European Parliament
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Committee on Industry, Research and Energy

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AMENDMENTS
21 - 300

Draft opinion
Henna Virkkunen
(PE754.773v01-00)

Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC

Proposal for a directive
(COM(2023)0192 – C9-0143/2023 – 2023/0132(COD))

AM_Com_LegOpinion

Amendment 21
Nicolás González Casares, Laura Ballarín Cereza

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 , ensure access to innovative and established medicines for patients ***and improve affordability of these medicines***, 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; ***promote innovation, in particular for unmet medical needs, while reducing regulatory burden and the environmental impact of medicines;*** and create a balanced and competitive system that keeps medicines affordable for health systems ***and patients*** while ***particularly*** rewarding ***targeted*** innovation ***that improves access to medicinal products in all Member States, where they address unmet medical needs and where preclincial studies and development has taken place in the Union, reinforcing our industrial ecosystems***.

Or. en

Amendment 22
Margarita de la Pisa Carrión
on behalf of the ECR Group

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	(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.	innovation, in particular for unmet medical needs, ***and, foster an appealing environment for the research, development, and manufacturing of pharmaceuticals within the Union*** while reducing regulatory and ***administrative burdesn 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.
	Or. en

Amendment 23
Susana Solís Pérez, Klemen Grošelj

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, ***and establishes a conducive environment for the research, development, and manufacturing of pharmaceuticals within the Union*** 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.

Or. en

Amendment 24
Pernille Weiss

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, ***and create an attractive environment for research, development and production of medicines in the Union*** 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.

Or. en

Amendment 25
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3 a) In parallel of this revision, the Union should build a new 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.

Or. en

Amendment 26
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Recital 4 a (new)

Text proposed by the Commission	*Amendment*
	(4 a) This revision should align with the EU's ambitions in industry, digitalization, and trade, acknowledging the critical role of the European life sciences sector, especially the pharmaceutical industry, in upholding the EU's competitive edge. Bolstering robust European research and development is crucial for European sovereignty within the ambit of a globally competitive geopolitical landscape. The pharmaceutical legislative framework should be attuned to the broader EU industrial strategy, echoing the Council's emphasis from 23 March 2023 on amplifying incentives for investment in innovation and the 2016 Council's guidance that any amendments, including those affecting the incentive system, should not hinder the creation of drugs for rare disease treatment. Advancements in innovation are pivotal for enhancing patient health outcomes and the wider public health sector.

Or. en

Amendment 27
Henna Virkkunen

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.

Or. en

Justification

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

Amendment 28
Susana Solís Pérez, Klemen Grošelj

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.

Or. en

Amendment 29
Nicolás González Casares, Laura Ballarín Cereza

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.

Or. en

Amendment 30
Patrizia Toia, Beatrice Covassi

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 ***should maintain*** 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

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.

technological developments induce innovation and development of medicinal products, including for ***children and patients affected by rare diseases in all*** 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.

Or. en

Amendment 31
Susana Solís Pérez, Klemen Grošelj

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.

Or. en

Amendment 32
Nicolás González Casares, Laura Ballarín Cereza

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 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 preclinical studies developed 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.

Or. en

Amendment 33
Patrizia Toia, Beatrice Covassi

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	(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 ***for***

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.	***paediatric and orphan medicinal products and in other*** 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.
	Or. en

Amendment 34
Pernille Weiss

Proposal for a directive
Recital 11 a (new)

Text proposed by the Commission	*Amendment*
	(11 a) This Directive should be consistent with the Union's objectives with regard to promotion of research, innovation and industrial competitiveness, including with regard to a globally competitive system of intellectual property (IP) incentives. The provisions of this Directive should be coordinated with the Union's industrial and digital strategies as well as its trade policy to ensure that the Union is capable of competing with challenger regions, as highlighted by the resolution of the European Parliament of 24 November 2021 on a pharmaceutical strategy for Europe[1a]. Likewise, the conclusions of the Council of 23 March 2023 on competitiveness, single market and the economy have stressed the importance of strengthening incentives for investments in innovation. In that regard, it should be considered how the European life science sector, including the pharmaceutical industry, contributes as a whole to meeting those objectives and thus how this Directive should work to support it.
	[1a] OJ C 224, 8.6.2022, p. 47.

Or. en

Amendment 35
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Recital 11 a (new)

Text proposed by the Commission	*Amendment*
	(11 a) It is however, difficult to establish a direct link between incentives offered nowadays at Union level and Union competitiveness in the pharmaceutical sphere vis a vis third country based companies. While incentives can make the EU a more attractive market for industry, they remain agnostic to medicines´ geographical origin. Medicines originating from third country based companies are eligible to all EU incentives. Equally, EU based innovative companies can benefit from incentives elsewhere if they sell their products in these markets. Therefore a reduction in the regulatory data protection period does not harm EU companies vis a vis non EU companies coming to the EU market in terms of competitiveness.

Or. en

Amendment 36
Pilar del Castillo Vera

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.

Or. en

Amendment 37
Nicolás González Casares, Laura Ballarín Cereza

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 pronlonging data protection for a medicinal product. Therefore, an incentive to extend the data protection period is proposed where a company can demonstrate this.

Or. en

Amendment 38
Pilar del Castillo Vera

Proposal for a directive
Recital 11 b (new)

Text proposed by the Commission	*Amendment*
	(11 b) This Directive recognizes that there is no trade-off between maintaining a competitive pharmaceutical industry in the EU and ensuring the affordability, accessibility, and availability of medicinal products in the EU.

Or. en

Amendment 39
Margarita de la Pisa Carrión
on behalf of the ECR Group

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 this regard, such as for pricing and reimbursement procedures***, 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.

Or. en

Amendment 40
Pernille Weiss

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 this regard, such as for pricing and reimbursement procedures***, 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.

Or. en

Amendment 41
Nicolás González Casares, Laura Ballarín Cereza

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. 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 ***Agency and the advisory and regulatory bodies established in other Union legislation, as relevant, should engage in consultations, in order to find consensus on the regulatory status of the product or the application of Union law to the borderline product in question. Where necessary, the Commission should be empowered to take the decision on the regulatory status or applicability of legal*** rules ***to the borderline product,the assessment and conclusions of which should be made publicly available. Furthermore, for transparency purposes, the respective opinions and conclusions of the Agency and the other advisory and regulatory bodies established in other Union legislation should be made publicly available***. 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.

Or. en

Amendment 42
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Recital 17 a (new)

Text proposed by the Commission	*Amendment*
	(17 a) For SoHO derived medicinal products each Member State shoud ensure through public service obligations that those manufacturers provide an appropriate and continuous supply of SoHO derived medicinal products to patients in their territory. Member States should negotiate fair and transparent prices for SoHO derived medicinal products that are derived from altruistic and unpaid donations. Member States should also ensure that affordable SoHO derived medicinal products are available to patients in their territory. In this regard, manufactureres of these products should report annually to authorities on the quantities prepared and the amount supplied for public use.

Or. en

Amendment 43
Pernille Weiss

Proposal for a directive
Recital 17 a (new)

Text proposed by the Commission	*Amendment*
	(17 a) Member States should take measures to promote the availability of medicinal products derived from substances of human origin and together with the Commission strengthen EU open

strategic autonomy with regard to plasma for fractionation intended for plasma-derived medicinal products.

Or. en

Amendment 44
Susana Solís Pérez, Klemen Grošelj

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 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	(18) Advanced therapy medicinal products that are prepared ***incidentally and exceptionally*** 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' ***). Hospital exemptions are granted strictly when there is no certified medicinal alternative available, nor an appropriate clinical trial or compassionate use program that aligns with the therapeutic needs for an ATMP for which the patient is qualified within the European jurisdiction, provided that the production of such therapy is a singular event and not part of a standard manufacturing cycle. The system for granting marketing authorizations is underpinned by the evidence from clinical trials, which is essential for confirming product safety and effectiveness. Therefore, it's crucial to ensure that the hospital exemption does not deplete the pool of clinical trial participants or jeopardize the reliability of the marketing authorization process for Advanced Therapy Medicinal Products***

relevant competent authorities shall inform the competent authorities of other Member States.

(ATMPs). 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 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 ***assist in the overall surveillance of the products' quality, safety, and effectiveness.***. 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.

Or. en

Amendment 45
Pernille Weiss

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	(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 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.	among Member States. To improve the application of hospital exemption this Directive introduces 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. 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.

Or. en

Amendment 46
Nicolás González Casares, Laura Ballarín Cereza

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	(18) Advanced therapy medicinal products that are prepared 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

among Member States. To improve the application of hospital exemption this Directive introduces 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 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.

application of hospital exemption this Directive introduces 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 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.

Or. en

Amendment 47
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Recital 18 a (new)

Text proposed by the Commission	*Amendment*
	(18 a) Hospital exemption pathway is a crucial way of providing patients with access to innovative and affordable treatments that may not be available through other channels. Any limitations to this pathway should avoided, but only based on efficacy, quality and safety criteria, without time restrictions or restrictions on quantities. Competent authorities must guarantee that the authorisation of other products through the centralized procedure does not adversely affect the activities and responsibilities of developers functioning under the hospital exemption. The Agency, as well as competent authorities

at the national level, should support academic institutions and other non-profit entities through the requirements of the hospital exemption clause and, when adequate, should provide guidance through centralised marketing authorisation procedure.

Or. en

Amendment 48
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Recital 18 a (new)

Text proposed by the Commission	*Amendment*
	(18 a) 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 European Medicines Agency (EMA) pilot programme for enhanced support to academic and non-profit developers of advanced therapy medicinal products, started in September 2022.

Or. en

Amendment 49
Pernille Weiss

Proposal for a directive
Recital 18 a (new)

Text proposed by the Commission	*Amendment*
	(18 a) 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 European Medicines Agency (EMA) pilot programme for enhanced support to academic and non-profit developers of advanced therapy medicinal products, started in September 2022.

Or. en

Amendment 50
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Recital 18 a (new)

Text proposed by the Commission	*Amendment*
	(18 a) The Agency ought to create a program aimed at assisting academic institutions and non-profit organizations in navigating the centralized marketing authorization process. This initiative should be informed by insights from the EMA's pilot program that began in September 2022, which provided specialized support to academic and non-profit developers of advanced therapy medicinal products.

Or. en

Amendment 51
Pernille Weiss

Proposal for a directive
Recital 19

Text proposed by the Commission	*Amendment*
(19) This Directive should be without prejudice to the provisions of Council Directive 2013/59/Euratom[41] ***, including with respect to justification and optimisation of protection of patients and other individuals subject to medical exposure to ionising radiation***. ***In the case***	(19) This Directive should be without prejudice to the provisions of Council Directive 2013/59/Euratom[41].

of radiopharmaceuticals used for therapy, marketing authorisations, posology and administration rules have to notably respect that Directive's requirements that exposures of target volumes are to be individually planned, and their delivery appropriately verified taking into account that doses to non-target volumes and tissues are to be as low as reasonably achievable and consistent with the intended therapeutic purpose of the exposure.

[41] Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17.1.2014, p. 1).

[41] Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17.1.2014, p. 1).

Or. en

Amendment 52
Pernille Weiss

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).

Or. en

Amendment 53
Nicolás González Casares, Laura Ballarín Cereza

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 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.	(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 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.

Or. en

Amendment 54

Nicolás González Casares, Laura Ballarín Cereza

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***[1]*** 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).***

Or. en

Amendment 55
Nicolás González Casares, Laura Ballarín Cereza

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 initital application for the decentralised procedure within 30 days of the sumission of the application should still have a second opportunity to opt into the procedure at a later point, in this case they should immeditately inform the applicant and the competent authority of the reference Member State for the decentralised procedure.***

Or. en

Amendment 56
Cristian-Silviu Buşoi

Proposal for a directive
Recital 41

Text proposed by the Commission	*Amendment*
(41) In the case of generic medicinal products of which the reference medicinal product has been granted a marketing authorisation under the centralised procedure, applicants seeking marketing authorisation should be able to choose either of the two procedures, on certain conditions. Similarly, the mutual-recognition or decentralised procedure should remain available as an option for certain medicinal products, even if they represent a therapeutic innovation or are of benefit to society or to patients. Since generic medicines account for a major part of the market in medicinal products, their access to the Union market should be facilitated in the light of the experience acquired, therefore, the procedures to include other Member States concerned to such procedure should be further simplified.	(41) In the case of ***products with well-known molecules,*** generic medicinal products of which the reference medicinal product has been granted a marketing authorisation under the centralised procedure***, hybrid medicinal products, well established and products with fixed dose combinations of known molecules***, applicants seeking marketing authorisation should be able to choose either of the two procedures, on certain conditions. Similarly, the mutual-recognition or decentralised procedure should remain available as an option for certain medicinal products, even if they represent a therapeutic innovation or are of benefit to society or to patients. Since generic medicines account for a major part of the market in medicinal products, their access to the Union market should be facilitated in the light of the experience acquired, therefore, the procedures to include other Member States concerned to such procedure should be further simplified.

Or. en

Amendment 57
Nicolás González Casares, Laura Ballarín Cereza

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 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	(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.	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***, often due to profitability considerations***. 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.
	Or. en

Amendment 58
Nicolás González Casares, Laura Ballarín Cereza

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. ***Puting in place tolls to evaluate access to medicines at a Union level is key to follow-up on 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).

[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).

Or. en

Amendment 59
Pernille Weiss

Proposal for a directive
Recital 46 a (new)

Text proposed by the Commission	*Amendment*
	(46 a) 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 the competence of the Member States, and recognising the disparities which can be observed in access to medicines 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.

Or. en

Amendment 60
Pernille Weiss

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.

Or. en

Amendment 61
Nicolás González Casares, Laura Ballarín Cereza

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 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	(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.

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. ***Such procurement efforts should be based on the principle of the 'most economically advantageous tender' ('MEAT' criteria), which aims to ensure the best value for money rather than most economically advantageous product. Such an approach could also help in defining adequate supply in relation to critical medicines and, thereby, compensate and incentivise industry, and support the application of these criteria in a coordinated way, at EU level. Predictability of supply would also be helped by medium-term contractual incentives to diversify and attract the next generation of manufacturing investments in Europe.*** 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.

Or. en

Amendment 62
Susana Solís Pérez, Klemen Grošelj

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 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	(48) Member State ***create shortages in other Member States. For this reason***, the Pharmaceutical Strategy for Europe 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***

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.

on pricing and procurement could contribute to more equal and timely access to medicines, including for Member States with lower purchasing power. The Commission may support joint price negotiation with pharmaceutical companies, as per 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 ***national pricing, reimbursment and*** 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.

Or. en

Amendment 63
Pernille Weiss

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***	(49) 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,

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***.

the Joint Procurement Agreement[48] and the proposed revised Financial Regulation[49]. In the ***event of joint procurement of medicinal products as a medical countermeasure in cases of serious cross-border threats to health, the provisions of Regulation (EU) 2022/2371 of the European Parliament and of the Council[49a] apply***.

[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.

[49] COM/2022/223 final.

[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.

[49] COM/2022/223 final.

Or. en

Amendment 64
Margarita de la Pisa Carrión
on behalf of the ECR Group

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,	(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.	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. ***Joint procurement should not have an adverse impact on access to medicines for countries not taking part in the procurement.***
[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.

