European Parliament
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Committee on Industry, Research and Energy

2023/0132(COD)

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AMENDMENTS
301 - 636

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

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

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

AM_Com_LegOpinion

Amendment 301
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 22 – paragraph 6 – subparagraph 1

Text proposed by the Commission	*Amendment*
The marketing authorisation holder shall update the ERA with new information without undue delay to the relevant competent authorities, in accordance with Article 90(2), if new information pertaining to the assessment criteria referred to in Article 29 becomes available and could lead to a change of the conclusions of the ERA. The update shall include any relevant information from environmental monitoring, including monitoring under Directive 2000/60/EC, from eco-toxicity studies, from new or updated risk assessments under other Union legislation, as referred to in paragraph 1, and environmental exposure data.	The marketing authorisation holder shall ***include analytical techniques and explanations in the methodology on the ERA and*** update the ERA with new information without undue delay to the relevant competent authorities, in accordance with Article 90(2), if new information pertaining to the assessment criteria referred to in Article 29 becomes available and could lead to a change of the conclusions of the ERA. The update shall include ***updates on the emissions of the medicinal product in manufacturing effluents and*** any relevant information from environmental monitoring, including monitoring under Directive 2000/60/EC, from eco-toxicity studies, from new or updated risk assessments under other Union legislation, as referred to in paragraph 1, and environmental exposure data.

Or. en

Amendment 302
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 22 – paragraph 6 – subparagraph 1

Text proposed by the Commission	*Amendment*
The marketing authorisation holder shall update the ERA with new information without undue delay to the relevant competent authorities, in accordance with Article 90(2), if new information pertaining to the assessment criteria	The marketing authorisation holder shall update the ERA with new information without undue delay to the relevant competent authorities, in accordance with Article 90(2), if new information pertaining to the assessment criteria

referred to in Article 29 becomes available and could lead to a change of the conclusions of the ERA. The update shall include any relevant information from environmental monitoring, including monitoring under Directive 2000/60/EC, from eco-toxicity studies, from new or updated risk assessments under other Union legislation, as referred to in paragraph 1, and environmental exposure data.	referred to in Article 29 becomes available and could lead to a change of the conclusions of the ERA***, including updates on the emissions of the medicinal product in manufacturing effluents***. The update shall include any relevant information from environmental monitoring, including monitoring under Directive 2000/60/EC, from eco-toxicity studies, from new or updated risk assessments under other Union legislation, as referred to in paragraph 1, ***the collation of sales data*** and environmental exposure data.

Or. en

Amendment 303
Pernille Weiss

Proposal for a directive
Article 22 – paragraph 6 – subparagraph 1

Text proposed by the Commission	*Amendment*
The marketing authorisation holder shall update the ERA with new information without undue delay to the relevant competent authorities, in accordance with Article 90(2), if new information pertaining to the assessment criteria referred to in Article 29 becomes available and ***could lead*** to a change of the conclusions of the ERA. The update shall include any relevant information from environmental monitoring, including monitoring under Directive 2000/60/EC, from eco-toxicity studies, from new or updated risk assessments under other Union legislation, as referred to in paragraph 1, and environmental exposure data.	The marketing authorisation holder shall update the ERA with new information without undue delay to the relevant competent authorities, in accordance with Article 90(2), if new information pertaining to the assessment criteria referred to in Article 29 becomes available and ***leads*** to a change of the conclusions of the ERA. The update shall include any relevant information from environmental monitoring, including monitoring under Directive 2000/60/EC, from eco-toxicity studies, from new or updated risk assessments under other Union legislation, as referred to in paragraph 1, and environmental exposure data.

Or. en

Amendment 304
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a directive
Article 22 – paragraph 6 – subparagraph 1

Text proposed by the Commission	*Amendment*
The marketing authorisation holder shall update the ERA with new information without undue delay to the relevant competent authorities, in accordance with Article 90(2), if new information pertaining to the assessment criteria referred to in Article 29 becomes available and ***could lead*** to a change of the conclusions of the ERA. The update shall include any relevant information from environmental monitoring, including monitoring under Directive 2000/60/EC, from eco-toxicity studies, from new or updated risk assessments under other Union legislation, as referred to in paragraph 1, and environmental exposure data.	The marketing authorisation holder shall update the ERA with new information without undue delay to the relevant competent authorities, in accordance with Article 90(2), if new information pertaining to the assessment criteria referred to in Article 29 becomes available and ***leads*** to a change of the conclusions of the ERA. The update shall include any relevant information from environmental monitoring, including monitoring under Directive 2000/60/EC, from eco-toxicity studies, from new or updated risk assessments under other Union legislation, as referred to in paragraph 1, and environmental exposure data.

Or. en

Amendment 305
Pernille Weiss

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

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

Or. en

Amendment 306
Nicolás González Casares, Laura Ballarín Cereza

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

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

Or. en

Amendment 307
Ville Niinistö
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
For an ERA conducted prior to [OP please insert the date = 18 months after the date of entering into force of this Directive], the competent authority shall request the marketing authorisation holder to update the ERA if missing information has been identified for medicinal products potentially harmful to the environment.	For an ERA conducted prior to [OP please insert the date = 18 months after the date of entering into force of this Directive], the competent authority shall request the marketing authorisation holder to update the ERA if missing information has been identified for medicinal products potentially harmful to the environment. ***The ERA shall be updated when new information becomes available, every 5 years at the latest.***

Or. en

Amendment 308
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 22 – paragraph 7

Text proposed by the Commission	*Amendment*
7. For medicinal products referred to in Articles 9 to 12, the applicant may refer to ERA studies conducted for the reference medicinal product when preparing the ERA.	7. For medicinal products referred to in Articles 9 to 12, the applicant may***, where appropriate,*** refer to ERA studies conducted for the reference medicinal product when preparing the ERA ***and shall provide any other data required in accordance with Annex II and the scientific guidelines as referred to in the first paragraph***.

Or. en

Amendment 309
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 22 – paragraph 7

Text proposed by the Commission	*Amendment*
7. For medicinal products referred to in Articles 9 to 12, the applicant may refer to ERA studies conducted for the reference medicinal product when preparing the ***ERA***.	7. For medicinal products referred to in Articles 9 to 12, the applicant may refer to ERA studies conducted for the reference medicinal product when preparing the ***ERAand shall provide any other data required in accordance with Annex II and the scientific guidelines referred to in the paragraph 5***.

Or. en

Amendment 310
Ville Niinistö
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
	7 a. In line with the Aarhus Convention[1a], full environmental assessment studies and summaries with outcomes shall be made publicly available and proactively shared with drinking water and wastewater operators. The competent authorities shall include this information in their repository of medicinal products.
	[1a] UN Convention on access to information, public participation in decision-making and access to justice in environmental matters, done at Aarhus, Denmark, on 25 June 1998.

Or. en

Amendment 311
Pernille Weiss

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

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

Or. en

Amendment 312
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 22 a (new)

Text proposed by the Commission	*Amendment*
	Article22a
	In accordance with Article 6(2), applicants for marketing authorization are required to incorporate data on patient experiences within their application dossiers. If inclusion of such data is not feasible, applicants must present a comprehensive explanation to the Agency. The Agency shall cooperate with patient organizations, Member State authorities, and other pertinent entities to develop guidance on the creation, execution, analysis, and reporting of studies that integrate substantial and significant patient experience data for regulatory purposes.

Or. en

Amendment 313
Pietro Fiocchi, Elisabetta De Blasis

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

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

available by the Agency.

Or. en

Amendment 314
Ville Niinistö
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
By [OP please insert the date = ***30*** months after the date of the entry into force of this Directive] the Agency shall, after consultation with the competent authorities of the Member States, the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environmental Agency (EEA), establish a programme for the ERA to be submitted in accordance with Article 22 of the medicinal products authorised before 30 October 2005 that have not been subject to any ERA and that the Agency has identified as potentially harmful to the environment in accordance with paragraph 2.	By [OP please insert the date = ***12*** months after the date of the entry into force of this Directive] the Agency shall, after consultation with the competent authorities of the Member States***, the European Centre for Disease Prevention and Control (ECDC)***, the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environmental Agency (EEA), establish a programme for the ERA to be submitted in accordance with Article 22 of the medicinal products authorised before 30 October 2005 that have not been subject to any ERA and that the Agency has identified as potentially harmful to the environment in accordance with paragraph 2.

Or. en

Amendment 315
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
By [OP please insert the date = 30 months after the date of the entry into force of this Directive] the Agency shall, after consultation with the competent authorities	By [OP please insert the date = 30 months after the date of the entry into force of this Directive] the Agency shall, after consultation with the competent authorities

of the Member States, the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environmental Agency (EEA), establish a programme for the ERA to be submitted in accordance with Article 22 of the medicinal products authorised before 30 October 2005 that have not been subject to any ERA and that the Agency has identified as potentially ***harmful*** to the environment in accordance with paragraph 2.	of the Member States, the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environmental Agency (EEA), establish a programme for the ERA to be submitted in accordance with Article 22 of the medicinal products authorised before 30 October 2005 that have not been subject to any ERA and that the Agency has identified as potentially ***posing an unacceptable risk*** to the environment in accordance with paragraph 2.

Or. en

Amendment 316
Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*
By [OP please insert the date = ***30*** months after the date of the entry into force of this Directive] the Agency shall, after consultation with the competent authorities of the Member States, the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environmental Agency (EEA), establish a programme for the ERA to be submitted in accordance with Article 22 of the medicinal products authorised before 30 October 2005 that have not been subject to any ERA and that the Agency has identified as potentially harmful to the environment in accordance with paragraph 2.	By [OP please insert the date = ***12*** months after the date of the entry into force of this Directive] the Agency shall, after consultation with the competent authorities of the Member States, the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environmental Agency (EEA), establish a programme for the ERA to be submitted in accordance with Article 22 of the medicinal products authorised before 30 October 2005 that have not been subject to any ERA and that the Agency has identified as potentially harmful to the environment in accordance with paragraph 2.

Or. en

Amendment 317
Pernille Weiss

Proposal for a directive

Article 23 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
This programme shall be made publicly available by the Agency.	This programme ***shall not exceed 10 years and*** shall be made publicly available by the Agency.

Or. en

Amendment 318
Pernille Weiss

Proposal for a directive
Article 23 – paragraph 2

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

Or. en

Amendment 319
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 23 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Agency shall set the scientific criteria for the identification of the medicinal products as potentially harmful	2. The Agency shall set the scientific criteria for the identification of the medicinal products as potentially harmful

to the environment and for the prioritisation of their ERA, using a risk based approach. For this task, the Agency ***may*** request from marketing authorisation holders the submission of relevant data or information.	to the environment and for the prioritisation of their ERA, using a risk based approach. For this task, the Agency ***shall consult all relevant stakeholders and*** request from marketing authorisation holders the submission of relevant data or information.

Or. en

Amendment 320
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a directive
Article 23 – paragraph 2

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

Or. en

Amendment 321
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 23 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Agency shall set the scientific criteria for the identification of the medicinal products ***as potentially harmful*** to the environment and for the prioritisation of their ERA, using a risk based approach. For this task, the Agency may request from marketing authorisation	2. The Agency shall set the scientific criteria for the identification of the medicinal products ***that pose a potential risk*** to the environment and for the prioritisation of their ERA, using a risk based approach. For this task, the Agency may request from marketing authorisation

holders the submission of relevant data or information.

holders the submission of relevant data or information.

Or. en

Amendment 322
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 23 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The marketing authorisation holders for medicinal products identified in the programme referred to in paragraph 1 shall submit the ERA to the Agency. The outcome of the assessment of the ERA including ***the data*** submitted by the marketing authorisation holder shall be made publicly available by the Agency.	3. The marketing authorisation holders for medicinal products identified in the programme referred to in paragraph 1 shall submit the ERA to the Agency. The outcome of the assessment of the ERA including ***a summary of ERA studies and their results as*** submitted by the marketing authorisation holder ***and the assessment of the ERA and scientific guidelines referred to in Article 22(5)*** shall be made publicly available by the Agency.

Or. en

Amendment 323
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 23 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The marketing authorisation holders for medicinal products identified in the programme referred to in paragraph 1 shall submit the ERA to the Agency. The outcome of the assessment of the ERA including ***the data*** submitted by the marketing authorisation holder shall be made publicly available by the Agency.	3. The marketing authorisation holders for medicinal products identified in the programme referred to in paragraph 1 shall submit the ERA to the Agency. The outcome of the assessment of the ERA**,** including ***full data sets and summaries of conducted ERA studies*** submitted by the marketing authorisation holder**,** shall be made publicly available by the Agency ***and shall be proactively shared with drinking***

and wastewater operators.

Or. en

Amendment 324
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a directive
Article 23 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The marketing authorisation holders for medicinal products identified in the programme referred to in paragraph 1 shall submit the ERA to the Agency. The outcome of the assessment of the ERA including the data submitted by the marketing authorisation holder shall be made publicly available by the Agency.	3. The ***current*** marketing authorisation holders for medicinal products identified in the programme referred to in paragraph 1 shall submit the ERA to the Agency. The outcome of the assessment of the ERA including the data submitted by the marketing authorisation holder shall be made publicly available by the Agency.

Or. en

Amendment 325
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 23 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Where there are several medicinal products identified in the programme referred to in paragraph 1 that contain the same active substance and that are expected to pose the same risks to the environment, the competent authorities of the Member States or the Agency shall ***encourage*** the marketing authorisation holders to conduct joint studies for the ERA, to minimise unnecessary duplication of data and use of animals.	4. Where there are several medicinal products identified in the programme referred to in paragraph 1 that contain the same active substance and that are expected to pose the same risks to the environment, the competent authorities of the Member States or the Agency shall ***inform and recommend*** the marketing authorisation holders ***of the possibility*** to conduct joint studies for the ERA, to minimise unnecessary duplication of data and use of ***animals. In this regard, to facilitate and foster the increased use of joint studies, the Agency shall oversee***

these in a cooridnating role, where necessary and appropriate.

Or. en

Amendment 326
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a directive
Article 23 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Where there are several medicinal products identified in the programme referred to in paragraph 1 that contain the same active substance and that are expected to pose the same risks to the environment, the competent authorities of the Member States or the Agency shall encourage the marketing authorisation holders to conduct joint studies for the ERA, to minimise unnecessary duplication of data and use of animals.	4. Where there are several medicinal products identified in the programme referred to in paragraph 1 that contain the same active substance and that are expected to pose the same risks to the environment, the competent authorities of the Member States or the Agency shall encourage the marketing authorisation holders to conduct joint studies for the ERA, to minimise unnecessary duplication of data and use of animals***, specifically to avoid unnecessary testing of vertebrate species and to follow the 3R rule***.

Or. en

Amendment 327
Susana Solís Pérez, Klemen Grošelj

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

Text proposed by the Commission	*Amendment*
	4 a. The Agency shall ensure that the ERA is followed by clear recommandations to the marketing authorisation holders on how to respect the guidelines and to fulfill the requirements in the future.

Or. en

Amendment 328
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a directive
Article 24 – paragraph 2

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

Or. en

Amendment 329
Pernille Weiss

Proposal for a directive
Article 24 – paragraph 2

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

Or. en

Amendment 330
Pernille Weiss

Proposal for a directive
Article 24 – paragraph 4

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

Directive.	Directive***, while taking into account outcomes from relevant Union initiatives, such as with regard to animal testing***.

Or. en

Amendment 331
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 24 – paragraph 4

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

Or. en

Amendment 332
Pernille Weiss

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

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

Or. en

Amendment 333
Pernille Weiss

Proposal for a directive
Article 25 – paragraph 2 – subparagraph 3

Text proposed by the Commission	*Amendment*
The Agency shall establish a repository of active substance master files, their assessments reports and their certificates and ensure that personal data is protected. The Agency shall ensure that the competent authorities of the Member State have access to this repository.	The Agency shall establish a repository of active substance master files, their assessments reports and their certificates and ensure that personal data ***and commercially sensitive information*** is protected. The Agency shall ensure that the competent authorities of the Member State have access to this repository.

Or. en

Amendment 334
Pernille Weiss

Proposal for a directive
Article 26 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Marketing authorisation applicants may, instead of submitting the relevant data on an active substance other than a chemical active substance, or on other substances present or used in the manufacture of a medicinal product, required in accordance with Annex II, rely on an additional quality master file, an additional quality master file certificate granted by the Agency in accordance with this Article ('additional quality master file certificate'), or a certificate confirming that the quality of that substance is suitably controlled by the relevant monograph of the European Pharmacopeia.	Marketing authorisation applicants may, instead of submitting the relevant data on an active substance other than a chemical active substance, or on other substances present or used in the manufacture of a medicinal product***, including raw materials and starting materials used for the manufacturing of cell therapies and gene therapies***, required in accordance with Annex II, rely on an additional quality master file, an additional quality master file certificate granted by the Agency in accordance with this Article ('additional quality master file certificate'), or a certificate confirming that the quality of that substance is suitably controlled by the relevant monograph of the European Pharmacopeia.

Or. en

Amendment 335
Cristian-Silviu Buşoi

Proposal for a directive

Article 26 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
Marketing authorisation applicants may only rely on an additional ***quality*** master file ***certificate*** if no certificate exists on the same additional ***quality*** master file.	Marketing authorisation applicants may only rely on an additional master file if no certificate exists on the same additional master file.

