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***I
REPORT

on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products
(COM(2018)0317 – C8-0217/2018 – 2018/0161(COD))

Committee on Legal Affairs

Rapporteur: Luis de Grandes Pascual

Symbols for procedures

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

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

Amendments to a draft act

Amendments by Parliament set out in two columns

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

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

Amendments by Parliament in the form of a consolidated text

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

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products
(COM(2018)0317 – C8-0217/2018 – 2018/0161(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2018)0317),

– having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C8-0217/2018),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 19 September 2018[1],

– having regard to Rule 59 of its Rules of Procedure,

– having regard to the report of the Committee on Legal Affairs and also the opinions of the Committee on International Trade and the Committee on the Environment, Public Health and Food Safety (A8-0039/2019),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

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

Amendment 1

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) By providing for a period of supplementary protection of up to five	(2) By providing for a period of supplementary protection of up to five

[1] OJ C 440, 6.12.2018, p. 100

years, Regulation (EC) No 469/2009 seeks to promote, within the Union, the research and innovation that is necessary to develop medicinal products, and to contribute to preventing the relocation of pharmaceutical research outside the Union to countries that may offer greater protection.

years, Regulation (EC) No 469/2009 seeks to ***provide a solution at Union level to prevent new disparities being created in national law, which could hinder the free movement of medicines within the internal market, while promoting***, within the Union, the research and innovation that is necessary to develop ***new generation of*** medicinal products ***that support the treatment of new diseases or offer more significant therapeutic effects, and contributing*** to preventing the relocation of pharmaceutical research outside the Union to countries that may offer greater protection, ***while at the same time ensuring access to medicines within the Union***.

Amendment 2

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2 a) The timely entry of generics and biosimilars onto the Union market is important as regards increasing competition, reducing prices and ensuring the sustainability of healthcare systems. Amending Regulation (EC) No 469/2009 so as to allow the production of generics and biosimilars for export and storage should not conflict with intellectual property rights, which remain one of the cornerstones of innovation, competitiveness and growth in the Member States. This Regulation should not interfere with the duration of market exclusivity rights during the term of a patent, which is underscored by the fact that immediate import is allowed after expiry, but represents a competitive disadvantage for the European generic medicines industry. This Regulation should take into account the concerns expressed by the European Parliament

and by the Council regarding the increasing number of examples of market failure in a number of Member States, where patients´ access to effective and affordable essential medicines is endangered by very high and unsustainable price levels.

Amendment 3

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) Since the adoption in 1992 of the predecessor to Regulation (EC) No 469/2009, markets have evolved significantly and there has been huge growth in the manufacture of generics and especially of biosimilars, in particular in third countries where protection does not exist or has expired.	(3) Since the adoption in 1992 of the predecessor to Regulation (EC) No 469/2009, markets have evolved significantly and there has been huge growth in the manufacture of generics and especially of biosimilars ***and active ingredients***, in particular in ***countries outside the Union (in '***third countries***')*** where protection does not exist or has expired.

Amendment 4

Proposal for a regulation
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) Pharmaceuticals are one of the pillars of healthcare rather than a mere object of trade. Insufficient access to essential medicinal products and the high prices of innovative medicines pose a serious threat to patients and to the sustainability of national health care systems.

Amendment 5

Proposal for a regulation
Recital 3 b (new)

Text proposed by the Commission	*Amendment*
	(3b) The Council, in its conclusions of 17 June 2016 on strengthening the balance in the pharmaceutical systems in the Union and its Member States, underlined the importance of timely availability of generics and biosimilars in order to facilitate patients' access to pharmaceutical therapies and to improve the sustainability of national health systems.

Amendment 6

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) The absence of any exception in Regulation (EC) No 469/2009 to the protection conferred by a supplementary protection certificate has had the unintended consequence of preventing manufacturers of generics and biosimilars established in the Union from manufacturing, ***even for the exclusive purpose of exporting to third country markets in which such protection does not exist or has expired. A further unintended consequence is that the protection conferred by the certificate makes it more difficult for those manufacturers*** to enter the Union market immediately after expiry of the certificate, given that they are not in a position to build up production capacity until the protection provided by the certificate has lapsed, by contrast with manufacturers located in third countries where protection does not exist or has expired.	(4) The absence of any exception in Regulation (EC) No 469/2009 to the protection conferred by a supplementary protection certificate has had the unintended consequence of preventing manufacturers of generics and biosimilars established in the Union from manufacturing ***within the Union***, ***with a view*** to entering the Union market immediately after expiry of the certificate ***(EU-Day1 Entry) and/or from exporting to third countries in which protection does not exist or has expired***, given that they are not in a position to build up production capacity until the protection provided by the certificate has lapsed, by contrast with manufacturers located in third countries where protection does not exist or has expired.

Amendment 7

Proposal for a regulation

Recital 5

Text proposed by the Commission	*Amendment*
(5) This puts manufacturers of generics and biosimilars established in the Union at a significant competitive disadvantage compared with manufacturers based in third countries that offer less or no protection.	(5) This puts manufacturers of generics and biosimilars established in the Union at a significant competitive disadvantage compared with manufacturers based in third countries that offer less or no protection ***or where protection has expired***. ***It is imperative, therefore, that the European Union strike a balance between, on the one hand, ensuring a level playing field between production activities on its territory and in third countries and, on the other, ensuring that the exclusive rights of certificate holders are guaranteed in relation to the Union market.***

Amendment 8

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(6) Without any intervention, the viability of ***the manufacture*** of generics and biosimilars in the Union could be under threat, with consequences for the Union's pharmaceutical industrial base as a whole.	(6) Without any intervention, the viability of ***manufactures*** of generics and biosimilars in the Union could be under threat, with consequences for the Union's pharmaceutical industrial base as a whole, ***which could affect the very functioning of the internal market through the loss of potential new business opportunities as well as diminishing investment at Union level and possibly hampering the creation of new jobs.***

Amendment 9

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) The aim of this Regulation is to	(7) The aim of this Regulation is to

ensure that manufacturers established in the Union ***are able*** to compete effectively in ***those*** third country markets where ***supplementary*** protection does not exist or has expired. It ***is intended to*** complement the efforts of the Union's trade policy to ensure open markets for Union-based manufacturers of medicinal products. Indirectly, it ***is also intended to*** put those manufacturers in a better position to enter the Union market immediately after expiry of the relevant supplementary protection certificate. It would also help ***to serve the aim of*** fostering access to medicines in the Union by helping to ensure a swifter entry of generic and biosimilar medicines onto the market after expiry of the relevant certificate.

promote the competitiveness of generics and biosimilars producers in the Union***, to enhance growth and job creation in the internal market and to contribute to a wider supply of products under uniform conditions. This will help producers*** to compete effectively in third country markets where protection does not exist or has expired ***and to ensure EU-Day1 Entry of generic and biosimilar medicines into the Union market after expiry of the relevant supplementary protection certificate***. It ***should also*** complement the efforts of the Union's trade policy to ensure open markets for Union-based manufacturers of medicinal products ***or of active ingredients***. ***It would*** put those manufacturers in a better position to enter the Union market immediately after expiry of the relevant supplementary protection certificate***, namely the EU-Day1 Entry***. It would also help fostering access to medicines in the Union by helping to ensure a swifter entry of generic and biosimilar medicines onto the market after expiry of the relevant certificate.

Amendment 10

Proposal for a regulation
Recital 8

Text proposed by the Commission	*Amendment*
(8) In ***those*** specific and limited circumstances, and in order to create a level playing field between Union-based manufacturers and third country manufacturers, it is appropriate to ***restrict the protection conferred by*** a supplementary protection certificate so as to allow making for the ***exclusive*** purpose of export to third countries and ***any related acts strictly necessary for making or for the actual export itself***.	(8) In ***these*** specific and limited circumstances, and in order to create a level playing field between Union-based manufacturers and third country manufacturers, it is appropriate to ***eliminate the unintentional effects of*** a supplementary protection certificate***, but not to the detriment of any other patent or intellectual property right existing in a Member State, so as to allow making of generic products, biosimilars and active ingredients*** for the purpose of export to third countries and ***of entry into the Union market immediately after expiry of the***

relevant supplementary protection certificate.