Or. en

Amendment 65
Susana Solís Pérez, Klemen Grošelj

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]*** .	(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 , which sets out purchasing procedures for public buyers, the Joint Procurement Agreement and the proposed revised Financial Regulation .

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.	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***, antibiotics and generic and biosimilar medicinal products***.

[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.

[49] COM/2022/223 final.

Or. en

Amendment 66
Patrizia Toia, Beatrice Covassi

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	(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 Union as well as information exchange, in particular for medicines for ***paediatric, rare as well as*** chronic diseases.
[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.

Or. en

Amendment 67
Nicolás González Casares, Laura Ballarín Cereza

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. In specific cases, those instruments could also support enhanced predictability through multi-annual contracts. The joint procurement of medicines or on Member States' behalf in the case of the COVID-19 pandemic, for example, provided a powerful tool to improve access, affordability, and security of supply, was of particular benefit to smaller EU Member States with less economic power.

Or. en

Amendment 68
Susana Solís Pérez, Klemen Grošelj

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]	(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 ***lack effective treatments or where only less-than-ideal therapies exist, with the aim of spurring pharmaceutical research and development that genuinely meets patient requirements.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 morbidity or mortality', 'relevant patient population ***', 'quality of life', 'burden of administration', 'appropriate standard of***

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***.

care', 'significant added therapeutic value', 'patient experience data' following scientific assessment by the Agency. The Agency ***shall include patient representatives in its decision-making processes,*** 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. ***Given that chronic diseases account for 86% of all deaths in the EU, the assessment of disease burden should not be limited to mortality and morbidity metrics alone but ought to incorporate relevant data on patient experiences, including aspects related to quality of life. The inclusion of new*** therapeutic ***indications to an authorised medicinal products contributes to the access of patients to additional therapies and therefore should be incentivised***.

Or. en

Amendment 69
Ville Niinistö
on behalf of the Verts/ALE Group

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***	(50) The establishment of a criteria-based definition of 'unmet medical need' is ***necessary to ensure incentives for*** the development of medicinal products in therapeutic areas that are currently underserved ***are appropriately allocated and to prevent unintended extensions of data protection based on unclear interpretation*** of unmet medical need. The

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.

criteria for 'unmet medical need' can be subsequently used by Member States to identify specific therapeutic areas of interest.

Or. en

Justification

There is no implementing act related to Article 83 which spells out what is meant by unment medical need, we clarified with the Commission that this is a drafting mistake.

Amendment 70
Margarita de la Pisa Carrión
on behalf of the ECR Group

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	(50) ***To incentivize*** the development of medicinal products in therapeutic areas that are currently underserved***, it's essential to establish a criteria-based definition of 'unmet medical need.' This concept should reflect scientific and technological advancements as well as current knowledge in underserved diseases. Since chronic diseases account for 86% of all deaths in the EU, the assessment of the disease burden should extend beyond***

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.

mortality and morbidity measurements. It is of vital importance to incorporate relevant patient experience data, including aspects related to quality of life, to gain a comprehensive understanding of unmet medical needs. 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’ ***and 'negative impact on quality of life'*** 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***, including patients organisations and respresentatives from the industry*** 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.

Or. en

Amendment 71
Pernille Weiss

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	(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.	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', '***quality of life',*** **'**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. The*** criteria for 'unmet medical need' can be subsequently used by Member States to identify specific therapeutic areas of interest.

Or. en

Amendment 72
Henna Virkkunen

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	(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.	criteria of satisfactory method of diagnosis, prevention or treatment, 'remaining morbidity or mortality', 'relevant patient population***', 'quality of life', 'burden of administration***' following scientific assessment by the Agency. The Agency will seek input from a broad range of authorities ***and*** 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.

Or. en

Justification

While important underserved areas exist, they evolve overtime. A (strict) definition of unmet needs will overlook patient populations and hinder innovation. Moreover, it will have severe consequences at P&R level, by giving a 'stamp' to product. To steer investments and innovation in underserved areas, we need a broader definition that does not overlook patient populations and can evolve overtime, alongside scientific developments.

Amendment 73
Pernille Weiss

Proposal for a directive
Recital 50 a (new)

Text proposed by the Commission	*Amendment*
	(50 a) The development of medical products in underserved therapeutic areas can greatly increase the quality of life for patients. In that regard, elements such as acute or chronic side effects, in particular in relation to the toxicity of a product, as well as the ability of patients to perform regular life activities, the presence of pain and the management of co-morbidities

should be considered in the assessment of improving quality of life. Improving quality of life can allow patients to return to job or education, which can not only bear a significant positive effect on the individual patient, but can also alleviate costs to society arising from productivity losses. Furthermore, novel medicinal products which have significant positive impacts on the quality of life of a patient can also alleviate the burden on family and carers, in particular as regards paediatric patients. This will in turn also have a societal impact in areas such as labour shortages and fiscal budgets.

Or. en

Amendment 74
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Recital 50 a (new)

Text proposed by the Commission	*Amendment*
	(50 a) Progress in treatments for overlooked therapeutic areas can greatly improve patient well-being, especially through better management of side effects, daily activities, pain, and concurrent illnesses. Improvements in patient quality of life ought to facilitate their return to work or education, benefiting both individuals and society by diminishing economic strains. Moreover, novel treatments can alleviate the responsibilities of caregivers, yielding broader social advantages. Identifying these therapeutic areas and unmet needs should include discussions with stakeholders such as patients, healthcare practitioners, and industry specialists.

Or. en

Amendment 75
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Recital 50 a (new)

Text proposed by the Commission	*Amendment*
	(50 a) Advancing treatments in neglected therapeutic areas can significantly enhance patient lives, particularly by considering the management of side effects, daily functioning, pain, and co-existing illnesses. Enhancements in patient quality of life may lead to their re-engagement in work or education, benefiting both the individual and society by reducing economic burdens. Additionally, new treatments can lessen the load on caregivers, with wider social benefits. Defining these therapeutic areas and unmet needs should involve consultation with stakeholders like patients, healthcare providers, and industry experts.

Or. en

Amendment 76
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Recital 51 a (new)

Text proposed by the Commission	*Amendment*
	(51 a) Repurposing of off-patent medicines to develop new therapeutic options should also be incentived as it can expand access to patients and reduce health inequalities

Or. en

Amendment 77

Cristian-Silviu Buşoi

Proposal for a directive
Recital 51 a (new)

Text proposed by the Commission	*Amendment*
	(51 a) Repurposing of off-patent medicines to develop new therapeutic options should also be incentived as it can expand access to patients and reduce health inequalities.

Or. en

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

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 accordingly support subsequent health technology assessments and decisions on pricing and reimbursement by Member States.	***deleted***

Or. en

Amendment 79
Nicolás González Casares, Laura Ballarín Cereza

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 accordingly support subsequent health technology assessments and decisions on pricing and reimbursement by Member States.	(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 accordingly support subsequent health technology assessments and decisions on pricing and reimbursement by Member States. ***National competent authorities and the Agency should promote, when possible, the use of comparative studies when giving regulatory advise prior to marketing authorization for medicinal products.***

Or. en

Amendment 80
Pernille Weiss

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 accordingly support subsequent health technology assessments and decisions on pricing and reimbursement by Member States.	(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 technology assessments and decisions on pricing and reimbursement by Member States.

Or. en

Amendment 81
Pilar del Castillo Vera

Proposal for a directive
Recital 52 a (new)

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

Or. en

Amendment 82
Susana Solís Pérez, Klemen Grošelj

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**.**

Or. en

Amendment 83
Pernille Weiss

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	(53) A marketing authorisation holder should***, within its responsibilities,*** ensure the appropriate and continuous supply of a

throughout its lifetime ***irrespective of whether that medicinal product is covered by a supply incentive or not***.	medicinal product throughout its lifetime.

Or. en

Amendment 84
Margarita de la Pisa Carrión
on behalf of the ECR Group

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 the scope of its control, be responsible for ensuring the consistent and proper*** supply of a medicinal product throughout its lifetime***,***

Or. en

Amendment 85
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Recital 53 a (new)

Text proposed by the Commission	*Amendment*
	(53 a) It is imperative in negotiations between developers and Member States to respect and adhere to the timelines set out by Directive 89/105/EEC, to accelerate and widen the availability of innovative therapies to patients.

Or. en

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

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 market a medicinal product in the Member States where the marketing authorisation is valid.

Or. en

Amendment 87
Pernille Weiss

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***.

Or. en

Justification

See amendments to new Article 58a.

Amendment 88
Ville Niinistö
on behalf of the Verts/ALE Group

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.

Or. en

Amendment 89
Pernille Weiss

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.

Or. en

Justification

See amendments to new Article 58a.

Amendment 90
Pernille Weiss

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***

Or. en

Justification

See amendments to new Article 58a.

Amendment 91
Nicolás González Casares, Laura Ballarín Cereza

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.	(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. ***In the case where a Member State does not react to the application by***

the marketing authoirsation holder within the deadline provided, it shall be considered that a statement of non objection has been provided and the condition in that Member State should be waived. The Commission should ensure that marketing authorisation holders are not unduly prevented from receiving the incentives for actions beyond their control.

Or. en

Amendment 92
Ville Niinistö
on behalf of the Verts/ALE Group

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***.	(56) Member States have the possibility to ***request a*** market launch ***of a centrally or decentrally approved product at any time after the marketing authorisation is valid in their Member State. Subsequently, marketing authorisation holders have nine months to apply for a pricing and reimbursement in that Member State, 18 months*** where ***the marketing authorisation holder is a SME, an entitiy not engaged in economic activity or an entity with limited experience in the Union system. Alternative timelines may be agreed between the*** Member State ***and the marketing authorisation holder. Marketing authorisation holders have the right to launch a product in*** a Member State ***before beign proactively approached by that Member State***.

Or. en

Amendment 93

Ville Niinistö
on behalf of the Verts/ALE Group

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 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.***	(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.

Or. en

Amendment 94
Pernille Weiss

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 Directive 89/105/EEC. The related negotiations between companies and the Member State should be conducted in good faith. ***Equally, to promote faster and wider access to medicines, it is critical that the timelines set out in that Directive are respected in***

negotiations between applicants and Member States, and that negotiations are conducted in good faith.

Or. en

Amendment 95
Ville Niinistö
on behalf of the Verts/ALE Group

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 Directive 89/105/EEC. The related negotiations between companies and the Member State should be ***tranparent and*** conducted in good faith.

Or. en

Amendment 96
Pernille Weiss

Proposal for a directive
Recital 58 a (new)

Text proposed by the Commission	*Amendment*
	(58 a) 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 or where the administration of a medicine 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 of making available medicinal products to patients and prescribing doctors, such as named patient supply, administering of medicine via a centre of excellence, early access or compassionate use programs, and other cross-border healthcare. 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.

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*[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).***

Or. en

Amendment 97
Pilar del Castillo Vera

Proposal for a directive
Recital 58 a (new)

Text proposed by the Commission	*Amendment*
	(58 a) Small patient populations, especially paediatric or rare disease ones, are often the most disadvantaged when it comes to access to medicines. In this regard, Directive 2011/24/EU shall be considered as an alternative pathway of making available medicinal products to patients, who need paediatric, orphan medicinal products or advanced therapy medicinal products. The medicines can be administered via a center of excellence, early access or compassionate use programs, or other cross-border healthcare services.

Or. en

Amendment 98
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Recital 58 a (new)

Text proposed by the Commission	*Amendment*
	(58 a) Supply assurance can also be achieved through national strategies that facilitate patient access, such as programs for named patients, tailored individual patient initiatives, and the uptake and optimization of cross-border healthcare options, as stipulated in Directive 2011/24/EU. It is crucial to bolster cross-border healthcare, especially for treatments that require specialized infrastructure or technical expertise that may be lacking in certain Member States.

Or. en

Amendment 99
Pernille Weiss

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***

Or. en

Amendment 100
Susana Solís Pérez, Klemen Grošelj

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.

Or. en

Amendment 101
Margarita de la Pisa Carrión
on behalf of the ECR Group

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.	***deleted***

Or. en

Amendment 102
Pernille Weiss

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 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 ***for the indication that is relevant to the public health emergency*** 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.

Or. en

Amendment 103
Nicolás González Casares, Laura Ballarín Cereza

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***,	(61) When a compulsory licence has been granted by a relevant authority in the Union to ***safeguard*** public health ,

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.	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 ***a*** crisis ***or safeguard public health interests as determined on a Member State level***. For this reason, data and market protection should be suspended when a compulsory licence has been issued to ***safeguard*** public health***.***. 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.

Or. en

Amendment 104
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Recital 61 a (new)

Text proposed by the Commission	*Amendment*
	(61 a) The WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) provides for a possibility, under conditions, to issue compulsory licences. This provides governments the authority to grant the use of a patented invention without the consent of the patent owner. The Doha Declaration on the TRIPS Agreement and Public Health provides that each WTO Member has not only the right to grant compulsory licences, but also the freedom to determine the grounds upon which such licences are granted.

Or. en

Amendment 105
Margarita de la Pisa Carrión
on behalf of the ECR Group

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.	***deleted***

Or. en

Amendment 106
Pernille Weiss

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 ***and only in the relevant Member States***. 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.

Or. en

Amendment 107
Nicolás González Casares, Laura Ballarín Cereza

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. A ‘suspension‘ of data and market protection ***to safeguard*** public health 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.

Or. en

Amendment 108
Pilar del Castillo Vera

Proposal for a directive
Recital 63

Text proposed by the Commission	*Amendment*
(63) It is currently possible for applicants for marketing authorisation of generic, biosimilar, hybrid and bio-hybrid medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain regulatory approvals for those medicinal products during the term of protection of the patent or Supplementary Protection	(63) It is currently possible for applicants for marketing authorisation of generic, biosimilar, hybrid and bio-hybrid medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain ***and vary*** regulatory approvals for those medicinal products during the term of protection of the patent or Supplementary Protection

Certificate (SPC) of the reference medicinal product, without this being considered patent or SPC infringement. The application of this limited exemption is however fragmented across the Union and it is considered necessary, in order to facilitate the market entry of generic, biosimilar, hybrid and bio-hybrid medicinal products ***that rely on a reference medicinal product***, 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. The exemption must be confined to ***conduct*** studies ***and*** trials and other activities needed for the regulatory approval process, health technology ***assessment and*** pricing reimbursement ***request***, even though this may require substantial amounts of test production to demonstrate reliable manufacturing. During the term of protection of the patent or SPC ***of*** the reference medicinal product, there can be no ***commercial use*** of the resulting final medicinal products obtained for the purposes of the regulatory approval process.

