availability of medicinal products, thereby supporting a more resilient and sustainable European health ecosystem.

Amendment 4
Proposal for a directive
Recital 11

Text proposed by the Commission	*Amendment*
(11) The Directive should work in synergy with the Regulation to enable innovation and promote competitiveness of the ***Union*** pharmaceutical industry, in particular ***SMEs***. In this respect a balanced system of incentives is proposed that rewards innovation especially in areas of unmet medical need and innovation that reaches patients and improves access across the Union. To make the regulatory system more efficient and innovation-friendly the Directive also aims at reducing administrative burden and simplifying procedures for undertakings.	(11) The Directive should work in synergy with the Regulation to enable innovation and promote competitiveness of the ***EU's*** pharmaceutical industry, in particular ***of SMEs. Furthermore, it aims to prioritize the expansion of EU-based clinical trials and the local production of active pharmaceutical ingredients, thereby reinforcing the strategic autonomy of the European health ecosystem***. In this respect a balanced system of incentives is proposed that rewards innovation especially in areas of unmet medical need***, EU-based innovation*** and innovation that reaches patients and improves access across the Union. To make the regulatory system more efficient and innovation-friendly the Directive also aims at reducing administrative burden and simplifying procedures for undertakings.

Amendment 5
Proposal for a directive
Recital 11 a (new)

Text proposed by the Commission	*Amendment*
	(11 a) This Directive should be in line with the EU's industrial, digital and trade aspirations. The European life sciences sector, and the pharmaceutical industry in

particular, are essential in ensuring EU's competitiveness. Maintaining and strengthening robust R&D sectors are key pillars of the shared European sovereignty in an increasingly competitive geopolitical context.

Amendment 6
Proposal for a directive
Recital 11 b (new)

Text proposed by the Commission	*Amendment*
	(11 b) However, to improve research and development in the pharmaceutical sphere stemming from the Union, as well as contributing to open EU strategic autonomy, it could be beneficial to establish a direct link between preclinical studies conducted in the Union and an incentive prolonging data protection for a medicinal product. Therefore, an incentive to extend the data protection period is proposed where a company can demonstrate this.

Amendment 7
Proposal for a directive
Recital 26

Text proposed by the Commission	*Amendment*
(26) In order to reward the compliance with all the measures included in the agreed paediatric investigation plan, for products covered by a supplementary protection certificate, if relevant information on the results of the studies conducted is included in the product information, a reward should be granted in the form of ***a six month*** extension of the supplementary protection certificate created by [Regulation (EC) No 469/2009 of the European Parliament and of the Council[42] - OP please replace reference by new instrument when adopted].	(26) In order to reward the compliance with all the measures included in the agreed paediatric investigation plan, for products covered by a supplementary protection certificate, if relevant information on the results of the studies conducted is included in the product information, a reward should be granted in the form of ***an*** extension of the supplementary protection certificate created by [Regulation (EC) No 469/2009 of the European Parliament and of the Council[42] - OP please replace reference by new instrument when adopted].

[42] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152, 16.6.2009, p. 10).

[42] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152, 16.6.2009, p. 10).

Amendment 8
Proposal for a directive
Recital 31

Text proposed by the Commission	*Amendment*
(31) Directive 2010/63/EU of the European Parliament and of the Council[43] 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 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 EMA and 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 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.	(31) Directive 2010/63/EU of the European Parliament and of the Council[43] 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 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 ***undertaken as a last resort and be*** optimised in order to provide the most satisfactory results whilst using the minimum number of animals***. The marketing authorisation applicant should not carry out animal tests in case scientifically satisfactory non-animal testing methods are available. Where scientifically satisfactory non-animal testing methods are not available, applicants that use animal testing should ensure that the principle of replacement, reduction and refinement of animal testing for scientific purposes has been with regard to any animal study conducted for the purpose of supporting the application***. The procedures of such testing should be designed to avoid causing pain, suffering, distress or lasting harm to animals and should follow the available EMA and 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 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.
[43] 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).	[43] 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 9
Proposal for a directive
Recital 39

Text proposed by the Commission	*Amendment*
(39) In the interest of as broad as possible access to medicinal products, a Member State that has an interest in receiving access to a particular medicinal product undergoing authorisation through the decentralised and mutual recognition procedures should be able to opt-into that procedure.	(39) In the interest of as broad as possible access to medicinal products, a Member State that has an interest in receiving access to a particular medicinal product undergoing authorisation through the decentralised and mutual recognition procedures should be able to opt-into that procedure. ***A Member State who did not join the initial application for the decentralised procedure within 30 days of the submission of the application should still have a second opportunity to opt into the procedure at a later point, in this case they should immediately inform the applicant and the competent authority of the reference Member State for the decentralised procedure.***

Amendment 10
Proposal for a directive

Recital 49 a (new)

Text proposed by the Commission	*Amendment*
	(49 a) Practices in procurement procedures for medicines differ between Member States and long-term availability is rarely a primary consideration. The 2014 Procurement Directive encourages a more strategic approach through award criteria, including criteria beyond price. Using the lowest price as the main selection criterion may reduce incentives for the industry to build for long-term supply in the EU. At the same time, vulnerability may be increased when public procurement procedures award contracts to a single company. Where challenges with access to a critical medicine and related affordability may be an issue, Member States can work together to increase buying power. Joint procurement between Member States can act as a powerful tool to improve access, affordability and security of supply, of particular benefit in smaller EU markets. This can improve the negotiating position of Member States to incentivise production capacities, as well as diversifying supply chains.

