European Parliament
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Committee on Industry, Research and Energy

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AMENDMENTS
637 - 765

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))

Amendment 637
Patrizia Toia, Beatrice Covassi

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

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

Or. en

Amendment 638
Cristian-Silviu Buşoi

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

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

Or. en

Amendment 639
Ville Niinistö
on behalf of the Verts/ALE Group

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

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

Or. en

Amendment 640
Nicolás González Casares, Laura Ballarín Cereza

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

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

Or. en

Amendment 641
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

Text proposed by the Commission	*Amendment*
(iii) pricing and reimbursement.	***deleted***

Or. en

Amendment 642
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
(iii) pricing and reimbursement.	***deleted***

Or. en

Amendment 643
Henna Virkkunen

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

Text proposed by the Commission	*Amendment*
(iii) pricing and reimbursement.	***deleted***

Or. en

Justification

A well-defined Bolar exemption that streamlines the regulatory approval process is crucial. It should cover strictly necessary activities, even when conducted by third parties in a reactive manner, while maintaining a precise scope to prevent misuse. Yet, extending the Bolar exemption to cover commercial or pre-commercial actions at the national level, such as pricing and reimbursement applications, is unwarranted. Such an extension would only facilitate risk-driven launches, jeopardizing patent rights' effectiveness in Europe and undermining their reliability.

Amendment 644
Cristian-Silviu Buşoi

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

Text proposed by the Commission	*Amendment*
(iii) pricing and reimbursement.	(iii) ***obtaining*** pricing and reimbursement ***approval***.

Or. en

Amendment 645
Ville Niinistö
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
(iii) pricing and reimbursement**.**	(iii) ***obtaining*** pricing and reimbursement ***approval;***

Or. en

Amendment 646
Patrizia Toia, Beatrice Covassi

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

Text proposed by the Commission	*Amendment*
(iii) pricing and reimbursement**.**	(iii) ***obtaining*** pricing and reimbursement ***approval***

Or. en

Amendment 647
Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*
(iii) pricing and reimbursement**.**	(iii) ***obtaining*** pricing and reimbursement ***approval;***

Or. en

Amendment 648
Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*
	(iii a) participating in public and private procurement tenders of medicinal products for which the fulfillment of the obligations laid out in the tender will commence after the expiry of the relevant patents or supplementary protection certificates;

Or. en

Amendment 649
Ville Niinistö
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
	(iii a) participating in public and private procurement tenders of medicinal products for which the fulfillment of the obligations laid out in the tender will commence after the expiry of the relevant patents or supplementary protection certificates;

Or. en

Amendment 650
Patrizia Toia, Beatrice Covassi

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

Text proposed by the Commission	*Amendment*
	(iii a) enabling public and private procurement of medicinal products after expiry of the relevant patents or supplementary protection certificate

Or. en

Amendment 651
Cristian-Silviu Buşoi

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

Text proposed by the Commission	*Amendment*

(iii a) enabling public and private procurement of medicinal products after expiry of the relevant patents or supplementary protection certificate;

Or. en

Amendment 652
Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*
	(iii b) complying with any other regulatory or administrative requirements necessary for the purpose of placing the medicinal product on the Union market or for export in third countries markets, after expiration of the patent or supplementary protection certificate.

Or. en

Amendment 653
Ville Niinistö
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
	(iii b) complying with any other regulatory or administrative requirements necessary for the purpose of placing the medicinal product on the Union market or for export in third countries markets, after expiration of the patent or supplementary protection certificate.

Or. en

Amendment 654
Patrizia Toia, Beatrice Covassi

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

Text proposed by the Commission	*Amendment*
	(iii b) complying with any other regulatory or administrative requirement in the Union or elsewhere;

Or. en

Amendment 655
Cristian-Silviu Buşoi

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

Text proposed by the Commission	*Amendment*
	(iii b) complying with any other regulatory or administrative requirement in the Union or elsewhere;

Or. en

Amendment 656
Patrizia Toia, Beatrice Covassi

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

Text proposed by the Commission	*Amendment*
	(iii c) ensuring the subsequent practical requirements associated with the abovementioned activities

Or. en

Amendment 657
Cristian-Silviu Buşoi

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

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

Or. en

Amendment 658
Patrizia Toia, Beatrice Covassi

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

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

Or. en

Justification

The deletion is intended only for the internal coherence of the structure of the article as amended by the MEPs. The deleted content is retaken in an amended form in a subsequent amendment (para 1a new) because the intention is to create it as a new paragraph

Amendment 659
Pilar del Castillo Vera

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

Text proposed by the Commission	*Amendment*
(b) the activities conducted exclusively for the purposes set out in point (a)***, may cover*** the submission of the application for a marketing authorisation and the ***offer***, manufacture, sale, supply, storage, import, use and purchase of ***patented medicinal*** products or processes, including by third party suppliers and service providers.	(b) the activities conducted exclusively for the purposes set out in point (a) ***include*** the submission of the application for a marketing authorisation and the ***offering***, manufacture, sale, supply, storage, import, ***export,*** use and purchase of products or processes, including by third party suppliers and service providers. ***This exception shall not cover the placing on the market in a Member State, while relevant patent rights or supplementary protection certificates are in force in that Member State, of the medicinal products purposes.***

Or. en

Amendment 660
Nicolás González Casares, Laura Ballarín Cereza

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

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

Or. en

Amendment 661
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

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

Or. en

Amendment 662
Pernille Weiss

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

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

Or. en

Amendment 663
Ville Niinistö
on behalf of the Verts/ALE Group

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

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

Or. en

Amendment 664
Patrizia Toia, Beatrice Covassi

Proposal for a directive
Article 85 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	The activities falling within the first paragraph include the offering, manufacture, sale, supply, storage, import, export, use and purchase of products or processes, including by third party suppliers and service providers.

Or. en

Amendment 665
Cristian-Silviu Buşoi

Proposal for a directive
Article 85 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	The activities falling within the first subparagraph may include the offering, manufacture, sale, supply, storage, import, export, use and purchase of products or processes, including by third party suppliers and service providers.