Amendment 11

Proposal for a regulation
Recital 9

Text proposed by the Commission	*Amendment*
(9) That exception should cover the making of the product***, including*** the product which ***corresponds to the medicinal product*** protected by a supplementary protection certificate in the territory of a Member State, for the exclusive purpose of export to third countries, ***as well as any upstream or downstream acts by the maker or by third parties in a contractual relationship with the maker, where such acts would otherwise require the consent of the certificate-holder, and are strictly necessary for making for the purpose of export or for the actual export itself. For instance, such acts may include the supply and import of active ingredients for the purpose of making the medicinal product to which the product covered by the certificate corresponds, or temporary storage of the product or advertising for the exclusive purpose of export to third country destinations***.	(9) That exception should cover the making of the product ***and of*** the product ***resulting from the making,*** which ***are both*** protected by a supplementary protection certificate in the territory of a Member State, for the purpose of export to third countries ***or of placing the product on the Union market after the expiry of the certificate***.

Amendment 12

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(10) The exception should not cover placing the product made for the exclusive purpose of export ***on the market*** in the Member State where a supplementary protection certificate is in force, ***either directly or indirectly*** after export, nor	(10) The exception should not cover placing a ***medicinal*** product made for the purpose of export to third countries ***or placing it on the Union's market on the first day after the expiry of the certificate*** in the Member State where a

should it cover re-importation of the product to the market of a Member State in which a certificate is in force. Moreover, it should not cover any act or activity for the purpose of import of ***medicinal*** products***,*** or ***parts of*** medicinal products, into the Union merely for the purposes of repackaging and re-exporting.

supplementary protection certificate is in force, nor should it cover re-importation of the ***medicinal*** product to the market of a Member State in which a certificate is in force. Moreover, it should not cover any act or activity for the purpose of import of products or medicinal products, into the Union merely for the purposes of repackaging and re-exporting.

Amendment 13

Proposal for a regulation
Recital 11

Text proposed by the Commission	*Amendment*
(11) By limiting the scope of the exception to making for the purpose of export ***outside the Union*** and acts strictly necessary for such making or for the actual export itself, the exception introduced by this Regulation ***will*** not unreasonably conflict with normal exploitation of the product in the Member State where the certificate is in force, nor ***unreasonably*** prejudice the legitimate interests of the certificate-holder, taking account of the legitimate interests of third parties.	(11) By limiting the scope of the exception to making for the purpose of export ***to third countries and of placing into the Union market as from day 1 after the certificate has expired***, the exception introduced by this Regulation ***should*** not unreasonably conflict with normal exploitation of the product in the Member State where the certificate is in force, nor prejudice the legitimate interests of the certificate-holder, ***whilst also*** taking account of the legitimate interests of third parties.

Amendment 14

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) Safeguards should accompany the exception ***in order to increase transparency, to help*** the holder of a supplementary protection certificate to ***enforce its protection in the Union and to reduce the risk of illicit diversion onto the Union market during the term*** of the ***certificate.***	(12) ***Effective and proportionate*** safeguards should accompany the exception***, for the purpose of helping*** the holder of a supplementary protection certificate to ***check compliance with the conditions set out in this Regulation. Those safeguards should not negatively affect competition among companies and should allow the exception to work***

effectively without hampering achievement of the main objectives of the ***exception.***

Amendment 15

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) To this end, this Regulation should impose a ***once-off*** duty on the person making ***the*** product for the exclusive ***purpose*** of export, ***requiring that*** person to provide certain information to the authority which granted the supplementary protection certificate in the Member State where the making is to take place. The information should be provided before the making is intended to start for the first time in that Member State. The making ***and related acts, including those performed in Member States other than the one of making in cases where the product is protected by a certificate in those other Member States too,*** should only fall within the scope of the exception where the maker has sent this notification to the competent industrial property authority (or other designated authority) of the Member State of making***. The once-off duty to provide information to the authority should apply in each Member State where making is to take place, both as regards the making*** in that Member State***, and as regards*** related acts***, whether performed in that or another*** Member State, ***related to that making***. The authority should be required to publish ***that information***, in the interests of transparency ***and for the purpose of informing the holder of the certificate of the maker's intention***.	(13) To this end, this Regulation should impose a duty on the ***maker, namely the legal*** person ***established in the Union, on whose behalf the*** making ***of a product or medicinal product containing that*** product***,*** for the ***purpose*** of export ***to third countries or of placing on the Union market after the expiry of the certificate, is carried out, including the possibility of the legal person itself directly doing the making***, where***by*** that person ***is required*** to provide certain information to the authority which granted the supplementary protection certificate in the Member State where the making is to take place. ***It is the responsibility of the maker established in the Union to verify that protection does not exist or has expired in a country of export, or whether it is subject to any limitations or exemptions in that country. A common notification form for the notification of the authority should be provided for that purpose.*** The information should be provided before the making is intended to start for the first time in that Member State. The making should only fall within the scope of the exception where the maker has sent this notification to the competent industrial property authority (or other designated authority) of the Member State of making ***and has informed the holder of the supplementary protection certificate granted about the name and address of the maker and the number of the certificate*** in that Member State. ***The making should be notified***. ***Should making take place in more than one***

Member State, ***a notification should be required in each of those Member States***. The authority should be required ***in each of these Member States. The authority should be required*** to publish ***the certificate number of the relevant product or medicinal product***, in the interests of transparency***. Certain confidential or commercially sensitive information notified to the authority should not be published, but could be provided, if so requested by a court or other competent authority and in those circumstances only***.

Amendment 16

Proposal for a regulation
Recital 13 a (new)

Text proposed by the Commission	*Amendment*
	(13 a) Without prejudice to the protection of confidential or commercially sensitive information, the maker should also inform the certificate holder, in writing, of its intention to make a product pursuant to the exception.

Amendment 17

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(14) In addition, this Regulation should impose certain due diligence requirements on the maker as a condition for the exception to operate. The maker should be required to inform persons within its supply chain, through appropriate means, in particular contractual means, that the product is covered by the exception introduced by this Regulation and is intended for the ***exclusive*** purpose of export. A maker who failed to comply with	(14) In addition, this Regulation should impose certain due diligence requirements on the maker as a condition for the exception to operate. The maker should be required to inform persons within its supply chain, through appropriate ***and documented*** means, in particular contractual means, that the product is covered by the exception introduced by this Regulation and is intended for the purpose of export ***and/or EU-Day1 Entry***.

these due diligence requirements would not benefit from the exception***, nor would any third party performing a related act in the same or a different Member State where a certificate conferring protection for the product was in force,*** and the holder of the relevant certificate would therefore be entitled to enforce its rights under the certificate.	A maker who failed to comply with these due diligence requirements would not benefit from the exception and the holder of the relevant certificate would therefore be entitled to enforce its rights under the ***supplementary protection*** certificate.

Amendment 18

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) This Regulation does not affect the application of Union measures that aim to prevent infringements and facilitate enforcement of intellectual property rights, including Directive 2004/48/EC of the European Parliament and of the Council[41] and Regulation (EU) No 608/2013 of the European Parliament and of the Council[42].	(17) This Regulation does not affect the application of Union measures that aim to prevent infringements and facilitate enforcement of intellectual property rights, including Directive 2004/48/EC of the European Parliament and of the Council[41] and Regulation (EU) No 608/2013 of the European Parliament and of the Council[42]. ***Furthermore, a medicinal product bearing an active Unique Identifier as per Articles 3(d) of Commission Delegated Regulation (EU) 2016/161[42a] would indicate that the product is not exclusively intended for the purpose of export to third countries. Therefore, this Regulation should only prohibit a product exclusively intended for the purpose of export to third countries bearing such an active Unique Identifier. That prohibition shall not apply to products intended for the purpose of storage for EU-Day1 Etry.***
[41] Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L157, 30.4.2004, p. 45).	[41] Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L157, 30.4.2004, p. 45).
[42] Regulation (EU) No 608/2013 of the European Parliament and of the Council of	[42] Regulation (EU) No 608/2013 of the European Parliament and of the Council of

12 June 2013 concerning customs enforcement of intellectual property rights (OJ L 181, 29.6.2013, p. 15).

12 June 2013 concerning customs enforcement of intellectual property rights (OJ L 181, 29.6.2013, p. 15).

[42 a] Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 9.2.2016, p. 1).