Or. en

Amendment 336
Cristian-Silviu Buşoi

Proposal for a directive
Article 26 – paragraph 1 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	Marketing authorisation applicants may also, instead of submitting the relevant data on a platform technology used in the context of the manufacturing process of a medicinal product, rely on a platform technology master file, or a platform technology master file certificate granted by the Agency in accordance with this Article. Marketing authorisation applicants may only rely on an additional platform technology master file if no certificate exists on the same additional platform technology master file.

Or. en

Amendment 337
Cristian-Silviu Buşoi

Proposal for a directive
Article 26 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Article 25, paragraphs 1 to 5, 7 and 8 shall also apply mutadis mutandis to additional ***quality*** master file certification.	2. Article 25, paragraphs 1 to 5, 7 and 8 shall also apply mutadis mutandis to additional master file certification.

Or. en

Amendment 338
Susana Solís Pérez, Klemen Grošelj

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

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

Or. en

Amendment 339
Pernille Weiss

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

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

Or. en

Amendment 340
Cristian-Silviu Buşoi

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

Text proposed by the Commission	*Amendment*
(b) additional ***quality*** master files for which a certificate may be used in order to provide specific information ***on the quality of a substance present or used in the manufacture of a medicinal product***;	(b) additional master files for which a certificate may be used in order to provide specific information ***referred to in paragraphs 1 and 1a of this Article***;

Or. en

Amendment 341
Cristian-Silviu Buşoi

Proposal for a directive
Article 26 – paragraph 3 – point b a (new)

Text proposed by the Commission	*Amendment*
	(b a) the rules governing the content and format of the application for an additional master file certificate;

Or. en

Amendment 342
Cristian-Silviu Buşoi

Proposal for a directive
Article 26 – paragraph 3 – point c

Text proposed by the Commission	*Amendment*
(c) the rules for the examination of ***applications for making publicly available of*** additional ***quality*** master file ***certificates***;	(c) the rules for the examination of ***an application for an*** additional master file ***certificate and for the granting of the certificate***;

Or. en

Amendment 343
Cristian-Silviu Buşoi

Proposal for a directive
Article 26 – paragraph 3 – point d

Text proposed by the Commission	*Amendment*
(d) the rules for introducing changes to the additional ***quality*** master file and the certificate;	(d) the rules for introducing changes to the additional master file and the certificate;

Or. en

Amendment 344
Cristian-Silviu Buşoi

Proposal for a directive
Article 26 – paragraph 3 – point e

Text proposed by the Commission	*Amendment*
(e) the rules on access for competent authorities of the Member State to the ***additional*** quality master file and its assessment report;	(e) the rules on access for competent authorities of the Member State to the quality master file and its assessment report;

Or. en

Amendment 345
Cristian-Silviu Buşoi

Proposal for a directive
Article 26 – paragraph 3 – point f

Text proposed by the Commission	*Amendment*
(f) the rules on access for marketing authorisation applicants and marketing authorisation holders relying on an additional ***quality*** master file certificate to the additional ***quality*** master file and to the assessment report.	(f) the rules on access for marketing authorisation applicants and marketing authorisation holders relying on an additional master file certificate to the additional master file and to the assessment report.

Or. en

Amendment 346
Pernille Weiss

Proposal for a directive
Article 26 a (new)

Text proposed by the Commission	*Amendment*
	Article 26a
	Additional platform technology master files
	1. Marketing authorisation applicants may, instead of submitting the relevant data on the quality, safety and efficacy of a medicinal product, required in accordance with Annex II, rely on an additional platform technology master file or an additional platform technology master file certificate granted by the Agency in accordance with this Article ('additional platform technology master file certificate').
	2. Article 25(1) to (5), (7) and (8) shall also apply mutatis mutandis to additional platform technology master file certification.
	3. The description of the platform technology master file shall represent the applicant's basis for relevant data on quality, safety and efficacy of the medicinal product as required in Annex II. To adequately describe the platform technology master file, appropriate information as laid down in scientific guidelines published by the Agency shall be provided.
	4. The Commission is empowered to adopt delegated acts in accordance with Article 215 to supplement this Directive by specifying:
	(a) the rules governing the content and format of the application for an additional platform technology master file certificate;
	(b) additional platform technology master files for which a certificate may be used in order to provide specific information on the platform technology on the basis of which a substance present or used in the manufacture of a medicinal product is

manufactured;

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

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

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

(f) the rules on access for marketing authorisation applicants and marketing authorisation holders relying on a additional platform technology master file certificate to the additional platform technology master file and to the assessment report.

5. The Agency shall develop and publish scientific guidelines on the requirements for an additional platform technology master file.

6. If requested by the Agency, the manufacturer of a substance present or used in the manufacturing of a medicinal product for which an application for an additional platform technology master file certificate has been submitted or the additional platform technology master file certificate holder shall undergo an inspection to verify the information contained in the application or the master file. If the holder of the additional platform technology master file refuses to undergo such an inspection, the Agency may suspend or terminate the application for the additional platform technology master file certificate.

Or. en

Amendment 347
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 28 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(b a) the creation of the product occurred within a regulatory sandbox as outlined by Article 114 (2) of [revised Regulation (EC) No 726/2004], unless exceptions are warranted by scientific and technical reasoning.

Or. en

Amendment 348
Susana Solís Pérez, Klemen Grošelj

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

Text proposed by the Commission	*Amendment*
	6 a. When enacting delegated acts under this Article, the Commission shall engage in dialogue with the Agency, national competent authorities, the Pharmaceutical Committee, and pertinent interested parties.

Or. en

Amendment 349
Susana Solís Pérez, Klemen Grošelj

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

Text proposed by the Commission	*Amendment*
	6 b. The Commission shall submit a report on the acquired experience with adapted frameworks to the European Parliament and the Council of the European Union. The inaugural report is due five years following [insert date = 18 months post-implementation of this

	Directive] and on a five-year cycle subsequently. Depending on the report's findings, the Commission may propose legislative changes to the overarching pharmaceutical laws, reflecting the practical insights gained from employing adapted frameworks.

Or. en

Amendment 350
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 29 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) shall verify whether the particulars and documentations submitted in support of the application comply with Articles 6 and 9 to 14 (‘validation’), and examine whether the conditions for issuing a marketing authorisation set out in Articles 43 to 45 are complied with;	(a) shall verify ***within 20 days*** whether the particulars and documentations submitted in support of the application comply with Articles 6 and 9 to 14 (‘validation’), and examine whether the conditions for issuing a marketing authorisation set out in Articles 43 to 45 are complied with;

Or. en

Amendment 351
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 29 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the competent authority of the Member State considers that the marketing authorisation application is incomplete, or contains critical deficiencies that may prevent the evaluation of the medicinal product it shall inform the applicant accordingly and shall set a time limit for submitting the missing information and documentation. If the	3. Where the competent authority of the Member State considers that the marketing authorisation application is incomplete, or contains critical deficiencies that may prevent the evaluation of the medicinal product it shall inform the applicant accordingly and shall set a time limit ***of minimum 14 days*** for submitting the missing information and

applicant fails to provide the missing information and documentation within the time limit set, the application shall be considered to have been withdrawn.

documentation. If the applicant fails to provide the missing information and documentation within the time limit set, the application shall be considered to have been withdrawn ***by default***.

Or. en

Amendment 352
Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*
The competent authority of the Member State shall summarise the deficiencies in writing. On this basis, the competent authority of the Member State shall inform the applicant accordingly and set a time limit to address the deficiencies. The application shall be suspended until the applicant addresses the deficiencies. If the applicant fails to address those deficiencies within the time limit set by the competent authority of the Member State, the application shall be considered as withdrawn.	The competent authority of the Member State shall summarise the deficiencies in writing. On this basis, the competent authority of the Member State shall inform the applicant accordingly and set a time limit ***of minimum 14 days*** to address the deficiencies. The application shall be suspended until the applicant addresses the deficiencies. If the applicant fails to address those deficiencies within the time limit set by the competent authority of the Member State, the application shall be considered as withdrawn ***by default***.

Or. en

Amendment 353
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 30 – paragraph 1

Text proposed by the Commission	*Amendment*
Member States shall take all appropriate measures to ensure that the procedure for granting a marketing authorisation for medicinal products is completed within a maximum of 180 days after the submission of a valid application from the date of	Member States shall take all appropriate measures to ensure that the procedure for granting a marketing authorisation for medicinal products is completed within a maximum of 180 days ***(excluding clock stops)*** after the submission of a valid

validation of a marketing authorisation application.

application from the date of validation of a marketing authorisation application.

Or. en

Amendment 354
Patrizia Toia, Beatrice Covassi

Proposal for a directive
Article 30 – paragraph 1

Text proposed by the Commission	*Amendment*
Member States shall take all appropriate measures to ensure that the procedure for granting a marketing authorisation for medicinal products is completed within a maximum of ***180*** days after the submission of a valid application from the date of validation of a marketing authorisation application.	Member States shall take all appropriate measures to ensure that the procedure for granting a marketing authorisation for medicinal products is completed within a maximum of ***120*** days after the submission of a valid application from the date of validation of a marketing authorisation application.

Or. en

Amendment 355
Patrizia Toia, Beatrice Covassi

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

Text proposed by the Commission	*Amendment*
	Without prejudice to national provisions regarding the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes, where a marketing authorisation has been granted in accordance with [revised Regulation (EC) No 726/2004], Member States shall ensure that the medicinal product is made available on the market within 90 days from the date of the issuing of the marketing authorisation as referred to in Article 16 of the [revised Regulation (EC) No 726/2004]

Or. en

Amendment 356
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 34 – paragraph 3

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

Or. en

Amendment 357
Pilar del Castillo Vera

Proposal for a directive
Article 34 – paragraph 3

Text proposed by the Commission	*Amendment*
3. ***The applicant shall inform all the competent authorities of all Member States of its application at the time of submission.*** The competent authority of a Member State may request for justified public health reasons to ***enter*** the procedure ***and shall inform*** the applicant and the competent authority of the reference Member State for the decentralised procedure ***of its request***	3. ***Based on information made available by the Coordination group for decentralised and mutual recognition procedures,*** the competent authority of a Member State may request for justified public health reasons to ***recognise*** the procedure ***within 15 days after the procedure has been closed, upon agreement with*** the applicant and the competent authority of the reference

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

Or. en

Amendment 358
Pilar del Castillo Vera

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

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

Or. en

Amendment 359
Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*

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

Or. en

Amendment 360
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 34 – paragraph 5

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

Or. en

Amendment 361
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 36 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The applicant shall inform the competent authorities of all Member States of its application at the time of submission. The competent authority of a Member State ***may request for justified public health reasons*** to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the mutual recognition procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay.	4. The applicant shall inform the competent authorities of all Member States of its application at the time of submission. The competent authority of a Member State ***shall have the possibility*** to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the mutual recognition procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay.

Or. en

Amendment 362
Pilar del Castillo Vera

Proposal for a directive
Article 36 – paragraph 4

Text proposed by the Commission	*Amendment*
4. ***The applicant shall inform the competent authorities of all Member States of its application at the time of submission.*** The competent authority of a Member State may request for justified public health reasons to ***enter*** the procedure ***and shall inform*** the applicant and the competent authority of the reference Member State for the mutual recognition procedure ***of its request within 30 days from the date of submission of the application***. The applicant shall provide the competent authorities of those Member States entering the procedure with the	4. ***Based on information made available by the Coordination group for decentralised and mutual recognition procedures,*** the competent authority of a Member State may request for justified public health reasons to ***recognise*** the procedure ***within 15 days after the procedure has been closed, upon agreement with*** the applicant and the competent authority of the reference Member State for the mutual recognition procedure. The applicant shall provide the competent authorities of those Member States entering the procedure with the

application without undue delay.	application without undue delay.

Or. en

Amendment 363
Nicolás González Casares, Laura Ballarín Cereza

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

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

Or. en

Amendment 364
Pilar del Castillo Vera

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

Text proposed by the Commission	*Amendment*
	4 a. In order to examine an application submitted in accordance with Articles 6 and 9 to 14, the competent authorities of the Member States shall verify within 30 days whether the particulars and documentations submitted in support of the application comply with Articles 6 and 9 to 14 ('validation'), and examine whether the conditions for issuing a marketing authorisation set out in Articles 43 to 45 are complied with;

Or. en

Amendment 365
Susana Solís Pérez, Klemen Grošelj

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

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

Or. en

Amendment 366
Patrizia Toia, Beatrice Covassi

Proposal for a directive
Article 38 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Within the coordination group, all disagreeing Member States concerned shall use their best endeavours to reach agreement on the action to be taken. They shall allow the applicant the opportunity to make its point of view known orally or in writing. If, within ***60*** days of the communication of the points of disagreement, the Member States reach an agreement by consensus, the reference Member State shall record the agreement, close the procedure and inform the applicant accordingly. The procedure laid down in Articles 34(7) or 36(8) shall apply.	3. Within the coordination group, all disagreeing Member States concerned shall use their best endeavours to reach agreement on the action to be taken. They shall allow the applicant the opportunity to make its point of view known orally or in writing. If, within ***30*** days of the communication of the points of disagreement, the Member States reach an agreement by consensus, the reference Member State shall record the agreement, close the procedure and inform the applicant accordingly. The procedure laid down in Articles 34(7) or 36(8) shall apply.

Or. en

Amendment 367
Patrizia Toia, Beatrice Covassi

Proposal for a directive
Article 38 – paragraph 4

Text proposed by the Commission	*Amendment*
4. If within the ***60***-day period laid down in paragraph 3, an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall be forwarded to the Commission, which shall apply the procedure laid down in Articles 41 and 42.	4. If within the ***30***-day period laid down in paragraph 3, an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall be forwarded to the Commission, which shall apply the procedure laid down in Articles 41 and 42.

Or. en

Amendment 368
Patrizia Toia, Beatrice Covassi

Proposal for a directive
Article 40 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The coordination group shall lay down a list of medicinal products for which a harmonised summary of product characteristics is to be drawn up, taking into account the proposals from the competent authorities of all Member States, and shall forward that list to the Commission.	2. The coordination group shall lay down a list of medicinal products for which a harmonised summary of product characteristics is to be drawn up, ***including the harmonisation of the approved paediatric indications, dosages and ages for which the product is recommended,*** taking into account the proposals from the competent authorities of all Member States, and shall forward that list to the Commission.

Or. en

Amendment 369
Patrizia Toia, Beatrice Covassi

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

Text proposed by the Commission	*Amendment*
When reference is made to the procedure laid down in this Article, the Committee for Medicinal Products for Human Use referred to in Article 148 of [revised Regulation (EC) No 726/2004] shall consider the matter concerned and shall issue a reasoned opinion within ***60*** days from the date when the matter was referred to it.	When reference is made to the procedure laid down in this Article, the Committee for Medicinal Products for Human Use referred to in Article 148 of [revised Regulation (EC) No 726/2004] shall consider the matter concerned and shall issue a reasoned opinion within ***30*** days from the date when the matter was referred to it.

Or. en

Amendment 370
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 42 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5 a. The Standing Committee on Medicinal Products for Human Use shall give its opinion in writing. Member States shall forward their written observations on the draft decision to the Commission within 10 days.

Or. en

Justification

Propose to add the 10 days (maximum) timeline for the Standing Committee, as indicated in recitals 147 of the Directive and 50 of the Regulation, as it is not mentioned in the binding provisions of the Directive or Regulation. In line with other principles to reduce the bureaucratic decision-making timeline, the Directive should explicitly mention in Article 42 that the maximum timeline for Standing Committee should not exceed 10 days. A confirmation in the reduction of the Standing Committee timelines contributes to narrowing the gaps for regulatory decision making with other regions.

Amendment 371

Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 43 – paragraph 3

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

Or. en

Amendment 372
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 43 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The ***competent*** authority ***of*** the Member State ***may*** consider ***and decide upon*** additional evidence ***available, independently from the data submitted*** by the marketing ***authorisation*** holder***. On that basis, the*** summary of ***product*** characteristics ***shall be updated if the additional evidence has an*** impact on the benefit-risk balance ***of a medicinal*** product.	4. The ***relevant*** authority ***in*** the Member State ***has the discretion to*** consider additional ***high-quality*** evidence ***sources, alongside the evidence provided*** by the marketing ***authorization*** holder***, for its scientific evaluation. If, after reviewing all evidence, including any supplementary information, the authority deems a modification to the product's*** summary of characteristics ***necessary due to its*** impact on the ***product's*** benefit-risk balance ***within its approved uses, it will promptly communicate its suggestion to the***

marketing authorization holder. The holder will receive all extra evidence and related study documents that the proposal is based on. They will also be asked to present their viewpoint on the provided evidence and, if required, will have the chance for an oral discussion regarding any proposed updates to the product ***summary with the authority. The authority will inform the marketing authorization holder of its decision without unnecessary delay. Should the marketing authorization holder disagree with the authority's decision, they can request a re-evaluation in writing. Upon such a request, the authority must immediately notify the Agency, providing a detailed account of the unresolved issues and reasons for disagreement, with a copy sent to the holder. Once the holder is informed that the Agency is involved, they must promptly submit their detailed reasons for the request to the Agency. Within 30 days of receiving these grounds, the Agency will review the authority's decision and issue a conclusive opinion, including the rationale for its conclusion. If the Agency's final opinion necessitates a change in the product's summary of characteristics, this summary will be accordingly updated.***

Or. en

Amendment 373
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 43 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The competent authorities of the Member States shall draw up an assessment report and make comments on the file as regards the results of the	5. The competent authorities of the Member States shall draw up an assessment report and make comments on the file as regards the results of the

pharmaceutical and non-clinical tests, the clinical studies, the risk management system, the environmental risk assessment and the pharmacovigilance system of the medicinal product concerned.	pharmaceutical and non-clinical tests, the clinical studies, the risk management system, the environmental risk assessment and the pharmacovigilance system of the medicinal product concerned. ***For expedited review processes, competent authorities shall agree binding timelines with the applicants to provide a full ERA after receiving the marketing authorisation.***

Or. en

Amendment 374
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 43 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The competent authorities of the Member States shall make the assessment report publicly available without undue delay, together with the reasons for their opinion, after deletion of any information of a commercially confidential nature. The justification shall be provided separately for each therapeutic indication applied for.	6. The competent authorities of the Member States shall make the assessment report publicly available without undue delay, together with the reasons for their opinion, after deletion of any information of a commercially confidential nature***, unless there is an overriding public interest in disclosure***. The justification shall be provided separately for each therapeutic indication applied for.