Certificate (SPC) of the reference medicinal product, without this being considered patent or SPC infringement. The application of this limited exemption is however fragmented across the Union and ***the objective of enabling a day-one entry of generic and biosimilar medicinal products has not been fully achieved. The timely entry of generic and biosimilar medicinal products into the Union market is important in order to increase competition, reduce prices, ensure that national healthcare systems are sustainable and improve patients' access to affordable medicines.*** It is considered necessary, in order to facilitate the market entry of ***medicinal products, in particular*** generic, biosimilar, hybrid and bio-hybrid medicinal products***, on day one after loss of the patent or SPC protection***, 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. The exemption must be confined to ***conducting*** studies***,*** trials and other activities needed for the regulatory approval process ***or administrative purposes***, health technology ***assessments, obtaining*** pricing ***and*** reimbursement***, and complying with other regulatory or administrative requirements, including after a marketing authorisation has been granted***, even though this may require substantial amounts of test production to demonstrate reliable manufacturing***, both by the applicants and by third party suppliers or service providers***. During the term of protection ***in a Member State*** of the patent or SPC the reference medicinal ***relevant*** product ***or process***, there can be no ***placing on the market (within the meaning of the Commission Notice – The 'Blue Guide' on the implementation of EU product rules 2022 2022/C 247/01) in that Member State*** of the resulting final medicinal products obtained for the purposes of the regulatory approval process.

Amendment 109
Cristian-Silviu Buşoi

Proposal for a directive
Recital 63

Text proposed by the Commission	*Amendment*
(63) It is currently possible for applicants for marketing authorisation of ***generic, biosimilar, hybrid and bio-hybrid*** medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain regulatory approvals for those medicinal products ***during the term of protection of the patent or Supplementary Protection Certificate (SPC) of the reference medicinal product***, without this being considered patent or SPC infringement. The application of this limited exemption is however fragmented across the Union and it is considered necessary, in order to facilitate the market entry of generic, biosimilar, hybrid and bio-hybrid medicinal products ***that rely on a reference medicinal product,*** 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. The exemption must be confined to ***conduct*** studies ***and*** trials and other activities needed for the regulatory approval process, health technology ***assessment and*** pricing reimbursement request, even though this may require substantial amounts of test production to demonstrate reliable manufacturing. During the term of protection of the patent or SPC ***of the reference*** medicinal product, there can be no ***commercial use*** of the resulting final medicinal products obtained for the purposes of the regulatory approval process.	(63) It is currently possible for applicants for marketing authorisation of medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain ***and vary*** regulatory approvals for those medicinal products, without this being considered patent or SPC infringement. The application of this limited exemption is however fragmented across the Union and ***the objective of enabling a day-one entry of generic and biosimilar medicinal products has not been fully achieved. The timely entry of generic and biosimilar medicinal products into the Union market is important in order to increase competition, reduce prices, ensure that national healthcare systems are sustainable and improve patients' access to affordable medicines.*** It is considered necessary, in order to facilitate the market entry of ***medicinal products, in particular*** generic, biosimilar, hybrid and bio-hybrid medicinal products***, on day one after loss of the patent or SPC protection*** 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. The exemption must be confined to ***conducting*** studies***,*** trials and other activities needed for the regulatory approval process, health technology ***assessments, obtaining*** pricing ***and*** reimbursement request***, the public and private procurement of medicinal products to be supplied immediately after expiry of the relevant patents or SPC and complying with other regulatory or***

administrative requirements, including after a marketing authorisation has been granted, even though this may require substantial amounts of test production to demonstrate reliable manufacturing ***both by the applicants and by third party suppliers or service providers***. During the term of protection ***in a MS*** of the patent or SPC ***for the relevant*** medicinal product ***or process***, there can be no ***placing on the market (within the meaning of the Commission Notice – The 'Blue Guide' on the implementation of EU product rules 2022 2022/C 247/01) in that Member State*** of the resulting final medicinal products obtained for the purposes of the regulatory approval process.

Or. en

Amendment 110
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Recital 63

Text proposed by the Commission	*Amendment*
(63) It is currently possible for applicants for marketing authorisation of ***generic, biosimilar, hybrid and bio-hybrid*** medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain regulatory approvals ***for those medicinal products during the term of protection of the*** patent or Supplementary Protection Certificate (SPC) ***of the reference medicinal product, without this being considered patent or SPC*** infringement. ***The application of this limited exemption is however fragmented across the Union and it is considered necessary, in order to facilitate the market entry of generic, biosimilar, hybrid and bio-hybrid medicinal products that rely on a reference medicinal product, to clarify its***	(63) ***The timely entry of generics and biosimilars onto the Union market is important, notably to increase competition, to reduce prices and to ensure both the sustainability of national healthcare systems and better access to affordable medicines by patients in the EU. The importance of such timely entry has been underlined by the Council in its conclusions of 17 June 2016 on strengthening the balance in the pharmaceutical systems in the Union and its Member States.*** It is currently possible for applicants for marketing authorisation of medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain regulatory approvals ***and variations thereof, without this being considered***

scope in order to ensure a harmonised application in all Member States, both in terms of beneficiaries and in terms of activities covered. The exemption must be confined to conduct studies and trials and other activities needed for the regulatory approval process, health technology assessment and pricing reimbursement request, even though this may require substantial amounts of test production to demonstrate reliable manufacturing. During the term of protection of the patent or SPC of the reference medicinal product, there can be no commercial use of the resulting final medicinal products obtained for the purposes of the regulatory approval process.

patent or Supplementary Protection Certificate (SPC) infringement.

Or. en

Amendment 111
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Recital 63

Text proposed by the Commission	*Amendment*
(63) It is currently possible for applicants for marketing authorisation of ***generic, biosimilar, hybrid and bio-hybrid*** medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain regulatory approvals ***for those medicinal products during the term of protection of the*** patent or Supplementary Protection Certificate (SPC) ***of the reference medicinal product, without this being considered patent or SPC*** infringement. ***The application of this limited exemption is however fragmented across the Union and it is considered necessary, in order to facilitate the market entry of generic, biosimilar, hybrid and bio-hybrid medicinal products that rely on a reference medicinal product, to clarify its***	(63) ***The timely entry of generics and biosimilars onto the Union market is important, notably to increase competition, to reduce prices and to ensure both the sustainability of national healthcare systems and better access to affordable medicines by patients in the EU. The importance of such timely entry has been underlined by the Council in its conclusions of 17 June 2016 on strengthening the balance in the pharmaceutical systems in the Union and its Member States.*** It is currently possible for applicants for marketing authorisation of medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain regulatory approvals ***and variations thereof, without this being considered***

scope in order to ensure a harmonised application in all Member States, both in terms of beneficiaries and in terms of activities covered. The exemption must be confined to conduct studies and trials and other activities needed for the regulatory approval process, health technology assessment and pricing reimbursement request, even though this may require substantial amounts of test production to demonstrate reliable manufacturing. During the term of protection of the patent or SPC of the reference medicinal product, there can be no commercial use of the resulting final medicinal products obtained for the purposes of the regulatory approval process.

patent or Supplementary Protection Certificate (SPC) infringement.

Or. en

Amendment 112
Pernille Weiss

Proposal for a directive
Recital 63

Text proposed by the Commission	*Amendment*
(63) It is currently possible for applicants for marketing authorisation of generic, biosimilar, hybrid and bio-hybrid medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain regulatory approvals for those medicinal products during the term of protection of the patent or Supplementary Protection Certificate (SPC) of the reference medicinal product, without this being considered patent or SPC infringement. The application of this limited exemption is however fragmented across the Union and it is considered necessary, in order to facilitate the market entry of generic, biosimilar, hybrid and bio-hybrid medicinal products that rely on a reference medicinal product, to clarify its scope in order to ensure a harmonised application in	(63) It is currently possible for applicants for marketing authorisation of generic, biosimilar, hybrid and bio-hybrid medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain regulatory approvals for those medicinal products during the term of protection of the patent or Supplementary Protection Certificate (SPC) of the reference medicinal product, without this being considered patent or SPC infringement. The application of this limited exemption is however fragmented across the Union and it is considered necessary, in order to facilitate the market entry of generic, biosimilar, hybrid and bio-hybrid medicinal products that rely on a reference medicinal product, 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. The exemption must be confined to conduct studies and trials and other activities needed for the regulatory approval process, health technology assessment ***and pricing reimbursement request, even though this may require substantial amounts of test production to demonstrate reliable manufacturing***. During the term of protection of the patent or SPC of the reference medicinal product, there can be no commercial use of the resulting final medicinal products obtained for the purposes of the regulatory approval process.	all Member States, both in terms of beneficiaries and in terms of activities covered. The exemption must be confined to conduct studies and trials and other activities needed for the regulatory approval process, ***and*** health technology assessment. During the term of protection of the patent or SPC of the reference medicinal product, there can be no commercial use of the resulting final medicinal products obtained for the purposes of the regulatory approval process.

Or. en

Amendment 113
Henna Virkkunen

Proposal for a directive
Recital 63

Text proposed by the Commission	*Amendment*
(63) It is currently possible for applicants for marketing authorisation of generic, biosimilar, hybrid and bio-hybrid medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain regulatory approvals for those medicinal products during the term of protection of the patent or Supplementary Protection Certificate (SPC) of the reference medicinal product, without this being considered patent or SPC infringement. The application of this limited exemption is however fragmented across the Union and it is considered necessary, ***in order to facilitate the market entry of generic, biosimilar, hybrid and bio-hybrid medicinal products that rely on a reference medicinal product,*** to clarify its scope in order to ensure a harmonised application in all Member States, both in	(63) It is currently possible for applicants for marketing authorisation of generic, biosimilar, hybrid and bio-hybrid medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain regulatory approvals for those medicinal products during the term of protection of the patent or Supplementary Protection Certificate (SPC) of the reference medicinal product, without this being considered patent or SPC infringement. The application of this limited exemption is however fragmented across the Union and it is considered necessary, to clarify its scope ***and limitations*** in order to ensure a harmonised application in all Member States, both in terms of beneficiaries and in terms of activities covered. The exemption must be confined to conduct studies and trials and other activities needed for the

terms of beneficiaries and in terms of activities covered. The exemption must be confined to conduct studies and trials and other activities needed for the regulatory approval process***, health technology assessment and pricing reimbursement request, even though this may require substantial amounts of test production to demonstrate reliable manufacturing***. During the term of protection of the patent or SPC of the reference medicinal product, there can be no commercial use of the resulting final medicinal products obtained for the purposes of the regulatory approval process.

regulatory approval process. During the term of protection of the patent or SPC of the reference medicinal product, there can be no commercial use of the resulting final medicinal products obtained for the purposes of the regulatory approval process. ***Any (excess) patented products that were manufactured for the purpose of Art 85 (a) or (b) shall not be commercially exploited, including after the approval of said marketing authorization application. These should be dealt with in accordance with TRIPS Article 46.***

Or. en

Justification

See justification to Article 85.

Amendment 114
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Recital 63 a (new)

Text proposed by the Commission	*Amendment*
	(63 a) The application of this limited exemption is however fragmented across the Union and it is considered necessary, in order to facilitate entering the market of any Member State of medicinal products and in particular generic, biosimilar, hybrid and bio-hybrid medicinal products, upon expiry of the corresponding patent or supplementary protection certificate (EU 'Day-one' entry) that rely on a reference medicinal product, 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. The exemption must be confined to conduct studies, trials and other activities needed for the administrative or

regulatory approval process, health technology assessment and and for obtaining pricing and reimbursement, as well as the public and private procurement of medicinal products to be supplied immediately after tbe expiry of the corresponding patent or supplementary protection certificate), even though this may require substantial amounts of test production to demonstrate reliable manufacturing both by the applicant or third party suppliers or service providers. During the term of protection of the patent or SPC of the medicinal product, there can be no placing on the market (within the meaning of the Commission Notice – The 'Blue Guide' on the implementation of EU product rules 2022 2022/C 247/01) in that Member State) of the resulting final medicinal products obtained for the purposes of the regulatory approval process.

Or. en

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

Proposal for a directive
Recital 63 a (new)

Text proposed by the Commission	*Amendment*
	(63 a) The application of this limited exemption is however fragmented across the Union and it is considered necessary, in order to facilitate entering the market of any Member State of medicinal products and in particular generic, biosimilar, hybrid and bio-hybrid medicinal products, upon expiry of the corresponding patent or supplementary protection certificate (EU 'Day-one' entry) that rely on a reference medicinal product, 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. The exemption must be confined to conduct studies, trials and other activities needed for the administrative or regulatory approval process, health technology assessment and and for obtaining pricing and reimbursement, as well as the public and private procurement of medicinal products to be supplied immediately after tbe expiry of the corresponding patent or supplementary protection certificate), even though this may require substantial amounts of test production to demonstrate reliable manufacturing both by the applicant or third party suppliers or service providers. During the term of protection of the patent or SPC of the medicinal product, there can be no placing on the market (within the meaning of the Commission Notice – The 'Blue Guide' on the implementation of EU product rules 2022 2022/C 247/01) in that Member State) of the resulting final medicinal products obtained for the purposes of the regulatory approval process.

Or. en

Amendment 116
Pilar del Castillo Vera

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	(64) It will allow ***all steps required to effectively launch on day-one after patent or SPC protection***, inter alia, to conduct ***activities*** to support ***regulatory approval, health technology assessments,*** pricing and reimbursement ***and other regulatory procedures and requirements in the Union or elsewhere, including after a marketing authorisation has been***

of the patent or SPC protection.	***granted,*** as well as the manufacture or purchase of patent protected active substances for the ***aforementioned purposes***, contributing to ***the timely market entry of medicinal products, in particular*** the market entry of generics and biosimilars***,*** on day one ***after*** loss of the patent or SPC protection***, under fair competitive conditions***.

Or. en

Amendment 117
Cristian-Silviu Buşoi

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 steps required to effectively launch on day-one after patent or SPC protection***, inter alia, to conduct ***activities*** to support ***regulatory approval, health technology assessments,*** pricing and reimbursement ***and other regulatory procedures and requirements in the Union or elsewhere, including after a marketing authorisation has been granted,*** as well as the manufacture or purchase of active substances for the ***aforementioned purposes***, contributing to ***the timely market entry of medicinal products, in particular*** the market entry of generics and biosimilars***,*** on day one ***after*** loss of the patent or SPC protection***, under fair competitive conditions***.

Or. en

Amendment 118
Ville Niinistö
on behalf of the Verts/ALE Group

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 steps required to effectively launch on day-one after patent and SPC protection***, inter alia, to conduct ***activities*** to support ***regulatory approval, health technology assessment,*** pricing and reimbursement as well as the manufacture or purchase of patent protected active substances for the ***aforementioned purposes***, contributing to the market entry of generics and biosimilars on day one of loss of the patent or SPC protection.

Or. en

Amendment 119
Nicolás González Casares, Laura Ballarín Cereza

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 steps required to effectively launch on day-one after patent and SPC protection***, inter alia, to conduct ***activities*** to support ***regulatory approval, health technology assessment,*** pricing and reimbursement as well as the manufacture or purchase of patent protected active substances for the ***aforementioned purposes***, contributing to the market entry of generics and biosimilars on day one of loss of the patent or SPC protection.

Or. en

Amendment 120
Pernille Weiss

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, inter alia, 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.

Or. en

Amendment 121
Henna Virkkunen

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, inter alia, 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.

Or. en

Justification

See justification to Article 85.