Amendment 19

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(19) ***In order to ensure that holders of supplementary protection certificates already in force are not deprived of their acquired rights,*** the exception provided for in this Regulation should only apply to certificates ***that are granted on or after a specified date after entry into force, irrespective of when the application for the certificate was first lodged***. ***The date specified*** should allow a reasonable time for applicants and other relevant market players to adjust to the changed legal context and to make appropriate investment and manufacturing location decisions in a timely way. ***The*** date should also allow sufficient time for public authorities to put in place appropriate arrangements to receive and publish notifications of the intention to make, and should take due account of pending applications for certificates.	(19) The exception provided for in this Regulation should only apply to certificates ***the basic patent for which expired on or after 1 January 2021***. ***That*** date ***takes into account the need to provide for a transitional period sufficiently long to ensure that holders of supplementary protection certificates are not deprived of their acquired rights and*** should allow a reasonable time for applicants and other relevant market players to adjust to the changed legal context and to make appropriate investment and manufacturing location decisions in a timely way. ***That*** date should also allow sufficient time for public authorities to put in place appropriate arrangements to receive and publish notifications of the intention to make, and should take due account of pending applications for certificates.

Amendment 20

Proposal for a regulation
Recital 19 a (new)

Text proposed by the Commission	*Amendment*
	(19a) This Regulation should not have any retroactive effect.

Amendment 21

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) The Commission should carry out an evaluation of this Regulation. Pursuant to paragraph 22 of the Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making of 13 April 2016[43], that evaluation should be based on the five criteria of effectiveness, efficiency, relevance, coherence and added value and should provide the basis for impact assessments of possible further measures. The evaluation should take into account exports to outside the Union and the ability of generics and especially biosimilars to enter markets in the Union as soon as possible after a certificate lapses. In particular, this evaluation should review the effectiveness of the exception in the light of the aim to restore a global level playing field for generic and biosimilar firms in the Union and a swifter entry of generic and especially biosimilar medicines onto the market after a certificate lapses. It should also study the impact of the exception on research and production of innovative medicines by holders of certificates in the Union and consider the balance between the different interests at stake, including those of public health.	(20) The Commission should carry out ***a regular*** evaluation of this Regulation. ***Given the paramount importance of access to and affordability of medicinal products for public health and public expenditure, a regular evaluation cycle of this Regulation is justified.*** Pursuant to paragraph 22 of the Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making of 13 April 2016[43], that evaluation should be based on the five criteria of effectiveness, efficiency, relevance, coherence and added value and should provide the basis for impact assessments of possible further measures. The evaluation should take into account ***the impact of the SPC system on access to affordable medicines as well as the waiver, including*** exports to outside the Union and the ability of generics and especially biosimilars to enter markets in the Union as soon as possible after a certificate lapses***. Such regular evaluation should also address the effects of this Regulation on manufacturing within the Union by Union established makers for reasons of stockpiling with a view to Day1 entry into the Union market when a certificate expires. In this context, it would be important to ascertain whether manufacturing previously taking place outside of the Union, would be moved to within its territory***. In particular, this evaluation should review the effectiveness

	of the exception in the light of the aim to restore a global level playing field for generic and biosimilar firms in the Union and a swifter entry of generic and especially biosimilar medicines onto the market after a certificate lapses ***and examine the case for a possible extension of the scope of the exception granted by the waiver so as to allow Union-based manufacturers of generics and biosimilars to manufacture for stockpiling purposes***. It should also study the impact of the exception ***and its possible extension*** on research and production of innovative medicines by holders of certificates in the Union and consider the balance between the different interests at stake, including ***access to medicines within the Union and*** those of public health.
[43] OJ L 123, 12.5.2016, p. 1.	[43] OJ L 123, 12.5.2016, p. 1.

Amendment 22

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(21) It is necessary and appropriate for the achievement of the basic objective**,** of providing a level playing field for generic and biosimilar manufacturers with their competitors in third country markets where protection does not exist or has expired, to lay down rules ***restricting the exclusive right of a supplementary protection certificate holder to make*** the product in question during the term of the certificate**,** ***and also to impose certain information and labelling obligations on makers wishing to take advantage of those rules***. This Regulation complies with the principle of proportionality, and does not go beyond what is necessary in order to achieve the objectives pursued, in accordance with Article 5(4) of the Treaty	(21) It is necessary and appropriate for the achievement of the basic objective of providing a level playing field for generic and biosimilar manufacturers with their competitors in third country markets where protection does not exist or has expired, to lay down rules ***enabling the making of*** the product in question during the term of the certificate. This Regulation complies with the principle of proportionality, and does not go beyond what is necessary in order to achieve the objectives pursued, in accordance with Article 5(4) of the Treaty on European Union.

on European Union.

Amendment 23

Proposal for a regulation
Recital 22

Text proposed by the Commission	*Amendment*
(22) This Regulation respects fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union. In particular, this Regulation seeks to ensure full respect for the right to property in Article 17 of the Charter by maintaining the core rights of the supplementary protection certificate, by confining the exception to certificates ***by confining the exception to certificates granted*** on or after ***a specified date after entry into force of this Regulation*** and by imposing certain conditions on the application of the exception,	(22) This Regulation respects fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union. In particular, this Regulation seeks to ensure full respect for the right to property in Article 17 of the Charter by maintaining the core rights of the supplementary protection certificate, by confining the exception to certificates ***basic patent of which expired*** on or after ***1 January 2021*** and by imposing certain conditions on the application of the exception, ***as well as respect for the right to health care set out in Article 35 of the Charter by making medicines more accessible to Union patients, for the principle of proportionality set out in Article 52 of the Charter, and the right to health protection for European citizens set out in point (a) of Article 6 TFEU .***

Amendment 24

Proposal for a regulation
Article 1 – paragraph 1 – point -1 (new)
Regulation (EC) No 469/2009
Article 1 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(-1) in Article 1, the following point is added:
	" (ea) 'maker' means a legal person established in the Union on whose behalf the making of a product or a medicinal product containing that product, for the

purpose of export to third countries or storing during the final 2 years of validity of the certificate is done;"

Amendment 25

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) No 469/2009
Article 4

Text proposed by the Commission	*Amendment*
(1) Article 4 is replaced by the following:	***deleted***
'Article 4	
Subject matter of protection and exceptions to rights conferred	
1. Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.	
2. The certificate referred to in paragraph 1 shall not confer protection against a particular act against which the basic patent conferred protection if, with respect to that particular act, the following conditions are met:	
(a) the act comprises:	
(i) making for the exclusive purpose of export to third countries; or	
(ii) any related act that is strictly necessary for that making or for the actual export itself;	
(b) the authority referred to in Article 9(1) of the Member State where that making is to take place ('the relevant Member State') is notified by the person doing the making ('the maker') of the	

information listed in paragraph 3 no later than 28 days before the intended start date of making in that Member State;

(c) the maker ensures that a logo, in the form set out in Annex -I, is affixed to the outer packaging of the product or, if there is no outer packaging, to its immediate packaging;

(d) the maker complies with the requirements of paragraph 4.

3. The information for the purposes of paragraph 2(b) shall be as follows:

(a) the name and address of the maker;

(b) the address, or addresses, of the premises where the making is to take place in the relevant Member State;

(c) the number of the certificate granted in the relevant Member State, and identification of the product, by reference to the proprietary name used by the holder of that certificate;

(d) the number of the authorisation granted in accordance with Article 40(1) of Directive 2001/83/EC or Article 44(1) of Directive 2001/82/EC for the manufacture of the corresponding medicinal product or, in the absence of such authorisation, a valid certificate of good manufacturing practice as referred to in Article 111(5) of Directive 2001/83/EC or Article 80(5) of Directive 2001/82/EC covering the premises where the making is to take place;

(e) the intended start date of making in the relevant Member State;

(f) an indicative list of the intended third country or third countries to which the product is to be exported.

4. The maker shall ensure, through appropriate means, that persons in a contractual relationship with the maker who perform acts falling within paragraph 2(a)(ii) are fully informed and

aware of the following:

(a) that those acts are subject to the provisions of paragraph 2;

(b) that the placing on the market, import or re-import of the product might infringe the certificate referred to in that paragraph where, and as long as, that certificate applies.