Or. en

Amendment 666
Patrizia Toia, Beatrice Covassi

Proposal for a directive
Article 85 – paragraph 2

Text proposed by the Commission	*Amendment*
This exception shall not cover the placing on the market of the medicinal products ***resulting from such activities.***	This exception shall not cover the placing on the market ***in a Member State, while relevant patent rights or supplementary protection certificates are in force in that Member State,*** of the medicinal products ***manifactured for the purposes set out in point a***

Or. en

Amendment 667
Cristian-Silviu Buşoi

Proposal for a directive
Article 85 – paragraph 2

Text proposed by the Commission	*Amendment*
This exception shall not cover the placing on the market of the medicinal products ***resulting from such activities***.	This exception shall not cover the placing on the market ***in a Member State, while relevant patent rights or supplementary protection certificates are in force in that Member State,*** of the medicinal products ***manufactured for the aforementioned purposes***.

Or. en

Amendment 668
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 85 – paragraph 2

Text proposed by the Commission	*Amendment*
This exception shall not cover the placing on the market of the medicinal products resulting from such activities.	This exception shall not cover the placing on the market of the medicinal products resulting from such activities ***before expiry of relevant patent or supplementary protection certificates***.

Or. en

Amendment 669
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 85 – paragraph 2

Text proposed by the Commission	*Amendment*
This exception shall not cover the placing on the market of the medicinal products resulting from such activities.	This exception shall not cover the placing on the market of the medicinal products resulting from such activities ***before expiry of relevant patent or supplementary protection certificates***.

Or. en

Amendment 670
Pilar del Castillo Vera

Proposal for a directive
Article 85 a (new)

Text proposed by the Commission	*Amendment*
	Article 85a
	Applications, decision-making procedures and decisions to regulate marketing authorizations or the prices of generics, biosimilars, hibryds and biohibrids or to determine their inclusion within the scope of public health insurance system of medicinal products shall be considered by Member States as regulatory or administrative procedures which, as such, are independent from the enforcement of intellectual property rights. The protection

of intellectual property rights shall not be a valid ground to refuse, suspend, delay, withdraw or revoke decisions relating to marketing authorisations, the price of generics, biosimilars, hibryds and biohibrids or its inclusion within the public health insurance system. The applications, decision-making procedures and decisions referred to in paragraph 1 shall not be subject to conditions which expose applicants to a risk of infringement of the intellectual property rights. Paragraphs 1, 2 and 3 shall apply without prejudice to the Union and national legislation relating to the protection of intellectual property.

Or. en

Amendment 671
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 85 a (new)

Text proposed by the Commission	*Amendment*
	Article 85a
	Prohibition on patent linkage
	1. Member States shall not, when conducting regulatory or administrative procedures in regards to activities carried out in accordance with Article 85, enforce intellectual property rights as a valid ground for refusal, suspension, delay, withdrawal or revocation of marketing authorisation, pricing and reimbursement decisions or tender bids in regards to public and private procurement of medicinal products.
	2. If the market authorization holder ceases to commercialise a medicinal product in the Union, the Commission shall have a public purchase option for all related intellectual property rights.

Or. en

Amendment 672
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 85 a (new)

Text proposed by the Commission	*Amendment*
	Article85a
	Prohibition on patent linkage
	1. Member States shall not, when conducting regulatory or administrative procedures in regards to activities carried out in accordance with Article 85, enforce intellectual property rights as a valid ground for refusal, suspension, delay, withdrawal or revocation of marketing authorisation, pricing and reimbursement decisions or tender bids in regards to public and private procurement of medicinal products.
	2. If the market authorization holder ceases to commercialise a medicinal product in the Union, the Commission shall have a public purchase option for all related intellectual property rights.

Or. en

Amendment 673
Pernille Weiss

Proposal for a directive
Article 86 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Where an application for marketing authorisation, includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a	Where an application for marketing authorisation, includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a

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

Or. en

Amendment 674
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 86 – paragraph 1 – subparagraph 1 a (new)

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

Or. en

Amendment 675
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 86 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
The first subparagraph shall also apply where completion of the agreed paediatric investigation plan fails to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned.	***This paragraph*** shall also apply where completion of the agreed paediatric investigation plan fails to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned.

Or. en

Amendment 676
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 86 – paragraph 1 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	The periods of extension referred to in this paragraph shall not apply to orphan medicinal products which have elected for and benefited from the extension of market exclusivity provided in Article 72(3) of [revised Regulation 726/2004].

Or. en

Amendment 677
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 86 a (new)

Text proposed by the Commission	*Amendment*
	Article86a
	Measuring pharmaceutical access within the EU
	1.The Commission, in collaboration with Member States, shall develop objective

and specific indicators to measure pharmaceutical access within the EU. The indicators related to pharmaceutical access should include but not be limited to availability, health system and patient affordability and accesibility of medicines.

(a) The Commission shall ensure that these indicators are evidence-based, measurable, and regularly reviewed to reflect the evolving healthcare landscape within the EU. Additionally, the Commission shall ensure that confidentiality of pricing and reimbursement data is overcome to avoid distorsion estimates.

(b) The Commission, in collaboration with Member States, shall produce a quinquennial report on the state of pharmaceutical access within the Union. This report shall comprehensively analyse the indicators defined in paragraph 1, evaluating their effectiveness in gauging access to medicines. The Commission shall also establish a public database for annual update of paramenters defined in the quinquennial report.

Or. en

Amendment 678
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

Text proposed by the Commission	*Amendment*
to conduct a post-authorisation environmental risk assessment study, collection of monitoring data or information on use, if there are concerns about the risks to the environment ***or public health, including antimicrobial*** resistance, due to an authorised medicinal product, or related active substance.	to conduct a post-authorisation environmental risk assessment study, collection of monitoring data or information on use, if there are concerns about the risks to the environment ***and/or antibiotic*** resistance, due to an authorised medicinal product, or related active substance. ***Such measures may be imposed at both initial marketing authorisations***

and as response to a review where a risk to the environment has been identified

Or. en

Amendment 679
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 89 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The marketing authorisation holder shall incorporate any safety or efficacy conditions referred to in Articles 44, 45 and 87 in the risk management system.	1. The marketing authorisation holder shall incorporate any safety or efficacy conditions referred to in Articles 44, 45 and 87 ***(1a and b),*** in the risk management system.