Amendment 11
Proposal for a directive
Recital 53

Text proposed by the Commission	*Amendment*
(53) A marketing authorisation holder should ensure the appropriate and continuous supply of a medicinal product throughout its lifetime irrespective of whether that medicinal product is covered by a supply incentive or not.	(53) A marketing authorisation holder should***, within its responsibilities,*** ensure the appropriate and continuous supply of a medicinal product throughout its lifetime irrespective of whether that medicinal product is covered by a supply incentive or not.

Amendment 12
Proposal for a directive

Recital 59 a (new)

Text proposed by the Commission	*Amendment*
	(59 a) If negotiations between Member States and developers are conducted sincerely but fail to result in an agreement on the distribution and ongoing supply of a therapy, the introduction of a mediation process is warranted. This mechanism, overseen by the Commission, should safeguard developers from unfairly missing out on incentives due to factors beyond their influence.

Amendment 13
Proposal for a directive
Article 18 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
For integral combinations of a medicinal product and a medical device the marketing authorisation applicant shall submit data establishing the safe and effective use of the integral combination of the medicinal product and the medical device.	For integral combinations of a medicinal product and a medical device the marketing authorisation applicant shall submit data establishing the safe and effective use of the integral combination of the medicinal product and the medical device***, particularly for pediatric patients, encompassing aspects such as storage, assembly, cleanliness, and the technique required for application or intake***.

Amendment 14
Proposal for a directive
Article 18 – paragraph 1 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	In case of combined products intended for paediatric use, a risk/benefit analysis should be taken into account following the opinion of the Paediatric Working Party of the Agency, established in accordance with Article 142 of the Regulation.

Amendment 15
Proposal for a directive
Article 18 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The application for a marketing authorisation for an integral combination of a medicinal product with a medical device shall include the ***documentation*** supporting the compliance of the medical device part with the general safety and performance requirements as referred to in paragraph 2 in accordance with Annex II, including, where relevant, the conformity assessment report by a notified body.	3. The application for a marketing authorisation for an integral combination of a medicinal product with a medical device shall include the ***evidence*** supporting the compliance of the medical device part with the general safety and performance requirements as referred to in paragraph 2 in accordance with Annex II, including, where relevant, the conformity assessment report by a notified body.

Amendment 16
Proposal for a directive
Article 24 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The setting-up of the system of ERA monographs shall be based on a risk-based prioritisation of active substances.	2. The setting-up of the system of ERA monographs shall be based on a risk-based prioritisation of active substances ***and data requested***.

Amendment 17
Proposal for a directive
Article 24 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Agency in cooperation with the competent authorities of the Member States shall conduct a proof-of-concept pilot of ERA monographs to be completed within three years after entering into force of this Directive.	4. The Agency in cooperation with the competent authorities of the Member States shall conduct a proof-of-concept pilot of ERA monographs to be completed within three years after entering into force of this Directive ***while taking into account outcomes from relevant Union initiatives, such as with regard to animal testing***.

Amendment 18
Proposal for a directive
Article 24 – paragraph 5 – point e a (new)

Text proposed by the Commission	*Amendment*
	(e a) the risk-based prioritisation of data requirements for active substances, including to avoid unnecessary animal testing.

Amendment 19
Proposal for a directive
Article 34 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The applicant shall inform all the competent authorities of all Member States of its application at the time of submission. The competent authority of a Member State ***may request for justified public health reasons*** to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the decentralised procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay.	3. The applicant shall inform all the competent authorities of all Member States of its application at the time of submission. The competent authority of a Member State ***shall have the possibility*** to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the decentralised procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay.

Amendment 20
Proposal for a directive
Article 34 – paragraph 4 – subparagraph 2

Text proposed by the Commission	*Amendment*
The competent authority of the reference Member State for the decentralised procedure shall summarise the deficiencies in writing. On this basis, the competent authority of the reference Member State for the decentralised procedure shall inform the applicant and the competent authorities of the Member States concerned accordingly and set a time limit to address the deficiencies. The application shall be suspended until the applicant addresses the	The competent authority of the reference Member State for the decentralised procedure shall summarise the deficiencies in writing. On this basis, the competent authority of the reference Member State for the decentralised procedure shall inform the applicant and the competent authorities of the Member States concerned accordingly and set a time limit ***of minimum 14 days*** to address the deficiencies. The application shall be

deficiencies. If the applicant fails to address those deficiencies within the time limit set by the competent authority of the reference Member State for the decentralised procedure, the application shall be considered as withdrawn.

suspended until the applicant addresses the deficiencies. If the applicant fails to address those deficiencies within the time limit set by the competent authority of the reference Member State for the decentralised procedure, the application shall be considered as withdrawn.