Amendment 122
Cristian-Silviu Buşoi

Proposal for a directive
Recital 65

Text proposed by the Commission	*Amendment*
(65) The competent authorities should	(65) ***Avoiding that circumstances may***

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.

encourage inappropriate market behaviours hampering the emergence of generic and biosimilar medicinal products, ensuring timely availability of generic and biosimilar medicinal products and ending patent linkage were highlighted as priorities by Council conclusions and a resolution of the European Parliament. The competent authorities should refuse the validation for an application for a marketing authorisation referring to data of a reference medicinal product ***or for an application for pricing and reimbursement or for the public and private procurement of medicinal products to be supplied immediately after expiry of the relevant patents or SPC*** 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 ***or pricing and reimbursement***. 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 ***and cannot be subject to any requirements that expose an applicant to a risk of infringement of the relevant patent or SPC***.

Or. en

Amendment 123
Pilar del Castillo Vera

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	(65) ***Avoiding that circumstances may encourage inappropriate market behaviours hampering the emergence of generic and biosimilar medicinal products, ensuring timely availability of generic and biosimilar medicinal products***

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.

and ending patent linkage were highlighted as priorities by Council conclusions[1a] and a resolution of the European Parliament[2a]. The competent authorities should refuse the validation for an application for a marketing authorisation referring to data of a reference medicinal product ***or for an application for pricing and reimbursement*** 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 ***or pricing and reimbursement***. 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 ***and cannot be subject to any requirements that expose an applicant to a risk of infringement of the relevant patent or SPC***.

[1a] Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States and Council Conclusions on Access to medicines and medical devices for a Stronger and Resilient EU

[2a] European Parliament resolution of 2 March 2017 on EU options for improving access to medicine

Or. en

Amendment 124
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Recital 65 a (new)

Text proposed by the Commission	*Amendment*
	(65 a) Under EU law, originator reference product patent protection status

is not a criterion to be considered by authorities when granting a marketing authorisation, approving pricing or granting reimbursement status or any regulatory approval for a generic medicinal product, due to its anitcompetitive effects. In the context of the goals of the revision of the pharmaceutical framework, it is therefore appropriate to explicitly prohibit patent linkage practices in this context.

Or. en

Amendment 125
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Recital 65 a (new)

Text proposed by the Commission	*Amendment*
	(65 a) Under EU law, originator reference product patent protection status is not a criterion to be considered by authorities when granting a marketing authorisation, approving pricing or granting reimbursement status or any regulatory approval for a generic medicinal product, due to its anticompetitive effects. In the context of the goals of the revision of the pharmaceutical framework, it is therefore appropriate to explicitly prohibit patent linkage practices in this context.

Or. en

Amendment 126
Susana Solís Pérez, Klemen Grošelj

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 system for all medicinal products.

Or. en

Amendment 127
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Recital 68 a (new)

Text proposed by the Commission	*Amendment*
	(68 a) In line with European Green Deal and the European Union Strategic Approach to Pharmaceuticals in the Environment, this regulatory framework should also contribute to avoiding potential risks to the environment. The evaluation of the framework showed that strengthened measures to reduce the environmental impact of medicinal products in the would be necessary.

Or. en

Amendment 128
Henna Virkkunen

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	(69) The pollution of waters and soils with pharmaceutical residues is an emerging environmental problem, and there is scientific evidence that the ***levels of some of these*** substances ***may pose a risk to*** the environment from their

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]).

manufacturing, use and disposal. 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]).

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[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 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)

[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 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).	(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).	[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).

Or. en

Justification

As written, the text gave the interpretation that all pharmaceutical residues present in the environment pose a problem.

Amendment 129
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Recital 69 a (new)

Text proposed by the Commission	*Amendment*
	(69 a) A progressive reform towards unitary packaging of medicines, in particular in hospital pharmacies, could result in a decrease of the materials used for the packaging of medicines, a reduction of the carbon footprint of the transport of medicines, a reduction in medicines waste, a better management of pollution from pharmaceutical waste, a prevention of tension and shortages of medicines, and an innovative tool to fight against antimicrobial resistance. The use of single dose unit, in hospital environnement, could represent an improvement in favor of minimizing the risk of medication errors and therefore increased patient protection.

Or. en

Amendment 130
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Recital 69 a (new)

Text proposed by the Commission	*Amendment*
	(69 a) There is strong scientific evidence that the emissions of active substances during manufacturing are a threat to the environment and public health. Therefore, the requirements to protect the environment and public health should be extended in order to cover the entire lifecycle of medicinal products, starting from manufacturing, through use and to disposal.

Or. en

Amendment 131
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Recital 70

Text proposed by the Commission	*Amendment*
(70) Marketing authorisation applications for medicinal products in the Union should include an Environmental Risk Assessment (ERA) and risk mitigation measures. ***If*** the applicant fails to submit a complete or sufficiently substantiated environmental risk assessment or they do not propose risk mitigation measures to sufficiently address the risks identified in the environmental risk assessment, the marketing authorisation should be refused. The ERA should be updated when new data or knowledge about relevant risks become available.	(70) Marketing authorisation applications for medicinal products in the Union should include an Environmental Risk Assessment (ERA) and risk mitigation measures. ***The proven efficacy and safety of a medicinal product for human use should remain a top criteria in terms of marketing authorisation, however applicants for marketing authorisation should ensure they complete the ERA in parallel with the marketing authorisation application to be able sufficiently mitigate negative environmental impacts. The ERA should also evaluate the risks to the environment and public health, including antimicrobial resistance that arise in the manufacturing of medicinal products.If*** the applicant fails to submit a complete or sufficiently substantiated environmental risk assessment or they do not propose risk mitigation measures to sufficiently address

	the risks identified in the environmental risk assessment, the marketing authorisation should be refused. The ERA should be updated ***in a timely manner*** when new data or knowledge about relevant risks become available ***and risk mitigation measures should be adapted accordingly***. ***Moreover, to take into account the additional exposure resulting from the use of the medicinal product, the ERA should be updated in any case five years after the initial authorisation.***

Or. en

Amendment 132
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Recital 70

Text proposed by the Commission	*Amendment*
(70) Marketing authorisation applications for medicinal products in the Union should include an Environmental Risk Assessment (ERA) and risk mitigation measures. If the applicant fails to submit a complete or sufficiently substantiated environmental risk assessment or they do not propose risk mitigation measures to sufficiently address the risks identified in the environmental risk assessment, the marketing authorisation should be ***refused***. The ERA should be updated when new data or knowledge about relevant risks become available.	(70) Marketing authorisation applications for medicinal products in the Union should include an Environmental Risk Assessment (ERA) and risk mitigation measures ***in instances where the ERA indicates that medicinal products may be hazardous to the environment***. If the applicant fails to submit a complete or sufficiently substantiated environmental risk assessment or they do not propose risk mitigation measures to sufficiently address the risks identified in the environmental risk assessment ***and does not rectify deficiencies highlighted by the Agency or relevant authority***, the marketing authorisation ***holder*** should be ***subject to proportionate measures taken to ensure compliance while not hindering or postponing patient access to medications***. The ERA should be updated when new data or knowledge about relevant risks become available.

Or. en

Amendment 133
Henna Virkkunen

Proposal for a directive
Recital 70

Text proposed by the Commission	*Amendment*
(70) Marketing authorisation applications for medicinal products in the Union should include an Environmental Risk Assessment (ERA) and risk mitigation measures. If the applicant fails to submit a complete or sufficiently substantiated environmental risk assessment or they do not propose risk mitigation measures to sufficiently address the risks identified in the environmental risk assessment, the marketing authorisation ***should be refused***. The ERA should be updated when new data ***or knowledge*** about relevant risks become available.	(70) Marketing authorisation applications for medicinal products in the Union should include an Environmental Risk Assessment (ERA) and risk mitigation measures ***where medicinal products are demonstrated to pose a risk to the environment according to the ERA***. If the applicant fails to submit a complete or sufficiently substantiated environmental risk assessment or they do not propose risk mitigation measures to sufficiently address the risks identified in the environmental risk assessment, ***and fails to address shortcomings indicated by the Agency or competent authority,*** the marketing authorisation ***shall be provisional while not prohibiting or delaying patient access to medicines***. The ERA should be updated when new data ***that changes the ERA conclusions or evidence*** about relevant risks become available.

Or. en

Justification

Refusing a marketing authorization based solely on environmental concerns could harm the established system for approving medicines and limit patient access to treatments. The ERA should not be the sole reason for denial. Article 22(6) specifies the need for precise and harmonized updates to ERA when conclusions change. While other EU legislation allows for addressing shortcomings in ERAs, it seems that, in this context, initial submission flaws may automatically lead to refusal.

Amendment 134
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive

Recital 70

Text proposed by the Commission	*Amendment*
(70) Marketing authorisation applications for medicinal products in the Union should include an Environmental Risk Assessment (ERA) and risk mitigation measures. If the applicant fails to submit a complete or sufficiently substantiated environmental risk assessment ***or*** they do not propose risk mitigation measures to sufficiently address the risks identified in the environmental risk assessment, the marketing authorisation should be refused. The ERA should be updated ***when*** new data or knowledge about relevant risks become available.	(70) Marketing authorisation applications for medicinal products in the Union should include an Environmental Risk Assessment (ERA) and risk mitigation measures. If the applicant fails to submit a complete or sufficiently substantiated environmental risk assessment***,*** they do not propose risk mitigation measures to sufficiently address the risks identified ***or the environmental risk is deemed unacceptable*** in the environmental risk assessment, the marketing authorisation should be refused. The ERA should be updated ***each time*** new data or knowledge about relevant risks become available.

Or. en

Amendment 135
Pernille Weiss

Proposal for a directive
Recital 70

Text proposed by the Commission	*Amendment*
(70) Marketing authorisation applications for medicinal products in the Union should include an Environmental Risk Assessment (ERA) and risk mitigation measures. If the applicant fails to submit a complete or sufficiently substantiated environmental risk assessment or they do not propose risk mitigation measures to sufficiently address the risks identified in the environmental risk assessment, the marketing authorisation ***should be refused***. The ERA should be updated when new data or knowledge about relevant risks become available.	(70) Marketing authorisation applications for medicinal products in the Union should include an Environmental Risk Assessment (ERA) and risk mitigation measures. If the applicant fails to submit a complete or sufficiently substantiated environmental risk assessment or they do not propose risk mitigation measures to sufficiently address the risks identified in the environmental risk assessment, ***it should be possible to refuse*** the marketing authorisation. The ERA should be updated when new data or knowledge about relevant risks become available.

Or. en

Amendment 136
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Recital 70 a (new)

Text proposed by the Commission	*Amendment*
	(70 a) 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 may still be placed on the market for reasons in the interest of public health, and with certain post authorisation conditions and oblgiations. Where a medicinal product has been authorised and the ERA is imcomplete for the reason above, the marketing authorisation holder should submit the completed ERA in the timeline agreed with the authorities and deliver upon any other post authorisation obligations.

Or. en

Amendment 137
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Recital 70 b (new)

Text proposed by the Commission	*Amendment*
	(70 b) Detailed requirements for an ERA should be set out in the annexes to this Directive for medicinal products that have been authorised prior to October 2005, i.e. prior to the requirement of submitting an ERA, specific provisions should be introduced to set up a programme for the environmental risk assessement of those products that are identified as potentially harmful to the environment. Moreover, the establishment of a single Union assessment of the environmental

properties of active substances for veterinary use by means of an active substance based review ('monograph') system could be potential alternative. Such a system should be set up by the Agency following a positive recommendation of the Commission.

Or. en

Amendment 138
Henna Virkkunen

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 (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.	(71) Marketing authorisation applicants should ***consider the relevance of*** environmental risk ***assessments*** 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 ***while not prohibiting or delaying patient access to medicinal products***.
[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.

Or. en

Justification

Art. 22 (1) specifies that the ERA guideline of EMA is relevant for APIs. Recital 71 however reads as if ERA procedures i.e. guidance of other EU legislation should be considered, therefore the wording should be adapted clearly only asking to consider existing ERAs under other EU legislations.

Amendment 139
Pernille Weiss

Proposal for a directive
Recital 72

Text proposed by the Commission	*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.	(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, there is not a scientifically agreed method to set regulatory values for the contribution of manufacturing to antimicrobial resistance other than for antibiotic resistance. The Commission should therefore issue guidelines on how to conduct ERAs for AMR selection for microbials other than bacteria after consulting the EMA, the European Centre for Disease Prevention and Control (ECDC) and the European Environment Agency.***

Or. en

Amendment 140
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Recital 72

Text proposed by the Commission	*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.	(72) ***Like every industrial sector, the production of medicines has a negative impact on the environment through CO2 emissions deriving from the medicines' global supply chains and through pharmaceutical effluents from the production, use and disposal. In addition,*** 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, ***addressing*** manufacturing***, use and disposal through monitoring, assessing and preventing the negative impact, addressing inefficiencies and developing greener pharmaceuticals is crucial to mitigate threats to public health***.

Or. en

Amendment 141
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Recital 72

Text proposed by the Commission	*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.	(72) The emissions and discharges of antimicrobials to the environment from manufacturing sites may lead to ***the proliferation of*** antimicrobial resistance (“AMR”), which is a global concern regardless ***of*** 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.

Or. en

Amendment 142
Henna Virkkunen

Proposal for a directive
Recital 72

Text proposed by the Commission	*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.	(72) The emissions and discharges of ***antibiotics*** to the environment from manufacturing sites may lead to ***antibiotic*** resistance ("***ABR***"), 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 ***antibiotic resistance*** selection during manufacturing ***of the antibiotics***.

Or. en

Justification

We currently lack a standardized way to assess how manufacturing affects Antimicrobial Resistance (AMR). There's no agreed-upon method for setting regulatory values, like Environmental Quality Standards (EQS) and Predicted No Effect Concentrations (PNECs), to guard against AMR. While there are suggestions, such as using publicly available, standardized effect data, there's no uniform method for determining PNECs for resistance across different antimicrobials. This means it is not possible to thoroughly evaluate the risks posed by AMR at the moment.

Amendment 143
Henna Virkkunen

Proposal for a directive
Recital 74

Text proposed by the Commission	*Amendment*
(74) For medicinal products authorised prior to October 2005, without any ERA, specific provisions should be introduced to set up a risk based prioritisation programme for the ERA submission or	(74) For medicinal products authorised prior to October 2005, without any ERA, specific provisions should be introduced to set up a risk based prioritisation programme for the ERA submission or update by the ***current*** market authorisation

update by the market authorisation holders.	holders ***for those medicinal products that present a serious risk to the environment***.

Or. en

Amendment 144
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Recital 74

Text proposed by the Commission	*Amendment*
(74) For medicinal products authorised prior to October 2005, without any ERA, specific provisions should be introduced to set up a risk based prioritisation programme for the ERA submission or update by the market authorisation holders.	(74) For medicinal products ***that present a significant risk to the environment, and*** authorised prior to October 2005, without any ERA, specific provisions should be introduced to set up a risk based prioritisation programme for the ERA submission or update by the market authorisation holders.

Or. en

Amendment 145
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Recital 74 a (new)

Text proposed by the Commission	*Amendment*
	(74 a) In order to reduce duplication, optimise resources, reduce the use of animals in research, address current lack of understanding and resources on the individual and aggregated impact of pharmaceutical substances in the environment, and in line with the Aarhus Convention, all data related to the environmental risk assessment studies should be made publicly available and easily accessible in a database established by the Agency.