5. Paragraph 2 shall apply in the case only of certificates granted on or after [OP: please insert the date of the first day of the third month that follows the month in which this amending Regulation is published in the Official Journal)].';

Amendment 26

Proposal for a regulation
Article 1 – paragraph 1 – point 1 a (new)
Regulation (EC) No 469/2009
Article 5

Present text	*Amendment*
	(1a) Article 5 is replaced by the following:
Article 5	**'**Article 5
Effects of the certificate	Effects of the certificate
Subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.	***1.*** Subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.
	2. By way of derogation from paragraph 1, the certificate shall not confer protection against certain acts which would otherwise require the consent of the holder of the certificate referred to in Article 11 ('the certificate holder') if the following conditions are met:
	(a) the acts comprises:

(i) making a product, or a medicinal product containing that product, for the purpose of export to third countries; or

(ii) making a product, or a medicinal product containing that product, for the purpose of storing it in the Member State of making, during the final 2 years of validity of the certificate referred to in paragraph 1, in order to place that product on the market of Member States as from day 1 after the expiry of the certificate in those Member States;

(iii) any related act that is strictly necessary for that making or for the actual export itself;

(iv) the act excludes any act or activity for import of medicinal products, or parts thereof, onto the Union merely for the purpose of repackaging and re-exporting.

(b) the maker notifies the authority referred to in Article 9 (1) of the Member State where that making is to take place ('the relevant Member State') of the information listed in points (a), (b), (c), (e) and (f) of paragraph 3 no later than two months before the start date of making in that Member State;

(c) the maker informs the certificate holder, in writing, of the information listed in points (a) and (c) of paragraph 3, no later than two months before the start date of making in that Member State;

(d) the notification to the certificate holder does not contain any confidential or commercially sensitive information;

(e) the information provided by the maker to the certificate holder is treated as strictly confidential by the certificate holder and is not published; in addition, the information provided to the certificate holder is used exclusively for the purposes of verifying whether the requirements of this Regulation have been met and, where applicable, initiating legal proceedings for non-compliance;

(f) in the case of products made for the purpose of export to third countries, the maker ensures that a logo, in the form set out in Annex -Ia, is affixed to the outer packaging of the product referred to in paragraph 2(a)(i) or, if the product forms part of a medicinal product, the outer packaging of the medicinal product;

(g) the maker ensures that the medicinal product manufactured pursuant to paragraph 2(a)(i) does not bear an active Unique Identifier as laid down in Articles 3(d) of Commission Delegated Regulation (EU) 2016/161. Where appropriate, the competent authority shall have access to the data in the repositories mandated by Directive 2011/62/EU and Delegated Regulation (EU) 2016/161 in order to verify compliance;

(h) the maker complies with paragraph 4.

3. The information for the purposes of paragraph 2(b), which shall be treated in a strictly confidential manner by all parties, shall be as follows:

(a) the name and address of the maker;

(b) the Member State where the making and, if applicable, also the storage, is to take place;

(c) the number of the certificate granted in the Member State of making;

(d) the intended start date of making in the relevant Member State;

(e) an indicative list of the intended third country or third countries to which the product is to be exported.

4. For the purposes of the notification under point (b) of paragraph 2, the maker shall use the standard form contained in Annex -I to this Regulation.

5. The authorities of the Member States referred to in Article 9(1) shall

under no circumstances disclose any business sensitive information provided by the maker, neither to the certificate holder nor to the public.

6. The maker shall ensure, through appropriate and documented means, that persons in a contractual relationship with the maker who perform acts falling within paragraph 2(a) are fully informed and aware of the following:

(a) that those acts are subject to paragraph 2;

(b) that the placing on the market, import or re-import of the product referred to in point (a)(i) of paragraph 2 could amount to an infringement of the certificate referred to in paragraph 1 where, and as long as, that certificate applies.

7. Paragraph 2 shall apply to certificates that are applied for on or after the entry into force of this Regulation. It shall also apply in the case of certificates for which the basic patent expired on or after 1 January 2021.

Amendment 27

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 469/2009
Article 11 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The ***notification sent to an authority as*** referred to in Article ***4(2)(b)*** shall be published by ***that*** authority ***within 15 days of receipt of the notification.;***	4. The ***the competent industrial property office*** referred to in Article ***9(1)*** shall ***publish without undue delay the information listed in point (c) of Article 5(3). The remaining information notified under Article 5 (3) shall not*** be published by ***the*** authority ***or made available for inspection by the public. However, the office shall provided that information, upon request, to a court or other***

	competent authority for the purposes of any legal proceedings in which Article 5(2) is considered. The national authority shall take appropriate measures to preserve the confidentiality of that information.

Amendment 28

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 469/2009
Article 21a

Text proposed by the Commission	*Amendment*
Article 21a	Article 21a
Evaluation	Evaluation
No later than five years ***after the date referred to in Article 4(5), and*** every ***five years thereafter***, the Commission shall carry out an evaluation of Articles 4(2) to (4) and 11 and present a report on the main findings to the European Parliament, the Council and the European Economic and Social Committee.;	Every ***three*** years, the Commission shall carry out an evaluation of ***the SPC manufacturing waiver pursuant to*** Articles 4(2) to (4) and 11 ***as well as of the SPC system regarding the ability of generics to enter the Union market and the access to medicines and public health,*** and present a report on the main findings to the European Parliament, the Council and the European Economic and Social Committee***. Special account shall be taken on the effects of stockpiling with a view to Day1 entry into the Union market when a certificate expires***;

Amendment 29

Proposal for a regulation
Annex
Regulation (EC) No 469/2009
Annex -I

Text proposed by the Commission	*Amendment*
Annex	Annex -***I***
Logo	***Standard form to be used by makers for notifications under point (b) of Article***

4(2)

a. Name and address of the maker

b. Address(es) of the premises where the making is to take place in the relevant Member State

c. Number of the certificate granted in the relevant Member State, and identification of the product, by reference to its international non-proprietary name, if available;

d. Earliest intended start date of making in the relevant Member State

e. Indicative list of the third country or third countries to which the product is intended to be exported

Amendment 30

Proposal for a regulation
Annex
Regulation (EC) No 469/2009
Annex -I a (new)

Text proposed by the Commission	*Amendment*
	Annex -Ia
	Logo
	

EXPLANATORY STATEMENT

Background

The EU regime concerning the supplementary protection certificate (SPC) for medicinal products was introduced in 1992 and provides for additional patent-like protection for pharmaceutical products subject to market authorisation, by up to 5 years after patent expiry. It seeks to compensate for the loss of patent protection caused by the length of time taken to obtain marketing authorisation for the product in question, thus ensuring that the pharmaceutical industry benefits from a period of effective protection which is enough to cover the investments put into research and working as an incentive for innovation in the EU.

The Commission's Single Market Strategy announced the assessment of a possible exception to the SPC protection in the EU with the aim to boost the competitiveness of EU-based manufacturers of generics and biosimilars and to tackle the competitive disadvantages that they may face vis-à-vis manufacturers located outside the EU in terms of access to export markets where SPC-protection does not exist and of timely entry into EU markets following expiry of the SPC.

In its Resolution of 26 May 2016 on the Single Market Strategy, the European Parliament endorsed the need for actions on the EU SPC regime and urged "*the Commission to introduce and implement before 2019 an SPC manufacturing waiver to boost the competitiveness of the European Generics and Biosimilar Industry in a global environment, as well as to maintain and create additional jobs and growth in the EU, without undermining the market exclusivity granted under the SPC regime in protected markets"*.

To this end, the Commission is now proposing to amend Regulation (EC) No 469/2009 of the European Parliament and of the Council concerning the supplementary protection certificate for medicinal products, with the aim of introducing the so-called 'export manufacturing waiver to SPC', thanks to which, in the future, EU-based companies will be entitled to manufacture a generic or biosimilar version of an SPC-protected medicine during the term of the certificate, if done exclusively for the purpose of exporting to a non-EU market where protection has expired or never existed.

Position of the Rapporteur

Your rapporteur agrees with the purpose of the Commission legislative proposal, which, from his point of view, reflects a rigorous, measured and balanced reconciliation of the interests at stake. It is true that this proposal was put forward in the last year of the legislature and that might create additional difficulties. However, it is also true that, far from being the result of improvisation, it relayed on several in-depth studies, a public consultation and an impact assessment in order to select the option that best contributes to increasing the competitiveness of the EU pharmaceutical sector as a whole.

In this regard, the Rapporteur considers that, without prejudice to the profound respect he has

for different points of view, it would be a mistake to look at this proposal as a mere collision of interests between generic and innovative companies or as a false dichotomy between the most vulnerable and the interests of the largest companies.