Or. en

Amendment 680
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 92 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The procedures for examination of applications for variations shall be proportionate to the risk and impact involved. Those procedures shall range from procedures that allow implementation only after approval based on a complete scientific assessment to procedures that allow immediate implementation and subsequent notification by the marketing authorisation holder to the competent authority. Such procedures may also include updates by the marketing authorisation holder of their information held in a database.	3. The procedures for examination of applications for variations shall be proportionate to the risk and impact involved. Those procedures shall range from procedures that allow implementation only after approval based on a complete scientific assessment to procedures that allow immediate implementation and subsequent notification by the marketing authorisation holder to the competent authority. Such procedures may also include updates by the marketing authorisation holder of their information held in a database. ***Accelerated assessment procedures shall also be foreseen for***

variations which are of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation.

Or. en

Justification

Recognition in the proposed legislation, through the expansion ofconditional authorization to new indications, that the benefit ofthe medicine's new indication for immediate availability topatients is greater than the risk inherent in the fact that additionaldata are still required, is acknowledged and welcome.Commensurate with the recognition of the importantimprovements new indications for treating, preventing ordiagnosing seriously debilitating or life-threatening diseases canprovide to patients, new indications addressing an unmet needs inthese areas should be eligible for an accelerated assessment.

Amendment 681
Pernille Weiss

Proposal for a directive
Article 94 – paragraph 1

Text proposed by the Commission	*Amendment*
1. On the basis of relevant paediatric clinical studies received in accordance with Article 45(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council[76] , the competent authorities of the Member States may vary the marketing authorisation of the medicinal product concerned accordingly and update the summary of product characteristics and package leaflet of the medicinal product concerned. The competent authorities shall exchange information regarding the studies submitted and, as appropriate, their implications for any marketing authorisations concerned.	1. On the basis of relevant paediatric clinical studies received in accordance with Article 45(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council[76] , the competent authorities of the Member States may***, following a consultation of the marketing authorisation holder,*** vary the marketing authorisation of the medicinal product concerned accordingly and update the summary of product characteristics and package leaflet of the medicinal product concerned. The competent authorities shall exchange information regarding the studies submitted and, as appropriate, their implications for any marketing authorisations concerned.
[76] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation	[76] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation

(EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).	(EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).

Or. en

Amendment 682
Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*
	(e a) facilitate harm reduction from adverse events through developing and implementing corrective patient safety plans for safe medicinal product administration and handling which can include the deployment of digital medication safety systems in hospitals and ambulatory care settings.

Or. en

Amendment 683
Patrizia Toia, Beatrice Covassi

Proposal for a directive
Article 101 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The management of funds intended for activities connected with pharmacovigilance, the operation of communication networks and market surveillance shall be under the permanent control of the competent authorities of the Member States in order to guarantee their independence in the performance of those pharmacovigilance activities.	1. The management of funds intended for activities connected with pharmacovigilance, the operation of communication networks and market surveillance shall be under the permanent control of the competent authorities of the Member States in order to guarantee their independence in the performance of those pharmacovigilance activities. ***The competent authorities should guarantee that not less than 10% of these activities and funds are focused on***

paediatric populations

Or. en

Amendment 684
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 104 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The marketing authorisation holder shall ensure that information to the public is presented objectively and is not misleading.	2. The marketing authorisation holder shall ensure that information to the public is presented objectively and is not misleading***, and it is presented in a clear and adjusted language***.

Or. en

Amendment 685
Pernille Weiss

Proposal for a directive
Article 105 – paragraph 2

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

Or. en

Amendment 686
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 105 – paragraph 2

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

Or. en

Amendment 687
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 105 – paragraph 2

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

Or. en

Amendment 688
Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*
Each Member State shall record all suspected adverse reactions that occur in its territory and that are brought to its attention from healthcare professionals and patients. This shall include all authorised medicinal products and medicinal products used in accordance with Article 3, paragraphs 1 or 2. Member States shall involve patients and healthcare	Each Member State shall record all suspected adverse reactions that occur in its territory and that are brought to its attention from healthcare professionals and patients. This shall include all authorised medicinal products and medicinal products used in accordance with Article 3, paragraphs 1 or 2. Member States shall involve patients and healthcare

professionals, as appropriate, in the follow-up of any reports they receive in order to comply with Article 97(1), points (c) and (e).	professionals, as appropriate, in the follow-up of any reports they receive in order to comply with Article 97(1), points (c) and (e)***, and shall seek to inform directly those stakeholders that reported a suspected adverse drug reaction on decisions taken in relation to the safety of the medicinal product***.

Or. en

Amendment 689
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 112 a (new)

Text proposed by the Commission	*Amendment*
	Article112a
	Medicines under additional monitoring
	1.The Agency shall, in collaboration with the Member States, set up, maintain and make public a list of medicinal products that are subject to additional monitoring. That list shall include the international non-proprietary names and active substances of:
	(a) medicinal products authorised in the Union that contain a new active substance which was not contained in any medicinal product authorised in the Union;
	(b) any biological medicinal product not covered by point (a) that was authorised after [date of implementation];
	(c) medicinal products that are authorised pursuant to this Regulation, subject to the conditions referred to in point (f) of Article 12(4), point (a) of Article 20(1) or Articles 18, 19, 30 or 113;
	(d) medicinal products that are authorised pursuant to [revised Directive 2001/83/EC], subject to the conditions referred to in points (b) and (c) of the first paragraph of Article 44, Article 45, or

point (a) of the first subparagraph of Article 87(1) thereof.

At the request of the Commission, following consultation with the Pharmacovigilance Risk Assessment Committee, medicinal products that are authorised pursuant to this Regulation subject to the conditions referred to in points (d), (e) or (g) of Article 12(4), point (b) of Article 20 (1) or Article 46(2), may also be included in the list referred to in paragraph 1 of this Article.

At the request of a national competent authority, following consultation with the Pharmacovigilance Risk Assessment Committee, medicinal products that are authorised pursuant to [revised Directive 2001/83/EC] subject to the conditions referred to in points (a), (d) or (f) of the first paragraph of Article 44, point (b) of the first subparagraph of Article 87 or Article 100(2) thereof, may also be included in the list referred to in paragraph 1 of this Article.

2. The list referred to in paragraph 1 shall include an electronic link to the product information and to the summary of the risk management plan.