Or. en

Amendment 146
Pilar del Castillo Vera

Proposal for a directive
Recital 76

Text proposed by the Commission	*Amendment*
(76) To ensure that all children in the Union have access to the products specifically authorised for paediatric use, when an agreed paediatric investigation plan has led to the authorisation of a paediatric indication for a product already marketed for other therapeutic indications, the marketing authorisation holder should be obliged to ***place*** the product in the same markets within two years of the date of approval of the indication.	(76) To ensure that all children in the Union have access to the products specifically authorised for paediatric use, when an agreed paediatric investigation plan has led to the authorisation of a paediatric indication for a product already marketed for other therapeutic indications, the marketing authorisation holder should be obliged to ***make*** the product ***available for ordering for paediatric patients*** in the same markets within two years of the date of approval of the indication.

Or. en

Amendment 147
Cristian-Silviu Buşoi

Proposal for a directive
Recital 79

Text proposed by the Commission	*Amendment*
(79) As a general rule, risk management plans for generic and biosimilar medicinal products should not be developed and submitted, considering that the reference medicinal product has such a plan, except in specific cases, where a risk management plan should be provided. Furthermore, as a general rule a marketing authorisation should be granted for an unlimited period; exceptionally, one renewal may be decided only on justified grounds related to the safety of the medicinal product.	(79) As a general rule, risk management plans for generic and biosimilar medicinal products should not be developed and submitted, considering that the reference medicinal product has such a plan, except in specific cases, where a risk management plan should be provided. Furthermore, ***given that the marketing authorisation holder has to forthwith submit any new data that might impact the benefit-risk balance of its products and given that national competent authorities have several tools available to continuously***

monitor the benefits and risks of authorised medicines, such as assessment of PSURs, signal detection and referrals, regulatory action will be taken as needed throughout the lifecycle of the product. Therefore, as a general rule a marketing authorisation should be granted for an unlimited period; exceptionally, one renewal may be decided only on justified grounds related to the safety of the medicinal product.

Or. en

Amendment 148
Susana Solís Pérez, Klemen Grošelj

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 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	(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 ***and 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 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 a certification scheme also for additional quality master files i.e. for active substances other than

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.	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 ***as well as for the raw and initial materials employed in the production of cell and gene therapies, such as cytokines, culture media, reagents, plasmids, and viral vectors***.

Or. en

Amendment 149
Pernille Weiss

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 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	(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 ***and 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 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

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.

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, 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***.

Or. en

Amendment 150
Nicolás González Casares, Laura Ballarín Cereza

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 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	(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 , instead of 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 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

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.

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.

Or. en

Amendment 151
Henna Virkkunen

Proposal for a directive
Recital 96

Text proposed by the Commission	*Amendment*
(96) Scientific and technological progresses in data analytics and data infrastructure provide valuable support to the development, authorisation and supervision of medicinal products. The digital transformation has affected regulatory decision-making, making it more data-driven and multiplying the possibilities for regulatory authorities to access evidence, across the lifecycle of a medicinal product. This Directive recognises the competent authorities of the Member States' capacity to access and analyse data submitted independently from the marketing authorisation applicant or marketing authorisation holder. On ***this*** basis***, competent authorities*** of the ***Member States*** should ***take initiative to update*** the summary of product characteristics in case new ***efficacy or safety data impacts the benefit-risk*** balance of a medicinal product.	(96) Scientific and technological progresses in data analytics and data infrastructure provide valuable support to the development, authorisation and supervision of medicinal products. The digital transformation has affected regulatory decision-making, making it more data-driven and multiplying the possibilities for regulatory authorities to access evidence, across the lifecycle of a medicinal product. This Directive recognises the competent authorities of the Member States' capacity to access and analyse data submitted independently from the marketing authorisation applicant or marketing authorisation holder. On ***the*** basis of the ***totality of evidence made available to the Agency, the Agency*** should ***be able to propose updates to*** the summary of product characteristics in case new ***evidence has an impact on the benefit risk*** balance of a medicinal product. ***In such case, the Agency and the marketing***

authorisation holder should collaborate to determine the particulars of any such update.

Or. en

Justification

Labelling changes, except for safety, should be discussed with the marketing authorization holder (MAH) responsible for the product. Being legally accountable for use, it is best positioned to provide insights. MAHs possess extensive knowledge, ensuring optimal label changes. This approach allows dialogue on evidence supporting changes, enhancing patient safety and meeting healthcare needs. Imposing labels without collaboration undermines existing regulatory processes, violating pharmaceutical legislation obligations and evidence assessment.

Amendment 152
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Recital 100

Text proposed by the Commission	*Amendment*
(100) It is necessary to take account of changes arising as a result of international harmonisation of definitions, terminology and technological developments in the field of pharmacovigilance.	(100) It is necessary to take account of changes arising as a result of international harmonisation of definitions, terminology and technological developments in the field of pharmacovigilance ***and digitalisation***.

Or. en

Amendment 153
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Recital 105

Text proposed by the Commission	*Amendment*
(105) Experience has shown the need to maintain to a certain extent the principle of the use in medicinal products of those colours authorised as food additives. However, it is also appropriate to foresee a specific assessment for the use of the	(105) Experience has shown the need to maintain to a certain extent the principle of the use in medicinal products of those colours authorised as food additives. However, it is also appropriate to foresee a specific assessment for the use of the

colour in medicines when a food additive is removed from Union list of food additives. Therefore, in this specific case, EMA should carry out its own assessment for the use of the colour in medicines, taking into account the EFSA opinion and its underlying scientific evidence, as well as any additional scientific evidence and giving particular consideration to the use in medicines. EMA should also be responsible for following any scientific evidence for the colours retained for specific medicine use only. Directive 2009/35/EC should therefore be repealed.

colour in medicines when a food additive is removed from Union list of food additives ***when it has a functionality beyond colouring***. Therefore, in this specific case, EMA should carry out its own assessment for the use of the colour in medicines, taking into account the EFSA opinion and its underlying scientific evidence, as well as any additional scientific evidence and giving particular consideration to the use in medicines. EMA should also be responsible for following any scientific evidence for the colours retained for specific medicine use only. Directive 2009/35/EC should therefore be repealed.

Or. en

Amendment 154
Nicolás González Casares, Laura Ballarín Cereza

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	(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 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***

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.

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.

Or. en

Amendment 155
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Recital 110

Text proposed by the Commission	*Amendment*
(110) The quality of medicinal products manufactured or available in the Union should be guaranteed by requiring that the active substances used in their composition comply with the principles of good manufacturing practice in relation to those medicinal products. It has proved necessary to reinforce the Union provisions on inspections and to compile a Union database of the results of those inspections.	(110) The quality of medicinal products manufactured or available in the Union should be guaranteed by requiring that the active substances used in their composition comply with the principles of good manufacturing practice in relation to those medicinal products ***and that manufacturing is carried out in compliance with local environmental and occupational health and labour rights standards***. It has proved necessary to reinforce the Union provisions on inspections and to compile a Union database of the results of those inspections.

Or. en

Amendment 156

Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Recital 123

Text proposed by the Commission	*Amendment*
(123) Certain Member States impose on wholesalers who supply medicinal products to pharmacists and on persons authorised to supply medicinal products to the public certain public service obligations. Those Member States should be able to continue to impose those obligations on wholesalers established within their territory. They should also be able to impose them on wholesalers in other Member States on condition that they do not impose any obligation more stringent than those that they impose on their own wholesalers and provided that such obligations may be regarded as warranted on grounds of public health protection and are proportionate in relation to the objective of such protection.	(123) Certain Member States impose on wholesalers who supply medicinal products to pharmacists and on persons authorised to supply medicinal products to the public certain public service obligations. Those Member States should be able to continue to impose those obligations on wholesalers established within their territory. They should also be able to impose them on wholesalers in other Member States on condition that they do not impose any obligation more stringent than those that they impose on their own wholesalers and provided that such obligations may be regarded as warranted on grounds of public health protection and are proportionate in relation to the objective of such protection. ***Member States should also impose certain obligations of public services to wholesalers within the limits of their responsibilities to ensure that medicinal products made available on one market are not placed on another market to avoid creating a shortage for patients.***

Or. en

Amendment 157
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Recital 123 a (new)

Text proposed by the Commission	*Amendment*
	(123 a) Pharmacists have always had a 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. As responsible for dispensing the medicinal products, pharmacists also monitor its proper use and compliance by the patient, provide advice in particular to avoid the risks of iatrogenics (all the undesirable effects caused by taking one or more medications) and carry out medication reviews. In an hospital environment, hospital pharmacists are even setting up pharmaceutical consultations and designing personalised pharmaceutical plans, in cooperation with health professionals, patients and carers. Hospital pharmacists and community pharmacists could play a major role in the progressive digitalisation of package leaflets.

Or. en

Amendment 158
Pernille Weiss

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 and indelible by users, including especially the target patient groups. 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 serve function and readability, rather than aesthetics, and secondarily consider the environmental sustainability of the leaflet.***

Or. en

Amendment 159
Ville Niinistö
on behalf of the Verts/ALE Group

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 are complementary to the paper leaflet that is crucial for patients with limited digital health literacy*** can facilitate access to medicinal products, medicinal products distribution and should always guarantee equal quality of information to all patients compared to the paper form of product information. ***Ensuring the protection of personal data pursuant to Regulation 2016/679 and prohibition of the identification, profiling or tracking of individuals is necessary in this regard.***

Or. en

Amendment 160
Ville Niinistö
on behalf of the Verts/ALE Group

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	(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.	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, ***as an addition to the paper leaflet,*** while ensuring 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, 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.***

Or. en

Amendment 161
Susana Solís Pérez, Klemen Grošelj

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	(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.	harmonised standards developed at EU level. ***Based on the findings from hospital pilots, the obligation to provide a paper leaflet should be lifted for medicinal products not intended for self administration by the patient***

Or. en

Amendment 162
Ville Niinistö
on behalf of the Verts/ALE Group

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 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.	***deleted***

Or. en

Justification

See Recital 128.

Amendment 163
Nicolás González Casares, Laura Ballarín Cereza

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 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.	(129) Member States ***should make*** the package leaflet available electronically ***and*** they should also ensure that a paper version of the package leaflet is ***provided.***. 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. ***However, Member States may choose to use only electronic leaflets for a limited range of medicinal products dispensed to in hospital patients where the provision of medical information can be ensured by health professional. The Commission should be empowered in the future to, by means of delegated acts, transition completely to electronic leaflets.***

Or. en

Amendment 164
Susana Solís Pérez, Klemen Grošelj

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 will facilitate their redistribution between Member States, language requirements on labels will remain a challenge. Removing the obligation for an official language and 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.

Or. en

Amendment 165
Nicolás González Casares, Laura Ballarín Cereza

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 ***and private*** support to the research and development of medicinal products, the reporting of public ***and private*** contribution for the development of a particular medicinal product should be a requirement for all medicines. ***This should apply also to any independent legal entity from which it obtained a license in relation to the medicinal*** product ***in its previous phases of development. The information*** should ***be dissagregated to each stage of drug research and development, basic research, pre-clinical research, phase I, II, III of the clinical investigation of the medicinal product; as well as post-market studies***. Therefore, the provisions of this Directive ensure, without prejudice to the rules on the protection of confidential and personal data, transparency regarding any direct ***and indirect*** financial support received from any public authority or public body to carry out any activities for the research and development of medicinal products.

Or. en

Amendment 166
Ville Niinistö
on behalf of the Verts/ALE Group

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. The provisions of this Directive ***are*** without prejudice to the rules on the protection of confidential and personal data, ***and ensure*** transparency regarding any direct ***and indirect*** financial support received from any public authority***,*** public body***, philantropic and other not-profit organisation including academia*** to carry out any activities for the research and development of medicinal products. ***In addition, when submitting a request for pricing and reimbursement, marketing authorisation holders should disclose, upon request, the company's expenditure related to the research and development costs of the product.***

Or. en

Amendment 167
Pernille Weiss

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	(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.

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 ***of the Union*** to carry out any activities for the research and development of medicinal products.

Or. en

Amendment 168
Susana Solís Pérez

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	(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 ***EU*** public authority or ***EU*** public body to carry out any activities for the research and

development of medicinal products.

development of medicinal products.

Or. en

Amendment 169
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Recital 133

Text proposed by the Commission	*Amendment*
(133) In order to ensure a harmonised and consistent reporting of public contribution for the development of a particular medicinal products, the Commission should be able to adopt implementing acts to clarify the principles and format that the marketing authorisation holder should adhere to when reporting this information.	(133) In order to ensure a harmonised and consistent reporting of public ***and private*** contribution for the development of a particular medicinal products, the Commission should be able to adopt implementing acts to clarify the principles and format that the marketing authorisation holder should adhere to when reporting this information.

Or. en

Amendment 170
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Recital 135

Text proposed by the Commission	*Amendment*
(135) Advertising, even of medicinal products not subject to a prescription, could affect public health and distort competition. Therefore, advertising of medicinal products should meet certain criteria. Persons qualified to prescribe, administer or supply medicinal products can properly evaluate the information available in advertising because of their knowledge, training and experience. The advertising of medicinal products to persons who cannot properly assess the risk associated with their use may lead to medicinal product misuse or	(135) Advertising, even of medicinal products not subject to a prescription, could affect public health and distort competition. Therefore, advertising of medicinal products should meet certain criteria ***ensuring high standards of protection***. Persons qualified to prescribe, administer or supply medicinal products can properly evaluate the information available in advertising because of their knowledge, training and experience. The advertising of medicinal products to persons who cannot properly assess the risk associated with their use may lead to

overconsumption which is liable to harm public health. Therefore advertisement to the general public of medicinal products that are available only on medical prescription should be prohibited. Furthermore, distribution of samples free of charge to the general public for promotional ends is to be prohibited, also teleshopping for medicinal products shall be prohibited pursuant to Directive 2010/13/EU of the European Parliament and of the Council[65] . It should be possible within certain restrictive conditions to provide samples of medicinal products free of charge to persons qualified to prescribe or supply them so that they can familiarise themselves with new products and acquire experience in dealing with them.

medicinal product misuse or overconsumption which is liable to harm public health. Therefore advertisement to the general public of medicinal products that are available only on medical prescription should be prohibited. Furthermore, distribution of samples free of charge to the general public for promotional ends is to be prohibited, also teleshopping for medicinal products shall be prohibited pursuant to Directive 2010/13/EU of the European Parliament and of the Council***[65]***. It should be possible within certain restrictive conditions to provide samples of medicinal products free of charge to persons qualified to prescribe or supply them so that they can familiarise themselves with new products and acquire experience in dealing with them.

[65] Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive) (OJ L 095 15.4.2010, p. 1).

Or. en

Amendment 171
Pernille Weiss

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	(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 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

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.

preparation of delegated acts.

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

Or. en

Amendment 172
Margarita de la Pisa Carrión
on behalf of the ECR Group

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 the Member States and which are industrially prepared or manufactured by a method involving an industrial process***.