Amendment 21
Proposal for a directive
Article 34 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Within 120 days after validation of the application, the competent authority of the reference Member State for the decentralised procedure shall prepare an assessment report, a summary of product characteristics, the labelling and the package leaflet and shall send them to the Member States concerned and to the applicant.	5. Within 120 days after validation of the application, the competent authority of the reference Member State for the decentralised procedure shall prepare an assessment report, a summary of product characteristics, the labelling and the package leaflet and shall send them to the Member States concerned and to the applicant. ***During this period, a competent authority of a Member State may request to enter the procedure after validation and shall inform the applicant and the competent authority of the reference Member State for the decentralised procedure.***

Amendment 22
Proposal for a directive
Article 36 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The applicant shall inform the competent authorities of all Member States of its application at the time of submission. The competent authority of a Member State ***may request for justified public health reasons*** to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the mutual recognition procedure of its request within 30 days from the date of submission of the	4. The applicant shall inform the competent authorities of all Member States of its application at the time of submission. The competent authority of a Member State ***shall have the possibility*** to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the mutual recognition procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the

application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay.

competent authorities of those Member States entering the procedure with the application without undue delay.

Amendment 23
Proposal for a directive
Article 36 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4 a. In order to examine an application submitted in accordance with Articles 6 and 9 to 14, the competent authorities of the Member States shall verify within 20 days whether the particulars and documentations submitted in support of the application comply with Articles 6 and 9 to 14 ('validation'), and examine whether the conditions for issuing a marketing authorization set out in Articles 43 to 45 are complied with.

Amendment 24
Proposal for a directive
Article 43 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The competent authorities of the Member States shall, without undue delay, make publicly available the national marketing authorisation together with the summary of product characteristics, the package leaflet as well as any conditions established in accordance with Articles 44, 45 and any obligations imposed subsequently in accordance with Article 87, together with any deadlines for the fulfilment of those conditions and obligations for each medicinal product that they have authorised.	3. The competent authorities of the Member States shall, without undue delay, make publicly available the national marketing authorisation together with the summary of product characteristics, the package leaflet***, the antimicrobial stewardship plan and special information requirements referred to in Article 17 (1) and Annex I*** as well as any conditions established in accordance with Articles 44, 45 and any obligations imposed subsequently in accordance with ***Article 17 (2) and*** Article 87, together with any deadlines for the fulfilment of those conditions and obligations for each medicinal product that they have authorised.

Amendment 25
Proposal for a directive
Article 81 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The regulatory data protection period shall be ***six*** years from the date when the marketing authorisation for that medicinal product was granted in accordance with Article 6(2). For marketing authorisations that belong to the same global marketing authorisation the period of data protection shall start from the date when the initial marketing authorisation was granted in the Union.	1. The regulatory data protection period shall be ***nine*** years from the date when the marketing authorisation for that medicinal product was granted in accordance with Article 6(2). For marketing authorisations that belong to the same global marketing authorisation the period of data protection shall start from the date when the initial marketing authorisation was granted in the Union.

Amendment 26
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 1 – point a – introductory part

Text proposed by the Commission	*Amendment*
(a) 24 months, where the marketing authorisation holder demonstrates that the conditions referred to in Article 82(1) are fulfilled within two years, from the date when the marketing authorisation was granted or, within ***three*** years from that date for any of the following entities:	(a) 24 months, where the marketing authorisation holder demonstrates that the conditions referred to in Article 82(1) are fulfilled within two years, from the date when the marketing authorisation was granted or, within ***four*** years from that date for any of the following entities:

Amendment 27
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(a a) 12 months, where the marketing authorisation holder demonstrates that significant preclinical development of the medicinal product has been done within the Union as referred to in Article 82a;

Amendment 28

Proposal for a directive
Article 81 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) ***six*** months, where the marketing authorisation applicant demonstrates at the time of the initial marketing authorisation application that the medicinal product addresses an unmet medical need as referred to in Article 83;	(b) ***12*** months, where the marketing authorisation applicant demonstrates at the time of the initial marketing authorisation application ***or subsequent variation*** that the medicinal product addresses an unmet medical need ***at least in one of its indications*** as referred to in Article 83;

Amendment 29
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) ***six*** months, for medicinal products containing a new active substance, where the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency;	(c) ***12*** months, for medicinal products containing a new active substance, where the clinical trials supporting the initial marketing authorisation application ***or subsequent variation*** use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency ***in consultation with health technology assessment authorities, set out in a delegated act in accordance with article 215***;

Amendment 30
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 1 – point d a (new)

Text proposed by the Commission	*Amendment*
	(d a) 12 months, where the marketing authorisation applicant has submitted a clinical trial application for a new medicinal product within the territory of the EU;

Amendment 31
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 1 – point d b (new)

Text proposed by the Commission	*Amendment*
	(d b) 12 months, where the marketing authorisation applicant supports the establishment of public-private partnerships, University Hospital Institutes, centres of excellence and bioclusters to accelerate research and development of a new medicinal product;

Amendment 32
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 1 – point d c (new)

Text proposed by the Commission	*Amendment*
	(d c) 12 months, for medicinal products containing a majority, as defined by the Agency, of critical active pharmaceutical ingredients produced within the EU.

Amendment 33
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
In the case of a conditional marketing authorisation granted in accordance with Article 19 of [revised Regulation (EC) No 726/2004] the prolongation referred to in the first subparagraph, point (b), shall only apply if, ***within four years of the granting of the conditional marketing authorisation,*** the medicinal product has been granted a marketing authorisation in accordance with Article 19(7) of [revised Regulation (EC) No 726/2004.	In the case of a conditional marketing authorisation granted in accordance with Article 19 of [revised Regulation (EC) No 726/2004] the prolongation referred to in the first subparagraph, point (b), shall only apply if, ***during the regulatory data protection period*** the medicinal product has been granted a marketing authorisation in accordance with Article 19(7) of [revised Regulation (EC) No 726/2004. ***The prolongations referred to in the first subparagraph, points (b), (c) and (d), may each only be granted once and may only be granted during the period of regulatory data protection referred to in paragraph (1).***

Amendment 34

Proposal for a directive
Article 81 – paragraph 2 – subparagraph 3

Text proposed by the Commission	*Amendment*
The prolongation referred to in the first subparagraph, point (d), may only be granted once.	***deleted***

Amendment 35
Proposal for a directive
Article 81 – paragraph 2 – subparagraph 3 a (new)

Text proposed by the Commission	*Amendment*
	The above incentives may be combined up to a maximum of 13 years.