3. In the cases referred to in points (a) and (b) of paragraph 1 of this Article, the Agency shall remove a medicinal product from the list five years after the Union reference date referred to in Article 108(5) of [revised Directive 2001/83/EC]. In the cases referred to in points (c) and (d) of paragraph 1 of this Article, the Agency shall remove a medicinal product from the list once the conditions have been fulfilled.

4. For medicinal products included in the list referred to in paragraph 1, the summary of product characteristics and the package leaflet shall include the statement 'This medicinal product is subject to additional monitoring'. The statement shall be preceded by an inverted black triangle, and shall be followed by a

	standardised explanatory sentence.
	5. The Agency shall, in cooperation with the competent authorities, develop and conduct awareness campaigns on the promotion of information about medicines under additional monitoring. Those campaigns shall be intended to raise awareness amongst healthcare professionals, patients, consumers and the general public of the pharmacovigilance system and the additional monitoring of medicines.

Or. en

Amendment 690
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 123 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) scientific guidance on post-authorisation efficacy studies.	(b) scientific guidance on post-authorisation efficacy studies***, following the consultation process established under Article 162 of the [revised Regulation (EU) 726/2004]***.

Or. en

Amendment 691
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 143 – paragraph 1 – subparagraph 2 – point a a (new)

Text proposed by the Commission	*Amendment*
	(a a) environmental impact assessment of the product's manufacturing process;

Or. en

Amendment 692
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 143 – paragraph 1 – subparagraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(b a) proof that the product's supply chain is diversified, identifying alternatives for each component;

Or. en

Amendment 693
Nicolás González Casares, Laura Ballarín Cereza

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

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

Or. en

Amendment 694
Nicolás González Casares, Laura Ballarín Cereza

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

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

authorization holders;

Or. en

Amendment 695
Nicolás González Casares, Laura Ballarín Cereza

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

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

Or. en

Amendment 696
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
	(j a) use an appropriate wastewater treatment system.

Or. en

Amendment 697
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 147 – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
For the purposes of points (f) and (g), manufacturing authorisation holders shall verify compliance, respectively, by the manufacturer or distributors of active substances with good manufacturing practice and good distribution practices by conducting audits at the manufacturing and distribution sites of the manufacturer and distributors of active substances. Manufacturing authorisation holders shall verify such compliance either by themselves or through an entity acting on their behalf under a contract.	For the purposes of points (f) and (g), manufacturing authorisation holders shall verify compliance, respectively, by the manufacturer or distributors of active substances with good manufacturing practice and good distribution practices by conducting audits at the manufacturing and distribution sites of the manufacturer and distributors of active substances. Manufacturing authorisation holders shall verify such compliance either by themselves or through an entity acting on their behalf under a contract. ***Manufacturing authorisation holders may diversify their contracts with manufacturer or distributors of active substances if needed to ensure an adequate, constant and timely provision to comply with their public service obligations for supply.***

Or. en

Amendment 698
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 148 – paragraph 8 – introductory part

Text proposed by the Commission	*Amendment*
8. The competent authority of the Member State supervising the decentralised site pursuant to paragraph 4 shall ***cooperate*** with the relevant authorities responsible for the supervision of the manufacturing or testing activities under other Union acts as regards the following:	8. ***In order to ensure the smooth functioning of the decentralised sites with activities relevant for other Union legal frameworks,*** the competent authority of the Member State supervising the decentralised site pursuant to paragraph 4 shall ***coordinate their activities and supervisory tasks*** with the relevant authorities responsible for the supervision of the manufacturing or testing activities under other Union acts as regards the following:

Or. en

Amendment 699
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 148 – paragraph 8 a (new)

Text proposed by the Commission	*Amendment*
	8 a. The competent authorities referred to paragraph 8 shall guarantee that the modalitities of coordination shall not adversely affect the preparation of SoHO therapies on a Member State level.

Or. en

Amendment 700
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 148 – paragraph 9

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

Or. en

Amendment 701
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 159 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
At the request of a third country, the Commission shall assess whether that	At the request of a third country, the Commission shall assess whether that

country's regulatory framework applicable to active substances exported to the Union and the respective control and enforcement activities ensure a level of protection of public health equivalent to that of the Union.	country's regulatory framework applicable to active substances exported to the Union and the respective control and enforcement activities ensure a level of protection of public ***and worker's*** health ***and environment*** equivalent to that of the Union.

Or. en

Amendment 702
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 159 – paragraph 2 – subparagraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) the country's rules for good manufacturing practice;	(a) the country's rules for good manufacturing practice; ***including local environmental manufacturing standards, occupational health and labour rights standards;***

Or. en

Amendment 703
Nicolás González Casares, Laura Ballarín Cereza

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

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

Or. en

Amendment 704
Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*
	(b a) the principles and measures on reducing the environmental impact of medicinal products and active substances in manufacturing and distribution

Or. en

Amendment 705
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 160 – paragraph 2

Text proposed by the Commission	*Amendment*
Where relevant, these principles shall be ***specified in coherence*** with any principles of good practices established under any other Union legal framework.	Where relevant, these principles shall be ***aligned with*** with any principles of good practices established under any other Union legal framework.

Or. en

Amendment 706
Pernille Weiss

Proposal for a directive
Article 163 – paragraph 1

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

it is valid.	operations for which it is valid.

Or. en

Amendment 707
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 166 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) obtain, including by financial transactions, ***their supplies of medicinal products only from persons who are themselves in possession of a*** wholesale ***distribution authorisation in the Union or a manufacturing authorisation referred to in Article 163(3);***	(c) obtain, including by financial transactions, ***(except in the case of financial transactions for equivalent activities. Member States shall rely on the information contained in the repositories system to ensure*** wholesale ***distributors comply with their supply obligations.***

Or. en

Amendment 708
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 166 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) supply, including by financial transaction, medicinal products only to persons who are themselves wholesale distribution authorisation holders or who are authorised or entitled to supply medicinal products to the public;	(d) supply, including by financial transaction ***(except in the case of financial transactions within the same corporate group)*** , medicinal products only to persons who are themselves wholesale distribution authorisation holders or who are authorised or entitled to supply medicinal products to the public;

Or. en

Amendment 709

Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 166 – paragraph 1 – point g – point v

Text proposed by the Commission	*Amendment*
(v) the batch number of the medicinal products, at least for medicinal products bearing the safety features referred to in Article 67;	(v) the batch ***number and serial*** number of the medicinal products, at least for medicinal products bearing the safety features referred to in Article 67;

Or. en

Amendment 710
Pernille Weiss

Proposal for a directive
Article 166 – paragraph 1 – point l

Text proposed by the Commission	*Amendment*
(l) continuously guarantee the appropriate and continued supply of an adequate range of medicinal products to meet the requirements of a specific geographical area, and deliver the supplies requested over the whole of the area in question, within a reasonable timeframe, which shall be defined in the national legislation;	***deleted***

Or. en

Justification

See amendment to Article 166 – paragraph 1 a (new).