Or. en

Amendment 375
Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*
(g) in case of medicinal products for which there is substantial uncertainty as to the surrogate endpoint relation to the expected health outcome, where	(g) in case of medicinal products for which***, on duly justified grounds described in the assessment report,*** there is substantial uncertainty as to the surrogate

appropriate and relevant for the benefit-risk balance, a post-authorisation obligation to substantiate the clinical benefit;	endpoint relation to the expected health outcome, where appropriate and relevant for the benefit-risk balance, ***with particular attention to new active substances and therapeutic indications,*** a post-authorisation obligation to substantiate the clinical benefit;

Or. en

Amendment 376
Pernille Weiss

Proposal for a directive
Article 44 – paragraph 1 – subparagraph 1 – point h

Text proposed by the Commission	*Amendment*
(h) to conduct post-authorisation environmental risk assessment studies, collection of monitoring data or information on use, where identified or potential concerns about risks to the environment ***or*** public health, ***including*** antimicrobial resistance need to be further investigated after the medicinal product has been marketed;	(h) to conduct post-authorisation environmental risk assessment studies, collection of monitoring data or information on use, where identified or potential concerns about risks to the environment***, including*** public health, ***and in particular*** antimicrobial resistance need to be further investigated after the medicinal product has been marketed;

Or. en

Amendment 377
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 47 – paragraph 1 – point d

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

Or. en

Amendment 378
Pernille Weiss

Proposal for a directive
Article 47 – paragraph 1 – point d

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

Or. en

Amendment 379
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 47 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) the environmental risk assessment is incomplete or insufficiently substantiated by the applicant or if the risks identified in the environmental risk assessment have not been sufficiently addressed by the applicant;	(d) the environmental risk assessment is incomplete or insufficiently substantiated ***or the reason for the imcomplete nature of the ERA are not duly justified or subtantiated*** by the applicant or if the risks identified in the environmental risk assessment have not been sufficiently addressed by the applicant ***or by the risk mitigation measures by the applicant, in accordance Article 22 (3) this Directive***;

Or. en

Amendment 380
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

Proposal for a directive
Article 47 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) the environmental risk assessment is incomplete or insufficiently substantiated by the applicant or if the risks identified in the environmental risk assessment have not been sufficiently addressed by the applicant;	(d) the environmental risk assessment is incomplete or insufficiently substantiated by the applicant or if the risks identified in the environmental risk assessment have not been sufficiently addressed by the applicant***, with the exception of medicinal products authorised before 30 october 2005 to avoid restricting patients' access to existing treatments***;

Or. en

Amendment 381
Pernille Weiss

Proposal for a directive
Article 47 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. The national marketing authorisation may furthermore be refused if, after verification of the particulars and documentations referred to in Article 6 and subject to the specific requirements laid down in Articles 9 to 14, the view is taken that the environmental risk assessment is incomplete or insufficiently substantiated by the applicant or if the risks identified in the environmental risk assessment have not been sufficiently addressed by the applicant and the competent authority deems that post-authorisation environmental risk assessment studies in accordance with Article 44(1), point (h), would be an insufficient measure to ensure environmental protection.

Or. en

Amendment 382
Susana Solís Pérez, Klemen Grošelj

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

Text proposed by the Commission	*Amendment*
(e) is an antimicrobial; or	(e) is an ***antibiotic with an identified*** antimicrobial ***resistance risk***; or

Or. en

Amendment 383
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
(e) is an antimicrobial***; or***	(e) is an antimicrobial ***of systemic administration;***

Or. en

Amendment 384
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

Text proposed by the Commission	*Amendment*
(e) is an antimicrobial; or	(e) is an antimicrobial ***for systemic use***; or

Or. en

Amendment 385
Pernille Weiss

Proposal for a directive

Article 51 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(e a) is an antibiotic; or

Or. en

Amendment 386
Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*
(f) contains an active substance ***which*** are persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, or persistent, mobile and toxic, or very persistent and very mobile for which medical prescription is required as risk minimisation measure with regard to the environment, unless the use of the medicinal product and the patient safety require otherwise.	(f) contains an active substance ***or any of its ingredients or constituent parts*** are persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, or persistent, mobile and toxic, or very persistent and very mobile ***or listed in Annex X of Directive 2000/60/EC or Annex I of Directive 2006/118/EC*** for which medical prescription is required as risk minimisation measure with regard to the environment, unless the use of the medicinal product and the patient safety require otherwise.

Or. en

Amendment 387
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 51 – paragraph 2

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

concerned or submitting certain antimicrobial medicinal products to special medical prescription or restricted prescription.	prescription.

Or. en

Amendment 388
Nicolás González Casares, Laura Ballarín Cereza

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

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

Or. en

Amendment 389
Pilar del Castillo Vera

Proposal for a directive
Article 56 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
The marketing authorisation holder of a medicinal product placed on the market in a Member State shall, within the limits of its responsibility, ensure appropriate and continued supplies of that medicinal product to wholesale distributors, pharmacies or persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.	The marketing authorisation holder of a medicinal product placed on the market in a Member State shall, within the limits of its ***contractual*** responsibility, ensure appropriate and continued supplies of that medicinal product to wholesale distributors, pharmacies or 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 Marketing authorisation holders comply with their supply obligations.***

Or. en

Amendment 390
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 56 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
The marketing authorisation holder of a medicinal product placed on the market in a Member State shall, within the limits of its responsibility, ensure appropriate and continued supplies of that medicinal product to wholesale distributors, pharmacies or persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.	The marketing authorisation holder of a medicinal product placed on the market in a Member State ***or a wholesale distributor who is designated by the marketing authorisation holder*** shall, within the limits of its responsibility, ensure appropriate and continued supplies of that medicinal product to wholesale distributors, ***in accordance with Articles 166 and 167,*** pharmacies or ***and*** persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.

Or. en

Amendment 391
Pernille Weiss

Proposal for a directive
Article 56 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
The marketing authorisation holder of a medicinal product placed on the market in a Member State shall, within the limits of its responsibility, ensure appropriate and continued supplies of that medicinal product to wholesale distributors, pharmacies or persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.	The marketing authorisation holder of a medicinal product placed on the market in a Member State shall, within the limits of its responsibility, ensure appropriate and continued supplies of that medicinal product to wholesale distributors ***in accordance with Articles 166 and 167***, pharmacies or persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.

Or. en

Amendment 392
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 56 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
The marketing authorisation holder of a medicinal product placed on the market in a Member State shall, within the limits of its responsibility, ensure appropriate and continued supplies of that medicinal product to wholesale distributors, pharmacies ***or*** persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.	The marketing authorisation holder of a medicinal product placed on the market in a Member State shall, within the limits of its responsibility, ensure appropriate and continued supplies of that medicinal product to wholesale distributors, 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 393
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 56 – paragraph 3 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	For SoHO-derived medicinal products, which are obtained from altruistic and unpaid donations, Member States shall ensure, through public service obligations, that manufacturers, within the limits of their responsibilities, provide an appropriate and continuous supply to patients in each Member State. Member States shall negociate fair and transparent prices for SoHO-derived medicinal products and ensure that low-profit products are also available to patients and that there is a continuous investment on research and innovation for those

products.

When medicinal products are derived from donated SoHOs, manufacturers must, as for public service obligation in the Member States, report annually to the authorities the amount of processed locally-collected SoHOs and medicinal products prepared from them.

Or. en

Amendment 394
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 56 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The marketing authorisation holder shall, at all stages of manufacturing and distribution ensure that the starting materials and ingredients of the medicinal products and the medicinal products themselves comply with the requirements of this Directive and, where relevant, the [revised Regulation (EC) No 726/2004] and other Union law and shall verify that such requirements are met.	4. The marketing authorisation holder shall, at all stages of manufacturing and distribution***, within the limits of its responsability,*** ensure that the starting materials and ingredients of the medicinal products and the medicinal products themselves comply with the requirements of this Directive and, where relevant, the [revised Regulation (EC) No 726/2004] and other Union law and shall verify that such requirements are met.

Or. en

Amendment 395
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 56 – paragraph 7

Text proposed by the Commission	*Amendment*
7. Where the marketing authorisation holder considers or has reason to believe that the medicinal product it has made available on the market is not in conformity with the marketing	7. Where the marketing authorisation holder considers or has reason to believe that the medicinal product it has made available on the market is not in conformity with the marketing

authorisation or this Directive and the [revised Regulation (EC) No 726/2004] it shall immediately take the necessary corrective actions to bring that medicinal product into conformity, to withdraw it or recall it, as appropriate. The marketing authorisation holder shall immediately inform the competent authorities and the distributors concerned to that effect.	authorisation or this Directive and the [revised Regulation (EC) No 726/2004] it shall immediately take the necessary corrective actions to bring that medicinal product into conformity, to withdraw it or recall it, as appropriate***, in consultation with the competent authorities***. The marketing authorisation holder shall immediately inform the competent authorities and the distributors concerned to that effect.

Or. en

Amendment 396
Pilar del Castillo Vera

Proposal for a directive
Article 56 – paragraph 9

Text proposed by the Commission	*Amendment*
9. Upon request the marketing authorisation holder shall provide the competent authority with all data relating to the volume of sales of the medicinal product, and any data in its possession relating to the volume of prescriptions.	9. Upon request the marketing authorisation holder shall provide the competent authority with all data relating to the volume of sales of the medicinal product ***in the EU or Member State. The Marketing Authorisation Holder could rely on the information contained in the repositories system referred to in Article 67, paragraph 2, second sub-paragraph, point (e) for the provision of data relating to the volume of sales of the medicinal product*** , and any data in its possession relating to the volume of prescriptions.

Or. en

Amendment 397
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 56 – paragraph 9

Text proposed by the Commission	*Amendment*
9. Upon request the marketing authorisation holder shall provide the competent authority with all data relating to the volume of sales of the medicinal product, and any data in its possession relating to the volume of prescriptions.	9. Upon request the marketing authorisation holder shall provide the competent authority with all data relating to the volume of sales of the medicinal product ***in the EU or Member State***, and any data in its possession relating to the volume of prescriptions ***in the EU or Member State***. ***The marketing Authorisation Holder could rely on the information contained in the repositories system referred to in Article 67, paragraph 2, second sub-paragraph, point (e) for the provision of data relating to the volume of sales of the medicinal product.***

Or. en

Amendment 398
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 57 – title

Text proposed by the Commission	*Amendment*
Responsibility to report on public financial support	Responsibility to report on public financial support ***and cost data for all applicable research and development activities of medicinal products***

Or. en

Amendment 399
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 57 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The marketing authorisation holder shall declare to the public any direct financial support received from any public authority or publicly funded body, in	1. The marketing authorisation holder shall declare to the public any direct ***and indirect*** financial support received from any ***foreign or european private entity,***

relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support.

including philantropic entities, public authority or publicly funded body***,*** ***including tax advantages and subsidies***, in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support.

Or. en

Amendment 400
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 57 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The marketing authorisation holder shall declare to the public any direct financial support received from any public authority or publicly funded body, in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support.	1. The marketing authorisation holder shall declare to the public any direct ***and indirect*** financial support received from any public authority or publicly funded body, ***philantropic or non-for profit organisation or fund*** in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support.

Or. en

Amendment 401
Henna Virkkunen

Proposal for a directive
Article 57 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The marketing authorisation holder shall declare to the public any direct financial support received from any public authority or publicly funded body, in	1. The marketing authorisation holder shall declare to the public any direct financial support received from any public authority or publicly funded body ***based in***

relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support.	***the European Union***, in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity ***based in the European Union*** that received that support.

Or. en

Justification

The R&D funding disclosure requirement aims to (indirectly) address affordability of medicines in Europe (see impact assessment p.23). Its applicability therefore should be limited to EU funding and not include funding from outside the EU. Funding in the EU member states does not require EU action as it is regulated by individual member states, in the framework of their healthcare system and budgets.

Amendment 402
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

Proposal for a directive
Article 57 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The marketing authorisation holder shall declare to the public any direct financial support received from any public authority or publicly funded body, in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support.	1. The marketing authorisation holder shall declare to the public any direct financial support received from any public authority or publicly funded body ***of the European Union***, in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support.

Or. en

Amendment 403
Pernille Weiss

Proposal for a directive
Article 57 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The marketing authorisation holder shall declare to the public any direct financial support received from any public authority or publicly funded body, in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support.	1. The marketing authorisation holder shall declare to the public any direct financial support received from any public authority or publicly funded body ***of the Union***, in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support.

Or. en

Amendment 404
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 57 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. The marketing authorisation holder shall declare all cases where the product was acquired at any stage of development from an entity not engaged in an economic activity ('not-for-profit entity') or a public-private research consortium.

Or. en

Amendment 405
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 57 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. The marketing authorisation holder shall also report an estimate of the costs incurred for the research and development of the medicinal product

covered by a national or a centralised marketing authorization.

Or. en

Amendment 406
Ville Niinistö
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
(ii) the public authority ***or*** publicly funded body that provided the financial support referred to in point (i);	(ii) the public authority**,** publicly funded body***, philantropic or non-for profit organisation or fund*** that provided the financial support referred to in point (i);

Or. en

Amendment 407
Henna Virkkunen

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

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

Or. en

Justification

The R&D funding disclosure requirement aims to (indirectly) address affordability of medicines in Europe (see impact assessment p.23). Its applicability therefore should be limited to EU funding and not include funding from outside the EU. Funding in the EU member states does not require EU action as it is regulated by individual member states, in the framework of their healthcare system and budgets.

Amendment 408
Pernille Weiss

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

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

Or. en

Amendment 409
Nicolás González Casares, Laura Ballarín Cereza

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

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

Or. en

Amendment 410
Henna Virkkunen

Proposal for a directive
Article 57 – paragraph 2 – point a – point iii

Text proposed by the Commission	*Amendment*
(iii) the legal entity that received the support referred to in point (i).	(iii) the legal entity ***based in the European Union*** that received the support referred to in point (i).

Or. en

Justification

The R&D funding disclosure requirement aims to (indirectly) address affordability of medicines in Europe (see impact assessment p.23). Its applicability therefore should be

limited to EU funding and not include funding from outside the EU. Funding in the EU member states does not require EU action as it is regulated by individual member states, in the framework of their healthcare system and budgets.

Amendment 411
Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*
	(iii a) any independent legal entity from which it obtained a license in relation to, or acquired, the medicinal product in its previous phases of development, and at which stage of the research and development process. The marketing authorisation holder shall, as much as possible, include in the report information on any public or private funding received by the independent entity for its research activities in relation to the medicinal product.

Or. en

Amendment 412
Ville Niinistö
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
	(iii a) the percentage of total research and development costs covered by the financial support referred to in paragraph 1;

Or. en

Amendment 413

Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*
	(iii b) an estimate of the total costs incurred for the research and development of the medicinal product, which shall be disaggregated to each stage of drug research and development, including basic research, pre-clinical research, phase I, II, III of the clinical investigation of the medicinal product; as well as post-market studies.

Or. en

Amendment 414
Ville Niinistö
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
	(iii b) where applicable, information related to acquiring of product license from a not-for-profit-entity or a public-private consortium, including the amount of public funding invested prior to acquisition of the product, stage of development and name of the entity.

Or. en

Amendment 415
Pernille Weiss

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

Text proposed by the Commission	*Amendment*

6 a. The Agency shall provide a publicly accessible website to facilitate access to the electronic links communicated to the Agency in accordance with paragraphs 2 and 3, sorted, where relevant, by medicine and by Member State.

Or. en

Amendment 416
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 57 a (new)

Text proposed by the Commission	*Amendment*
	Article57a
	Responsibility to report on research and development costs
	In addition to the information listed in Article 57, the marketing authorisation holder shall, when submitting an application for reimbursement in a Member State for a nationally or centrally authorised product, declare upon request from the national competent authority responsible for pricing and reimbursement a detailed externally-audited reporting on the company's expenditure related to the research and development cost of the medicinal product.

Or. en

Amendment 417
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 58 – title

Text proposed by the Commission	*Amendment*
Traceability of substances used in the manufacture of medicinal products	Traceability of substances used in the manufacture of medicinal products ***and manufacturing in the environmental impact assessment***

Or. en

Amendment 418
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 58 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The marketing authorisation holder shall, when necessary, ensure the traceability of an active substance, starting material, excipient or any other substance intended or expected to be present in a medicinal product at all stages of manufacturing and distribution.	1. The marketing authorisation holder shall, when necessary, ensure the traceability of an active substance, starting material, excipient or any other substance intended or expected to be present in a medicinal product at all stages of manufacturing and distribution ***as laid down in the batch record and related systems***.

