be aligned with Annex VI.	aligned with Annex VI.

Or. en

Amendment 142
Nicolás González Casares, Tiemo Wölken

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.*** 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.

Or. en

Amendment 143
Nicolás González Casares, Tiemo Wölken

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 144
Nicolás González Casares, Tiemo Wölken

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 145
Nicolás González Casares, Tiemo Wölken

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	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],***

the duration period of the compulsory licence.	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 146
Nicolás González Casares, Tiemo Wölken

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 147
Nicolás González Casares, Tiemo Wölken

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 148
Nicolás González Casares, Tiemo Wölken

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 149
Nicolás González Casares, Tiemo Wölken

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 150
Nicolás González Casares, Tiemo Wölken

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 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 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 151
Nicolás González Casares, Tiemo Wölken

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).	***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.*** 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).	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 152
Nicolás González Casares, Tiemo Wölken

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]	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***

(‘Pharmaceutical Committee’). The Commission may invite bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 or national bodies responsible for pricing and reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.	***or 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 Decision 75/320/EEC***[1]*** (‘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.
_____	_____
[75] Council Decision of 20 May 1975 setting up a pharmaceutical committee (OJ L 147, 9.6.1975, p. 23).	[75] Council Decision of 20 May 1975 setting up a pharmaceutical committee (OJ L 147, 9.6.1975, p. 23).
	Or. en

Amendment 153
Nicolás González Casares, Tiemo Wölken

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 154
Nicolás González Casares, Tiemo Wölken

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 155
Nicolás González Casares, Tiemo Wölken

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 156
Nicolás González Casares, Tiemo Wölken

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 157
Nicolás González Casares, Tiemo Wölken

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 158
Nicolás González Casares, Tiemo Wölken

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 159
Nicolás González Casares, Tiemo Wölken

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 160
Nicolás González Casares, Tiemo Wölken

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 161
Nicolás González Casares, Tiemo Wölken

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 162
Nicolás González Casares, Tiemo Wölken

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 163
Nicolás González Casares, Tiemo Wölken

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 ***productsand*** subsequent variations;

Or. en

Amendment 164
Nicolás González Casares, Tiemo Wölken

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

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

Or. en

Amendment 165
Nicolás González Casares, Tiemo Wölken

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

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

Or. en

Amendment 166
Nicolás González Casares, Tiemo Wölken

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

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

Or. en

Amendment 167
Nicolás González Casares, Tiemo Wölken

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

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

Or. en

Amendment 168
Nicolás González Casares, Tiemo Wölken

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

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

medicinal products or processes, including by third party suppliers and service providers.	service providers.

Or. en

Amendment 169
Nicolás González Casares, Tiemo Wölken

Proposal for a directive
Article 85 – paragraph 2

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

Or. en

Amendment 170
Nicolás González Casares, Tiemo Wölken

Proposal for a directive
Article 85 a (new)

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

product in the Union, the Commission shall have a public purchase option for all related intellectual property rights.

Or. en

Amendment 171
Nicolás González Casares, Tiemo Wölken

Proposal for a directive
Article 86 a (new)

Text proposed by the Commission	*Amendment*
	Article86a
	Measuring pharmaceutical access within the EU
	1.The Commission, in collaboration with Member States, shall develop objective and specific indicators to measure pharmaceutical access within the EU. The indicators related to pharmaceutical access should include but not be limited to availability, health system and patient affordability and accesibility of medicines.
	(a) The Commission shall ensure that these indicators are evidence-based, measurable, and regularly reviewed to reflect the evolving healthcare landscape within the EU. Additionally, the Commission shall ensure that confidentiality of pricing and reimbursement data is overcome to avoid distorsion estimates.
	(b) The Commission, in collaboration with Member States, shall produce a quinquennial report on the state of pharmaceutical access within the Union. This report shall comprehensively analyse the indicators defined in paragraph 1, evaluating their effectiveness in gauging access to medicines. The Commission shall also establish a public database for annual update of paramenters defined in the quinquennial report.