Amendment 36
Proposal for a directive
Article 82 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
The prolongation of the data protection period referred to in Article 81(2), first subparagraph, point (a), shall only be granted to medicinal products if they are ***released and continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the*** patients in the Member States in which the marketing authorisation is valid.	The prolongation of the data protection period referred to in Article 81(2), first subparagraph, point (a), shall only be granted to medicinal products if they are ***made available to*** patients ***or prescribing doctors who requested the medicinal product,*** in the Member States in which the marketing authorisation is valid.

Amendment 37
Proposal for a directive
Article 82 – paragraph 2 – subparagraph 3 – introductory part

Text proposed by the Commission	*Amendment*
The application for a variation shall contain documentation from the Member States in which the marketing authorisation is valid. Such documentation shall:	The application for a variation shall contain documentation from the Member States ***competent authority*** in which the marketing authorisation is valid. Such

documentation shall:

Amendment 38
Proposal for a directive
Article 82 – paragraph 2 – subparagraph 4 a (new)

Text proposed by the Commission	*Amendment*
	Where the conditions set out in paragraph 1 have not been fully satisfied within the time set out in Article 81(2), first subparagraph, point (a), due to duly justified circumstances out of the control of the marketing authorisation holder, the Member State shall confirm the conditions in paragraph 1 have been satisfied in their territory, subject to guarantee that these conditions will be fulfilled in an acceptable period of time agreed between the marketing authorisation holder and the Member State. Where the conditions set out in paragraph 1 cannot be fully satisfied due to circumstances fully within the control of the Member State, the Member State shall confirm the conditions in paragraph 1 have been satisfied in their territory.

Amendment 39
Proposal for a directive
Article 82 – paragraph 3

Text proposed by the Commission	*Amendment*
3. To receive the documentation referred to in paragraph 2, third subparagraph, the marketing authorisation holder shall make a request to the relevant Member State. Within 60 days from the request of the marketing authorisation holder, the ***Member State*** shall issue a confirmation of compliance or, a reasoned statement of non-compliance or alternatively provide a statement of non-objection to prolong the period of regulatory data protection pursuant to this	3. To receive the documentation referred to in paragraph 2, third subparagraph, the marketing authorisation holder shall make a request to the relevant Member State ***competent authority***. Within 60 days from the request of the marketing authorisation holder, the ***competent authority*** shall issue a confirmation of compliance or, a reasoned statement of non-compliance ***based on objective and verifiable criteria,*** or alternatively provide a statement of non-objection to prolong the period of regulatory data protection

Article.	pursuant to this Article. ***When a competent authority issues a justified statement of non-fulfilment, it must detail the requisite actions that would allow the conditions to be met and enable the resubmission of a request for confirmation of fulfilment within a reasonable time frame. The authority shall subsequently provide a confirmation of fulfilment or a reasoned statement of non-fulfilment within two months from the date of the resubmission request.***
	The Commission is tasked with creating a mediation mechanism via implementing acts. This mechanism will support dialogue between developers and Member States to address disputes arising from a declaration of non-compliance by a Member State after earnest negotiations, or due to negotiation delays. Within this framework, there will be an option for a Commission decision that can supersede the documents referred to in paragraph 2.

Amendment 40
Proposal for a directive
Article 82 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
In cases where a Member State has not replied to the application of the marketing authorisation holder within the deadline referred to in paragraph 3, it shall be considered that a statement of non-objection has been provided.	In cases where a Member State has not replied to the application of the marketing authorisation holder within the deadline referred to in paragraph 3, it shall be considered that a statement of non-objection has been provided. ***Should a Member State fail to adhere to the deadlines specified in Articles 2 and 6 of Directive 89/105/EEC, the conditions outlined in paragraph 1 will cease to be applicable within that Member State's jurisdiction with regard to the extension period.***

Amendment 41
Proposal for a directive

Article 82 – paragraph 4 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Time limits other than those set out in paragraphs 1 to 3 may apply if a Member State and a marketing authorization holder reach an agreement to that effect.

Amendment 42
Proposal for a directive
Article 82 – paragraph 4 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	The Commission shall ensure that Marketing Authorisation Holders are not unduly prevented from receiving the incentives for actions beyond their control.

Amendment 43
Proposal for a directive
Article 82 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The Commission shall check the application referred to in paragraph 2, subparagraph 2, and grant approval or rejection to the prolongation referred to in Article 81(2). In those cases in which one or more Member States have issued a reasoned statement for refusal of the prolongation, the Commission shall ensure that the reasons described are justified and substantiated. The Commission shall ensure that Marketing Authorisation Holders are not unduly prevented from receiving the incentives for actions beyond their control.