Or. en

Amendment 419
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 58 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The marketing authorisation holder shall***, when necessary,*** ensure the traceability of an active substance, starting material, excipient or any other substance intended or expected to be present in a medicinal product at all stages of manufacturing and distribution.	1. The marketing authorisation holder shall ensure the traceability of an active substance, starting material, excipient or any other substance intended or expected to be present in a medicinal product at all stages of manufacturing and distribution.

Or. en

Amendment 420
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 58 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. The marketing authorisation holder shall include the manufacturing process of the substances referred to in paragraph 1 as an integral part of the environmental impact assessment referred to in Article 22 and in line with requirements set in Annex II.

Or. en

Amendment 421
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 58 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The marketing authorisation ***holder and its*** suppliers shall have in place systems and procedures to identify the other natural or legal persons to whom products referred to in paragraph 2 have been supplied. This information shall, upon request, be made available to the competent authorities.	4. The marketing authorisation ***holder´s*** suppliers shall have in place systems and procedures to identify the other natural or legal persons to whom products referred to in paragraph 2 have been supplied. This information shall, upon request, be made available to the competent authorities.

Or. en

Amendment 422
Pernille Weiss

Proposal for a directive

Article 58 a (new)

Text proposed by the Commission	*Amendment*
	Article58a
	Obligation to submit an application for pricing and reimbursement in all Member States
	1. The marketing authorisation holder shall, upon request by a Member State in which the marketing authorisation is valid, submit in good faith and within the limits of its responsibilities an application for pricing and reimbursement for the medicinal product no later than two years from the date when the Member State made its request, or within four years from that date for any of the following entities:
	(i) SMEs;
	(ii) entities not engaged in an economic activity ('not-for-profit entity'); and
	(iii) undertakings that, by the time of granting the marketing authorisation, have received not more than seven centralised marketing authorisations for the undertaking concerned or, in the case of an undertaking belonging to a group, for the group of which it is part, since the establishment of the undertaking or the group, whichever is earliest.
	For the purposes of this Directive and [revised Regulation (EC) No 726/2004], the Commission shall by ... [18 months after the date of entry into force of this Directive] adopt delegated acts in accordance with Article 215 to supplement this Directive by laying down the criteria to qualify as a micro, small and medium-sized enterprise, taking into account the specificities of enterprises of this sector within the Union.
	The marketing authorisation holder shall notify that it fulfilled the obligations set out in the first subparagraph through the EU Access to Medicines Notification

System provided for in Article 58b.

2. For the purposes of paragraph 1 of this Article, Member States shall make their request within two years of the granting of a marketing authorisation and notify this in the EU Access to Medicines Notification System provided for in Article 58b. Following the filing for pricing and reimbursement by the marketing authorisation holder, Directive 89/105/EEC shall apply. Where a Member State has not complied with the time limits laid down in Directive 89/105/EEC, the obligation on the marketing authorisation holder set out in this Article shall be considered to be fulfilled in that Member State. Without prejudice to the deadline and procedure set out in paragraph 1, Member States shall in the case of vaccines have included this product in their national immunisation programme, or shall have initiated the process for this, before making their request.

3. By way of derogation from paragraph 1, the marketing authorisation holder for a designated orphan medicinal product or for an advanced therapy medicinal product may choose instead:

(a) to make a medicinal product available to patients and the prescribing doctors who requested it; or

(b) to submit an application for pricing and reimbursement in good faith and within the limits of its responsibility only in the Member States where the relevant patient population has been identified.

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

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

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

7. The Commission shall by means of implementing acts establish a conciliation mechanism to facilitate discussions between applicants and Member States to resolve potential disputes related to the process for submission of applications for pricing and reimbursement and with respect to the timelines set out in Directive 89/105/EEC. In respect of national competences with regard to assessments on the added value of a medicinal product or subsequent decisions on pricing and reimbursement as well as on budgetary decisions and the allocation of financial resources in the area of protection and improvement of human health, the conciliation mechanism shall exclude opinions on these issues. In the event of continued disagreement between an applicant and a Member State regarding the fulfilment of the obligations set out in this Article, the Commission shall be empowered to issue a legally binding Commission decision following an opinion of the Agency.

8. The provisions of this Article shall not prevent a marketing authorisation holder

	from submitting an application for pricing and reimbursement and placing a medicinal product on the market of a Member State without a Member State having made a request in accordance with paragraph 1.
	9. The Commission shall assess barriers to timely access to medicinal products in each Member State as well as on an aggregated Union level and publish a report with the results of its assessment. The report shall be drawn up for the first time by [OP: Please insert date of the end of the second year after the date of entry into force of this Directive] and every four years thereafter.

Or. en

Amendment 423
Henna Virkkunen

Proposal for a directive
Article 58 a (new)

Text proposed by the Commission	*Amendment*
	Article58a
	Obligation to submit an application for pricing and reimbursement in all Member States
	1. The marketing authorisation holder shall, upon request by a Member State in which the marketing authorisation is valid, submit in good faith and within the limits of its responsibility an application for pricing and reimbursement for the medicinal product no later than two years from the date when the Member State made its request, or within four years from that date for any of the following entities:
	(i) SMEs;
	(ii) entities not engaged in an economic activity ('not-for-profit entity'); and

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

For the purposes of this Directive and [revised Regulation (EC) No 726/2004], the Commission shall by ... [18 months after the date of entry into force of this Directive] adopt delegated acts in accordance with Article 215 to supplement this Directive by laying down the criteria to qualify as a micro, small and medium-sized enterprise, taking into account the specificities of enterprises of this sector within the Union. The marketing authorisation holder shall notify that it fulfilled the obligations set out in the first subparagraph through the EU Access to Medicines Notification System provided for in Article 58b.

2. For the purposes of paragraph 1of this Article, Member States shall make their request within two years of the granting of a marketing authorisation. Following the filing for pricing and reimbursement by the marketing authorisation holder, Directive89/105/EEC shall apply. Where a Member State has not complied with the timelines laid down in Directive 89/105/EEC, the obligation on the marketing authorisation holder set out in this Article shall be considered to be fulfilled in that Member State.

3. By way of derogation from paragraph 1, the marketing authorisation holder for a designated orphan medicinal product or for an advanced therapy medicinal product may choose instead: (a) to make a medicinal product directly available to patients and the prescribing doctors who requested it; or

(b) to submit an application for pricing and reimbursement within the limits of its

responsibility only in the Member States where the relevant patient population has been identified and/ or where there is appropriate infrastructure to diagnose and administer the medicinal product.

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

5. The Commission shall, after consultation of the Agency and other relevant stakeholders, adopt by means of implementing acts a list of products to be exempted from the obligations set out in this Article. Inclusion of a medicinal product in that list may be based on criteria such as the administration of a medicinal product in most Member States being impracticable. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).

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

7. The Commission shall by means of implementing acts establish a conciliation mechanism to facilitate discussions between applicants and Member States to resolve potential process-related disputes with regards to the submitted applications for pricing and reimbursement and with respect to the timelines set out in Directive 89/105/EEC. The conciliation mechanism expressively excludes any other matters such as relating to the value assessment of medicinal products and the allocation of

resources assigned to medical care or price levels. In the event of continued disagreement between an applicant and a Member State regarding the fulfilment of the obligations set out in this Article, the Commission shall be empowered to issue a legally binding Commission decision following an opinion of the Agency.

8. Member States and the Marketing Authorization Holders may request the Commission to discuss issues related to the practical implementation of this Article and to align with any other relevant stakeholders on any further guidance required to ensure the appropriate implementation thereof based on clear and predictable criteria. These guidelines shall be reviewed and updated regularly in consultation with all relevant parties to account for new technologies and any relevant changes in the access ecosystem.

Or. en

Justification

In some situations filing for Pricing & Reimbursement is not legally possible because of local submission rules (e.g. if price / reimbursement in reference countries are not available yet; or because there is not any comparative trial data available yet). We need language to clarify that it should focus on the process of submitting, and exclude value assessment/price which is a Member State competence. As this would be a very new process/obligation, guidelines should be established with EU Member States, Market Authorisation Holders (MAHs) and other relevant stakeholders. The requests should also be product-based, and not for every single indication.

Amendment 424
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 58 a (new)

Text proposed by the Commission	*Amendment*
	Article 58a
	Obligation to launch products in Member

States

1. The marketing authorisation holder shall, upon request by a Member State in which the marketing authorisation is valid, release and continuously supply into the supply chain the requested product in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member State no later than nine months from the date when the Member State made its request, or within 18 months from that date for any of the following entities:

(i) SMEs;

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

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

2. The obligation laid down in paragraph 1 shall not prevent the marketing authorisation holder from submitting a pricing and reimbursement application in a Member State before receiving the request.

3. Following agreement between a Member State and a marketing authorisation holder, timelines other than those set out in paragraph 1 may apply.

4. For products authorised under [revised Regulation 726/2004], the marketing authorisation holder shall notify the Agency about the result of placing on the market of the products, in order to fulfil obligations set out in Article 138(2) of [revised Regulation 726/2004].

5. Following the filing for pricing and reimbursement by the marketing authorisation holder, Directive 89/105/EEC shall apply.

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

Or. en

Justification

Some countries have a pre-requirement to have the product already reimbursed in a Member State. Since this is not linked to the marketing authorization date but rather to the request, we believe 9 & 18 months is a sufficient time frame.

Amendment 425
Pernille Weiss

Proposal for a directive
Article 58 b (new)

Text proposed by the Commission	*Amendment*
	Article 58b
	EU Access to Medicines Notification System
	1. The Commission shall, in collaboration with the Member States, set up and maintain an electronic notification system (the "EU Access to Medicines Notification System") as a single-entry point for the notification of compliance with the obligations set out in Article 58a. The EU Access to Medicines Notification System shall be interoperable with the other Union-wide data repositories for medicinal products.
	2. The marketing authorisation holder shall use the EU Access to Medicines Notification System to notify their compliance with the obligations set out in Article 58a. In the Member States where the marketing authorisation is valid, the national competent authority shall use the EU Access to Medicines Notification System to indicate that the marketing authorisation holder has fulfilled its

obligations set out in Article 58a.

3. By ... [3 years following the date of entry into force of this Directive], the Commission shall adopt implementing acts to establish technical and organisational requirements, including on security aspects and data governance, which are necessary for the practical implementation of the EU Access to Medicines Notification System. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).

4. By ... [5 years after the date of entry into force of this Directive] and every 3 years thereafter, the Commission shall present a report to the European Parliament and the Council on the use and functioning of the EU Access to Medicines Notification System.

5. By ... [5 years after the date of entry into force of this Directive], the Commission shall assess the feasibility of extending the EU Access to Medicines Notification System to other areas of the process for pricing of medicinal products as set out in Directive 89/105/EEC and, if appropriate, adopt implementing acts to establish this extended system. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).

Or. en

Amendment 426
Pilar del Castillo Vera

Proposal for a directive
Article 59 – paragraph 1

Text proposed by the Commission	*Amendment*
Where medicinal products are authorised for a paediatric indication following completion of an agreed paediatric investigation plan and those medicinal	Where medicinal products are authorised for a paediatric indication following completion of an agreed paediatric investigation plan and those medicinal

products have already been marketed with other therapeutic indications, the marketing authorisation holder shall, within two years of the date on which the paediatric indication is authorised, place the medicinal product on the market taking into account the paediatric indication in all Member States where the medicinal product is already placed on the market.

products have already been marketed with other therapeutic indications, the marketing authorisation holder shall, within two years of the date on which the paediatric indication is authorised, place the medicinal product on the ***Union*** market taking into account the paediatric indication***, and make the medicinal product available to patients and the prescribing doctors who requested it*** in all Member States where the medicinal product is already placed on the market.

Or. en

Amendment 427
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

Proposal for a directive
Article 63 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States may decide that the package leaflet shall be made available in paper format or electronically, or both. In the absence of such specific rules in a Member State, a package leaflet in paper format shall be included in the packaging of a medicinal product. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients.	3. ***After carefully considering all relevant factors, including but not limited to the level of digitalisation of the country and the status of digital literacy of its citizens,*** Member States may decide that the package leaflet shall be made available in paper format or electronically, or both***. The electronic format should allow the reactive integration of new data on the drug including pharmacovigilance data***. In the absence of such specific rules in a Member State, a package leaflet in paper format shall be included in the packaging of a medicinal product***. If a Member State decides that the package leaflet shall be made available electronically, a paper package leaflet in addition to the electronic format may always be made available on a voluntary basis***. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily

accessible to all patients.

Or. en

Amendment 428
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 63 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States ***may decide*** that the ***package leaflet shall be made*** available in paper ***format or electronically, or both***. ***In the absence of such specific rules in a Member State,*** a package leaflet in paper ***format shall be*** included ***in*** the packaging of a medicinal product. ***If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients.***	3. Member States ***shall ensure*** that the ***prospectus is*** available in paper ***and electronic form***. ***The marketing authorisation holder shall ensure that*** a package leaflet in paper ***form is*** included ***on*** the packaging of a medicinal product.

Or. en

Amendment 429
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a directive
Article 63 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States may decide that the package leaflet shall be made available in paper format or electronically, or both. In the absence of such specific rules in a Member State, a package leaflet in paper format shall be included in the packaging of a medicinal product. If the package leaflet is only made available	3. Member States may decide that the package leaflet shall be made available in paper format or electronically, or both. In the absence of such specific rules in a Member State, a package leaflet in paper format shall be included in the packaging of a medicinal product***. If a Member State decides that the package leaflet shall be***

electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients.	***only made available electronically, it shall not preclude the marketing authorisation holder from providing the package leaflet in paper format in addition to the electronic format on a voluntary basis***. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients.

Or. en

Amendment 430
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 63 – paragraph 3

Text proposed by the Commission	*Amendment*
3. ***Member States may decide that*** the package leaflet shall be made available in ***paper format or electronically, or both. In the absence of such specific rules in a Member State, a package leaflet in*** paper format ***shall be included in the packaging of a medicinal product. If the package leaflet is only made available electronically, the patient's right to a*** printed copy of the package leaflet ***should be guaranteed upon request and free of charge and it should*** be ensured that the information in digital format is easily accessible to all patients.	3. The package leaflet shall be made available in ***both electronic and*** paper format***. The*** printed copy of the package leaflet ***shall be included in the product's packaging. It shall*** be ensured that the information in digital format is easily accessible to all patients.

Or. en

Amendment 431
Pilar del Castillo Vera

Proposal for a directive
Article 63 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States may decide that the package leaflet shall be made available in paper format or electronically, or both. In the absence of such specific rules in a Member State, a package leaflet in paper format shall be included in the packaging of a medicinal product. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients.	3. Member States may decide that the package leaflet shall be made available in paper format or electronically, or both. In the absence of such specific rules in a Member State, a package leaflet in paper format shall be included in the packaging of a medicinal product***. If a Member State decides that the package leaflet shall be made available electronically, a package leaflet in paper format in addition to the electronic format may always be made available on a voluntary basis***. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients.

Or. en

Amendment 432
Cristian-Silviu Buşoi

Proposal for a directive
Article 63 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States may decide that the package leaflet shall be made available in paper format or electronically, or both. In the absence of such specific rules in a Member State, a package leaflet in paper format shall be included in the packaging of a medicinal product. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients.	3. Member States may decide that the package leaflet shall be made available in paper format or electronically, or both. In the absence of such specific rules in a Member State, a package leaflet in paper format shall be included in the packaging of a medicinal product***. If a Member State decides that the package leaflet shall be made available electronically, a package leaflet in paper format in addition to the electronic format may always be made available on a voluntary basis***. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should

be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients.

Or. en

Amendment 433
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 63 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States ***may decide*** that the package leaflet ***shall be made*** available in paper format ***or*** electronically***, or both***. ***In the absence of such specific rules in a*** Member ***State, a package leaflet in paper format shall be included in the packaging of a medicinal product. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the*** information ***in digital format is easily accessible to all patients***.	3. Member States ***shall ensure*** that the package leaflet ***is*** available in paper format ***and*** electronically. Member ***States may choose to use only electronic leaflets for a limited range of medicines dispensed to in-hospital patients where the provision of medical*** information ***will be ensured by health professionals***.

Or. en

Amendment 434
Massimiliano Salini, Aldo Patriciello

Proposal for a directive
Article 63 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States may decide that the package leaflet shall be made available in paper format or electronically, or both. In the absence of such specific rules in a Member State, a package leaflet in paper format shall be included in the packaging	3. Member States may decide that the package leaflet shall be made available in paper format or electronically, or both. In the absence of such specific rules in a Member State, a package leaflet in paper format shall be included in the packaging

of a medicinal product. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients.

of a medicinal product***. If a Member State chooses to provide the package leaflet in an electronic format, there is always the option to voluntarily offer a paper version of the package leaflet in addition to the electronic one***. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients.

Or. en

Amendment 435
Pernille Weiss

Proposal for a directive
Article 63 – paragraph 3

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

Or. en

Amendment 436
Andreas Glück

Proposal for a directive
Article 63 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States may decide that the package leaflet shall be made available ***in paper format or*** electronically, or ***both***. In the absence of such specific rules in a Member State, a package leaflet in paper format shall be included in the packaging of a medicinal product. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge ***and*** it should be ensured that the information in digital format is easily accessible to all patients.	3. Member States may decide that the package leaflet shall be made available electronically, or ***electronically and in paper format***. In the absence of such specific rules in a Member State, a package leaflet in paper format shall be included in the packaging of a medicinal product. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge**.** It should be ensured that the information in digital format is easily accessible to all patients.