Amendment 711
Pernille Weiss

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

Text proposed by the Commission	*Amendment*

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

Or. en

Amendment 712
Pernille Weiss

Proposal for a directive
Article 166 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. Member States shall designate wholesale distribution authorisation holders who shall continuously guarantee the appropriate and continued supply of an adequate range of medicinal products to meet the requirements of a specific geographical area, and deliver the supplies requested over the whole of the area in question, within a reasonable timeframe, which shall be defined in national legislation.

Or. en

Amendment 713
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 167 – paragraph 1

Text proposed by the Commission	*Amendment*
1. With regard to the supply of medicinal products to pharmacists and persons authorised or entitled to supply medicinal products to the public, Member States shall not impose upon the wholesale distribution authorisation holder that has been granted by another Member State any	1. With regard to the supply of medicinal products to pharmacists and persons authorised or entitled to supply medicinal products to the public, Member States shall not impose upon the wholesale distribution authorisation holder that has been granted by another Member State any

obligation, in particular public service obligations, more stringent than those they impose on persons whom they have themselves authorised to engage in equivalent activities.	obligation, in particular public service obligations, more stringent than those they impose on persons whom they have themselves authorised to engage in equivalent activities. ***Member States shall rely on the information contained in the repositories system to ensure wholesale distributors comply with their supply obligations.***

Or. en

Amendment 714
Pilar del Castillo Vera

Proposal for a directive
Article 167 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The wholesale distributors of a medicinal product placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.	2. The wholesale distributors of a medicinal product placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered. ***Member States shall rely on the information contained in the repositories system referred to in Article 67, paragraph 2, second sub-paragraph, point (e) to ensure wholesale distributors comply with their supply obligations.***

Or. en

Amendment 715
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 167 – paragraph 2

Text proposed by the Commission	*Amendment*

2. The wholesale distributors of a medicinal product placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.	2. The wholesale distributors of a medicinal product placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product***, in a sufficient quantity and a timely manner,*** to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.

Or. en

Amendment 716
Patrizia Toia, Beatrice Covassi

Proposal for a directive
Article 167 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The wholesale distributors of a medicinal product placed on the market in a Member State shall, within the limits of their responsibilities, ensure ***appropriate and continued supplies of*** that medicinal ***product*** to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.	2. The wholesale distributors of a medicinal product placed on the market in a Member State shall, within the limits of their responsibilities, ensure that medicinal ***products are released and continuously supplied*** to pharmacies and persons authorised to supply medicinal products ***in a sufficient quantity*** so that the needs of patients in the Member State in question are covered.

Or. en

Amendment 717
Susana Solís Pérez

Proposal for a directive
Article 167 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3 a. To ensure continued supply to patients, the wholesale distributors shall not be authorised to supply medicinal products in another Member State should

this, in any way, prevent them from covering the needs of the patients in the Member States concerned.

Or. en

Amendment 718
Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*
(a) the natural or legal person offering the medicinal products is authorised or entitled to supply medicinal products to the public, also at a distance, in accordance with national legislation of the Member State in which that person is established;	(a) the natural or legal person offering the medicinal products is authorised or entitled to supply medicinal products to the public, also at a distance, in accordance with national legislation of the Member State in which that person is established ***and in accordance with national legislation of the Member State to which the products are supplied***;

Or. en

Amendment 719
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Chapter XII a (new)

Text proposed by the Commission	*Amendment*
	XII a Chapter XII(a)
	Public procurement of medicinal products
	Article 174a
	Procurement of medicinal products
	1. Member States may consider strategic approaches when engaging in procurement procedures, including criteria beyond price, in line with Directive 2014/24/EU on public procurement. When doing so they may put

in place practices supporting security of supply and availability of medicines including:

a) preliminary market consultation;

b) awarding multiple contracts to reduce the risk of supply disruptions and mantain a competitive environment;

c) increased use of "most economically advantageous tender" (MEAT) award criteria in public tenders, using qualitative criteira such as security of supply and production in the EU/EEA or in countries with which the EU has concluded an agreement on government procurement;

(d) ensuring that the duration of contracts is tailored to favour predictability of demand and long-term availability.

Article 174b

Joint procurement of medicinal products

1. The Commission and any of the Member States may engage, as contracting parties, in a joint procurement procedure with a view to the purchase of medicinal products.

2. A joint procurement procedure as referred to in paragraph 1 shall be preceded by a Joint Procurement Agreement between the parties determining the practical arrangements governing that procedure and the decision-making process with regard to the choice of the procedure, the joint procurement assessment as referred to in paragraph 3, point (c), the assessment of the tenders and the award of the contract.

3. The joint procurement procedure referred to in paragraph 1 of this Article shall comply with the following conditions:

(a) participation in the joint procurement procedure is open to all Member States, European Free Trade Association States and Union candidate countries, as well as the Principality of Andorra, the

Principality of Monaco, the Republic of San Marino and the Vatican City State, by way of derogation from Article 165(2) of Regulation (EU, Euratom) 2018/1046;

(b) the rights and obligations of the countries referred to in point (a) that do not participate in the joint procurement are respected, in particular those relating to the protection and improvement of human health;

(c) before the launch of a joint procurement procedure, the Commission prepares a joint procurement assessment which shall indicate the general envisaged conditions of the joint procurement procedure, including as regards possible restrictions to parallel procurement and negotiation activities by the participating countries for the medicinal product in question during the specific joint procurement procedure; that assessment shall take into account the need to ensure security of supply of medicinal products concerned to the participating countries. Based on the joint procurement assessment and the relevant information provided therein, such as on envisaged price ranges, manufacturers, delivery time frames and the proposed deadline for decision on participation, the parties to the Joint Procurement Agreement shall express their interest in participating at an early stage. Those parties to the Joint Procurement Agreement which have expressed their interest shall subsequently decide on their participation in the joint procurement procedure under the conditions jointly agreed with the Commission, taking into account the information proposed in the joint procurement assessment;

(d) the joint procurement does not affect the internal market, does not constitute discrimination or a restriction of trade and does not cause distortion of competition; and

(e) the joint procurement does not have any direct financial impact on the budget

of the countries referred to in point (a) that do not participate in the joint procurement.