Amendment 44
Proposal for a directive
Article 82 – paragraph 4 b (new)

Text proposed by the Commission	*Amendment*
	4b. The Commission shall make publicly available any information related to the decision taken on the grant or refusal of the prolongation of the data exclusivity period after deletion of information of a commercially confidential nature.

Amendment 45
Proposal for a directive
Article 82 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Commission, based on the experience of Member States and relevant stakeholders, may adopt ***implementing*** measures relating to the procedural aspects outlined in this Article and regarding the conditions mentioned in paragraph 1. Those ***implementing*** acts shall be adopted in accordance with the procedure referred to in Article ***214(2)***.	6. The Commission, based on the experience of Member States and relevant stakeholders, may adopt ***delegated*** measures relating to the procedural aspects outlined in this Article and regarding the conditions mentioned in paragraph 1. Those ***delegated*** acts shall be adopted in accordance with the procedure referred to in Article ***215***.

Amendment 46
Proposal for a directive
Article 82 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6 a. The Commission, via implementing acts, shall compile a list of products that, either due to their nature or other duly justified and accredited limiting factors or technical specificities, shall be exempt from the stipulations outlined in Article 81(2), point (a), and within this same Article 81, paragraphs 1 to 7. These specified products will be granted an automatic extension of the data protection period for 12 months, as detailed in Article 81(2), point (a). The adoption of these implementing acts shall proceed in line with the examination procedure described in Article 214(2) and

(3).

Amendment 47
Proposal for a directive
Article 82 a (new)

Text proposed by the Commission	*Amendment*
	Article 82a
	Prolongation of the data protection period for medicinal products developed primarily within the Union
	1. A regulatory data protection period of one year shall be granted for a medicinal product if the marketing authorisation holder can demonstrate that the majority of its preclinical development was performed in the Union, even if another independent legal entity performed those studies, in initial stages of development, before the marketing authorisation holder acquired it.
	2. By [OP please insert the date =12 months after the date of entering into force of this Directive] the Commission shall adopt a delegated act setting out the procedural aspects regarding the conditions mentioned in paragraph 1. Those delegated acts shall be adopted in accordance with the procedure referred to in Article 215. Before the adoption of the delegated act, the Commission shall publish a study on the most adequate indicators to evaluate that the provision in paragraph 1 is met. with a particular focus on those indicators that could most effectively promote research and development within the Union, particularly for SMEs.
	3. The Commission shall adopt delegated measures relating to the procedural aspects outlined in this Article and regarding the conditions mentioned in paragraph 1. Those delegated acts shall be adopted in accordance with the procedure referred to in Article 215.

When setting up the conditions mentioned in paragraph 1, the Commission shall take into account the conclusions drawn from the study mentioned in paragraph 2.

Amendment 48
Proposal for a directive
Article 83 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the use of the medicinal product results in a meaningful reduction in disease morbidity or mortality for the relevant patient population.	(b) the use of the medicinal product results***:***
	(i) in a meaningful reduction in disease morbidity or mortality***,*** for the relevant patient population ***or***
	(ii) a meaningful prevention, delay of the onset, or delay of progression of the disease or its complications.

Amendment 49
Proposal for a directive
Article 83 – 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 of [revised Regulation (EC) No 726/2004].	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 of [revised Regulation (EC) No 726/2004]***, representatives of patients' organisations in the relevant disease areas, healthcare professionals, representatives of pharmaceutical industry, members from patient organizations related to the pertinent disease areas, and other relevant stakeholders***.

Amendment 50
Proposal for a directive

Article 86 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Where an application for marketing authorisation, includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a six-month extension of the period referred to in Article 13, paragraphs 1 and 2 of [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted].	Where an application for marketing authorisation, includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a six-month extension of the period referred to in Article 13, paragraphs 1 and 2 of [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted]. ***Where the agreed paediatric investigation plan is conducted in relation to a disease that is different from the one for which the medicinal product is intended in the adult population, the holder of the patent or supplementary protection certificate shall be entitled to a 12-month extension of the period.***

Amendment 51
Proposal for a directive
Article 147 – paragraph 1 – subparagraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(a a) maintain the market adequately supplied with the registered products, in an adequate and continuous manner, so that the needs of patients are covered;

Amendment 52
Proposal for a directive
Article 147 – paragraph 1 – subparagraph 1 – point g

Text proposed by the Commission	*Amendment*
(g) use only active substances that have been manufactured in accordance with good manufacturing practice for active substances and distributed in accordance with good distribution practices for active substances;	(g) use only active substances that have been manufactured in accordance with good manufacturing practice for active substances and distributed in accordance with good distribution practices for active substances***, which include reliable, constant and timely delivery of the active***

substances to the manufacturing authorization holders;

Amendment 53
Proposal for a directive
Article 147 – paragraph 1 – subparagraph 1 – point j a (new)

Text proposed by the Commission	*Amendment*
	(j a) comply with the risk mitigating measures in accordance with Article 22(4). In this regard, they shall comply and permit representatives of competent authorities of Member States to access their manufacturing premises, sites, and any outdoor facilities and effluents at any time. This obligation shall also apply where decentralised manufacturing or testing takes place.

Amendment 54
Proposal for a directive
Article 147 – paragraph 1 – subparagraph 3 a (new)

Text proposed by the Commission	*Amendment*
	Manufacturing authorisation holders may diversify their contracts with manufacturer or distributors of active substances if needed to ensure an adequate, constant and timely provision to comply with their public service obligations for supply.