Indeed, the generics and biosimilars manufacturers and their great value are not at stake here, since it is undeniable that their emergence in the field of global health has meant a genuine positive revolution in terms of access to essential medicines. That is why the Rapporteur fully supports the proposed introduction of an exception to the SPC protection as a way to remove an unintended legal barrier that was preventing EU-based manufacturers of generics and biosimilars from competing on export markets where competition is fierce and restore a level playing field between EU-based manufacturing and manufacturing in non-EU countries.

Nevertheless, it would be unfair to forget that scientific advances and the development of new medicines are essential to treat diseases and lengthen human life and that a strong intellectual property rights framework is key for encouraging pharmaceutical investment in R&D in the EU. In this context, it is important that SPC-protected medicines retain their full market exclusivity in the EU and that appropriate safeguards are put in place in order to ensure transparency, help the SPC holder to enforce its protection in the EU and avoid the risk of illicit diversion onto the Union market of generics and biosimilars in respect of which the original product is protected by an SPC.

Taking all this into account, the Rapporteur seeks to strike a balance between, on one hand, the imperative to keep the attractiveness of the EU as a hub for investments in innovative pharmaceutical research and, on the other hand, the need to ensure the competitiveness of EU-based manufacturers of generics and biosimilars and create the conditions for them to compete on equal terms on the fast-growing global markets. To this end, the rapporteur considers that further clarifications and adjustments should be made to the proposal and presents in this draft report a series of amendments. These amendments do not go beyond the scope of the Commission's proposal, but aim at making its implementation more streamlined and transparent, while keeping the proposal targeted, proportionate and balanced and taking into account the interests of the various stakeholders.

In this vein, amendments were introduced to clarify that only export to third countries outside the EU is covered by the exception (recital 3) and to identify more explicitly the objectives that this proposal intends to achieve (recital 7).

Changes were also made to bring the text in line with the definitions of 'product' and 'medicinal product' provided for in points (a) and (b) of Article 1 of Regulation (EC) No 469/2009 and clarify the subject matter of the exception (point (i) of article 4, paragraph 2, point (a) and recitals 7, 8 and 9).

In order to ensure a more robust and transparent implementation of the safeguards provided for in the Commission's proposal, an additional requirement to inform directly the SPC holders of the intention to make a product pursuant to the exception was included in the text. This obligation is without prejudice to the protection of confidential or commercially sensitive information (see also in this regard the proposed deletion of point (d) of Article 4, paragraph 3) and aims at ensuring that the SPC holders have access to the necessary information in order to assess whether the conditions to benefit from the exception are respected and there are no infringements of their IP rights (recital 13a and Article 4, paragraph 2, point (ba) new).

Along the same line and so that parties can be granted enough time to verify if the conditions for the application of the exception are fulfilled, the Rapporteur also proposes to extend to three months the deadline for the notification to the competent industrial property authority and for informing the SPC holder (recitals 13, Article 4, paragraph 2, points (b) and (ba) new).

In the same vein, a clarification is added to the relevant parts of the text to ensure that both the competent authority and the SPC holder are informed of any changes or updates of the information provided to them (Article 4, paragraph 2, point (bc) new).

A new standard form for the notification to the authority is also added as Annex I to the proposal (Article 4, paragraph 3a).

As to the publication of the information provided by the maker, this obligation is limited to certain elements, in view of the introduction of an obligation of the maker to inform directly the SPC holder and in line with the objective of protection of confidential or commercially sensitive information (Article 11, paragraph 4).

Regarding the anti-diversion measures, an addition is made to Recital 17 to clarify that this Regulation does not affect the rules on the unique identifier provided for in Commission Delegated Regulation (EU) 2016/161.

Finally, concerning the application in time of this Regulation, the Rapporteur proposes that the exception applies in the case of the certificates whose basic patent expired on or after 2023. This solution took into consideration: the importance of tackling the identified problems as soon as possible, as well as ensuring legal certainty by providing for a uniform date of application of the waiver, but also the need to propose a transitional period long enough to ensure the protection of acquired rights and previous investment decisions and give the market players and the authorities a reasonable time to adapt themselves to the changed legal context.

3.12.2018

OPINION OF THE COMMITTEE ON INTERNATIONAL TRADE

for the Committee on Legal Affairs

on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products
(COM(2018)0317 – C8-0217/2018 – 2018/0161(COD))

Rapporteur for opinion: Lola Sánchez Caldentey

AMENDMENTS

The Committee on International Trade calls on the Committee on Legal Affairs, as the committee responsible, to take into account the following amendments:

Amendment 1

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2 a) The timely entry of generics and biosimilars onto the Union market is important for increasing competition, reducing prices and ensuring the sustainability of healthcare systems; and amending Regulation (EC) No 469/2009 so as to allow the production of generics and biosimilars for export and storage does not conflict with intellectual property rights, which remain one of the cornerstones of innovation, competitiveness and growth in the Member States. The proposal does not

	interfere with the duration of market exclusivity rights during the patent, which is underscored by the fact that immediate import is allowed after expiry, but represents a competitive disadvantage for the European generic medicines industry. The proposal takes into account the concerns expressed by the European Parliament and by the Council regarding that the increasing number of examples of market failure in a number of Member States, where patients access to effective and affordable essential medicines is endangered by very high and unsustainable price levels.

Amendment 2

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) Since the adoption in 1992 of the predecessor to Regulation (EC) No 469/2009, markets have evolved significantly and there has been huge growth in the manufacture of generics and especially of biosimilars, in particular in third countries where protection does not exist or has expired.	(3) Since the adoption in 1992 of the predecessor to Regulation (EC) No 469/2009, markets have evolved significantly and there has been huge growth in the manufacture of generics and especially of biosimilars, in particular in ***countries outside the EU ('***third countries***')*** where protection does not exist or has expired.

Justification

Clarification of the countries to which the regulation applies.

Amendment 3

Proposal for a regulation
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) Pharmaceuticals are one of the pillars of healthcare rather than a mere object of trade. Insufficient access to

essential medicinal products and high prices of innovative medicines pose a serious threat to the sustainability of national health care systems, and a serious threat to patients.

Amendment 4

Proposal for a regulation
Recital 3 b (new)

Text proposed by the Commission	*Amendment*
	(3b) The Council, in its conclusions on strengthening the balance in the pharmaceutical systems in the Union and its Member States, has underlined the importance of timely availability of generics and biosimilars in order to facilitate patients' access to pharmaceutical therapies and to improve the sustainability of national health systems.

Amendment 5

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) The absence of any exception in Regulation (EC) No 469/2009 to the protection conferred by a supplementary protection certificate has had the unintended consequence of preventing manufacturers of generics and biosimilars established in the Union from manufacturing, ***even for the exclusive purpose of exporting to third country markets in which such protection does not exist or has expired. A further unintended consequence is that the protection conferred by the certificate makes it more difficult for those manufacturers*** to enter the Union market immediately after expiry of the certificate, given that they are not in	(4) The absence of any exception in Regulation (EC) No 469/2009 to the protection conferred by a supplementary protection certificate has had the unintended consequence of preventing manufacturers of generics and biosimilars established ***within*** the Union from manufacturing, ***with a view*** to enter the Union market immediately after expiry of the certificate ***and/or export to countries outside the Union ('third countries') in which*** protection does not exist or has expired, given that they are not in a position to build up production capacity until the protection provided by the certificate has lapsed, by contrast with

a position to build up production capacity until the protection provided by the certificate has lapsed, by contrast with manufacturers located in third countries where protection does not exist or has expired.	manufacturers located in third countries where protection does not exist or has expired.

Amendment 6

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) The aim of this Regulation is to ensure that manufacturers established in the Union are able to compete effectively in those third country markets where supplementary protection does not exist or has expired. It is intended to complement the efforts of the Union's trade policy to ensure open markets for Union-based manufacturers of medicinal products. ***Indirectly,*** it is also intended to put those manufacturers in a better position to enter the Union market immediately after expiry of the relevant supplementary protection certificate. It would also help to serve the aim of fostering access to medicines in the Union by helping to ensure a swifter entry of generic and biosimilar medicines onto the market after expiry of the relevant certificate.	(7) The aim of this Regulation is to ensure that manufacturers established in the Union are able to compete effectively in those third country markets where supplementary protection does not exist or has expired. It is intended to complement the efforts of the Union's trade policy to ensure open markets for Union-based manufacturers of medicinal products. It is also intended to put those manufacturers in a better position to enter the Union market immediately after expiry of the relevant supplementary protection certificate***, i.e. day-1 entry***. It would also help to serve the aim of fostering access to medicines in the Union by helping to ensure a swifter entry of generic and biosimilar medicines onto the market after expiry of the relevant certificate.