Or. en

Amendment 173
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 1 – paragraph 4

Text proposed by the Commission	*Amendment*
4. In cases where, taking into account all its characteristics, a product falls within the definition of a 'medicinal product' and within the definition of a product covered by other Union law and there is a conflict between this Directive and other Union ***law, the provisions of this Directive*** shall ***prevail***.	4. In cases where, taking into account all its characteristics, ***questions arise as to the regulatory status of product or*** a product falls within the definition of a 'medicinal product' and within the definition of a product covered by other Union law and there is a conflict between this Directive and other Union ***legislation, the Agency and the advisory and regulatory bodies established in other Union legislation*** shall ***consult as relevant, in order to find consensus on the regulatory status of the product or the***

application of Union law to the product. Where the Agency and the advisory and regulatory bodies established in other Union legislation cannot reach consensus on the regulatory status or Union law applicable to the product:

(a) The Commission shall be empowered to take a decision on the regulatory status or the Union law applicable to the law in question, duly taking into account the relevant opinions and conclusions of the Agency and other advisory bodies and regulatory bodies established under Union law. This decision along with the supporting analysis and conclusion shall be made publicly available.

(b) For transparency purposes, the respective opinions and conclusions of the Agency and the relevant advisory and regulatory bodies should be made publicly available.

Or. en

Amendment 174
Nicolás González Casares, Laura Ballarín Cereza

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 days.	***deleted***

Or. en

Amendment 175
Margarita de la Pisa Carrión
on behalf of the ECR Group

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 days.	6. Medicinal products referred to in paragraph 5, point ***(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.

Or. en

Amendment 176
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 1 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6 a. The stipulations mentioned in paragraph 5, sections (a) and (b), as well as paragraph 6, are contingent upon the provision that all referenced items are formulated to cater to the unique requirements of individual patients. Furthermore, these items must adhere to all protocols set forth by the Convention on the Elaboration of a European Pharmacopoeia. This includes conformity with all relevant general and specific Monographs that have been ratified in accordance with that Convention.

Or. en

Amendment 177
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 1 – paragraph 10

Text proposed by the Commission	*Amendment*
10. This Directive shall not affect the application of national legislation prohibiting or restricting the following:	***deleted***
(a) the sale, supply or use of medicinal products as contraceptives or abortifacients;	
(b) the use of any specific type of substance of human origin or animal cells, on grounds not dealt with in the aforementioned Union law;	
(c) the sale, supply or use of medicinal products containing, consisting of or derived from these animal cells or substances of human origin, on grounds not dealt with in Union law.	

Or. en

Amendment 178
Susana Solís Pérez, Klemen Grošelj

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 patient ('advanced therapy medicinal products prepared under hospital exemption').	1. By way of derogation from Article 1(1), only this Article shall apply to advanced therapy medicinal products prepared ***incidentally and exceptionally*** on a non-routine basis ***as defined in this paragraph and*** 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 patient ('advanced therapy medicinal products prepared under hospital exemption').
	Within the context of this Article, 'non-routine basis' refers to the tailored

preparation of an advanced therapy medicinal product under a hospital exemption, which occurs sporadically, under extraordinary circumstances, and is not part of a regular process, aimed at addressing the unique health requirements of a specific patient.

This is applicable when no medicinal product with central authorization is accessible, nor is there a suitable clinical trial or program for compassionate use active for that particular medical need, for which the patient qualifies within the European Union. Indicators that an activity is conducted routinely include:

(a) production of a product through processes that are standardized or repetitive;

(b) engagement in planning processes that extend beyond the immediate clinical requirements of individual patients. The Agency is authorized to formulate guidelines for the practical application of what constitutes a 'non-routine basis'. In doing so, it must engage with national regulatory authorities and key stakeholders, including entities holding hospital exemption approvals, the pharmaceutical industry, and patient groups.

Reflecting advancements in science and technology, the Commission has the authority to update the definition of 'non-routine' through implementing acts.

Or. en

Amendment 179
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 2 – paragraph 1

Text proposed by the Commission	*Amendment*
1. By way of derogation from Article	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 patient ('advanced therapy medicinal products prepared under hospital exemption').	1(1), only this Article shall apply to advanced therapy medicinal products prepared 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 patient ('advanced therapy medicinal products prepared under hospital exemption').

Or. en

Amendment 180
Pernille Weiss

Proposal for a directive
Article 2 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. 1a. For the purpose of this Article, 'non-routine basis' means an advanced therapy medicinal product prepared under hospital exemption on an incidental and exceptional basis to meet the special needs of an individual patient, where there is neither a centrally authorised medicinal product available,nor an ongoing relevant clinical trial or compassionate use programme for the same indication with an advanced therapy medicinal product for which the patient is eligible in the Union. The following measures shall be an indication that an activity occurs on a routine basis:
	(a) the manufacturing of a product using standardised or repetitive processes; or
	(b) the use of processes that involve planning in advance, beyond what is needed to address the immediate clinical needs of individual patients.

Or. en

Amendment 181
Pernille Weiss

Proposal for a directive
Article 2 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
The manufacturing of an advanced therapy medicinal product prepared under hospital exemption shall require an approval by the competent authority of the Member State ('hospital exemption approval'). Member States shall notify any such approval, as well as subsequent changes, to the Agency.	The manufacturing of an advanced therapy medicinal product prepared under hospital exemption shall require an approval by the competent authority of the Member State ('hospital exemption approval'). Member States shall notify any such approval, as well as subsequent changes, to the Agency ***which shall publish such approval in the repository referred to in paragraph 6***. ***The hospital exemption approval shall be valid for a period of 12 months.***

Or. en

Amendment 182
Susana Solís Pérez, Klemen Grošelj

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. ***Approval will be contingent on an evaluation of the risks and benefits, adhering to the stipulations and interpretations provided in this Article. Such approval will not exceed a one-year term and can only be renewed after a thorough review to confirm the ongoing necessity of the hospital exemption for individual patient requirements. This includes verifying the continued absence of any centrally approved product, suitable clinical trial, compassionate use***

program, or other regulated options within the EU since the original approval was granted, and ensuring that the production of the product remains infrequent as specified in this article.

The Commission is empowered to elaborate on the particulars of submitting and updating applications for hospital exemption approval as delineated in this Article, through implementing acts.

Or. en

Amendment 183
Pernille Weiss

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 efficacy of the advanced therapy medicinal products prepared under hospital exemption. Before a hospital exemption approval is granted, the competent authority of the Member State shall confirm that no advanced therapy medicinal product is authorised within the Union for the same therapeutic indication, and that the manufacturing of such medicinal product complies with the requirements for preparation on a non-routine basis as set out in paragraph 1.***

Or. en

Amendment 184
Nicolás González Casares, Laura Ballarín Cereza

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 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]. ***This shall include site inspections and GMP CPF accreditation, 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).	

Or. en

Amendment 185
Nicolás González Casares, Laura Ballarín Cereza

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	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.

competent authority of the Member State at least annually. The competent authority of the Member State shall ***set the requirements for the collection and reporting of such data, in a structured and standarized way that allows obtaining more 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 sufficient scientific and regulatory advice is provided to non-profit and academic institutions in order to ensure appropriate reporting mechanisms.***

Or. en

Amendment 186
Susana Solís Pérez, Klemen Grošelj

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***, quality***, 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 ***collected data must encompass ongoing monitoring results for an adequate duration following the product's use. 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.

Or. en

Amendment 187
Pernille Weiss

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***, quality***, safety and the efficacy of advanced therapy medicinal products prepared under hospital exemption***, as well as any relevant data from patient follow-up,*** 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.

Or. en

Amendment 188
Margarita de la Pisa Carrión
on behalf of the ECR Group

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	4. Member States shall ensure that data on the use***, quality***, safety and the efficacy of advanced therapy medicinal products prepared under hospital exemption***, as well as any relevant data from patient follow-up*** 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

prepared under hospital exemption with the requirements referred to in paragraph 3.	compliance of advanced therapy medicinal products prepared under hospital exemption with the requirements referred to in paragraph 3.

Or. en

Amendment 189
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 2 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4 a. Competent authorities shall ensure that sufficient scientific and regulatory advice is provided to non-profit and academic institutions in order to assist them through the requirements of the hospital exemption clause. In cases where a product under hospital exemption becomes a suitable candidate to begin a centralized marketing authorization procedure, competent authorities shall assist non-profit and academic institutions also through this authorization process.

Or. en

Amendment 190
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 2 – paragraph 5

Text proposed by the Commission	*Amendment*
5. If a hospital exemption approval is revoked due to safety or efficacy concerns the competent authority of the Member States that approved the hospital exemption shall inform the Agency and the competent authorities of the other Member States.	5. ***Should the holder of the hospital exemption approval fail to meet the conditions outlined in the preceding paragraphs, the authorization will be withdrawn by the national regulatory authority.*** If a hospital exemption approval is revoked due to ***quality,*** safety or efficacy

concerns the competent authority of the Member States that approved the hospital exemption shall inform the Agency and the competent authorities of the other Member States ***as well as inform the patient who has received the advanced therapy medicinal product produced under the hospital exemption***. ***Additionally, there should be a notification to the patient who has been administered the advanced therapy medicinal product formulated under the hospital exemption.***

Or. en

Amendment 191
Pernille Weiss

Proposal for a directive
Article 2 – paragraph 5

Text proposed by the Commission	*Amendment*
5. If a hospital exemption approval is revoked due to safety or efficacy concerns the competent authority of the Member States that approved the hospital exemption shall inform the Agency and the competent authorities of the other Member States.	5. If a hospital exemption approval is revoked due to ***quality,*** safety or efficacy concerns the competent authority of the Member States that approved the hospital exemption shall inform the Agency and the competent authorities of the other Member States.

Or. en

Amendment 192
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 2 – paragraph 5

Text proposed by the Commission	*Amendment*
5. If a hospital exemption approval is revoked due to safety or efficacy concerns the competent authority of the Member States that approved the hospital exemption	5. If a hospital exemption approval is revoked due to ***quality,*** safety or efficacy concerns the competent authority of the Member States that approved the hospital

shall inform the Agency and the competent authorities of the other Member States.	exemption shall inform the Agency and the competent authorities of the other Member States.

Or. en

Amendment 193
Susana Solís Pérez, Klemen Grošelj

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***, quality***, 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 ***, such an EU-wide registry will be obligatory and open to the public, requiring regular updates to remain current and encompass a catalogue of the advanced therapy medicinal products formulated under hospital exemption currently employed in the Union, also specifying instances where such approval has been suspended or revoked***.

Or. en

Amendment 194
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 2 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The competent authority of the	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.	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***, as well as of information on the authorisation, suspension or withdrawal of hospital exemption approvals, reimbursement prices, and public and private contributions to the development of the product; which shall be updated regularly***.

Or. en

Amendment 195
Pernille Weiss

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***, quality***, 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 ***publicly accessible*** repository of that data***, as well as of information on the authorisation, suspension or withdrawal of hospital exemption approvals, which shall be updated regularly***.

Or. en

Amendment 196

Margarita de la Pisa Carrión
on behalf of the ECR Group

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***, quality***, 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 ***public*** repository of that data.

Or. en

Amendment 197
Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*
(b) the format for collection and reporting of data referred to in paragraph 4;	(b) the format for collection and reporting of data referred to in paragraph ***3 and*** 4;

Or. en

Amendment 198
Pernille Weiss

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	***deleted***

products under hospital exemption on a non-routine basis.

Or. en

Justification

See amendment to Article 2 – paragraph 1 a (new).

Amendment 199
Susana Solís Pérez, Klemen Grošelj

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.	(d) the modalities for ***harmonised implementation of the*** preparation and use of advanced therapy medicinal products under hospital exemption on a non-routine basis.

Or. en

Amendment 200
Nicolás González Casares, Laura Ballarín Cereza

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.***	(d) the modalities for preparation and use of advanced therapy medicinal products under hospital exemption***;***

Or. en

Amendment 201
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive

Article 2 – paragraph 7 – subparagraph 1 – point d a (new)

Text proposed by the Commission	*Amendment*
	(d a) the modalities of guidance for academic and other not-for-profit entities through the requirements of the hospital exemption clause and the centralised marketing authorisation procedure.

Or. en

Amendment 202
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 2 – paragraph 7 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	the data collection by Member States should cover the application of the hospital exemption, details of the patient group treated including patient counts, and the outcomes related to clinical efficacy and safety, as well as quality of life assessments.

Or. en

Amendment 203
Susana Solís Pérez, Klemen Grošelj

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 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	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.	entering into force of this Directive] and then every five years thereafter. ***The contents of these reports, which detail the data, will be accessible to the public and will be taken into account during future legislative deliberations or amendments, subsequent to consultations with involved parties.***

Or. en

Amendment 204
Pernille Weiss

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 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.	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 ***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.

Or. en

Amendment 205
Margarita de la Pisa Carrión
on behalf of the ECR Group

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 ***public access*** report on the experience acquired with the hospital exemption approvals on the basis of

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.	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.

Or. en

Amendment 206
Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*
	8 a. Competent authorities shall guarantee that the authorization of products through the centralized procedure shall not adversely affect the activities and responsibilities of developers functioning under the hospital exemption as outlined in paragraphs 3 and 4.

Or. en

Amendment 207
Nicolás González Casares, Laura Ballarín Cereza

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 specifications of an authorised healthcare professional and for use by an individual patient under their direct personal responsibility. However, in such case	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***, or prepared in accordance***

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.	***with the specifications of a competent authority***. 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.

Or. en

Amendment 208
Pernille Weiss

Proposal for a directive
Article 3 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
For allergen medicinal products supplied in accordance with this paragraph, the competent authorities of the Member State may request the submission of relevant information in accordance with Annex II.	***deleted***

Or. en

Justification

See AM to Annex I one of the revised pharmaceutical regulation.

Amendment 209
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Without prejudice to Article 30 of [revised Regulation (EC) No 726/2004], Member States may temporarily authorise the use and distribution of an unauthorised medicinal product in response to a ***suspected or*** confirmed spread of	2. Without prejudice to Article 30 of [revised Regulation (EC) No 726/2004], ***only*** Member States may temporarily authorise ***in the case of an official sanitary emergency, if doesn't exist other effective therapeutical alternative,*** the use and

pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm.

distribution of an unauthorised medicinal product in response to a confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm.

Or. en

Amendment 210
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 3 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States ***shall ensure that marketing authorisation holders, manufacturers and healthcare professionals are not subject to civil or administrative liability for any consequences*** resulting from the use of a medicinal product otherwise than for the authorised therapeutic indications or from the use of an unauthorised medicinal product, where such use is recommended ***or required*** by a competent authority in response to the ***suspected or*** confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm. Such provisions shall apply whether or not a national or a centralised marketing authorisation has been granted.	3. Member States ***will be responsable*** resulting from the use of a medicinal product otherwise than for the authorised therapeutic indications or from the use of an unauthorised medicinal product, where such use is recommended by a competent authority in response to the ***officiatly*** confirmed spread ***(indicated in the article 3.2)*** of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm. Such provisions shall apply whether or not a national or a centralised marketing authorisation has been granted.