Or. en

Justification

Package leaflets should generally be digitized. This offers many advantages, for example adaption of content for products which are already in circulation or facilitated cross-border exchanges

Amendment 437
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

Proposal for a directive
Article 63 – paragraph 3 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	By derogation from paragraph 3, when the medicinal products is not delivered directly to the patients, such as in hospital environment, the package leaflet may be available only in electronic format.

Or. en

Amendment 438
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
	3 a. If a Member State has decided that the package leaflet is only to be made available electronically, patients shall be made aware of their right to a printed copy of the package leaflet. If the package leaflet is only to be made available electronically, a package leaflet in paper format may still be provided on a voluntary basis by the marketing authorisation holder in addition to the electronic package leaflet.

Or. en

Amendment 439
Pietro Fiocchi, Elisabetta De Blasis

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

Text proposed by the Commission	*Amendment*
	3 a. By derogation from paragraph 3, where the medicinal product is not intended to be delivered directly to the patient, the package leaflet may be made available electronically only.

Or. en

Amendment 440
Cristian-Silviu Buşoi

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

Text proposed by the Commission	*Amendment*
	3 a. By derogation from paragraph 3, where the medicinal product is not

intended to be delivered directly to the patient, the package leaflet may be made available electronically only.

Or. en

Amendment 441
Pilar del Castillo Vera

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

Text proposed by the Commission	*Amendment*
	3 a. By derogation from paragraph 3, where the medicinal product is not intended to be delivered directly to the patient, the package leaflet may be made available electronically only.

Or. en

Amendment 442
Massimiliano Salini, Aldo Patriciello

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

Text proposed by the Commission	*Amendment*
	3 a. By derogation from paragraph 3, if the medicinal product is not meant to be directly administered to the patient, the package leaflet can be provided electronically exclusively.

Or. en

Amendment 443
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 63 – paragraph 4 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	A package leaflet shall include key information summarising benefit and harma data for each authorised indication.

Or. en

Amendment 444
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
	4 a. Where the medicinal product is not intended to be delivered directly to and administered by the patient, the Commission is empowered to adopt delegated acts in accordance with Article 215 to amend paragraph 3 of this Article by making only the electronic version of the package leaflet mandatory in this specific context. In such a case, a package leaflet in paper format may still be provided on a voluntary basis by the marketing authorisation holder in addition to the electronic package leaflet.

Or. en

Amendment 445
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 63 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend paragraph 3 by making mandatory the electronic version	***deleted***

of the package leaflet. That delegated act shall also establish the patient's right to a printed copy of the package leaflet upon request and free of charge. The delegation of powers shall apply as of [OP please insert the date = five years following 18 months after the date of entering into force of this Directive].

Or. en

Amendment 446
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 63 – paragraph 5

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

Or. en

Amendment 447
Pernille Weiss

Proposal for a directive
Article 63 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend paragraph 3 by	***deleted***

making mandatory the electronic version of the package leaflet. That delegated act shall also establish the patient's right to a printed copy of the package leaflet upon request and free of charge. The delegation of powers shall apply as of [OP please insert the date = five years following 18 months after the date of entering into force of this Directive].

Or. en

Amendment 448
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a directive
Article 63 – paragraph 5

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

Or. en

Amendment 449
Cristian-Silviu Buşoi

Proposal for a directive
Article 63 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Commission is empowered to	5. The Commission is empowered to

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

Or. en

Amendment 450
Pilar del Castillo Vera

Proposal for a directive
Article 63 – paragraph 5

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

Or. en

Amendment 451
Massimiliano Salini, Aldo Patriciello

Proposal for a directive
Article 63 – paragraph 5

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

Or. en

Amendment 452
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 63 – paragraph 5

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

Or. en

Amendment 453
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 63 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies.	6. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies. ***Member States shall implement this article after the publication of the Commissions implementing acts on the common standards for electronic versions of the package leaflet.***

Or. en

Amendment 454
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 63 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies.	6. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies. ***The Commission shall consult the European Data Protection Supervisor and the Agency in this process.***

Or. en

Amendment 455
Pernille Weiss

Proposal for a directive
Article 63 – paragraph 6

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

Or. en

Amendment 456
Pilar del Castillo Vera

Proposal for a directive
Article 63 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies.	6. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies ***at the latest by [1 year after publication of the text]***.

Or. en

Amendment 457
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a directive
Article 63 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies.	6. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies ***at the latest by [1 year after publication of the text]***.

Or. en

Amendment 458
Cristian-Silviu Buşoi

Proposal for a directive
Article 63 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies.	6. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies ***at the latest by [1 year after publication of the text]***.

Or. en

Amendment 459
Massimiliano Salini, Aldo Patriciello

Proposal for a directive
Article 63 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common	6. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common

standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies.	standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies ***at the latest by [1 year after publication of the text]***.

Or. en

Amendment 460
Pietro Fiocchi, Elisabetta De Blasis

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

Text proposed by the Commission	*Amendment*
	6 a. After consultation with Member States and relevant stakeholders, the Agency shall implement a system providing public access to the electronic version of the package leaflet, the summary of product characteristics and the labelling on the database provided in Article 138 of [revised Regulation (EC) No 726/2004] The system shall be implemented by the Agency and used by all Member States at the latest by [30 months after publication].

Or. en

Amendment 461
Massimiliano Salini, Aldo Patriciello

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

Text proposed by the Commission	*Amendment*
	6 a. Following consultation with Member States and pertinent stakeholders, the Agency will make a system available to accommodate the electronic product information in the database specified in Article 138(1)(n) and 138(2) of the Revised Regulation. By

[30 months after publication], at the latest, the Agency will have the system operational and all Member States will be using it.

Or. en

Amendment 462
Pilar del Castillo Vera

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

Text proposed by the Commission	*Amendment*
	6 a. The Agency shall make available a system to accommodate the electronic product information in the database provided in Article 138(1)(n) and 138(2) of the Revised Regulation … after consultation with Member States and the relevant stakeholders. The system shall be implemented by the Agency and used by all Member States at the latest by [30 months after publication].

Or. en

Amendment 463
Cristian-Silviu Buşoi

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

Text proposed by the Commission	*Amendment*
	6 a. The Agency shall make available a system to accommodate the electronic product information in the database provided in Article 138(1)(n) and 138(2) of the Revised Regulation … after consultation with Member States and the relevant stakeholders. The system shall be implemented by the Agency and used by all Member States at the latest by [30 months after publication].

Or. en

Amendment 464
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 63 – paragraph 7

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

Or. en

Amendment 465
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 63 – paragraph 7

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

Or. en

Amendment 466
Pernille Weiss

Proposal for a directive
Article 63 – paragraph 7

Text proposed by the Commission	*Amendment*
7. ***Where*** the package leaflet ***is made available*** electronically, the individual right to privacy shall be ensured. Any technology giving access to the information shall not allow the identification or tracking of individuals, nor shall it be used for commercial purposes.	7. ***When accessing*** the package leaflet electronically, the individual right to privacy shall be ensured. Any technology giving access to the information shall ***ensure the protection of personal data according to relevant Union legislation, and shall*** not allow the identification***,*** ***profiling*** or tracking of individuals, nor shall it be used for commercial purposes ***including advertising and marketing activities***.

Or. en

Amendment 467
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 63 – paragraph 7

Text proposed by the Commission	*Amendment*
7. Where the package leaflet is made available electronically, the individual right to privacy shall be ensured. Any technology giving access to the information shall not allow the identification or tracking of individuals, nor shall it be used for commercial purposes.	7. Where the package leaflet is made available electronically, the individual right to privacy shall be ensured. Any technology giving access to the information shall ***ensure the protection of personal data pursuant to Regulation 2016/679 and*** not allow the identification***,*** ***profiling*** or tracking of individuals, nor shall it be used for commercial purposes.

Or. en

Amendment 468
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 63 – paragraph 7 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	The progressive transition to the electronic version of the package leaflet shall be supported by pharmacists in their duties to compound, dispense and sell medicinal products that patients need, to provide advice on their proper use and possible adverse effects and, if needed, to design a personalised pharmaceutical plans, as prescription assistance software and dispensing assistance software evolve.

Or. en

Amendment 469
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 63 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	7 a. The competent authority of the Member State or, where appropriate, the Agency, shall supervise the technology providing access to the electronic version of the package leaflet, ensuring compliance with paragraph 7. The competent authority of the Member State shall decide on the means of storage and access to the electronic version of the prospectus which shall be available through the national web portals and the web portal of the European Agency for Medicinal product within the meaning of Article 102(1).
	In addition to the measures specified in paragraph 2, for medicinal products included in the list referred to in Article 112 a of [revised Regulation (EC) No

726/2004], the following additional declaration shall be included: "This drug is subject to additional monitoring". This reference shall be preceded by the symbol referred to in Article 112 bis and followed by a standard explanatory phrase.

Or. en

Amendment 470
Pernille Weiss

Proposal for a directive
Article 63 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	7 a. The Agency shall develop a system providing public access to the electronic version of package leaflets. By ... [12 months after the date of entry into force of this Directive], the system shall be accessible in all Member States.

Or. en

Amendment 471
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 64 – paragraph 2 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	In addition to the measures specified in paragraph 2, for medicinal products included in the list referred to in Article 112a of the [revised Regulation (EC) No 726/2004], the following additional statement shall be included 'This medicinal product is subject to additional monitoring'. This statement shall be preceded by the symbol referred to in Article 112a and followed by a standardised explanatory sentence.

Or. en

Amendment 472
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 64 – paragraph 3

Text proposed by the Commission	*Amendment*
3. ***The package leaflet*** shall ***reflect the results of consultations with target patient groups to ensure that it*** is legible, ***clear*** and easy to ***use***.	3. ***In addition to the measures specified in paragraph 2, for medicinal products included in the list referred to in Article 112a of the [revised Regulation (EC) No 726/2004], the following additional statement*** shall ***be included 'This medicinal product is subject to additional monitoring'. This statement shall be preceded by the symbol referred to in the aforementioned Article and followed by a standardised explanatory sentence that*** is ***appropriate, clearly*** legible, and easy to ***understand by users***.

Or. en

Amendment 473
Pernille Weiss

Proposal for a directive
Article 64 – paragraph 3

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

Or. en

Amendment 474
Susana Solís Pérez, Klemen Grošelj

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

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

Or. en

Amendment 475
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 66 – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
(a) the name of the ***medicinal*** product and***, if necessary, the route of administration***;	(a) the name of the ***medical*** product and ***the international non-proprietary name (INN) either in the local language or in Latin***;

Or. en

Amendment 476
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 66 – paragraph 3 – point a a (new)

Text proposed by the Commission	*Amendment*
	(a a) Pharmaceutical form

Or. en

Amendment 477
Margarita de la Pisa Carrión

on behalf of the ECR Group

Proposal for a directive
Article 66 – paragraph 3 – point b

Text proposed by the Commission	*Amendment*
(b) the ***method*** of administration;	(b) the ***route*** of administration;

Or. en

Amendment 478
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 66 a (new)

Text proposed by the Commission	*Amendment*
	Article66a
	Labelling of blister packs in case of unit dose dispensing
	Wherever a Member State imposes dispensing of medicinal products by pharmacists, to fight against antibioresistance, or for any other reason, it ensures that the doses are packaged and labelled on unit dose pre-cut blisters. Each per-cut blister shall include the following labelling particulars :
	(a) the name of the medicinal product;
	(b) the strength of the medicinal product;
	(c) a data matrix barcode in which the following information is encoded:
	(i) the Global Trading Index Number (GTIN);
	(ii) the expiry date;
	(iii) the batch number. Member States shall promote the use of unit dose pre-cut blisters in hospital environment and, progressively, in dispensing pharmacies, when necessary.

Or. en

Amendment 479
Pernille Weiss

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

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

Or. en

Amendment 480
Pilar del Castillo Vera

Proposal for a directive
Article 67 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Member States may, for the purposes of reimbursement, pharmacovigilance, pharmacoepidemiology or for data protection prolongation for market launch use the information contained in the repositories system referred to paragraph 2, second subparagraph, point (e).	6. Member States may, for the purposes of reimbursement, pharmacovigilance, pharmacoepidemiology***, shortage monitoring or prevention, for implementation of Article 56(3), for compliance with enforcement of distributor public service obligations, making product information available electronically,*** or for data protection prolongation for market launch use the information contained in the repositories system referred to paragraph 2, second subparagraph, point (e).

Or. en

Amendment 481
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 67 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Member States may, for the purposes of reimbursement, pharmacovigilance***, pharmacoepidemiology or for data protection prolongation for market launch*** use the information contained in the ***repositories*** system referred to ***paragraph 2,*** second subparagraph***, point (e)***.	6. Member States may, for the purposes of reimbursement, pharmacovigilance ***and pharmaco-epidemiology,*** use the information contained in the ***repository*** system referred to ***in the*** second subparagraph ***of paragraph 2, letter e)***.

Or. en

Amendment 482
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 67 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Member States may, for the purposes of reimbursement, pharmacovigilance, pharmacoepidemiology or ***for data protection prolongation for market launch*** use the information contained in the repositories system referred to paragraph 2, second subparagraph, point (e).	6. Member States may, for the purposes of reimbursement, pharmacovigilance, pharmacoepidemiology or ***monitoring of medicine shortages*** use the information contained in the repositories system referred to paragraph 2, second subparagraph, point (e).

Or. en

Amendment 483
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

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

Or. en

Amendment 484
Pernille Weiss

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

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

Or. en

Amendment 485
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 69 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The marketing authorisation holder shall ensure availability of educational material to healthcare professionals, ***including through medical sales representatives as referred to in Article 175(1), point (c)***, regarding the appropriate use of diagnostic tools, testing or other diagnostic approaches related to antimicrobial-resistant pathogens, that may	1. The marketing authorisation holder shall ensure availability of educational material to healthcare professionals, , regarding the appropriate use of diagnostic tools, testing or other diagnostic approaches related to antimicrobial-resistant pathogens, that may inform on the use of the antimicrobial. ***As referred to in paragraph 1 (b) of Article 17, the***

inform on the use of the antimicrobial.	***competent authority responsible for approving the antimicrobial shall review the content of the educational material and validate the final version.***

Or. en

Amendment 486
Pernille Weiss

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

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

Or. en

Amendment 487
Nicolás González Casares, Laura Ballarín Cereza

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

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

Or. en

Amendment 488
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 69 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The text of the awareness card shall be aligned with Annex VI.	3. The text of the awareness card shall be ***standarded by the Agency and shall be*** aligned with Annex VI.

Or. en

Amendment 489
Susana Solís Pérez, Klemen Grošelj

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

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

Or. en

Amendment 490
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 69 a (new)

Text proposed by the Commission	*Amendment*
	Article69a
	The marketing authorization holder may add to the fixed-dose combination medicinal product's packaging an "awareness card" in digital or paper form. This card shall inform patients about the importance therapeutic

adherence and available support for adherence in their Member State. The content of the awareness card should comply with Annex VI.

Or. en

Amendment 491
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 74 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The competent authorities of the Member State may also grant a full or partial exemption to the obligation that the labelling and the package leaflet must be in an official language or official languages of the Member State where ***the*** medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State. ***For the purpose of multi-language packages, Member States may allow the use on the labelling and*** package leaflet ***of an*** official language of ***the Union that is commonly understood in*** the Member ***States where the multi-language package is marketed***.	4. ***Based on any of the grounds listed in Article 75,*** the competent authorities of the Member State may also grant a full or partial exemption to the obligation that the labelling and the package leaflet must be in an official language or official languages of the Member State where ***a*** medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State. ***When a competent authority grants an exemption to the language requirements that apply to the paper*** package leaflet***, the patients' right to a printed copy of the document in the*** official language ***or official languages*** of the Member ***State should be guaranteed upon request and free of charge***.

Or. en

Amendment 492
Susana Solís Pérez

Proposal for a directive
Article 74 – paragraph 4 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	The offical language obligation as mentioned in paragraph 1 shall not apply when the medicinal product is not

intended to be delivered to the patient for slef-administration.In this case a single appropriate language could be used.

Or. en

Amendment 493
Pernille Weiss

Proposal for a directive
Article 74 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4 a. Where a competent authority grants a full or partial exemption to the language requirements in accordance with paragraph 4, patients' right to a copy of the document in the official language of the Member State shall be guaranteed upon request and free of charge.

Or. en

Amendment 494
Cristian-Silviu Buşoi

Proposal for a directive
Article 74 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4 a. By derogation, when dully justified (eg. health emergencies), the official language obligation as mentioned in Article 74.1 shall not apply when the product is not intended to be delivered to the patient for self-administration.

Or. en

Amendment 495
Pilar del Castillo Vera

Proposal for a directive
Article 74 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4 a. The official language obligation as mentioned in Article 74.1 shall not apply when the product is not intended to be delivered to the patient for self-administration. In this case a single appropriate language can be used.

Or. en

Amendment 496
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 80 – title

Text proposed by the Commission	*Amendment*
Regulatory data ***and*** market protection	Regulatory data***,*** market protection ***and market exclusivity***

Or. en

Amendment 497
Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*
	2 a. The period referred to in parragraph 2 shall be extended by an addittional period of one year, where the marketing authorization holder obtains, during the data protection period referred to in Article 81, an authorisation for an additional therapeutic indication for which the marketing authorisation holder has demonstrated, with supporting data, a significant clinical benefit in comparison with existing therapies. This extension

may only be granted once.