Amendment 7

Proposal for a regulation
Recital 8

Text proposed by the Commission	*Amendment*
(8) In those specific and limited circumstances, and in order to create a level playing field between Union-based manufacturers and third country	(8) In those specific and limited circumstances, and in order to create a level playing field between Union-based manufacturers and third country

manufacturers, it is appropriate to ***restrict the protection conferred by*** a supplementary protection certificate so as to ***allow*** making for the exclusive purpose of export to third countries and any related acts strictly necessary for making or for the actual export itself.

manufacturers, ***and to offer better access to generic and biosimilar medicines to Union citizens,*** it is appropriate to ***overcome the above mentioned unintended effects deriving from*** a supplementary protection certificate so as to ***enable (i)*** the making ***exclusively for*** export to third countries ***and (ii) entry onto the Union market immediately after expiry of the relevant supplementary protection certificate, as well as*** and any related acts strictly necessary for ***that*** making or for the actual export ***or that entry onto the Union market*** itself.

Amendment 8

Proposal for a regulation
Recital 9

Text proposed by the Commission	*Amendment*
(9) That exception should cover the making of the product, including the product which corresponds to the medicinal product protected by a supplementary protection certificate in the territory of a Member State, for the exclusive purpose of export to third countries, as well as any upstream or downstream acts by the maker or by third parties in a contractual relationship with the maker, where such acts would otherwise require the consent of the certificate-holder, and are strictly necessary for making for the purpose of export ***or*** for the actual export itself. For instance, such acts may include the supply and import of active ingredients for the purpose of making the medicinal product to which the product covered by the certificate corresponds, or temporary storage of the product or advertising for the exclusive purpose of export to third ***country destinations.***	(9) That exception should cover the making of the product, including the product which corresponds to the medicinal product protected by a supplementary protection certificate in the territory of a Member State, for the exclusive purpose of export to ***countries outside the Union ('***third countries***') and to prepare for Day-1 entry in the Union's market***, as well as any upstream or downstream acts by the maker or by third parties in a contractual relationship with the maker, where such acts would otherwise require the consent of the certificate-holder, and are strictly necessary for making for the purpose of export***,*** for the actual export itself ***and for Day-1 entry***. For instance, such acts may include the supply and import of active ingredients for the purpose of making the medicinal product to which the product covered by the certificate corresponds, or temporary storage of the product or advertising for the exclusive purpose of export to ***markets in countries outside the Union ('***third ***countries') or Day-1 entry in the Union's***

market.

Amendment 9

Proposal for a regulation
Recital 11

Text proposed by the Commission	*Amendment*
(11) By limiting the scope of the exception to making for the ***purpose*** of export outside the Union and acts strictly necessary for such making or for the actual export itself, the exception introduced by this Regulation will not unreasonably conflict with normal exploitation of the product in the Member State where the certificate is in force, nor unreasonably prejudice the legitimate interests of the certificate-holder, taking account of the legitimate interests of third parties.	(11) By limiting the scope of the exception to making for the ***purposes*** of ***day-1 entry*** and of export outside the Union and acts strictly necessary for such making or for the actual export itself, the exception introduced by this Regulation will not conflict with normal exploitation of the product in the Member State where the certificate is in force, nor prejudice the legitimate interests of the certificate-holder, taking account of the legitimate interests of third parties. ***In this regard, the Commission's study[1a] states that "neither the production for export, nor the production for stockpiling purposes run counter to the legal objectives of the SPC system", and "arguably the only effect of prohibiting stockpiling would be to boost the business opportunities of non-EU companies to the disadvantage of generic manufacturers established here."***

Amendment 10

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) Safeguards should accompany the exception ***in order to increase transparency***, ***to help*** the holder of a supplementary protection certificate to ***enforce its protection in the Union and to reduce the risk of illicit diversion onto the***	(12) ***Reasonable, proportionate and appropriate*** safeguards should accompany the exception***, for the exclusive purpose of helping*** the holder of a supplementary protection certificate to ***check compliance with the conditions set out hereunder, but***

Union market during the term of the certificate.

without affecting fair competition among companies. The safeguards should ensure the necessary confidentiality and protection of commercially sensitive information of the applicant, in compliance with existing EU legislation and recommendations, such as Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on trade secrets and the EMA/HMA Guidance Document on the identification of commercially confidential information and personal data.

Amendment 11

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) To this end, this Regulation should impose a once-off duty on the person ***making the product for the exclusive purpose of export***, requiring that person to provide certain information to the authority which granted the supplementary protection certificate in the Member State where the making is to take place. The information should be provided before the making is intended to start for the first time in that Member State. The making and related acts, including those performed in Member States other than the one of making in cases where the product is protected by a certificate in those other Member States too, should only fall within the scope of the exception where the maker has sent this notification to the competent industrial property authority (or other designated authority) of the Member State of making. The once-off duty to provide information to the authority should apply in each Member State where making is to take place, both as regards the making in that Member State, and as regards related acts, whether performed in that or another	(13) To this end, ***to the extent it intends to rely on the exception and in the interest of transparency,*** the person ***responsible*** for the ***making ('the maker'), or any*** person ***acting on its behalf should*** provide ***a warning letter to the registered holder(s) of the certificate, at its (their) registered address(es). This letter should not include commercially sensitive information or confidential details of a company business plan, to limit any anti-competitive effects. To that end, the information required in the warning letter should notably comply with existing EU legislation and recommendations, such as Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June2016 on trade secrets and the EMA/HMA Guidance Document on the identification of commercially confidential information and personal data. For the same reasons, the warning letter and the information it contains should be treated as strictly confidential by the holder of the certificate and should not be used by the holder of the certificate for any other***

Member State, related to that making. The authority should ***be required to publish that*** information***, in the interests of transparency and for the purpose of informing*** the holder of the certificate ***of the maker's intention.***

purpose than ensuring that the maker has complied with the scope and conditions of the exception. This Regulation should***, additionally,*** impose a once-off duty on the person making the product, requiring that person to provide certain information to the authority which granted the supplementary protection certificate in the Member State where the making is to take place. The information should be provided before the making is intended to start for the first time in that Member State. The making and related acts, including those performed in Member States other than the one of making in cases where the product is protected by a certificate in those other Member States too, should only fall within the scope of the exception where the maker has sent this notification to the competent industrial property authority (or other designated authority) of the Member State of making***.*** The once-off duty to provide information to the authority should apply in each Member State where making is to take place, both as regards the making in that Member State, and as regards related acts, whether performed in that or another Member State, related to that making. The authority should ***keep the notification and the*** information ***it contains confidential and specific measures should be taken to protect such confidentiality. The authority may only disclose the information to*** the holder of the certificate ***only if disclosure is ordered by a court (i) upon request from the holder*** of the ***certificate (and other persons entitled under national law to start an infringement action on the basis of the certificate), (ii) after the maker was given the opportunity to attend and to be heard, (iii) if the holder of the certificate has, in a justified and proportionate manner, provided evidence rendering plausible that the maker did not comply with the conditions for the exception to apply, and (iv) if the holder of the certificate and the court have taken appropriate measures to keep the notification and the information it***

contains confidential and avoid their disclosure to third parties. The maker should be required to inform the competent authority as well as the certificate holder of any changes to the information provided in the notifications.

Amendment 12

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(14) In addition, this Regulation should impose certain due diligence requirements on the maker as a condition for the exception to operate. The maker should be required to inform ***persons*** within its supply chain, through appropriate means, in particular contractual means, that the product is covered by the exception introduced by this Regulation and is intended for the exclusive purpose of export. A maker who failed to comply with these due diligence requirements would not benefit from the exception, nor would any third party performing a related act in the same or a different Member State where a certificate conferring protection for the product was in force, and the holder of the relevant certificate would therefore be entitled to enforce its rights under the certificate.	(14) In addition, this Regulation should impose certain due diligence requirements on the maker as a condition for the exception to operate. The maker should be required to inform ***the undertakings*** within its supply chain, through appropriate means, in particular contractual ***or documented*** means, that the product is covered by the exception introduced by this Regulation and is intended for the exclusive purpose of export ***or Day-1 entry***. A maker who failed to comply with these due diligence requirements would not benefit from the exception, nor would any third party performing a related act in the same or a different Member State where a certificate conferring protection for the product was in force, and the holder of the relevant certificate would therefore be entitled to enforce its rights under the certificate.