Amendment 55
Proposal for a directive
Article 195 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission may suspend***, revoke*** or vary a marketing authorisation if a serious risk to the environment ***or*** public health has	2. The competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission may suspend or vary a marketing authorisation if a serious risk to the environment***, including*** public health***,***

been identified and not sufficiently addressed by the marketing authorisation holder.	has been identified and not sufficiently addressed by the marketing authorisation holder***, with the exception of medicinal products authorised before 30 October 2005 to avoid restricting patients' access to existing treatments***. ***Should the environmental risks, which also encompass public health dangers, surpass the therapeutic benefits for the intended patients and if these risks are not adequately reducible, the relevant Member State authorities or the Commission may revoke the marketing authorization of the holder.***

Amendment 56
Proposal for a directive
Article 196 – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
(f) a serious risk to ***the environment or to public health via*** the environment has been identified and not sufficiently addressed by the marketing authorisation holder.	(f) a serious risk to the environment has been identified and not sufficiently addressed by the marketing authorisation holder ***via conditions laid out in Articles 44(h) or 87(c)***.

Amendment 57
Proposal for a directive
Article 208 a (new)

Text proposed by the Commission	*Amendment*
	Article 208a
	Fostering research, innovation and production of medicinal products in the Union
	1. The Commission shall establish a strategy on research, innovation and production of medicinal products in the Union, based on the results published in the report defined in paragraph 2. Member States shall be encouraged to participate in this strategy.
	2. By... [two years after the date of entry

into force of this Directive] the Commission shall present an impact assessment evaluating potential measures to be implemented at Union level, and at a Member State level to foster research, innovation and production of critical medicinal products in the Union. This report shall evaluate the effect of measures such as:

(a) funding and push and pull incentives directed to foster research and innovation in the Union, including public and private funding for preclinical and clinical research and innovation;

(b) public-private partnerships in research and innovation;

(c) regulatory support for public research and innovation entities;

(d) incentives for production of critical medicinal products inside the Union. Proposed measures shall be in line with developing a strategic autonomy for the Union regarding medicinal products.

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

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

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

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

PROCEDURE – COMMITTEE ASKED FOR OPINION

Title	Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC
References	COM(2023)0192 – C9-0143/2023 – 2023/0132(COD)
Committee responsible Date announced in plenary	ENVI 14.9.2023
Opinion by Date announced in plenary	ITRE 14.9.2023
Rapporteur for the opinion Date appointed	Henna Virkkunen 5.10.2023
Discussed in committee	28.11.2023
Date adopted	22.2.2024
Result of final vote	+: 34 –: 26 0: 2
Members present for the final vote	Hildegard Bentele, Michael Bloss, Marc Botenga, Martin Buschmann, Cristian-Silviu Buşoi, Jerzy Buzek, Maria da Graça Carvalho, Ignazio Corrao, Beatrice Covassi, Josianne Cutajar, Nicola Danti, Marie Dauchy, Christian Ehler, Nicolás González Casares, Christophe Grudler, Henrike Hahn, Robert Hajšel, Ivo Hristov, Ivars Ijabs, Romana Jerković, Seán Kelly, Łukasz Kohut, Zdzisław Krasnodębski, Marisa Matias, Eva Maydell, Marina Mesure, Angelika Niebler, Ville Niinistö, Johan Nissinen, Mauri Pekkarinen, Tsvetelina Penkova, Morten Petersen, Manuela Ripa, Sara Skyttedal, Maria Spyraki, Riho Terras, Grzegorz Tobiszowski, Henna Virkkunen, Pernille Weiss
Substitutes present for the final vote	Pascal Arimont, Laura Ballarín Cereza, Jakop G. Dalunde, Margarita de la Pisa Carrión, Francesca Donato, Alicia Homs Ginel, Alin Mituța, Luděk Niedermayer, Susana Solís Pérez
Substitutes under Rule 209(7) present for the final vote	Alexander Bernhuber, Sara Cerdas, Ibán García Del Blanco, Mircea-Gheorghe Hava, Radan Kanev, Guy Lavocat, Javi López, Karen Melchior, Jessica Polfjärd, Bergur Løkke Rasmussen, Caroline Roose, Birgit Sippel, Dragoş Tudorache, Axel Voss

FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

34	+
ECR	Johan Nissinen, Margarita de la Pisa Carrión
ID	Marie Dauchy
PPE	Pascal Arimont, Hildegard Bentele, Alexander Bernhuber, Cristian-Silviu Buşoi, Jerzy Buzek, Maria da Graça Carvalho, Christian Ehler, Mircea-Gheorghe Hava, Radan Kanev, Seán Kelly, Eva Maydell, Angelika Niebler, Luděk Niedermayer, Jessica Polfjärd, Sara Skyttedal, Maria Spyraki, Riho Terras, Henna Virkkunen, Axel Voss, Pernille Weiss
Renew	Nicola Danti, Christophe Grudler, Ivars Ijabs, Guy Lavocat, Karen Melchior, Alin Mituța, Mauri Pekkarinen, Morten Petersen, Bergur Løkke Rasmussen, Susana Solís Pérez, Dragoş Tudorache