Or. en

Amendment 498
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 80 – paragraph 4

Text proposed by the Commission	*Amendment*
4. By way of derogation from the paragraphs 1 and 2, when a compulsory licence has been granted by a relevant authority in the Union to a party to ***address a*** public health ***emergency***, the data and market protection shall be suspended with regard to that party insofar as the compulsory licence requires, and during the duration period of the compulsory licence.	4. By way of derogation from the paragraphs 1 and 2, when a compulsory licence has been granted by a relevant authority in the Union to a party to ***safeguard*** public health, the data and market protection ***as well as the market exclusivity referred to in Article 71 of [revised Regulation (EC) No 726/2004],*** shall be suspended with regard to that party insofar as the compulsory licence requires, and during the duration period of the compulsory licence. ***Relevant authorities in the Union shall also be able to reduce the duration of data protection, market protection, or market exclusivity for medicinal products that are not protected by a patent or a supplementary protection certificate, where necessary to safeguard public health.***

Or. en

Amendment 499
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a directive
Article 80 – paragraph 4

Text proposed by the Commission	*Amendment*
4. By way of derogation from the paragraphs 1 and 2, when a compulsory licence has been granted by a relevant	4. By way of derogation from the paragraphs 1 and 2, when a compulsory licence has been granted by ***the final***

authority in the Union to a party to address a public health emergency, the data and market protection shall be suspended with regard to that party insofar as the compulsory ***licence*** requires, ***and during*** the duration period of the compulsory licence.	***decision of*** a relevant authority in the Union to a party to address a public health emergency, the data and market protection shall be suspended with regard to that party insofar as the compulsory ***license*** requires, ***for the indication relevant to the public health emergency, only for*** the duration period of the compulsory licence ***and, where relevant, only in the Member State(s) where the compulsory license is granted***. ***The marketing authorization holder of the medicinal product for which the data and market protection are suspended shall be notified by the relevant competent authority on or before the date such suspension takes effect.***
	Or. en

Amendment 500
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 80 – paragraph 4

Text proposed by the Commission	*Amendment*
4. By way of derogation from the paragraphs 1 and 2, when a compulsory licence has been granted by ***a relevant authority in the Union*** to a party to address a public health emergency, the data and market protection shall be suspended with regard to that party insofar as the compulsory ***licence*** requires, ***and during*** the duration period of the compulsory licence.	4. By way of derogation from the paragraphs 1 and 2, when a compulsory licence has been granted by ***the final decision of National Parliaments*** to a party to address a public health emergency, the data and market protection shall be suspended with regard to that party insofar as the compulsory ***license*** requires, ***for the indication relevant to the public health emergency, only for*** the duration period of the compulsory licence ***and, where relevant, only in the Member State(s) where the compulsory license is granted***. ***The marketing authorization holder of the medicinal product for which the data and market protection are suspended shall be notified by the relevant competent authority before the date such suspension takes effect.***

Or. en

Amendment 501
Massimiliano Salini, Aldo Patriciello

Proposal for a directive
Article 80 – paragraph 4

Text proposed by the Commission	*Amendment*
4. By way of derogation from the paragraphs 1 and 2, when a compulsory licence has been granted by a relevant authority in the Union to a party to address a public health emergency, the data and market protection shall be suspended with regard to that party insofar as the compulsory ***licence*** requires, ***and*** during ***the duration period of*** the compulsory ***licence***.	4. By way of derogation from the paragraphs 1 and 2, when a compulsory licence has been granted by ***the ultimate decision of*** a relevant authority in the Union to a party to address a public health emergency, the data and market protection shall be suspended with regard to that party insofar as the compulsory ***license*** requires, ***for the indication pertaining to the public health emergency, solely*** during the compulsory ***license's period, and, if applicable, exclusively within the Member State where the compulsory license is authorized***. ***The competent authority relevant to the suspension of data and market protection shall notify the marketing authorization holder of the medicinal product prior to the effective date of such suspension.***

Or. en

Amendment 502
Nicola Danti

Proposal for a directive
Article 80 – paragraph 4

Text proposed by the Commission	*Amendment*
4. By way of derogation from the paragraphs 1 and 2, when a compulsory licence has been granted by a relevant authority in the Union to a party to address a public health emergency, the data and market protection shall be suspended with	4. By way of derogation from the paragraphs 1 and 2, when a compulsory licence has been granted by a relevant authority in the Union to a party to address a public health emergency, the data and market protection shall be suspended with

regard to that party insofar as the compulsory licence requires, and ***during*** the duration period of the compulsory licence.	regard to that party insofar as the compulsory licence requires, and ***exclusively for*** the duration period of the compulsory licence ***and, where applicable, only in the Member States where the compulsory licence is granted***.

Or. en

Justification

The suspension should be clearly limited to match the scope of the compulsory licence that has been granted, in order to avoid disincentivizing innovation.

Amendment 503
Pernille Weiss

Proposal for a directive
Article 80 – paragraph 4

Text proposed by the Commission	*Amendment*
4. By way of derogation from the paragraphs 1 and 2, when a compulsory licence has been granted by a relevant authority in the Union to a party to address a public health emergency, the data and market protection shall be suspended with regard to that party insofar as the compulsory licence requires, and during the duration period of the compulsory licence.	4. By way of derogation from the paragraphs 1 and 2, when a compulsory licence has been granted by a relevant authority in the Union to a party to address a public health emergency, the data and market protection shall be suspended ***for the indication that is relevant to the public health emergency*** with regard to that party insofar as the compulsory licence requires, ***in the relevant Member States*** and during the duration period of the compulsory licence.

Or. en

Amendment 504
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
	4 a. The marketing authorisation

holder for the medicinal product for which a compulsory licence has been granted shall be informed of the decision without delay.

Or. en

Amendment 505
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 81 – paragraph 1

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

Or. en

Justification

A strong intellectual property framework is a pivotal element of a competitive innovation ecosystem. The proposals to reduce RDP from 8 to 6 years (together with uncertain and complex exclusivity modulations) will undermine investments in the development of transformational therapies and as a result adversely impact access/affordability objectives. RDP is an important ex ante consideration that underpins much R&D investment in Europe. It is the last to expire protection that is key for approximately one-third of innovative medicines. Weaker incentives may prevent a new product but also a new indication and/or formulation from being developed (or mean that it is developed outside Europe), thereby undermining the pipeline of off-patent medicines in the long term.

Amendment 506
Pernille Weiss

Proposal for a directive
Article 81 – paragraph 1

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

Or. en

Amendment 507
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 81 – paragraph 1

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

Or. en

Amendment 508
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

Proposal for a directive
Article 81 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The regulatory data protection	1. The regulatory data protection

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

Or. en

Amendment 509
Andreas Glück

Proposal for a directive
Article 81 – paragraph 1

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

Or. en

Justification

Tying incentive systems to market access is not the right approach and leads to uncertainty among producers. Supply of medical medicinal product in all Member States can also be achieved differently, for example by an obligation to submit an application for pricing and reimbursement in all Member States.

Amendment 510
András Gyürk, Ernő Schaller-Baross

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

Text proposed by the Commission	*Amendment*
Subject to a scientific evaluation by the relevant competent authority, the data protection period referred to in paragraph 1 shall be prolonged by*:*	Subject to a scientific evaluation by the relevant competent authority, the data protection period referred to in paragraph 1 shall be prolonged by ***24 months where***

Or. en

Amendment 511
Pernille Weiss

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

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

Or. en

Justification

See amendments to new Article 58a.

Amendment 512
Ville Niinistö
on behalf of the Verts/ALE Group

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

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

Or. en

Justification

6 years of regulatory data protection are guaranteed in trade agreements, therefore, we would be keen on aligning the base with that and keep 6 in paragraph 1As for prolongation, we believe the upon request obligation to launch is a more appropriate way, please see our AMs to Article 58a

Amendment 513
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

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

Or. en

Justification

Linking incentives to market access is an improper strategy that creates uncertainty for manufacturers. Ensuring the availability of medicinal products across all Member States could be better accomplished through mandatory pricing and reimbursement applications in each state. See also the AMs on article 82A and 82B

Amendment 514
Andreas Glück

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

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

that date for any of the following entities:

(i) SMEs within the meaning of Commission Recommendation 2003/361/EC;

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

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

Or. en

Justification

Tying incentive systems to market access is not the right approach and leads to uncertainty among producers. Supply of medical medicinal product in all Member States can also be achieved differently, for example by an obligation to submit an application for pricing and reimbursement in all Member States.

Amendment 515
András Gyürk, Ernő Schaller-Baross

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

Text proposed by the Commission	*Amendment*
(a) ***24 months, where*** the marketing authorisation ***holder demonstrates that the conditions referred to in Article 82(1) are fulfilled within two years, from the date when the marketing authorisation was*** granted ***or, within three years from that date for any of the following entities:***	(a) the marketing authorisation ***is*** granted ***in relation to a disease in respect of which there is no medicinal product authorised in the Union, or***

Or. en

Amendment 516
Susana Solís Pérez, Klemen Grošelj

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

Text proposed by the Commission	*Amendment*
(a) ***24*** months, where the marketing authorisation holder demonstrates that the conditions referred to in Article 82(1) are fulfilled within two years, from the date when the marketing authorisation was granted or, within ***three*** years from that date for any of the following entities:	(a) ***36*** months, where the marketing authorisation holder demonstrates that the conditions referred to in Article 82(1) are fulfilled within two years, from the date when the marketing authorisation was granted or, within ***four*** years from that date for any of the following entities:

Or. en

Amendment 517
András Gyürk, Ernő Schaller-Baross

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

Text proposed by the Commission	*Amendment*
(i) SMEs within the meaning of Commission Recommendation 2003/361/EC;	***deleted***

Or. en

Amendment 518
András Gyürk, Ernő Schaller-Baross

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

Text proposed by the Commission	*Amendment*
(ii) entities not engaged in an economic activity ('not-for-profit entity'); and	***deleted***

Or. en

Amendment 519
András Gyürk, Ernő Schaller-Baross

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

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

Or. en

Amendment 520
András Gyürk, Ernő Schaller-Baross

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

Text proposed by the Commission	*Amendment*
	(a a) in case of the marketing authorisation is granted in relation to a disease in respect of which there has already been a medicinal product authorised in the Union, the initial marketing authorisation application use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency

Or. en

Amendment 521
Nicolás González Casares, Laura Ballarín Cereza

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

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

Or. en

Amendment 522
András Gyürk, Ernő Schaller-Baross

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

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

Or. en

Amendment 523
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

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

Or. en

Justification

Recognizing and incentivizing pharmaceutical advancements that address Unmet Medical Needs is crucial for healthcare progress. Extending additional incentives for medicinal products representing genuine therapeutic breakthroughs is a positive step. It encourages research and development in areas critical to patient care, ensuring healthcare systems meet a broader range of patient needs rather than focusing solely on areas with commercial potential.

Amendment 524
Pernille Weiss

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

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

Or. en

Amendment 525
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

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

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

Or. en

Amendment 526
András Gyürk, Ernő Schaller-Baross

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

Text proposed by the Commission	*Amendment*
(c) six months, for medicinal products containing a new active substance, where the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency;	***deleted***

Or. en

Amendment 527
Ville Niinistö
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
(c) six months, for medicinal products containing a new active substance, where the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency;	***deleted***

Or. en

Amendment 528
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

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

Text proposed by the Commission	*Amendment*
(c) ***six*** months, for medicinal products containing a new active substance, where the clinical trials supporting the initial	(c) ***12*** months, for medicinal products containing a new active substance, where the clinical trials supporting the initial

marketing authorisation application use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency;	marketing authorisation application use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency ***in consultation with health technology assessment authorities, set out in a delegated act in accord with article 215***;

Or. en

Amendment 529
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

Text proposed by the Commission	*Amendment*
(c) ***six*** months, ***for medicinal products containing a new active substance, where the clinical trials supporting the initial*** marketing ***authorisation*** application ***use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency;***	(c) ***A period of twelve*** months, ***during which the applicant for*** marketing ***authorization shows, either at the point of the first*** application ***for marketing authorization or upon modification, that the pharmaceutical product fulfills a previously unaddressed healthcare necessity in at least one of its uses, as mentioned in Article 83.***

Or. en

Justification

Expanding incentives for submitting post-approval comparative clinical trial data is essential, given that providing this data at the initial marketing authorisation stage is often unfeasible. This approach prevents delays in filing due to awaiting trial data. However, in cases like treatments for Unmet Medical Needs or when comparative studies are unethical or impractical, such as in rare or pediatric diseases, this incentive may not be applicable.

Amendment 530
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
(c) six months, for medicinal products ***containing a new active substance,*** where the clinical trials supporting the ***initial*** marketing authorisation application use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency;	(c) six months, for medicinal products where the clinical trials supporting the marketing authorisation application use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency;

Or. en

Amendment 531
Nicolás González Casares, Laura Ballarín Cereza

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

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

Or. en

Amendment 532
Ville Niinistö
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
(d) ***12*** months, where the marketing authorisation holder obtains, during the data protection period, an authorisation for an additional therapeutic indication for which the marketing authorisation holder has demonstrated, with supporting data, a	(d) ***six*** months, where the marketing authorisation holder obtains, during the data protection period, an authorisation for an additional therapeutic indication for which the marketing authorisation holder has demonstrated, with supporting data, a

significant clinical benefit in comparison with existing therapies.	significant clinical benefit in comparison with existing therapies.

Or. en

Amendment 533
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

Text proposed by the Commission	*Amendment*
	(d a) 12 months, where the applicant for marketing authorisation undertakes to facilitate the formation of public-private partnerships, centers of excellence, and bioclusters, thereby expediting the research and development of a new medicinal product.

Or. en

Amendment 534
Susana Solís Pérez, Klemen Grošelj

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

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

Or. en

Amendment 535
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive

Article 81 – paragraph 2 – subparagraph 1 – point d b (new)

Text proposed by the Commission	*Amendment*
	(d b) 12 months, for new medicinal products developed, produced, used and diposed in full respect of the scientific guidelines of the environmental risk assessment of medicinal products for human use.

Or. en

Amendment 536
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

Text proposed by the Commission	*Amendment*
	(d b) 12 months, for medicinal products containing critical active pharmaceutical ingredients produced in the Union or the EEA.

Or. en

Amendment 537
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

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

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

Or. en

Amendment 538
Susana Solís Pérez, Nicola Danti, Klemen Grošelj

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

Text proposed by the Commission	*Amendment*
	(d d) 12 months, for medicinal products containing critical active pharmaceutical ingredients produced within the EU.

Or. en

Amendment 539
Ville Niinistö
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
In the case of a conditional marketing authorisation granted in accordance with Article 19 of [revised Regulation (EC) No 726/2004] the prolongation referred to in the first subparagraph, point (b), shall only apply if, within ***four*** years of the granting of the conditional marketing authorisation, the medicinal product has been granted a marketing authorisation in accordance with Article 19(7) of [revised Regulation (EC) No 726/2004.	In the case of a conditional marketing authorisation granted in accordance with Article 19 of [revised Regulation (EC) No 726/2004] the prolongation referred to in the first subparagraph, point (b), shall only apply if, within ***three*** years of the granting of the conditional marketing authorisation, the medicinal product has been granted a marketing authorisation in accordance with Article 19(7) of [revised Regulation (EC) No 726/2004.

Or. en

Amendment 540
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

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

Or. en

Amendment 541
Nicolás González Casares, Laura Ballarín Cereza

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

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

Or. en

Amendment 542
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

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

Or. en

Amendment 543
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 81 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency shall set the scientific guidelines referred to in paragraph 2, point (c), on criteria for proposing a comparator for a clinical trial, taking into account the results of the consultation of the Commission and the authorities or bodies involved in the mechanism of consultation referred to in Article 162 of [revised Regulation (EC) No 726/2004].	***deleted***

Or. en

Amendment 544
Ville Niinistö
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
	3 a. All product-specific regulatory protection periods shall be made publicly available in the medicine repository on the website of the national competent authority and the Agency.

Or. en

Amendment 545
Andreas Glück

Proposal for a directive
Article 82

Text proposed by the Commission	*Amendment*

[...]	***deleted***

Or. en

Amendment 546
Pernille Weiss

Proposal for a directive
Article 82

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

Or. en

Justification

See amendments to new Article 58a.

Amendment 547
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 82

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

Or. en

Amendment 548
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 82

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

Or. en

Justification

Please see Article 58a.

Amendment 549
András Gyürk, Ernő Schaller-Baross

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

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

Or. en

Amendment 550
Susana Solís Pérez, Klemen Grošelj

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

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

Or. en

Amendment 551
András Gyürk, Ernő Schaller-Baross

Proposal for a directive
Article 82 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
The prolongation referred to in the first subparagraph shall apply to medicinal products that have been granted a centralised marketing authorisation, as referred to in Article 5 or that have been granted a national marketing authorisation through the decentralised procedure, as referred to in Chapter III, Section 3.	***deleted***

Or. en

Amendment 552
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 82 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
The prolongation referred to in the first subparagraph shall apply to medicinal products that have been granted a centralised marketing authorisation, as referred to in Article 5 or that have been granted a national marketing authorisation through the decentralised procedure, as referred to in Chapter III, Section 3.	The prolongation referred to in the first subparagraph shall apply to medicinal products that have been granted a centralised marketing authorisation, as referred to in Article 5 or that have been granted a national marketing authorisation through the decentralised procedure, ***covering all the Member States entered into the decentralised procedure,*** as referred to in Chapter III, Section 3. ***The prolongation of the data protection period in regards medicinal products which obtained marketing authorisation in accordance with Articles 5 and 6 of [revised Regulation (EC) No 726/2004] as referred to in Article 81(2), first***

	subparagraph, point (a), shall apply to medicinal products if they are released and continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States concerned in which the marketing authorisation is valid.