Or. en

Amendment 211
Pernille Weiss

Proposal for a directive
Article 4 – paragraph 1 – point 2 – point d

Text proposed by the Commission	*Amendment*

(d) chemical, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis;	(d) chemical, e.g. elements***, including radioactive isotopes thereof (radionuclides)***, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis;

Or. en

Amendment 212
Pernille Weiss

Proposal for a directive
Article 4 – paragraph 1 – point 4

Text proposed by the Commission	*Amendment*
(4) 'starting material' means any material from which an active substance is manufactured or extracted;	(4) 'starting material' means any material***, including radioactive materials,*** from which an active substance is manufactured or extracted;

Or. en

Amendment 213
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
	(4 a) 'plasma for fractionation' means the liquid part of human blood separated from whole blood or collected by apheresis and intended to be used as the starting material for manufacture of plasma-derived medicinal products;

Or. en

Amendment 214
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive

Article 4 – paragraph 1 – point 10 a (new)

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

Or. en

Amendment 215
Pernille Weiss

Proposal for a directive
Article 4 – paragraph 1 – point 18

Text proposed by the Commission	*Amendment*
(18) 'radiopharmaceutical' means any medicinal product that, when ready for use, contains ***one or more*** radionuclides ***(radioactive isotopes) included for a medicinal purpose***;	(18) 'radiopharmaceutical' means any medicinal product that, when ready for use, contains ***a radioactive component and that is intended to treat or diagnose a disease, including radionuclide radiopharmaceuticals and complex radiopharmaceuticals, not including*** radionuclides ***used only for radiolabelling purposes, medical devices and in-vitro diagnostic devices***;

Or. en

Amendment 216
Pernille Weiss

Proposal for a directive
Article 4 – paragraph 1 – point 18 a (new)

Text proposed by the Commission	*Amendment*
	(18 a) 'radionuclide radiopharmaceuticals' means a radiopharmaceutical where the radionuclide or its salt is the active

substance;

Or. en

Amendment 217
Pernille Weiss

Proposal for a directive
Article 4 – paragraph 1 – point 18 b (new)

Text proposed by the Commission	*Amendment*
	(18 b) 'complex radiopharmaceutical' means a radiopharmaceutical where the radionuclide is bound to or within a carrier molecule to achieve the targeted accumulation, including ready-to-use dosage forms and kits for radiopharmaceutical preparation;

Or. en

Amendment 218
Pernille Weiss

Proposal for a directive
Article 4 – paragraph 1 – point 19

Text proposed by the Commission	*Amendment*
(19) 'radionuclide generator' means any system incorporating a fixed parent radionuclide from which ***is produced*** a daughter radionuclide ***which is to be obtained by elution or by any other method and used in a radiopharmaceutical***;	(19) 'radionuclide generator' means any system incorporating a fixed parent radionuclide from which a daughter radionuclide ***is produced, where the daughter radionuclide is used either as a medicinal product or as a radionuclide for radiolabelling purposes***;

Or. en

Amendment 219
Pernille Weiss

Proposal for a directive

Article 4 – paragraph 1 – point 20

Text proposed by the Commission	*Amendment*
(20) 'kit***' means any*** preparation ***to be reconstituted or combined with radionuclides in the final*** radiopharmaceutical, ***usually prior to its administration***;	(20) 'kit ***for radiopharmaceutical*** preparation***' means a pre-formulated medicinal product containing all ingredients required to directly prepare a*** radiopharmaceutical, ***with the exception of the radionuclide***;

Or. en

Amendment 220
Pernille Weiss

Proposal for a directive
Article 4 – paragraph 1 – point 21

Text proposed by the Commission	*Amendment*
(21) 'radionuclide precursor' means any other radionuclide produced for the radio-labelling of another substance prior to administration;	***deleted***

Or. en

Amendment 221
Susana Solís Pérez, Klemen Grošelj

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***,*** ***antiparasitics*** and antifungals;

Or. en

Amendment 222
Pernille Weiss

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 ***Regulations (EU) 2017/745 and (EU) 2017/746)*** and where the two are intended for use in the given combination in accordance with the summary of product characteristics;

Or. en

Amendment 223
Cristian-Silviu Buşoi

Proposal for a directive
Article 4 – paragraph 1 – point 28

Text proposed by the Commission	*Amendment*
(28) 'vaccine’ means any medicinal product that ***is intended to*** elicit an immune response for prevention, ***including post exposure*** prophylaxis, ***and for*** treatment of diseases caused by ***an*** infectious ***agent***;	(28) ‘vaccine’ means any medicinal product ***containing antigen(s) or genetic information for antigen(s)*** that elicit an immune response ***and therefore are intended*** for prevention, ***post-exposure*** prophylaxis, ***and/or*** treatment of diseases caused by infectious ***agents***;

Or. en

Amendment 224
Pernille Weiss

Proposal for a directive
Article 4 – paragraph 1 – point 28

Text proposed by the Commission	*Amendment*
(28) 'vaccine' means any medicinal product that is intended to elicit an immune response for prevention, including post exposure prophylaxis, ***and for treatment*** of diseases caused by an infectious agent;	(28) 'vaccine' means any medicinal product that is intended to elicit an immune response for prevention, including post exposure prophylaxis, of diseases caused by an infectious agent;

Or. en

Amendment 225
Pilar del Castillo Vera

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

Text proposed by the Commission	*Amendment*
	(30 a) 'platform technology' means a specific technology or a collection of technologies used in the manufacturing process and/or the quality control, the nonclinical or clinical testing of one or more medicinal products and/or components that rely on prior knowledge and are established under the same underlying scientific principles. The Commission should promote the development of Platform Technologies that should be part of an open platform, available for the different developers (academic, small biotech and big pharma) generating knowledge and data that once available can accelerate the process of development and evaluation of new therapies. In this context, the supported Platform Technology will appear in the status of PRE-COMPETITION and if it is having advantage of as an existing patent, it will be available under reasonable fee. These Platform Technologies once open to all the stakeholders can be easily updated while having regulatory support in benefit of EU patients. Or. {EN}en

Or. en

Amendment 226
Pernille Weiss

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

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

Or. en

Amendment 227
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
	(30 b) '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, will apply regardless of components added to the platform as part of the manufacturing process for a medicinal product;

Or. en

Amendment 228
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
(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;	(33) 'environmental risk assessment' means the evaluation of the ***potential*** risks to the environment, ***including*** risks to public health ***arising from risks to the environment***, 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;

Or. en

Amendment 229
Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*
(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;	(33) 'environmental risk assessment' means the evaluation of the ***risks and potential*** risks to the environment, or risks to public health, posed by the release of the medicinal product in the environment from the use***, manufacturing*** 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;

Or. en

Amendment 230

Cristian-Silviu Buşoi

Proposal for a directive
Article 4 – paragraph 1 – point 36 a (new)

Text proposed by the Commission	*Amendment*
	(36 a) 'Quality master file' means a document that contains a detailed description of the manufacturing process, quality control during manufacture and process validation of an active substance other than a chemical active substance, or of any other substances present or used in the manufacture of a medicinal product, required in accordance with Annex II, prepared in a separate document by the manufacturer of the substance or component.

Or. en

Amendment 231
Pilar del Castillo Vera

Proposal for a directive
Article 4 – paragraph 1 – point 36 a (new)

Text proposed by the Commission	*Amendment*
	(36 a) 'platform technology master file' means a document that contains a detailed description of a platform technology for which the underlying scientific principles under which the platform technology is established. This can encompass quality, pre-clinical and/or clinical data in relation to the medicinal products and/or components the platform technology refers to.

Or. en

Amendment 232
Cristian-Silviu Buşoi

Proposal for a directive
Article 4 – paragraph 1 – point 36 b (new)

Text proposed by the Commission	*Amendment*
	(36 b) Platform technology' means a collection of technologies used in the manufacturing process and/or the quality control of one or more medicinal products or their components that rely on shared prior knowledge and are established under the same underlying scientific principles. Platform technologies can encompass a variety of activities, including without being limited to similar formulations, manufacturing steps and analytical testing.

Or. en

Amendment 233
Cristian-Silviu Buşoi

Proposal for a directive
Article 4 – paragraph 1 – point 36 c (new)

Text proposed by the Commission	*Amendment*
	(36 c) 'Platform technology master file' means a document that contains all data relative to a platform technology for which there is reasonable certainty that the underlying scientific principles under which the platform technology is established will apply regardless of the active substance or other component of interest added to the platform as part of the manufacturing process of a medicinal product. The nature of the data to be included in the platform technology master file will be defined by the applicant depending on the type of platform technology. The platform technology master file needs to be supplied in a separate document by the platform technology owner.

Or. en

Amendment 234
Patrizia Toia, Beatrice Covassi

Proposal for a directive
Article 4 – paragraph 1 – point 38 a (new)

Text proposed by the Commission	*Amendment*
	(38 a) 'medicinal product authorised for a paediatric indication' means a medicinal product which is authorised for use in part or all of the paediatric population and in respect of which the details of the authorised indication are specified in the summary of the product characteristics

Or. en

Amendment 235
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 4 – paragraph 1 – point 39

Text proposed by the Commission	*Amendment*
(39) '***medicinal*** prescription' means ***any medicinal*** prescription issued by a ***professional person qualified*** to do so***;***	(39) 'Prescription' means ***a*** prescription ***for a medicinal product*** issued by a ***member of a regulated health profession within the meaning of Article 3 (1) (a) of Directive 2005/36/EC who is legally entitled*** to do so ***in the Member State in which the prescription is issued***

Or. en

Amendment 236
Cristian-Silviu Buşoi

Proposal for a directive
Article 4 – paragraph 1 – point 48

Text proposed by the Commission	*Amendment*
(48) ‘common name’ means the international non-proprietary name recommended by the World Health Organization for an active substance;	(48) ‘common name’ means the international non-proprietary name recommended by the World Health Organization for an active substance***, or, if one does not exist, the usual common name***;

Or. en

Amendment 237
Pernille Weiss

Proposal for a directive
Article 4 – paragraph 1 – point 53

Text proposed by the Commission	*Amendment*
(53) ‘micro, small and medium-sized enterprises’ means micro, small and medium-sized enterprises as defined in Article 2 of Commission Recommendation 2003/361/EC[72] ;	(53) ‘micro, small and medium-sized enterprises’ means micro, small and medium-sized enterprises as defined in Article 2 of Commission Recommendation 2003/361/EC[72] ***and, from ... [18 months after the date of entry into force of this Directive], it means micro, small and medium-sized enterprises as defined in the delegated act referred to in Article 58a(1)***;
[72] Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).	[72] Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

Or. en

Amendment 238
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 4 – paragraph 1 – point 61 a (new)

Text proposed by the Commission	*Amendment*

(61 a) 'adverse event' any health problem that occurs after administration without having to be caused by the administration of a medication. Afterwards, it will be determined if they are coincident or related.

Or. en

Amendment 239
Pernille Weiss

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 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 ***reasonable*** time over the whole of the area in question.

Or. en

Amendment 240
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 4 – paragraph 1 – point 70 a (new)

Text proposed by the Commission	*Amendment*
	(70 a) Decentralised manufacturing means a production model where manufacturing of medicinal products needs to take place in local sites close to patients.

Or. en

Amendment 241

Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
2. When an initial marketing authorisation has been granted in accordance with paragraph 1, any development concerning the medicinal product covered by the authorisation such as additional therapeutic indication, strengths, pharmaceutical forms, administration routes, presentations, as well as any variations of the marketing authorisation shall also be granted an authorisation in accordance with paragraph 1 or be included in the initial marketing authorisation. All those marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the marketing authorisations applications under Articles 9 to 12, including as regards the expiry of the regulatory data protection period for applications using a reference medicinal product.	2. When an initial marketing authorisation has been granted in accordance with paragraph 1, any development concerning the medicinal product covered by the authorisation such as additional therapeutic indication, strengths, pharmaceutical forms, administration routes, presentations, as well as any variations of the marketing authorisation shall also be granted an authorisation in accordance with paragraph 1 or be included in the initial marketing authorisation. All those marketing authorisations ***as well as those obtained by this marketing authorisation holder according to article 9 to 12*** shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the marketing authorisations applications under Articles 9 to 12, including as regards the expiry of the regulatory data protection period for applications using a reference medicinal product.

Or. en

Amendment 242
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
	2 a. 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.

Or. en

Justification

See amendments to new Article 26a

Amendment 243
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 6 – paragraph 5 – subparagraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(a a) in the absence of comparative studies, a justification to substantiate the reasons why the above mentioned studies could not be conducted;

Or. en

Amendment 244
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 6 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6 a. 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.

Or. en

Amendment 245
Nicolás González Casares, Laura Ballarín Cereza

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

Or. en

Amendment 246
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 9 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
Paragraph 1 shall also apply if the reference medicinal product has not been authorised in the Member State in which the application for the generic medicinal product is submitted***. In this case***, the applicant shall indicate in the application the name of the Member State in which the reference medicinal product is or has been authorised. At the request of the competent authority of the Member State in which the application is submitted, the competent authority of the other Member State shall transmit within a period of one month a confirmation that the reference medicinal product is or has been authorised together with the full composition of the reference medicinal product and if necessary, any	Paragraph 1 shall also apply if the reference medicinal product has not been authorised in the Member State in which the application for the generic medicinal product is submitted***, unless the applicant of the generic product is also the MAH or a related company of the reference medicinal product. In the latter case the complete dossier should be submitted. In the former case,***, the applicant shall indicate in the application the name of the Member State in which the reference medicinal product is or has been authorised. At the request of the competent authority of the Member State in which the application is submitted, the competent authority of the other Member State shall

other relevant documentation.	transmit within a period of one month a confirmation that the reference medicinal product is or has been authorised together with the full composition of the reference medicinal product and if necessary, any other relevant documentation.

Or. en

Amendment 247
Nicolás González Casares, Laura Ballarín Cereza

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 ***and*** clinical studies shall be provided to to the extent necessary to ***demonstrate (essential) similarity to*** the marketing authorisation for the reference medicinal product, and to demonstrate the safety and efficacy profile of the hybrid medicinal product ***in any additional indication***.

Or. en

Amendment 248
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 11 – paragraph 1

Text proposed by the Commission	*Amendment*
For a ***biological*** medicinal product that is similar to a reference biological medicinal	For a medicinal product that is similar to a reference biological medicinal product

product (‘biosimilar medicinal product’), the results of appropriate comparability tests and studies shall be provided to the competent authorities. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex II and the related detailed guidelines. The results of other tests and studies from the reference medicinal product's dossier shall not be provided.	(‘biosimilar medicinal product’), the results of appropriate comparability tests and studies shall be provided to the competent authorities. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex II and the related detailed guidelines. The results of other tests and studies from the reference medicinal product's dossier shall not be provided.