Amendment 13

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) This Regulation does not affect the application of Union measures that aim to prevent infringements and facilitate	(17) This Regulation does not affect the application of Union measures that aim to prevent infringements and facilitate

enforcement of intellectual property rights, including Directive 2004/48/EC of the European Parliament and of the Council[41] ***and*** Regulation (EU) No 608/2013 of the European Parliament and of the Council[42] .

enforcement of intellectual property rights, including Directive 2004/48/EC of the European Parliament and of the Council[41], Regulation (EU) No 608/2013 of the European Parliament and of the Council[42] ***and the unique identifier established in Commission Delegated Regulation (EU) 2016/161***.

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[41] Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L157, 30.4.2004, p. 45).

[42] Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights (OJ L 181, 29.6.2013, p. 15).

[41] Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L157, 30.4.2004, p. 45).

[42] Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights (OJ L 181, 29.6.2013, p. 15).

Amendment 14

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(19) In order to ***ensure that holders of supplementary protection certificates already in force are not deprived of their acquired rights***, the exception provided for in this Regulation should ***only*** apply ***to certificates that are granted on or after a specified date*** after entry into force, ***irrespective of when the application for the certificate was first lodged. The date specified should allow*** a reasonable time for applicants and other relevant market players to adjust to the changed legal context and to make appropriate investment and manufacturing location decisions in a timely way. ***The date should also allow sufficient time for public authorities to put in place appropriate arrangements to receive and publish***	(19) In order to ***boost the potential benefits for patients and for generics and biosimilars' producers established in the Union, the entry into*** force ***of*** the exception provided for in this Regulation should ***be within a reasonable timeframe so as*** to ensure that holders of supplementary protection certificates ***are able to adapt to the waiver,*** the exception ***provided should become applicable to certificates for which the basic patent expires*** after ***the*** entry into force ***of this*** Regulation, which ***allows*** a reasonable time for applicants and other relevant market players to adjust to the changed legal context and to make appropriate investment and manufacturing location decisions in a timely way.

notifications of the intention to make, and should take due account of pending applications for certificates.

Amendment 15

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(21) It is necessary and appropriate for the achievement of the basic objective, of providing a level playing field for generic and biosimilar manufacturers with their competitors in third country markets where protection does not exist or has expired, to lay down rules ***restricting the exclusive right of a supplementary protection certificate holder to make*** the product in question during the term of the certificate, and also to impose certain information ***and labelling*** obligations on makers wishing to take advantage of those rules. This Regulation complies with the principle of proportionality, and does not go beyond what is necessary in order to achieve the objectives pursued, in accordance with Article 5(4) of the Treaty on European Union.	(21) It is necessary and appropriate for the achievement of the basic objective, of providing a level playing field for generic and biosimilar manufacturers with their competitors in third country markets where protection does not exist or has expired, ***and to improve access to medicines for the Union citizens,*** to lay down rules ***enabling the making of*** the product in question during the term of the certificate, and also to impose certain information obligations on makers wishing to take advantage of those rules. This Regulation complies with the principle of proportionality, and does not go beyond what is necessary in order to achieve the objectives pursued, in accordance with Article 5(4) of the Treaty on European Union.

Amendment 16

Proposal for a regulation
Recital 22

Text proposed by the Commission	*Amendment*
(22) This Regulation respects fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union. In particular, this Regulation seeks to ensure full respect for the right to property in Article 17 of the Charter by	(22) This Regulation respects fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union. In particular, this Regulation seeks to ensure full respect for the right to property in Article 17 of the Charter by

maintaining the core rights of the supplementary protection certificate, by confining the exception to certificates granted on or after a specified date after entry into force of this Regulation and by imposing certain conditions on the application of the exception.	maintaining the core rights of the supplementary protection certificate***, the right to health care in Article 35 of the Charter by making medicines more accessible to EU patients, the principle of proportionality in Article 52 of the Charter, point (a) of Article 6 TFEU on the right to health protection for European citizens, while allowing a reasonable predictability for applicants and other relevant market players, by confining the exception to certificates for which the basic patent expires*** after ***the*** entry into force of this Regulation and by imposing certain conditions on the application of the exception.

Amendment 17

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) No 469/2009
Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The certificate referred to in paragraph 1 shall not confer protection against a particular act against which the basic patent conferred protection if, with respect to that particular act, the following conditions are met:	2. The certificate referred to in paragraph 1 shall not confer protection against a particular act against which the basic patent conferred protection if, with respect to that particular act, the following conditions are met:
(a) the act comprises:	(a) the act comprises:
(i) making for the exclusive purpose of export to third countries; or	(i) making for ***either:***
	a. the exclusive purpose of export to countries ***outside the European Union ('third countries') where no protection for the medicinal product exists or has expired***; or
	b. the exclusive purpose of selling or offering to sell in the Union market immediately after expiry of the certificate;
(ii) any related act that is strictly necessary for that making or for the actual	(ii) any related act that is strictly necessary for that making***, storing,*** or for

export itself;	the actual export itself;
	(iia) importing for the purposes of (i)
(b) the authority referred to in Article 9(1) of the Member State where that making is to take place ('the relevant Member State') is notified by the person doing the making ('the maker') of the information listed in paragraph 3 no later than ***28*** days before the intended start date of making in that Member State;	(b) the authority referred to in Article 9(1) of the Member State where making is to take place ('the relevant Member State') is notified by the person doing the making ('the maker') of the information listed in paragraph 3 no later than ***60*** days before the intended start date of making in that Member State;
(c) ***the maker ensures that a logo, in the form set out in Annex -I, is affixed to the outer packaging of the product or, if there is no outer packaging, to its immediate packaging;***	(c) ***The certificate holder is informed, in writing, by the maker, that a notification has been sent pursuant to paragraph 2(b) and is provided with the information listed in of paragraph 3 (c) of this article no later than 60 days before the start date of making in that Member State and in advance of any related act prior to that making that would otherwise be prohibited by the protection conferred by a certificate; the SPC holder should keep the warning letter and the information it contains strictly confidential and should not use them for any other purpose than ensuring that the maker has complied with the scope***
(d) the maker complies with the requirements of paragraph 4.	(d) the maker complies with the requirements of paragraph 4.
	If the information referred to in point (b) of the first subparagraph changes, the maker shall notify the authority referred to in Article 9(1) before these changes take effect. The notification and the information it contains should be kept confidential. The authority may only disclose the information to the SPC holder if disclosure is ordered by a court.

Amendment 18

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) No 469/2009
Article 4 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The information for the purposes of paragraph 2(b) shall be as follows:	3. The information for the purposes of paragraph 2(b) shall be ***treated as strictly confidential and be*** as follows:
(a) the name and address of the maker;	(a) the name and address of the maker;
(b) ***the address, or addresses, of the premises where the making is to take place in*** the relevant Member State;	(b) the relevant Member State ***where the making is to take place***;
(c) the number of the certificate granted in the relevant Member State, and identification of the product, by reference to the proprietary name used by the holder of that certificate;	(c) the number of the certificate granted in the relevant Member State, and identification of the product, by reference to the proprietary name used by the holder of that certificate;
(d) the number of the authorisation granted in accordance with Article 40(1) of Directive 2001/83/EC or Article 44(1) of Directive 2001/82/EC for the manufacture of the corresponding medicinal product or, in the absence of such authorisation, a valid certificate of good manufacturing practice as referred to in Article 111(5) of Directive 2001/83/EC or Article 80(5) of Directive 2001/82/EC covering the premises where the making is to take place;	
(e) the ***intended*** start date of making in the relevant Member State;	(e) the start date of making in the relevant Member State;
(f) an indicative list of the intended third country or third countries to which the product is to be exported.	