4. The Commission shall, in liaison with the Member States, ensure coordination and the exchange of information between the entities organising and participating in any action, including, but not limited to, joint procurement procedures for and development, stockpiling, distribution and donation of medicinal products, under different mechanisms established at Union level, in particular under:

(a) stockpiling under rescEU referred to in Article 12 of Decision No 1313/2013/EU;

(b) Regulation (EU) 2016/369;

(c) the Pharmaceutical Strategy for Europe;

(d) the EU4Health Programme established by Regulation (EU) 2021/522;

(e) Regulation (EU) 2021/697 of the European Parliament and of the Council (34); and

(f) other programmes and instruments supporting biomedical research and development at Union level for enhanced capacity and readiness to respond to cross-border threats and emergencies, such as measures adopted under Regulation (EU) 2022/2372.

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

Or. en

Amendment 720
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 175 – paragraph 2 – point d a (new)

Text proposed by the Commission	*Amendment*
	(d a) clear, impartial and independent information from an accredited health professional to the public about a medicinal product and its correct use, provided that it does not fall within the circumstances referred to in the preceding subparagraph and meets the conditions laid down in the legislation of each Member State.

Or. en

Amendment 721
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 177 – paragraph 1 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	Member States shall monitor the digital market services or products, websites, applications likely to broadcast advertising for prescription medicinal products for which advertising is prohibited according to article 177, paragraph 1.

Or. en

Amendment 722
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

Text proposed by the Commission	*Amendment*
	(b a) are antibiotics

Or. en

Amendment 723
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 177 – paragraph 2

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

Or. en

Amendment 724
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 177 – paragraph 4

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

Or. en

Amendment 725
Pernille Weiss

Proposal for a directive
Article 177 – paragraph 4

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

Or. en

Amendment 726
Pernille Weiss

Proposal for a directive
Article 185 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) any supply of samples shall be in response to a written request, signed and dated, from the persons qualified to prescribe or supply medicinal products;	(b) any supply of samples shall be in response to a written ***or electronic*** request, signed and dated, from the persons qualified to prescribe or supply medicinal products;

Or. en

Amendment 727
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

Text proposed by the Commission	*Amendment*
(g) no samples of medicinal products containing substances classified as	(g) no samples of medicinal products containing substances classified as

psychotropic or narcotic within the meaning of international conventions may be supplied.	***antibiotic,*** psychotropic or narcotic within the meaning of international conventions may be supplied.

Or. en

Amendment 728
Nicolás González Casares, Laura Ballarín Cereza

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

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

Or. en

Amendment 729
Nicolás González Casares, Laura Ballarín Cereza

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

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

Or. en

Amendment 730
Pernille Weiss

Proposal for a directive
Article 188 – paragraph 15 a (new)

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

Or. en

Amendment 731
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 195 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission may suspend***, revoke*** or vary a marketing authorisation if a serious risk to the environment ***or*** public health has been identified and not sufficiently addressed by the marketing authorisation holder.	2. The competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission may suspend or vary a marketing authorisation if a serious risk to the environment***, including*** public health***,*** has been identified and not sufficiently addressed by the marketing authorisation holder***, with the exception of medicinal products authorised before 30 october 2005 to avoid restricting patients' access to existing treatments***. ***Should the environmental risks, which also encompass public health dangers, surpass the therapeutic benefits for the intended patients and if these risks are not adequately reducible, the relevant Member State authorities or the Commission may revoke the marketing authorization of the holder.***

Or. en

Amendment 732

Pernille Weiss

Proposal for a directive
Article 195 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission may suspend***, revoke*** or vary a marketing authorisation if a serious risk to the environment ***or*** public health has been identified and not sufficiently addressed by the marketing authorisation holder.	2. The competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission may suspend or vary a marketing authorisation if a serious risk to the environment***, including*** public health***,*** has been identified and not sufficiently addressed by the marketing authorisation holder. ***The competent authorities of the Member States or, in the case of a centralised marketing authorisation, the Commission may revoke a marketing authorisation in such cases only if it deems that those risks clearly outweigh the loss of positive therapeutic effects of the medicinal product for the concerned patient population and the risks cannot be mitigated following a decision of suspension or modification.***

Or. en

Amendment 733
Andreas Glück

Proposal for a directive
Article 195 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission may suspend, revoke or vary a marketing authorisation if a serious risk to the environment or public health has been identified and not sufficiently addressed by the marketing authorisation holder.	2. The competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission may suspend, revoke or vary a marketing authorisation if a serious risk to the environment or public health has been identified and not sufficiently addressed by the marketing authorisation holder. ***The responsible authority must clearly consider whether this suspension is proportionate to the loss for the affected***

patients and should first consider further steps to reduce the risk.

Or. en

Justification

The suspension of a medicine may be a devastating judgment for affected patients. Therefore, it should be carefully looked at whether the advantages outweigh the disadvantages

Amendment 734
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 195 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission may suspend, ***revoke*** or vary a marketing authorisation if a serious risk to the environment or public health has been identified and not sufficiently addressed by the marketing authorisation holder.	2. The competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission may suspend, or vary a marketing authorisation if a serious risk to the environment or public health has been identified and not sufficiently addressed by the marketing authorisation holder ***via conditions laid out in Articles 44(h) or 87(c)***.

Or. en

Amendment 735
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 195 – paragraph 2

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

to the environment or public health has been identified and not sufficiently addressed by the marketing authorisation holder.	to the environment or public health has been identified and not sufficiently addressed by the marketing authorisation holder.