Or. en

Amendment 553
András Gyürk, Ernő Schaller-Baross

Proposal for a directive
Article 82 – paragraph 2

Text proposed by the Commission	*Amendment*
2. To receive a prolongation referred to in Article 81(2), first subparagraph, point (a), the marketing authorisation holder shall apply for a variation of the relevant marketing authorisation.	***deleted***
The application for a variation shall be submitted between 34 and 36 months after the date when the initial marketing authorisation was granted, or for entities referred to in Article 81(2), first subparagraph, point (a), between 46 and 48 months, after that date.	
The application for a variation shall contain documentation from the Member States in which the marketing authorisation is valid. Such documentation shall:	
(a) confirm that the conditions set out in paragraph 1 have been satisfied in their territory; or	
(b) waive the conditions set out in paragraph 1 in their territory for the purpose of the prolongation.	
Positive decisions adopted in accordance with Articles 2 and 6 of Council Directive 89/105/EEC[74] shall be considered equivalent to a confirmation referred to in	

the third subparagraph, point (a).

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*[74] **Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ L 40, 11.2.1989, p. 8).***

Or. en

Amendment 554
Susana Solís Pérez, Klemen Grošelj

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

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

Or. en

Amendment 555
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 82 – paragraph 2 – subparagraph 3 a (new)

Text proposed by the Commission	*Amendment*
	Where the conditions set out in paragraph 1 have not been fully satisified due to duly justified circumstances out of the control of the marketing authoristisation holder the Member State shall confirm the conditions in paragraph 1 have been satisified in their territory, subject to guarantee that these conditions will be fulfilled in an acceptable period of time

agreed between the marketing authorisation holder and the Member State.

Or. en

Amendment 556
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 82 – paragraph 2 – subparagraph 4

Text proposed by the Commission	*Amendment*
Positive decisions adopted in accordance with Articles 2 and 6 of Council Directive 89/105/EEC[74] shall be considered equivalent to a confirmation referred to in the third subparagraph, point (a).	Positive decisions adopted in accordance with Articles 2 and 6 of Council Directive 89/105/EEC***[1]*** shall be considered equivalent to a confirmation referred to in the third subparagraph, point (a)***, as long as the medicinal product is effectively continuously supplied on the market***.

[74] Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ L 40, 11.2.1989, p. 8).

Or. en

Amendment 557
András Gyürk, Ernő Schaller-Baross

Proposal for a directive
Article 82 – paragraph 3

Text proposed by the Commission	*Amendment*
3. To receive the documentation referred to in paragraph 2, third subparagraph, the marketing authorisation holder shall make a request to the relevant Member State. Within 60	***deleted***

days from the request of the marketing authorisation holder, the Member State shall issue a confirmation of compliance or, a reasoned statement of non-compliance or alternatively provide a statement of non-objection to prolong the period of regulatory data protection pursuant to this Article.

Or. en

Amendment 558
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 82 – paragraph 3

Text proposed by the Commission	*Amendment*
3. To receive the documentation referred to in paragraph 2, third subparagraph, the marketing authorisation holder shall make a request to the relevant Member State. Within 60 days from the request of the marketing authorisation holder, the ***Member State*** shall issue a confirmation of compliance or, a reasoned statement of non-compliance or alternatively provide a statement of non-objection to prolong the period of regulatory data protection pursuant to this Article.	3. To receive the documentation referred to in paragraph 2, third subparagraph, the marketing authorisation holder shall make a request to the relevant Member State ***competent authority***. Within 60 days from the request of the marketing authorisation holder, the ***competent authority*** shall issue a confirmation of compliance or, a reasoned statement of non-compliance ***based on objective and veriafable criteria,*** or alternatively provide a statement of non-objection to prolong the period of regulatory data protection pursuant to this Article. ***When a competent authority issues a justified statement of non-fulfilment, it must detail the requisite actions that would allow the conditions to be met and enable the resubmission of a request for confirmation of fulfilment within a reasonable e time frame. The authority shall subsequently provide a confirmation of fulfilment or a reasoned statement of non-fulfilment within two months from the date of the resubmission request.***

Or. en

Amendment 559
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 82 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3 a. The Commission is tasked with creating a mediation mechanism via implementing acts. This mechanism will support dialogue between developers and Member States to address disputes arising from a declaration of non-compliance by a Member State after earnest negotiations, or due to negotiation delays. Within this framework, there will be an option for a Commission decision that can supersede the documents referred to in paragraph 2.

Or. en

Amendment 560
András Gyürk, Ernő Schaller-Baross

Proposal for a directive
Article 82 – paragraph 4

Text proposed by the Commission	*Amendment*
4. In cases where a Member State has not replied to the application of the marketing authorisation holder within the deadline referred to in paragraph 3, it shall be considered that a statement of non-objection has been provided.	***deleted***
For medicinal products granted a centralised marketing authorisation the Commission shall vary the marketing authorisation pursuant to Article 47 of [revised Regulation (EC) No 726/2004] to prolong the data protection period. For medicinal products granted a marketing authorisation in accordance with the decentralised procedure, the competent authorities of the Member States shall vary the marketing authorisation	

pursuant to Article 92 to prolong the data protection period.

Or. en

Amendment 561
Susana Solís Pérez, Klemen Grošelj

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

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

Or. en

Amendment 562
András Gyürk, Ernő Schaller-Baross

Proposal for a directive
Article 82 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Member States representatives may request the Commission to discuss issues related to the practical application of this Article in the Committee established by Council Decision 75/320/EEC[75] ('Pharmaceutical Committee'). The Commission may invite bodies responsible for health technology assessment as referred to in Regulation	***deleted***

(EU) 2021/2282 or national bodies responsible for pricing and reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.

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[75] Council Decision of 20 May 1975 setting up a pharmaceutical committee (OJ L 147, 9.6.1975, p. 23).

Or. en

Amendment 563
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 82 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Member States representatives may request the Commission to discuss issues related to the practical application of this Article in the Committee established by Council Decisio***n 75/320/EEC***[75] (‘Pharmaceutical Committee’). The Commission may invite bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 or national bodies responsible for pricing and reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.	5. ***The Commission shall check the application referred to in paragraph 2, subparagraph 2, and grant approval or rejection to the prolongation referred to in Article 81(2). In those cases in which one or more Member States have issued a reasoned statement for refusal of the prolongation, the Commission shall ensure that the reasons described are justified and substantiated. The Commission shall ensure that Marketing Authorisation Holders are not unduly prevented from receiving the incentives for actions beyond their control.*** Member States representatives may request the Commission to discuss issues related to the practical application of this Article in the Committee established by Council Decisio***n 75/320/EEC75*** (‘Pharmaceutical Committee’). The Commission may invite bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 or national bodies responsible for pricing and reimbursement, as required, to participate in the deliberations of the Pharmaceutical

Committee.

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[75] Council Decision of 20 May 1975 setting up a pharmaceutical committee (OJ L 147, 9.6.1975, p. 23).

Or. en

Amendment 564
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 82 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5 a. The Commission shall make publicly available any information related to the decision taken on the grant or refusal of the prolongation of the data exclusivity period

Or. en

Amendment 565
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 82 – paragraph 5 b (new)

Text proposed by the Commission	*Amendment*
	5 b. Following the extension of the regulatory data protection as referred to in Article 81(2), the medicinal products should be released and continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorisation is valid, for the entire duration of the protection time.
	Where the marketing authorisation holder fails to comply with this obligation,

penalties should be established including the revocation of the extended regulatory protection period.

Or. en

Amendment 566
András Gyürk, Ernő Schaller-Baross

Proposal for a directive
Article 82 – paragraph 6

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

Or. en

Amendment 567
Susana Solís Pérez

Proposal for a directive
Article 82 – paragraph 6

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

Or. en

Amendment 568
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 82 – paragraph 6

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

Or. en

Amendment 569
Susana Solís Pérez, Klemen Grošelj

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

Text proposed by the Commission	*Amendment*
	6 a. The Commission, via implementing acts, shall compile a list of products that, either due to their nature or other duly justified and accredited limiting factors or technical specificites, shall be exempt from the stipulations outlined in Article 81(2), point (a), and within this same Article 81, paragraphs 1 to 7. These specified products will be granted an automatic extension of the data protection period for 12 months, as detailed in Article 81(2), point (a). The adoption of these implementing acts shall proceed in line with the examination procedure described in Article 214(2) and (3).

Or. en

Amendment 570
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 82 a (new)

Text proposed by the Commission	*Amendment*
	Article82a
	Pricing and refund request
	1. Within an agreed period following the granting of a marketing authorization, a Member State in which such authorization is valid may request the marketing authorization holder to submit an application for pricing and reimbursement.
	2. Within that period following receipt of an application in accordance with paragraph 1, the marketing authorization holder shall submit an application for pricing and reimbursement in that Member State. By way of derogation from paragraph 2, the following entities may submit an application for pricing and reimbursement within an extended period of time from the date of receipt of the application from the Member State:
	(i) SMEs;
	(ii) entities not engaged in an economic activity ("non-profit entity"); and
	(iii) companies which, at the time the marketing authorization is granted, have not received more than seven centralized marketing authorizations for the company concerned or, in the case of a company belonging to a group, for the group of which it is a member, since the creation of the company or the group, whichever condition is met first.
	3. The Commission shall, after consulting the Agency and relevant stakeholders, as patient's representatives or MHAs, establish a list of products exempted from

the conditions. Products shall be included in the list on the basis of relevant criteria, including cases where the administration of a medicinal product in the majority of Member States is impracticable, where the regulatory processes related to the application for pricing and reimbursement of a product are considered to be beyond the control of the marketing authorisation holder, or where for an orphan medicinal product or an advanced therapy medicinal product the product can be made available to patients without an application for pricing and reimbursement.

4. Time limits other than those set out in paragraphs 1 to 3 may apply if a Member State and a marketing authorization holder reach an agreement to that effect.

Or. en

Amendment 571
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 82 a (new)

Text proposed by the Commission	*Amendment*
	Article82a
	Prolongation of the data protection period for medicinal products developed within the Union
	1. A regulatory data protection period of one year shall be granted for a medicinal product if the marketing authorisation holder can demonstrate that its preclinical development was perfomed in the Union, even if another independent legal entity performed those studies, in initial stages of development, before the marketing authorisation holder acquired it.
	2. One year after the date of entering into force of this Directive [OP please insert the date =12 months after the date of

entering into force of this Directive], the Commission shall publish a study on the most adecuate indicators to evaluate that the provision in paragraph 1 is met. When performing the study, the Commission shall prioritize those indicators that could bring better outcomes for the promotion of research and development within the Union, specially that performed in SMEs.

3. The Commission shall adopt delegated measures relating to the procedural aspects outlined in this Article and regarding the conditions mentioned in paragraph 1. Those delegated acts shall be adopted in accordance with the procedure referred to in Article 215. When setting up the conditions mentioned in paragraph 1, the Commission shall take into account the conclusions drawn from the study mentioned in paragraph 2.

Or. en

Amendment 572
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 82 b (new)

Text proposed by the Commission	*Amendment*
	Article82b
	Medication Access Notification System
	1.The Commission, in collaboration with the Member States shall establish the electronic notification system electronic notification system ("Access to Medicinal Products to Medicinal Products") The Access to Medicinal Products Notification System shall be interoperable with other other Union data registers on medicinal products. medicinal products.
	2. The marketing authorisation holder marketing authorisation holder shall use the notification system EU Access to

Medicinal Products Notification System to report its compliance with the its compliance with the commitment set out in in Article 82a.

3. The Commission and Members States Medicament Agencies shall submit an evaluation report to the European European Parliament and the Council on the use use and functioning of the Notification System Medicinal Products within the EU.

Or. en

Amendment 573
Cristian-Silviu Buşoi

Proposal for a directive
Article 83 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. A medicinal product shall be considered as addressing an unmet medical need if at least one of its therapeutic indications relates to a life threatening or severely debilitating disease and the following conditions are met:	1. A medicinal product shall be considered as addressing an unmet medical need if at least one of its therapeutic indications relates to a ***progressive,*** life threatening or severely debilitating ***or chronic*** disease and the following conditions are met:

Or. en

Amendment 574
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 83 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. A medicinal product shall be considered as addressing an unmet medical need if at least one of its therapeutic indications relates to a life threatening ***or*** severely debilitating disease and the	1. A medicinal product shall be considered as addressing an unmet medical need if at least one of its therapeutic indications relates to a ***progressive,*** life threatening**,** severely debilitating ***or***

following conditions are met:

chronic disease and the following conditions are met:

Or. en

Amendment 575
Pilar del Castillo Vera

Proposal for a directive
Article 83 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. A medicinal product shall be considered as addressing an unmet medical need if at least one of its therapeutic indications relates to a life threatening ***or*** severely debilitating disease and the following conditions are met:	1. A medicinal product shall be considered as addressing an unmet medical need if at least one of its therapeutic indications relates to a ***progressive,*** life threatening***,*** severely debilitating ***or chronic*** disease and the following conditions are met:

Or. en

Amendment 576
Pernille Weiss

Proposal for a directive
Article 83 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. A medicinal product shall be considered as addressing an unmet medical need if at least one of its therapeutic indications relates to a life threatening or severely debilitating disease and the following conditions are met:	1. A medicinal product shall be considered as addressing an unmet medical need if at least one of its therapeutic indications relates to a ***progressive,*** life threatening or severely debilitating disease and the following conditions are met:

Or. en

Amendment 577
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive

Article 83 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. A medicinal product shall be considered as addressing an unmet medical need if at least one of its therapeutic indications relates to a life threatening or severely debilitating disease and the following conditions are met:	1. A medicinal product shall be considered as addressing an unmet medical need if at least one of its therapeutic indications relates to a life threatening***, chronic,*** or severely debilitating disease and the following conditions are met:

Or. en

Amendment 578
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 83 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) there is no medicinal product authorised in the Union for such disease, or, where despite medicinal products being authorised for such disease in the Union, the disease is associated with a remaining high morbidity or mortality;	(a) there is no medicinal product authorised in the Union for such disease, or, where despite medicinal products being authorised for such disease in the Union, the disease is associated with a remaining high morbidity or mortality; ***the product lessens the complexity or frequency of treatment or administration, or the profile of adverse reactions; the product enhances patients' quality of life;***

Or. en

Amendment 579
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 83 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) there is no medicinal product authorised in the Union for such disease, or, where despite medicinal products being	(a) there is no medicinal product***, medical service or SoHO preparation*** authorised in the ***Member State or the***

authorised for such disease in the Union, the disease is associated with a remaining high morbidity or mortality;	Union ***or other therapeutic option available*** for such disease, or, where despite medicinal products being authorised ***or therapeutic options available*** for such disease in the Union, the disease is associated with a remaining high morbidity or mortality; ***and***

Or. en

Justification

While we carefully considered requests of many patient organisations calling for inclusion of quality of life aspects in the definition of UMN, given that it is very vaguely interpreted, we think it would be counterproductive to add here for the purpose of extension of regulatory protection and agree with the Commission's approach. We acknowledge the importance of quality of life and included such data as obligatory for marketing authorisation, but for the purpose of adding further exclusivities we find it would serve as a loop hole and many products could be eligible for extra protection based on a vague interpretation of what meaningful QoL actually means.

Amendment 580
Andreas Glück

Proposal for a directive
Article 83 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) there is no medicinal product authorised in the Union for such disease, or, where despite medicinal products being authorised for such disease in the Union, the disease is associated with a remaining high morbidity or mortality;	(a) there is no medicinal product authorised in the Union for such disease, or, where despite medicinal products being authorised for such disease in the Union, ***a new form of administration leads to treatment of patients who previously had no access to the product or*** the disease is associated with a remaining high morbidity or mortality;

Or. en

Justification

In some cases the form of administration presents a hurdle for treatment . For example, the step from oral to intravenous administration . Therefore, the definition of unmet medical needs should include the development of a new form of administration.