26	-
NI	Martin Buschmann, Francesca Donato
S&D	Laura Ballarín Cereza, Sara Cerdas, Beatrice Covassi, Josianne Cutajar, Ibán García Del Blanco, Nicolás González Casares, Robert Hajšel, Alicia Homs Ginel, Ivo Hristov, Romana Jerković, Łukasz Kohut, Javi López, Tsvetelina Penkova, Birgit Sippel
The Left	Marc Botenga, Marisa Matias, Marina Mesure
Verts/ALE	Michael Bloss, Ignazio Corrao, Jakop G. Dalunde, Henrike Hahn, Ville Niinistö, Manuela Ripa, Caroline Roose

2	0
ECR	Zdzisław Krasnodębski, Grzegorz Tobiszowski

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

13.2.2024

LETTER OF THE COMMITTEE ON LEGAL AFFAIRS

Mr Pascal Canfin
Chair
Committee on the Environment, Public Health and Food Safety
BRUSSELS

Subject: Opinion on of the Committee on Legal Affairs on the Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC - (COM(2023)0192 – C9-0143/2023 – 2023/0132(COD))

Dear Mr Chair,

At its meeting of 29 November 2023, the Coordinators of the Committee on Legal Affairs decided to give an opinion in letter form on the Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (2023/0132(COD). The Committee on the Environment, Public Health and Food Safety and the Committee on Legal Affairs agreed that the latter will have shared competences under Rule 57 with the lead committee over Article 85 of the Directive (so-called “Bolar exemption”).

At its meeting of 13 February 2024, the Committee on Legal Affairs accordingly decided, by 23 votes in favour, 0 votes against and 0 abstentions[1], to call on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to take into account the elements outlined in this opinion, when preparing their report.

The proposed directive accompanies 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, where the Committee on Legal Affaires decided not to give an opinion. Both Committees nevertheless agreed that the wording of article 168 (Confidentiality) should not be substantially altered.

[1] The following Members were present for the final vote: Adrián Vázquez Lázara (Chair), Sergey Lagodinsky (Vice-Chair), Marion Walsmann (Vice-Chair), Lara Wolters (Vice-Chair), Isabel Benjumea Benjumea (for Javier Zarzalejos pursuant to Rule 209(7)), Ilana Cicurel, Ana Collado Jiménez (for Juan Ignacio Zoido Álvarez pursuant to Rule 209(7)), Pascal Durand, Ibán García Del Blanco, Catherine Griset (for Gunnar Beck pursuant to Rule 209(7)), Heidi Hautala, Virginie Joron, Pierre Karleskind, Gilles Lebreton, Karen Melchior, Witold Pahl, Anne-Sophie Pelletier (for Manon Aubry pursuant to Rule 209(7)), Jiří Pospíšil, Franco Roberti, Laurence Sailliet (for Geoffroy Didier pursuant to Rule 209(7)), Axel Voss, Tiemo Wölken, Kosma Złotowski.

In parallel to this revision of the general pharmaceutical legislation issued by the Commission on 26 April 2023, the Commission adopted, on 27 April 2023, four legislative proposals providing for a comprehensive reform of the regime of supplementary protection certificates (SPCs) - an intellectual property right - for both medicinal products and plant protection products. The Committee on Legal Affairs adopted the four reports at its meeting of 24 January 2024. The Committee on Legal Affairs believes it is therefore important for the European Parliament and the Council to look at all the related instruments together as part of the same package to ensure coherence and consistency. The Committee on Legal Affairs invites the Committee on the Environment, Public Health and Food Safety to carefully consider the SPC reports on medicinal products (the "Unitary" one and the recast) in the context of the pharma reform, in particular Article 35 related to the ban of patent linkage in order to ensure alignment within all legislative acts.

In that regard, the Committee on Legal Affairs takes note of the Commission's proposal for the Directive and the suggested Article 85 known as the "Bolar exemption". The aim of the exemption is to facilitate faster market entry of generics and biosimilars medicinal products, thereby increasing competition, after patent or SPC protection has expired to enable the entering into the Union's or Member States' markets on EU Day-One (recital 64). As explained in the related recital 63 of the proposal for the Directive, the application of this limited exemption is fragmented across the Union and this is why the Commission proposes "to clarify its scope in order to ensure a harmonised application in all Member States, both in terms of beneficiaries and in terms of activities covered ".

Article 85 of the proposal for Directive clarifies that the studies, trials and other activities, using the reference medicinal product, in order to obtain a marketing authorisation of generic or biosimilars, or for health technology assessment or for pricing and reimbursement, shall not be regarded as infringing patent rights or SPCs. The provision then specifies that those activities may encompass the submission of the application for a marketing authorisation and the offer, manufacture, sale, supply, storage, import, use and purchase of patented medicinal products, including by third party suppliers and service providers. Finally, its last paragraph states that the Bolar exemption shall not cover the placing on the market of the medicinal products resulting from such activities. The accompanying recitals proposed by the Commission provide additional background as well as interpretative information helping in the understanding of the scope of the exemption.

The Committee on Legal Affairs fully shares the Commission's objective of ensuring greater harmonisation and legal certainty when it comes to the application of the Bolar exemption with a view to encouraging health research and promoting generics, while not affecting IP rights of patent and/or SPC holders. The proposed exemption, meant to avoid legal uncertainty, strikes a good balance between providing legal certainty as regards the activities authorised with the objective of bringing new generic/biosimilar products to the market and the objective of ensuring that the protection and enforcement of IP rights of patent and/or SPCs holders are not unduly undermined. Indeed, in line with Articles 28 and 30 of the TRIPs agreement, it is necessary to guarantee that exceptions to the exclusive rights conferred by a patent do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Therefore the Committee on Legal Affairs considers that no amendments are needed neither

to Article 85 of the Commission proposal nor to the related recitals. Additionally, the Committee on Legal Affairs would welcome alignment with article 35 of the SPC reports on medicinal products relating to the ban of patent linkage.