Or. en

Amendment 736
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 195 – paragraph 3

Text proposed by the Commission	*Amendment*
3. A marketing authorisation may also be suspended, revoked or varied where the particulars supporting the application as provided for in Articles 6, 9 to 14 or Annexes I to V are incorrect or have not been amended in accordance with Article 90, or where any conditions referred to in Articles 44, ***45*** and 87 have not been fulfilled or where the controls referred to in Article 191 have not been carried out.	3. A marketing authorisation may also be suspended, revoked or varied where the particulars supporting the application as provided for in Articles 6, 9 to 14 or Annexes I to V are incorrect or have not been amended in accordance with Article 90, or where any conditions referred to in Articles 44, and 87 have not been fulfilled or where the controls referred to in Article 191 have not been carried out.

Or. en

Amendment 737
Susana Solís Pérez, Klemen Grošelj

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

Text proposed by the Commission	*Amendment*
(f) a serious risk to the environment or to public health via the environment has been identified and not sufficiently addressed by the marketing authorisation holder.	(f) a serious risk to the environment or to public health via the environment has been identified and not sufficiently addressed by the marketing authorisation holder***, with the exception of medicinal products authorised before 30 october 2005 to avoid restricting patients' access to existing treatments***.

Or. en

Amendment 738
Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*
The competent authority of the Member State may process personal health data from sources other than clinical studies to support their public health tasks and, in particular, the evaluation and monitoring to medicinal products, for the purpose of improving the robustness of the scientific assessment or verifying claims of the applicant or marketing authorisation holder.	The competent authority of the Member State may process personal health data from sources other than clinical studies ***including the Eudravigilance database, electronic health data obtained pursuant to the applicable rules of the European Health Data Space*** to support their public health tasks and, in particular, the evaluation and monitoring to medicinal products, for the purpose of improving the robustness of the scientific assessment or verifying claims of the applicant or marketing authorisation holder. ***The competent authorities must put in place sufficient, effective and specific technical and organisational measures to safeguard the fundamental rights and interests of data subjects in line with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725, including but not limited to clear and targeted data retention and deletion policies, state-of-the-art anonymisation and pseudonymisation requirements and techniques, confidentiality and data security measures, and access control mechanisms.***

Or. en

Amendment 739
Susana Solís Pérez, Klemen Grošelj

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

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

Or. en

Amendment 740
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 201 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States, in applying this Directive, shall ensure that when questions arise with regard to the regulatory status of a medicinal product, in relation to their link to substances of human origin as referred to in Regulation (EU) No [SoHO Regulation], the competent authorities of the Member States shall consult the relevant authorities established under that Regulation.	1. Member States, in applying this Directive, shall ensure that when questions arise with regard to the regulatory status of a medicinal product, in relation to their link to substances of human origin as referred to in Regulation (EU) No [SoHO Regulation], the competent authorities of the Member States shall consult the ***Agency and the*** relevant authorities established under that Regulation. ***The Agency shall oversee the examination and results of inquiries and disclose pertinent information, ensuring any commercially sensitive data is removed prior to publication.***

Or. en

Amendment 741
Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*
	2 a. The Commission, in applying this Directive, in order to improve regulatory certainty and cross-sectoral cooperation it shall on an annual basis, or more frequently where deemed necessary, organise joint meetings between the Agency and the relevant advisory and regulatory bodies established under other Union legislation to assess emergeing trends and questions on the regulatory status of products and to find agreement on common regulatory status principles. The summaries and conclusions of these joint meetings shall be made publicly available, including the opinions and conclusions of each of the respective bodies.

Or. en

Amendment 742
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 206 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Member States shall lay down the rules on penalties applicable to infringements of national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties must be effective, proportionate and dissuasive. Member States shall, without delay, notify the Commission of those rules and of those measures and shall notify without delay of any subsequent amendment affecting them.	Member States shall lay down the rules on penalties applicable to infringements of national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties must be effective, proportionate and dissuasive. Member States shall, without delay, ***and taking into consideration the provision in paragraph 4,*** notify the Commission of those rules and of those measures and shall notify without delay of any subsequent amendment affecting them.

Or. en

Amendment 743
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 206 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) non-compliance with the provisions laid down in this Directive on pharmacovigilance;	(d) non-compliance with the provisions laid down in this Directive on pharmacovigilance***, and the provisions laid down in paragraph 2 of Article 17 in relation to the stewardship plan for antimicrobials, and in Article 44 on national marketing authorisations subject to conditions***;

Or. en

Amendment 744
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
	(e a) non-compliance with the obligations laid down in Article 58a shall be subject to the imposition of effective, proportionate and dissuasive financial penalties.

Or. en

Amendment 745
Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*
	3 a. The European Commission shall lay down criteria for establishing the penalties, taking into account paragraphs

1, 2 and 3, and the highest penalties laid down amongst Member States before the application of this Directive.

Or. en

Amendment 746
Pernille Weiss

Proposal for a directive
Article 207 – title

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

Or. en

Amendment 747
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 207 – paragraph 1

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

Or. en

Amendment 748
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 207 – paragraph 1

Text proposed by the Commission	*Amendment*
Member States shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired.	Member States shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired ***and that the medicinal products gathered are managed appropriately, preventing any technically preventable environmental leakage***.

Or. en

Amendment 749
Pernille Weiss

Proposal for a directive
Article 207 – paragraph 1

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

Or. en

Amendment 750
Pilar del Castillo Vera

Proposal for a directive
Article 207 – paragraph 1

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

Or. en

Amendment 751
Susana Solís Pérez, Klemen Grošelj

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

Text proposed by the Commission	*Amendment*
	Member States shall promote awareness raising and educational campaigns for the general public on the environmental risks of pharmaceuticals and on how to improve disposal practices.

Or. en

Amendment 752
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
	1a. By ... [18 months after the date of entry into force of this Directive], Member States shall draw up national plans including measures designed to:
	(a) monitor the rates of correct and incorrect disposal of unused and expired medicinal products;
	(b) inform the general public about the environmental risks associated with incorrect disposal of medicinal products, in particular those that contain substances referred to in Article 22(2);
	(c) inform healthcare professionals about the environmental risks associated with incorrect disposal of unused or expired medicinal products, in particular those that contain substances referred to in Article 22(2);

(d) increase the rate of correct disposal of unused or expired medicinal products; and

(e) designate public and private actors responsible for the collection systems referred to in paragraph 1.