Or. en

Justification

As for all types of medicinal products, all follow-ons to biologic medicines should be regulated based on sound scientific principles and established regulatory standards of safety, efficacy, and quality. Currently there is regulatory uncertainty about how synthetic follow-ons to biologic medicines are approved. All follow-ons to biological medicines should be appropriately assessed following an enhanced Article 11 of the proposed Directive. Appropriate non-clinical and clinical tests are added in art 11, considering the proposed deletion of Art. 12. Relating to the fact that synthetic follow-ons are not per se biosimilars – the proposed new paragraph is introduced. Further explanation on the role of biosimilar medicinal product and synthetic follow-on medicinal product: Scientifically, differences in manufacturing processes may significantly alter the properties of synthetic polypeptide products and could result in adverse clinical consequences. A synthetic follow-on product will likely differ from the biological reference product with regard to impurity profile and could differ with regard to stability, for example a different tendency towards fibrillation. This may lead to increased immunogenicity. It is important that these factors as well as the overall complexity of the product are considered in the development and subsequent regulatory evaluation. Available analytical methods may be insufficient to establish therapeutic equivalence of a synthetic follow-on product to a biological reference product; this applies in particular to non-clinical models to predict immunogenicity.

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

Proposal for a directive
Article 11 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Where a medicinal product is not a biological medicinal product but it is similar to a reference biological medicinal product (‘synthetic follow-on medicinal

	product'), paragraph 1 shall apply and the synthetic follow-on medicinal product shall be subject to the requirements of this Directive and [revised Regulation 726/2004] applicable to biosimilar medicinal products.

Or. en

Amendment 250
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 12

Text proposed by the Commission	*Amendment*
Article 12	***deleted***
Applications concerning bio-hybrid medicinal products	
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.	

Or. en

Amendment 251
Nicolás González Casares, Laura Ballarín Cereza

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 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 ***and demonstration that this literature is relevant for the applied product***.

Or. en

Amendment 252
Pernille Weiss

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 and multi-medicinal product packages

Or. en

Amendment 253
Pernille Weiss

Proposal for a directive
Article 15 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where justified for therapeutic purposes, a marketing authorisation may be granted for a fixed dose combination medicinal product.	1. Where justified for ***preventative or*** therapeutic purposes, a marketing authorisation may be granted for a fixed dose combination medicinal product.

Or. en

Amendment 254
Cristian-Silviu Buşoi

Proposal for a directive
Article 15 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where justified for therapeutic purposes, a marketing authorisation may be granted for a fixed dose combination medicinal product.	1. Where justified for ***preventive or*** therapeutic purposes, a marketing authorisation may be granted for a fixed dose combination medicinal product.

Or. en

Amendment 255
Pernille Weiss

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 ***preventative or*** 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.

Or. en

Justification

See amendment to Article 4 – paragraph 1 – point 30 a (new).

Amendment 256
Cristian-Silviu Buşoi

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 ***preventive or*** 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.

Or. en

Amendment 257
Cristian-Silviu Buşoi

Proposal for a directive
Article 15 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
An applicant that intends to submit an application for a marketing authorisation for such a medicinal product shall seek, in advance, the agreement concerning the submission of such application by the competent authority concerned.	***deleted***

Or. en

Amendment 258
Cristian-Silviu Buşoi

Proposal for a directive
Article 15 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
Where justified for public health reasons and ***when the active substances cannot be combined within a fixed dose combination medicinal product***, a marketing authorisation may, in exceptional circumstances, be granted to a multi-medicinal product package.	Where justified for public health reasons and ***for a preventive or therapeutic purposes***, a marketing authorisation may, in exceptional circumstances, be granted to a multi-medicinal product package.

Or. en

Amendment 259
Cristian-Silviu Buşoi

Proposal for a directive
Article 15 – paragraph 3 – subparagraph 2

Text proposed by the Commission	*Amendment*
An applicant that intends to submit a an application for a marketing authorisation for such a medicinal product shall seek, in advance, the agreement concerning the submission of such application by the competent authority concerned.	***deleted***

Or. en

Amendment 260
Pernille Weiss

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***	1. A marketing authorisation shall be required for radiopharmaceuticals.

radiopharmaceuticals ***covered by a marketing authorisation under Article 5(1)***.

Or. en

Amendment 261
Margarita de la Pisa Carrión
on behalf of the ECR Group

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 ***radiopharmaceuticals*** generators, kits, and precursors radiopharmaceuticals.

Or. en

Amendment 262
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 16 – paragraph 2

Text proposed by the Commission	*Amendment*
2. A marketing authorisation shall not be required for a radiopharmaceutical prepared at the time of use by ***a*** person or ***by an*** establishment authorised***, according to national legislation, to use such*** radiopharmaceutical ***in an approved healthcare establishment exclusively from authorised*** radionuclide ***generators, kits*** or radionuclide ***precursors*** in accordance with the ***manufacturer's instructions***.	2. A marketing authorisation shall not be required ***for radionuclides or radionuclide generators solely used for radiolabelling purposes, or*** for a radiopharmaceutical prepared at the time of use by ***an authorised*** person or establishment ***using an*** authorised ***kit for*** radiopharmaceutical ***preparation in combination with a*** radionuclide or radionuclide ***generator*** in accordance with the ***summary of product characteristics of***

the kit ('kit-radiolabelling').

Or. en

Amendment 263
Pernille Weiss

Proposal for a directive
Article 16 – paragraph 2

Text proposed by the Commission	*Amendment*
2. A marketing authorisation shall not be required for a radiopharmaceutical prepared at the time of use by ***a*** person or ***by an*** establishment authorised***, according to national legislation, to use such*** radiopharmaceutical ***in an approved healthcare establishment exclusively from authorised*** radionuclide ***generators, kits*** or radionuclide ***precursors*** in accordance with the ***manufacturer's instructions***.	2. A marketing authorisation shall not be required ***for radionuclides or radionuclide generators solely used for radiolabelling purposes, or*** for a radiopharmaceutical prepared at the time of use by ***an authorised*** person or establishment ***using an*** authorised ***kit for*** radiopharmaceutical ***preparation in combination with a*** radionuclide or radionuclide ***generator*** in accordance with the ***summary of product characteristics of the kit ('kit-radiolabelling')***.

Or. en

Amendment 264
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 17 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) a description of the special information requirements outlined in Article 69 and listed in Annex I.	(b) a description of the special information requirements outlined in Article 69 and listed in Annex I***, for prior review and approval by the competent authority***.

Or. en

Amendment 265

Nicolás González Casares, Laura Ballarín Cereza

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*** impose obligations on the marketing authorisation holder if it finds the risk mitigation measures contained in the antimicrobial stewardship plan unsatisfactory.

Or. en

Amendment 266
Susana Solís Pérez, Klemen Grošelj

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 that the pack size of the antimicrobial corresponds to the usual posology and duration of treatment. ***The marketing authorisation holder shall ensure, wherever possible, that the antimicrobial may be dispensed per unit in a number corresponding to the quantities described on the prescription. If an antimicrobial can not 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.***

Or. en

Amendment 267
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 17 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3 a. Pharmacists should play a role in antimicrobial stewardship, including advising on the prudent use of antibiotics and other antimicrobials, as well as their correct disposal.

Or. en

Amendment 268
Susana Solís Pérez, Klemen Grošelj

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*** .

Or. en

Amendment 269
Patrizia Toia, Beatrice Covassi

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	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.	product and a medical device, taking into account the suitability of the use of the medicinal product together with the medical device. ***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***

Or. en

Amendment 270
Margarita de la Pisa Carrión
on behalf of the ECR Group

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 assessment report by a notified body.

Or. en

Amendment 271
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 18 – paragraph 4

Text proposed by the Commission	*Amendment*
4. In its evaluation of the ***integral***	4. In its evaluation of the medicinal

combination of a medicinal product ***with a medical device concerned,*** the competent ***authorities*** shall recognise the results of the assessment of compliance of the medical device ***part of that integral combination*** with the general safety and performance requirements in accordance with Annex I of Regulation (EU) 2017/745 ***including, where relevant, the results of the assessment by a notified body.***	product ***referred to in paragraph 1*** the competent ***authority*** shall recognise the results of the assessment of compliance of the medical device ***concerned*** with the general safety and performance requirements in accordance with Annex I of Regulation (EU) 2017/745

Or. en

Amendment 272
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 19 – paragraph 4

Text proposed by the Commission	*Amendment*
4. In its evaluation of the medicinal product referred to in paragraph 1 the competent authority shall recognise the results of the assessment of compliance of the medical device concerned with the general safety and performance requirements in accordance with Annex I of Regulation (EU) 2017/745 ***including, where relevant, the results of the assessment by a notified body.***	4. In its evaluation of the medicinal product referred to in paragraph 1 the competent authority shall recognise the results of the assessment of compliance of the medical device concerned with the general safety and performance requirements in accordance with Annex I of Regulation (EU) 2017/745

Or. en

Amendment 273
Nicolás González Casares, Laura Ballarín Cereza

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	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.

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 ***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.

Or. en

Amendment 274
Pernille Weiss

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 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.

Or. en

Amendment 275
Ville Niinistö
on behalf of the Verts/ALE Group

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 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.

Or. en

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

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 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.

Or. en

Amendment 277
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 22 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. The ERA shall evaluate possible risks to the environment due to use and disposal of the medicinal product according to the requirements referred to in Annex II. With regard to risks resulting from manufacturing, the ERA shall provide information on discharges and emissions of the active substance and other environmentally relevant substances according to the requirements referred to in Annex II.

Or. en

Amendment 278
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 22 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. The ERA shall indicate whether the medicinal product or any of its ingredients or other constituents is one of the following substances according to the criteria of Annex I to the Regulation (EC) No 1272/2008:	2. The ERA ***shall evaluate the possible risks to the environment due to the use and disposal of the medicinal product according to the requirements referred to in Annex II . It*** shall indicate whether the medicinal product or any of its ingredients or other constituents is one of the following substances according to the criteria of Annex I to the Regulation (EC) No 1272/2008:

Or. en

Amendment 279
Pernille Weiss

Proposal for a directive
Article 22 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. The ERA shall indicate whether the medicinal product or any of its ingredients or other constituents is one of the following substances according to the criteria of Annex I to the Regulation (EC) No 1272/2008:	2. The ERA shall indicate whether the medicinal product or any of its ingredients or other constituents is ***classified according to*** one of the following substances according to the criteria of Annex I to the Regulation (EC) No 1272/2008:

Or. en

Amendment 280
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 22 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) persistent, mobile and toxic (PMT)***, very persistent and very mobile (vPvM);***	(c) persistent, mobile and toxic (PMT)

Or. en

Amendment 281
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a directive
Article 22 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(c a) very persistent and very mobile (vPvM);

Or. en

Amendment 282

Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 22 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(c a) very persistent and very mobile (vPvM);

Or. en

Amendment 283
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a directive
Article 22 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
or are endocrine active agents.	or ***d)*** are endocrine active agents.

Or. en

Amendment 284
Pernille Weiss

Proposal for a directive
Article 22 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
or are endocrine ***active agents***.	***(d)*** endocrine ***disruptors***.

Or. en

Justification

Alignment with the language of Regulation (EC) No 1272/2008.

Amendment 285
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive

Article 22 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2 a. With regards to risks resulting from manufacturing the ERA shall provide information on discharged and emissions of the active susbtance(s) and other environmentally relevant susbtances according to the requirements referred to in Annex II.

Or. en

Amendment 286
Susana Solís Pérez, Klemen Grošelj

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 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.	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. ***When necessary, it 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 occuring in manufacturing effluents before these effluents leave the manufacturing sites.***

Or. en

Amendment 287
Ville Niinistö

on behalf of the Verts/ALE Group

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 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.	3. The applicant shall also include in the ERA risk mitigation measures to avoid or where it is not possible, ***to reduce discharges and emissions of the medicinal product to the environment and information on available techniques that will be used to reduce those discharges and emissions, in particular those occurring in manufacturing effluents before these effluents leave the manufacturing sites and to*** 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.

Or. en

Amendment 288
Nicolás González Casares, Laura Ballarín Cereza

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 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.	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 ***or in the cases where risks to the environment are identified in the scientific guidelines drawn up by the Agency on the ERA requirements for medicinal products for***

human use as referred to in paragraph 5. The applicant shall provide detailed explanation that the proposed mitigation measures are appropriate and sufficient to address the identified risks to the environment.

Or. en

Amendment 289
Pernille Weiss

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 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.	3. ***Where the ERA identifies a risk to the environment,*** 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.

Or. en

Amendment 290
Pietro Fiocchi, Elisabetta De Blasis

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 Directive 2000/60/EC, Directive	3. ***When the ERA indicate a risk to the environment,*** the applicant shall also include in the ERA risk mitigation measures to avoid or where it is not possible, limit emissions to water and soil

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.

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.

Or. en

Amendment 291
Margarita de la Pisa Carrión
on behalf of the ECR Group

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 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.	3. The applicant shall also include in the ERA risk ***of environmental*** 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.

Or. en

Amendment 292
Ville Niinistö
on behalf of the Verts/ALE Group

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	4. For antimicrobials ***and other substances which may cause***

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.

antimicrobial resistance, including products with an antimicrobial mode of action, the ERA 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.

Or. en

Amendment 293
Susana Solís Pérez, Klemen Grošelj

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 also by the healthcare professionnals 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.

Or. en

Amendment 294
Pietro Fiocchi, Elisabetta De Blasis

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 ***antibiotics*** shall include an evaluation of the risk for ***antibiotic*** resistance selection in the environment due to the manufacturing ***of the active substance or medicinal product within the European*** Union, use and disposal of the antimicrobial ***antibiotic*** taking into account, where relevant, the existing international standards that have established predicted no effect concentration (PNECs) specific for antibiotics.

Or. en

Amendment 295
Margarita de la Pisa Carrión
on behalf of the ECR Group

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 manufacturing, use and disposal of the ***antibiotic*** taking into account, where relevant, the existing international standards that have established predicted no effect concentration (PNECs) specific for antibiotics.

Or. en

Amendment 296
Pernille Weiss

Proposal for a directive
Article 22 – paragraph 4 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	By way of derogation from the first subparagraph, the obligation to conduct a risk assessment for antimicrobial resistance shall only cover the risk for antibiotic resistance. That derogation shall cease to apply by ... [3 years after the date of entry into force of this Directive].

Or. en

Amendment 297
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
	4 a. By ... [18 months after the date of entry into force of this Directive], the Commission shall, after having consulted the Agency, the European Environmental Agency (EEA), and the ECDC, issue guidelines on how to conduct the ERA for antimicrobials other than antibiotics.

Or. en

Amendment 298
Nicolás González Casares, Laura Ballarín Cereza

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	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 ***including environmental risk mitigation measures thereof***. Where

Chemical Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environmental Agency (EEA) ***on*** the drafting of these scientific guidelines.

appropriate, the Agency shall consult the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environmental Agency (EEA)***, the European Centre of Disease Control (ECDC) and other relevant stakeholders, including those managing residues from medicinal products and wastewater treatment*** the drafting of these scientific guidelines.

Or. en

Amendment 299
Pernille Weiss

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 European Environmental Agency (EEA)***, the ECDC and other relevant stakeholders, including those managing residues from medicinal products and their production in the environment,*** on the drafting of these scientific guidelines.

Or. en

Amendment 300
Ville Niinistö
on behalf of the Verts/ALE Group

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. The Agency shall consult ***the European Centre for Disease Prevention and Control (ECDC),*** the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environmental Agency (EEA) ***and other stakeholders, including drinking water and wastewater operators,*** on the drafting of these scientific guidelines.

Or. en