Yours sincerely,

Adrián Vázquez Lázara

PROCEDURE – COMMITTEE RESPONSIBLE

Title	Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC			
References	COM(2023)0192 – C9-0143/2023 – 2023/0132(COD)			
Date submitted to Parliament	26.4.2023			
Committee responsible Date announced in plenary	ENVI 14.9.2023			
Committees asked for opinions Date announced in plenary	BUDG 14.9.2023	ITRE 14.9.2023	IMCO 14.9.2023	JURI 14.9.2023
Not delivering opinions Date of decision	BUDG 23.5.2023	IMCO 23.5.2023		
Associated committees Date announced in plenary	JURI 14.9.2023			
Rapporteurs Date appointed	Pernille Weiss 15.5.2023			
Discussed in committee	20.9.2023	7.11.2023		
Date adopted	19.3.2024			
Result of final vote	+: –: 0:	66 2 9		
Members present for the final vote	Catherine Amalric, Margrete Auken, Marek Paweł Balt, Traian Băsescu, Alexander Bernhuber, Malin Björk, Delara Burkhardt, Sara Cerdas, Nathalie Colin-Oesterlé, Maria Angela Danzì, Bas Eickhout, Cyrus Engerer, Heléne Fritzon, Catherine Griset, Teuvo Hakkarainen, Anja Hazekamp, Martin Hojsík, Jan Huitema, Adam Jarubas, Karin Karlsbro, Joanna Kopcińska, Peter Liese, Javi López, César Luena, Elżbieta Katarzyna Łukacijewska, Marian-Jean Marinescu, Lydie Massard, Liudas Mažylis, Marina Mesure, Tilly Metz, Dolors Montserrat, Ville Niinistö, Ljudmila Novak, Henk Jan Ormel, Grace O'Sullivan, Jutta Paulus, Jessica Polfjärd, Erik Poulsen, Frédérique Ries, María Soraya Rodríguez Ramos, Sándor Rónai, Laurence Sailliet, Silvia Sardone, Günther Sidl, Ivan Vilibor Sinčić, Maria Spyraki, Edina Tóth, Achille Variati, Nikolaj Villumsen, Anders Vistisen, Alexandr Vondra, Mick Wallace, Pernille Weiss, Emma Wiesner, Michal Wiezik, Tiemo Wölken, Anna Zalewska, Stefania Zambelli			
Substitutes present for the final vote	João Albuquerque, Mercedes Bresso, Milan Brglez, Catherine Chabaud, Rosanna Conte, Nicolás González Casares, Ska Keller, Stelios Kympouropoulos, Massimiliano Salini, Andrey Slabakov, Vincenzo Sofo, Tomislav Sokol, Susana Solís Pérez, François Thiollet			
Substitutes under Rule 209(7) present for the final vote	Karolin Braunsberger-Reinhold, Sylvie Brunet, Marie Dauchy, Paola Ghidoni, Maria-Manuel Leitão-Marques			
Date tabled	21.3.2024			

FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

66	+
ECR	Joanna Kopcińska, Andrey Slabakov, Alexandr Vondra, Anna Zalewska
ID	Anders Vistisen
NI	Edina Tóth
PPE	Traian Băsescu, Alexander Bernhuber, Karolin Braunsberger-Reinhold, Nathalie Colin-Oesterlé, Adam Jarubas, Stelios Kympouropoulos, Peter Liese, Elżbieta Katarzyna Łukacijewska, Marian-Jean Marinescu, Liudas Mažylis, Dolors Montserrat, Ljudmila Novak, Henk Jan Ormel, Jessica Polfjärd, Laurence Sailliet, Massimiliano Salini, Tomislav Sokol, Maria Spyraki, Pernille Weiss, Stefania Zambelli
Renew	Catherine Amalric, Sylvie Brunet, Catherine Chabaud, Martin Hojsík, Jan Huitema, Karin Karlsbro, Erik Poulsen, Frédérique Ries, María Soraya Rodríguez Ramos, Susana Solís Pérez, Emma Wiesner, Michal Wiezik
S&D	João Albuquerque, Marek Paweł Balt, Mercedes Bresso, Milan Brglez, Delara Burkhardt, Sara Cerdas, Cyrus Engerer, Heléne Fritzon, Nicolás González Casares, Maria-Manuel Leitão-Marques, Javi López, César Luena, Sándor Rónai, Günther Sidl, Achille Variati, Tiemo Wölken
The Left	Malin Björk, Nikolaj Villumsen, Mick Wallace
Verts/ALE	Margrete Auken, Bas Eickhout, Ska Keller, Lydie Massard, Tilly Metz, Ville Niinistö, Grace O'Sullivan, Jutta Paulus, François Thiollet

2	-
ID	Marie Dauchy, Catherine Griset

9	0
ECR	Teuvo Hakkarainen, Vincenzo Sofo
ID	Rosanna Conte, Paola Ghidoni, Silvia Sardone
NI	Maria Angela Danzì, Ivan Vilibor Sinčić
The Left	Anja Hazekamp, Marina Mesure

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