Or. en

Amendment 753
Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*
	By ... [18 months after the date of entry into force of this Directive], Member States shall draw up national plans including measures designed to: (a) monitor the rates of correct and incorrect disposal of unused and expired medicinal products; (b) inform the general public about the environmental risks associated with incorrect disposal of medicinal products, in particular those that contain substances referred to in Article 22(2); (c) inform healthcare professionals about the environmental risks associated with incorrect disposal of unused or expired medicinal products, in particular those that contain substances referred to in Article 22(2); (d) increase the rate of correct disposal of unused or expired medicinal products; and (e) designate public and private actors responsible for the collection systems referred to in paragraph 1.

Or. en

Amendment 754
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
	The national plans shall be submitted to the Commission.

Or. en

Amendment 755
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
	From ... [five years after the date of entry into force of this Directive], the Commission is empowered to adopt delegated acts in accordance with Article 215 to amend paragraph 1a of this Article by supplementing or modifying the measures provided for in that paragraph if it is necessary to minimise the environmental risks posed by incorrect disposal of unused or expired medicinal products.

Or. en

Amendment 756
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 208 – paragraph 1

Text proposed by the Commission	*Amendment*
1. In order to guarantee independence and transparency, the Member States shall ensure that members of staff of the competent authority responsible for granting authorisations, rapporteurs and experts concerned with the authorisation	1. In order to guarantee independence and transparency, the Member States shall ensure that members of staff of the competent authority responsible for granting authorisations, rapporteurs and experts concerned with the authorisation

and surveillance of medicinal products have no financial or other interests in the pharmaceutical industry that could affect their impartiality. These persons shall make an annual declaration of their financial interests.	and surveillance of medicinal products have no financial or other interests in the pharmaceutical industry that could affect their impartiality ***and their independance***. These persons shall make an annual declaration of their financial interests ***and update them annually and whenever necessary***.

Or. en

Amendment 757
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 208 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2 a. The multidisciplinarity of experts may constitute a guarantee of the independence and impartiality of their work.

Or. en

Amendment 758
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 208 a (new)

Text proposed by the Commission	*Amendment*
	Article208a
	Fostering research, innovation and production of medicinal products in the Union
	1. The Commission shall establish an strategy to foster research, innovation and production of medicinal products in the Union, based on the results published in the report defined in paragraph 2. Member States shall be encouraged to participate in this strategy.

2. By... [one year after the date of entry into force of this Directive] the Commission shall present an impact assesment evaluating potential measures to be implemented at Union level, and at a Member State level to foster research, innovation and production of medicinal products in the Union. This report shall evaluate the effect of measures such as (a) funding and push and pull incentives directed to foster research and innovation in the Union, including public and private funding for preclinical and clinical research and innovation (b) public-private partnerships in research and innovation (c) regulatory support for public research and innovation entities (d) establishment of a public medicinal product production facility for products with low commertial interests (e) incentives for production inside the Union. Proposed measures shall be in line with developing a strategic autonomy for the Union regarding medicinal products.

Or. en

Amendment 759
Pernille Weiss

Proposal for a directive
Article 215 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
The power to adopt delegated acts referred to in Articles 4(2), 24(5), 25(9), 26(3), ***28, paragraphs 2 and 3***, 27(3), ***63(5)***, 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161, 210(4) and 213 shall be conferred on the Commission for a period of five years from [OP please insert the date of the entry into force of this Directive]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an	The power to adopt delegated acts referred to in Articles 4(2), 24(5), 25(9), 26(3), ***26a(4)***, 27(3), ***28(2) and (3), 58a(1), 63(4a)***, 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161***, 207(1c)***, 210(4) and 213 shall be conferred on the Commission for a period of five years from [OP please insert the date of the entry into force of this Directive]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for

identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.	periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

Or. en

Amendment 760
Pernille Weiss

Proposal for a directive
Article 215 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The delegation of power referred to in Articles 4(2), 24(5), 25(9), 26(3), ***27(3), 28, paragraphs 2 and 3, 63(5)***, 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161, 210(4) and 213 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	3. The delegation of power referred to in Articles 4(2), 24(5), 25(9), 26(3), ***26a(4), 27(3), 28(2) and (3), 58a(1), 63(4a)***, 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161***, 207(1c)***, 210(4) and 213 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Or. en

Amendment 761
Pernille Weiss

Proposal for a directive
Article 215 – paragraph 6

Text proposed by the Commission	*Amendment*
6. A delegated act adopted pursuant to Articles 6(2), 26(3), 24(5), ***28, paragraphs 2 and 3***, 27(3), ***63(5)***, 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161, 210(4) and 213 shall enter into force only if no	6. A delegated act adopted pursuant to Articles 6(2), 26(3), 24(5), ***26a(4)***, 27(3), ***28(2) and (3), 58a(1), 63(4a)***, 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161***, 207(1c)***, 210(4) and 213 shall enter into

objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.	force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Or. en

Amendment 762
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 216 – paragraph 1

Text proposed by the Commission	*Amendment*
By [OP please insert the date = 10 years following 18 months after the date of entering into force of this Directive], the Commission shall present a report to the European Parliament and the Council on the application of this Directive, including an assessment of the fulfilment of its objectives and the resources required to implement it.	By [OP please insert the date = 10 years following 18 months after the date of entering into force of this Directive], the Commission shall present a report to the European Parliament and the Council on the application of this Directive, including an assessment of the fulfilment of its objectives and the resources required to implement it***, in particular regarding the prolongation of data protection period to take into account the evolution of scientific knowledge and innovation***.

Or. en

Amendment 763
Pernille Weiss

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

Text proposed by the Commission	*Amendment*

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

Or. en

Amendment 764
Pernille Weiss

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

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

Or. en

Amendment 765
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Annex VI – paragraph 1 – point 8 a (new)

Text proposed by the Commission	*Amendment*
	(8 a) for products containing substances classified based on Annex I of Regulation (EC) No 1272/2008 as persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), persistent, mobile and toxic (PMT), very persistent and very mobile (vPvM) or are endocrine active agents, a

warning that improper use and disposal of the medicinal product, inter alia through toilets, contributes to deteriorating the aquatic environmen[A1] t.
[A1]Justification: Patients, healthcare professionals and pharmacists must be informed of the impact on the aquatic environment of products containing PBT, vPvB, PMT and vPvM substances, as well as endocrine disruptors, so they dispose properly of products and can make informed choices between alternative treatments.

Or. en