Amendment 581
Pernille Weiss

Proposal for a directive
Article 83 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) there is no medicinal product authorised in the Union for such disease, or, where despite medicinal products being authorised for such disease in the Union, the disease is associated with a remaining high morbidity ***or*** mortality;	(a) there is no medicinal product authorised in the Union for such disease, or, where despite medicinal products being authorised for such disease in the Union, the disease is associated with a remaining high morbidity***, high*** mortality ***or significant negative impact on quality of life***;

Or. en

Amendment 582
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 83 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) there is no medicinal product authorised in the Union for such disease, or, where despite medicinal products being authorised for such disease in the Union, the disease is associated with a remaining ***high*** morbidity ***or*** mortality;	(a) there is no medicinal product authorised in the Union for such disease, or, where despite medicinal products being authorised for such disease in the Union, the disease is associated with a remaining morbidity**,** mortality ***or adversely impacts the quality of life***;

Or. en

Amendment 583
Cristian-Silviu Buşoi

Proposal for a directive
Article 83 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*

(a) there is no medicinal product authorised in the Union for such disease, or, where despite medicinal products being authorised for such disease in the Union, the disease is associated with a remaining ***high*** morbidity ***or*** mortality;	(a) there is no medicinal product authorised in the Union for such disease, or, where despite medicinal products being authorised for such disease in the Union, the disease is associated with a remaining***,*** morbidity***,*** mortality ***or impacting the quality of life***;

Or. en

Amendment 584
Pilar del Castillo Vera

Proposal for a directive
Article 83 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) there is no medicinal product authorised in the Union for such disease, or, where despite medicinal products being authorised for such disease in the Union, the disease is associated with a remaining high morbidity ***or*** mortality;	(a) there is no medicinal product authorised in the Union for such disease, or, where despite medicinal products being authorised for such disease in the Union, the disease is associated with a remaining high morbidity***,*** mortality ***or impact on quality of life***;

Or. en

Amendment 585
Pernille Weiss

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

Text proposed by the Commission	*Amendment*
(b) the use of the medicinal product results in a meaningful reduction in disease morbidity ***or*** mortality for the relevant patient population.	(b) the use of the medicinal product results in***:*** ***(i)*** a meaningful reduction in disease morbidity***,*** mortality***, severity or long term side effects*** for the relevant patient population***; or*** ***(ii) a meaningful positive impact on***

quality of life; or

(iii) a meaningful delay of the onset of the disease or its complications.

Or. en

Amendment 586
Pilar del Castillo Vera

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

Text proposed by the Commission	*Amendment*
(b) the use of the medicinal product results in a meaningful reduction in disease morbidity ***or*** mortality for the relevant patient population.	(b) the use of the medicinal product results in***: (i)*** a meaningful reduction in disease morbidity***,*** mortality***, severity or side effects*** for the relevant patient population***; or (ii) a meaningful positive impact on quality of life; or (iii) a meaningful prevention, delay of the onset, or delay of progression of the disease or its complications***.

Or. en

Amendment 587
Cristian-Silviu Buşoi

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

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

Or. en

Amendment 588
Susana Solís Pérez, Klemen Grošelj

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

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

Or. en

Amendment 589
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

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

Or. en

Amendment 590
Cristian-Silviu Buşoi

Proposal for a directive
Article 83 – paragraph 1 – point b – point i (new)

Text proposed by the Commission	*Amendment*
	i) a meaningful reduction in disease morbidity, mortality, severity or side effects for the relevant patient population; or

Or. en

Amendment 591
Cristian-Silviu Buşoi

Proposal for a directive
Article 83 – paragraph 1 – point b – point ii (new)

Text proposed by the Commission	*Amendment*
	ii) a meaningful positive impact on quality of life; or

Or. en

Amendment 592
Cristian-Silviu Buşoi

Proposal for a directive
Article 83 – paragraph 1 – point b – point iii (new)

Text proposed by the Commission	*Amendment*
	iii) a meaningful prevention, delay of the onset, or delay of progression of the disease or its complications.

Or. en

Amendment 593
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 83 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(b a) the use of the medical product significantly improves the quality of life;

Or. en

Amendment 594
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 83 – paragraph 1 – point b b (new)

Text proposed by the Commission	*Amendment*
	(b b) the use of the medical product contributes to meaningful prevention, delays the onset, or slows the progression of the disease and its complications

Or. en

Amendment 595
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 83 – paragraph 1 – point b c (new)

Text proposed by the Commission	*Amendment*
	(b c) the use of a medical product leads to improvements in dosing and facilitates the administration of the medication, which includes enhancing treatment compliance;

Or. en

Amendment 596
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 83 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Designated orphan medicinal products referred to in Article 67 of [revised Regulation (EC) No 726/2004] shall be considered as addressing an unmet medical need.	***deleted***

Or. en

Amendment 597
Susana Solís Pérez, Klemen Grošelj

Proposal for a directive
Article 83 – paragraph 3

Text proposed by the Commission	*Amendment*
3. ***Where*** the Agency adopts scientific guidelines for the application of this Article it shall consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004].	3. ***In close cooperation with HTA bodies,*** the Agency adopts scientific guidelines for the application of this Article it shall ***take into account the effect of the condition on life expectancy with the provision of standard care; the influence of the condition on patient experience, encompassing quality of life, after administering the current standard of care; and the suitability of the present standard of care for the patient. In formulating these guidelines, the Agency shall include members from patient organizations related to the pertinent disease areas, and*** consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004].

Or. en

Amendment 598
Margarita de la Pisa Carrión
on behalf of the ECR Group

Proposal for a directive
Article 83 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the Agency adopts scientific guidelines for the application of this Article it shall consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004].	3. Where the Agency adopts scientific guidelines for the application of this Article it shall consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004]***, representatives from patient organisations in the relevant disease areas, healthcare professionals,***

representatives of the pharmaceutical industry, and other relevant stakeholders.

Or. en

Amendment 599
Pilar del Castillo Vera

Proposal for a directive
Article 83 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the Agency adopts scientific guidelines for the application of this Article it shall consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004].	3. Where the Agency adopts scientific guidelines for the application of this Article it shall consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004]***, representatives of patients' organisations in the relevant disease areas, healthcare professionals, representatives of pharmaceutical industry and other relevant stakeholders***.

Or. en

Amendment 600
Pernille Weiss

Proposal for a directive
Article 83 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the Agency adopts scientific guidelines for the application of this Article it shall consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004].	3. Where the Agency adopts scientific guidelines for the application of this Article it shall consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004]***, representatives of patients' organisations in the relevant disease areas, healthcare professionals, representatives of pharmaceutical industry and other relevant stakeholders***.

Or. en

Amendment 601
Cristian-Silviu Buşoi

Proposal for a directive
Article 83 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the Agency adopts scientific guidelines for the application of this Article it shall consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004].	3. Where the Agency adopts scientific guidelines for the application of this Article it shall consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004] ***representatives of patients' organisations in the relevant disease areas, healthcare professionals, representatives of pharmaceutical industry and other relevant stakeholders***.

Or. en

Amendment 602
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 83 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the Agency adopts scientific guidelines for the application of this Article it shall consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004].	3. Where the Agency adopts scientific guidelines for the application of this Article it shall consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004]***, and where relevant, representatives of patients' organisations in the relevant disease areas, healthcare professionals, academics and experts***.

Or. en

Amendment 603
Cristian-Silviu Buşoi

Proposal for a directive
Article 84 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. A regulatory data protection period of four years shall be granted for a medicinal product with respect to a new therapeutic indication not previously authorised in the Union, provided that:	1. A ***non-cumulative period of*** regulatory data protection period of four years shall be granted for a medicinal product with respect to a new therapeutic ***option, including a new*** indication***, posology, pharmaceutical form, method or route of administration or any other way in which the medicinal product may be used,*** not previously authorised in the Union, provided that:

Or. en

Amendment 604
Pilar del Castillo Vera

Proposal for a directive
Article 84 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. A regulatory data protection ***period*** of four years shall be granted for a medicinal product with respect to a new therapeutic indication not previously authorised in the Union, provided that:	1. A ***non-cumulative period of*** regulatory data protection of four years shall be granted for a medicinal product with respect to a new therapeutic ***option, including a new*** indication***, posology, pharmaceutical form, method or route of administration or any other way in which the medicinal product may be used,*** not previously authorised in the Union, provided that:

Or. en

Amendment 605
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a directive
Article 84 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. A regulatory data protection ***period*** of four years shall be granted for a medicinal product with respect to a new therapeutic indication not previously authorised in the Union, provided that:	1. A ***non-cumulative period of*** regulatory data protection of four years shall be granted for a medicinal product with respect to a new therapeutic ***option, including a new*** indication***, posology, pharmaceutical form, method or route of administration or any other way in which the medicinal product may be used,*** not previously authorised in the Union, provided that:

Or. en

Amendment 606
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 84 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. A regulatory data protection period of ***four*** years shall be granted for a medicinal product with respect to a new therapeutic indication not previously authorised in the Union, provided that:	1. A regulatory data protection period of ***two and a half*** years shall be granted for a medicinal product with respect to a new therapeutic indication not previously authorised in the Union, provided that:

Or. en

Amendment 607
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 84 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. A regulatory data protection period of ***four*** years shall be granted for a medicinal product with respect to a new therapeutic indication not previously authorised in the Union, provided that:	1. A regulatory data protection period of ***two*** years shall be granted for a medicinal product with respect to a new therapeutic indication not previously authorised in the Union, provided that:

Or. en

Amendment 608
Patrizia Toia, Beatrice Covassi

Proposal for a directive
Article 84 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) adequate non-clinical or clinical studies were carried out in relation to the therapeutic indication demonstrating that it is of significant clinical benefit, and	(a) adequate non-clinical or clinical studies were carried out in relation to the therapeutic indication demonstrating that it is of significant clinical benefit, ***including studies covering the paediatric population conducted according to a PIP*** and

Or. en

Amendment 609
Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a directive
Article 84 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) adequate ***non-clinical or*** clinical studies were carried out in relation to the therapeutic indication demonstrating that it is of significant clinical benefit, and	(a) adequate clinical studies ***with an active-comparator*** were carried out ***by the marketing authorisation holder*** in relation to the therapeutic indication demonstrating that it is of significant clinical benefit, and

Or. en

Amendment 610
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 84 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) adequate non-clinical or clinical	(a) adequate non-clinical or clinical

studies were carried out in relation to the therapeutic indication demonstrating that it is of significant clinical benefit, and	studies were carried out ***by the marketing authorisation applicant*** in relation to the therapeutic indication demonstrating that it is of significant clinical benefit, and

Or. en

Amendment 611
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a directive
Article 84 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) adequate non-clinical or clinical ***studies were carried out*** in relation to the therapeutic ***indication*** demonstrating that it is of significant ***clinical*** benefit, and	(a) adequate non-clinical or clinical ***evidence was provided*** in relation to the therapeutic ***option*** demonstrating that it is of significant benefit, and

Or. en

Amendment 612
Pilar del Castillo Vera

Proposal for a directive
Article 84 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) adequate non-clinical or clinical ***studies were carried out*** in relation to the therapeutic ***indication*** demonstrating that it is of significant ***clinical*** benefit, and	(a) adequate non-clinical or clinical ***evidence was provided*** in relation to the therapeutic ***option*** demonstrating that it is of significant benefit, and

Or. en

Amendment 613
Cristian-Silviu Buşoi

Proposal for a directive
Article 84 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) adequate non-clinical or clinical ***studies were carried out*** in relation to the therapeutic ***indication*** demonstrating that it is of significant ***clinical*** benefit, and	(a) adequate non-clinical or clinical ***evidence was provided*** in relation to the therapeutic ***option*** demonstrating that it is of significant benefit, and

Or. en

Amendment 614
Cristian-Silviu Buşoi

Proposal for a directive
Article 84 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the medicinal product is authorised in accordance with Articles 9 to 12 and has not previously benefitted from data protection, or 25 years have passed since the granting of the initial marketing authorisation of the medicinal product concerned.	(b) the medicinal product is authorised in accordance with Articles 9 to 12 and ***does not fall in the same global marketing authorization as a medicinal product that has*** has not previously benefitted from data protection ***or market exclusitvity***, or 25 years have passed since the granting of the initial marketing authorisation of the medicinal product concerned.

Or. en

Amendment 615
Pilar del Castillo Vera

Proposal for a directive
Article 84 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the medicinal product is authorised in accordance with Articles 9 to 12 and ***has not*** previously benefitted from data protection, or 25 years have passed since the granting of the initial marketing authorisation of the medicinal product concerned.	(b) the medicinal product is authorised in accordance with Articles 9 to 12 and ***does not fall in the same global marketing authorization as a medicinal product that has*** previously benefitted from data protection ***or market exclusivity***, or 25 years have passed since the granting of the initial marketing authorisation of the medicinal product concerned.

Or. en

Amendment 616
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a directive
Article 84 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the medicinal product is authorised in accordance with Articles 9 to 12 and ***has not*** previously benefitted from data protection, or 25 years have passed since the granting of the initial marketing authorisation of the medicinal product concerned.	(b) the medicinal product is authorised in accordance with Articles 9 to 12 and ***does not fall in the same global marketing authorization as a medicinal product that has*** previously benefitted from data protection ***or market exclusivity***, or 25 years have passed since the granting of the initial marketing authorisation of the medicinal product concerned.

Or. en

Amendment 617
Cristian-Silviu Buşoi

Proposal for a directive
Article 84 – paragraph 3

Text proposed by the Commission	*Amendment*
3. During the data protection period referred to in paragraph 1, the ***marketing authorisation shall indicate that the*** medicinal product ***is an existing*** medicinal product ***authorised in the Union that has been authorised with an additional therapeutic indication***.	3. During the data protection period referred to in paragraph 1, the medicinal product ***shall be designated as a value added*** medicinal product.

Or. en

Amendment 618
Pietro Fiocchi, Elisabetta De Blasis

Proposal for a directive

Article 84 – paragraph 3

Text proposed by the Commission	*Amendment*
3. During the data protection period referred to in paragraph 1, the ***marketing authorisation shall indicate that the*** medicinal product ***is an existing*** medicinal product ***authorised in the Union that has been authorised with an additional therapeutic indication***.	3. During the data protection period referred to in paragraph 1, the medicinal product ***shall be designated as a value added*** medicinal product.

Or. en

Amendment 619
Pilar del Castillo Vera

Proposal for a directive
Article 84 – paragraph 3

Text proposed by the Commission	*Amendment*
3. During the data protection period referred to in paragraph 1, the ***marketing authorisation shall indicate that the*** medicinal product ***is an existing*** medicinal product ***authorised in the Union that has been authorised with an additional therapeutic indication***.	3. During the data protection period referred to in paragraph 1, the medicinal product ***should be designated as a value added*** medicinal product.

Or. en

Amendment 620
Nicolás González Casares, Laura Ballarín Cereza

Proposal for a directive
Article 84 a (new)

Text proposed by the Commission	*Amendment*
	Article84a
	Reporting of research and development costs from the marketing authorisation holder
	1.Where the marketing authorisation holder benefits from data and market

protection granted under this Directive it shall:

(a) Upon request, submit to the Commission and/or the competent authorities of the Member States responsible for pricing and reimbursement an electronic report with detailed information on their expenditure in research and development activities related to the medicinal product.

(b) make the report available within 30 days from the receipt of the request;

(c) publish a summary of the report on the same webpage where the information described in Article 57 will be published. The link should be communicated to the competent authority of the Member State granting the marketing authorisation or, where appropriate, to the Agency.

(d) ensure that the electronic report and lay summary are accurate and have been audited by an independent external auditor.

2. The Commission shall promote transparency and data sharing mechanisms regarding reimbursement prices of medicinal products by the Member States.

3. The Commission shall adopt delegated acts to lay down the methodology and format in which the information should be reported and published pursuant to paragraph 1.

Or. en

Amendment 621
Cristian-Silviu Buşoi

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

Text proposed by the Commission	*Amendment*
Patent rights, or supplementary protection	Patent rights, or supplementary protection

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

Or. en

Amendment 622
Nicolás González Casares, Laura Ballarín Cereza

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

Text proposed by the Commission	*Amendment*
Patent rights, or supplementary protection certificates under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted] shall not be regarded as infringed when ***a reference medicinal product is used for the purposes of***:	Patent rights, or supplementary protection certificates under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted] shall not be regarded as infringed when:

Or. en

Amendment 623
Ville Niinistö
on behalf of the Verts/ALE Group

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

Text proposed by the Commission	*Amendment*
Patent rights, or supplementary protection certificates under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted] shall not be regarded as infringed when ***a reference medicinal product is used for the purposes of***:	Patent rights, or supplementary protection certificates under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted] shall not be regarded as infringed when:

Or. en

Amendment 624
Patrizia Toia, Beatrice Covassi

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

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

Or. en

Amendment 625
Pilar del Castillo Vera

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

Text proposed by the Commission	*Amendment*
(a) studies, trials and other activities conducted to generate data for ***an application***, ***for:***	(a) studies, trials and other activities ***are*** conducted to generate data for ***the purpose of: (i) obtaining a marketing authorisation of generic***, ***biosimilar, hybrid or bio-hybrid medicinal products and for subsequent variations; (ii) conducting a health technology assessment as defined in Regulation (EU) 2021/2282; (iii) obtaining pricing and reimbursement approval; (iv) complying with any other regulatory or administrative requirement in the Union or elsewhere; and the subsequent practical requirements associated with such activities.***

Or. en

Amendment 626
Cristian-Silviu Buşoi

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

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

Or. en

Amendment 627
Pernille Weiss

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

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

Or. en

Amendment 628
Nicolás González Casares, Laura Ballarín Cereza

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

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

Or. en

Amendment 629
Ville Niinistö
on behalf of the Verts/ALE Group

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

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

Or. en

Amendment 630
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

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

Or. en

Amendment 631
Pernille Weiss

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

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

Or. en

Amendment 632
Margarita de la Pisa Carrión
on behalf of the ECR Group

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

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

Or. en

Amendment 633
Patrizia Toia, Beatrice Covassi

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

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

Or. en

Amendment 634
Cristian-Silviu Buşoi

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

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

Or. en

Amendment 635
Ville Niinistö
on behalf of the Verts/ALE Group

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

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

Or. en

Amendment 636
Nicolás González Casares, Laura Ballarín Cereza

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

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

Or. en