Amendment 19

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) No 469/2009
Article 4 – paragraph 5

Text proposed by the Commission	*Amendment*
5. ***Paragraph*** 2 shall apply in the case only of certificates granted on or after [OP: please insert the date of the first day of the	5. ***The exception set out in paragraph*** 2 shall apply in the case only of certificates ***for which the basic patent expires*** after

third month that follows the month in which this amending Regulation is published in the Official Journal)].';

[OP: please insert the date of the first day of the third month that follows the month in which this amending Regulation is published in the Official Journal)];

Amendment 20

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EC) No 469/2009
Article 11 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The notification ***sent to an authority as*** referred to in Article 4(2)(b) ***shall be published by that*** authority ***within 15 days of receipt of*** the notification.	4. The ***authority referred to in Article 9(1) shall keep the*** notification referred to in Article ***4 (2) (b) and the information listed in paragraph 3 confidential and*** shall ***take appropriate measures to preserve such confidentiality.***
	The authority ***shall only disclose*** the notification ***and the information it contains if such disclosure is ordered by a court having competence under national law to hear an infringement action based on the certificate. A court shall only order such disclose if at least the following conditions are met:***
	(a) the person requesting the disclosure is the holder of the certificate (or a person entitled under national law to start an infringement action on the basis of the certificate
	(b) the maker is given the opportunity to attend the proceedings and to be heard before the court;
	(c) the holder of the certificate has, in a justified and proportionate manner, provided evidence rendering plausible that the maker did not comply with the conditions set out in paragraph 2;
	(d) the holder of the certificate and the court have taken appropriate measures to keep the notification and the information it contains confidential and avoid their

disclosure to third parties.

Amendment 21

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 469/2009
Article 21a – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	In the evaluation a specific chapter shall be dedicated to the effects of the entry into force of the amended Regulation on the development of local generic and biosimilar industry of third countries, particularly developing countries.

Amendment 22

Proposal for a regulation
Annex

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

PROCEDURE – COMMITTEE ASKED FOR OPINION

Title	Supplementary protection certificate for medicinal products
References	COM(2018)0317 – C8-0217/2018 – 2018/0161(COD)
Committee responsible Date announced in plenary	JURI 2.7.2018
Opinion by Date announced in plenary	INTA 2.7.2018
Rapporteur Date appointed	Lola Sánchez Caldentey 20.6.2018
Discussed in committee	5.11.2018
Date adopted	3.12.2018
Result of final vote	+: 20 –: 11 0: 1
Members present for the final vote	David Borrelli, David Campbell Bannerman, Santiago Fisas Ayxelà, Eleonora Forenza, Karoline Graswander-Hainz, Christophe Hansen, Heidi Hautala, Nadja Hirsch, France Jamet, Jude Kirton-Darling, Bernd Lange, David Martin, Emmanuel Maurel, Anne-Marie Mineur, Godelieve Quisthoudt-Rowohl, Inmaculada Rodríguez-Piñero Fernández, Tokia Saïfi, Joachim Schuster, Adam Szejnfeld, Iuliu Winkler
Substitutes present for the final vote	Reimer Böge, Klaus Buchner, Sajjad Karim, Gabriel Mato, Ralph Packet, Frédérique Ries, Pedro Silva Pereira, Jarosław Wałęsa
Substitutes under Rule 200(2) present for the final vote	Birgit Collin-Langen, Jonás Fernández, Alojz Peterle, Kosma Złotowski

FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

20	+
ECR	Kosma Złotowski
ENF	France Jamet
GUE/NGL	Eleonora Forenza, Emmanuel Maurel, Anne-Marie Mineur
NI	David Borrelli
PPE	Alojz Peterle, Adam Szejnfeld, Jarosław Wałęsa, Iuliu Winkler
S&D	Jonás Fernández, Karoline Graswander-Hainz, Jude Kirton-Darling, Bernd Lange, David Martin, Inmaculada Rodríguez-Piñero Fernández, Joachim Schuster, Pedro Silva Pereira
VERTS/ALE	Klaus Buchner, Heidi Hautala

11	-
ALDE	Nadja Hirsch, Frédérique Ries
ECR	David Campbell Bannerman, Sajjad Karim, Ralph Packet
PPE	Reimer Böge, Birgit Collin-Langen, Santiago Fisas Ayxelà, Christophe Hansen, Gabriel Mato, Godelieve Quisthoudt-Rowohl

1	0
PPE	Tokia Saïfi

Key to symbols:
+ : in favour
- : against
0 : abstention

27.11.2018

OPINION OF THE COMMITTEE ON THE ENVIRONMENT, PUBLIC HEALTH AND FOOD SAFETY

for the Committee on Legal Affairs

on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products
(COM(2018)0317 – C8-0217/2018 – 2018/0161(COD))

Rapporteur for opinion: Tiemo Wölken

SHORT JUSTIFICATION

In line with the European Parliaments position on EU options for improving access to medicines (2016/2057(INI)), the rapporteur welcomes the proposal for a regulation amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products.

Currently EU-based manufacturers of generics and/or biosimilar face problems on the EU Single Market which put them at a disadvantage compared to manufacturers located outside of the Union.

The rapporteur therefore intends to restore the level playing field between EU-based generic and biosimilar manufacturers and non EU-based ones, boosting the competitiveness of EU-based generic and biosimilar manufacturers especially in respect to the export to those countries where no supplementary protection certificate is in place, as well as facilitating Day-1 entry within the Union. For this, the rapporteur not only supports a manufacturing waiver for export, but also supports introducing a stockpiling waiver, giving generic and/or biosimilar manufacturers more incentives to manufacture within the Union and not in third countries.

The prices of new medicines have increased during the past decades to the point of sometimes being unaffordable for many European citizens, limiting their “right to benefit from medical treatment”, as stated in the Charter of Fundamental Rights of the EU. The entry of generics and biosimilar onto the EU market is important for reducing prices, ensuring sustainability of healthcare systems, whilst also having a positive effect on national health budgets. The faster entry into the EU market gives European citizens faster access to affordable medicinal

products. The introduction of the SPC Manufacturing Waiver helps to reduce barriers to access to medicines, including shortages of essential and other medicines. Producing within the EU can lead to enhanced security and quality of supply, reduced counterfeits and uncertainty due to import reliance.

Introducing the manufacturing and stockpiling waver will also strengthen the generic and biosimilar sector in Europe, and reinforce the EU's position as a hub for pharmaceutical innovation and manufacture, especially in the field of biosimilars, creating jobs and ensuring expertise remains within the Union.

AMENDMENTS

The Committee on the Environment, Public Health and Food Safety calls on the Committee on Legal Affairs, as the committee responsible, to take into account the following amendments:

Amendment 1

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) By providing for a period of supplementary protection of up to five years, Regulation (EC) No 469/2009 seeks to promote, within the Union, the research and innovation that is necessary to develop medicinal products, and to contribute to preventing the relocation of pharmaceutical research outside the Union to countries that may offer greater protection.	(2) By providing for a period of supplementary protection of up to five years, Regulation (EC) No 469/2009 seeks to ***provide a solution at Union level to prevent national legislation creating new disparities, which could hinder the free movement of medicines within the internal market while promoting***, within the Union, the research and innovation that is necessary to develop ***newer generation*** medicinal products ***that support the treatment of new diseases or offer better therapeutic effects, and contributing*** to preventing the relocation of pharmaceutical research outside the Union to countries that may offer greater protection.

Amendment 2

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) The proposal to amend the regulation so as to allow the production of generics and biosimilars for export and storage to make it possible for them to enter the Union market when the patent expires does not conflict with intellectual property rights, as they do not interfere with the duration of market exclusivity rights during the patent, which is underscored by the fact that immediate import is allowed after expiry, but represents a competitive disadvantage for the Union generic medicines industry.

Amendment 3

Proposal for a regulation
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) The timely entry of generics and biosimilars onto the Union market is important for increasing competition, reducing prices and ensuring the sustainability of healthcare systems.

Amendment 4

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) The absence of any exception in Regulation (EC) No 469/2009 to the protection conferred by a supplementary protection certificate has had the unintended consequence of preventing manufacturers of generics and biosimilars established in the Union from manufacturing, ***even for the exclusive*** purpose of exporting to third country markets in which such protection does not	(4) The absence of any exception in Regulation (EC) No 469/2009 to the protection conferred by a supplementary protection certificate has had the unintended consequence of preventing manufacturers of generics and biosimilars established in the Union from manufacturing ***such products***, ***with a view to enter the Union market immediately after expiry and/or for the*** purpose of

exist or has expired. A further unintended consequence is that the protection conferred by the certificate makes it more difficult for those manufacturers to enter the Union market immediately after expiry of the certificate, given that they are not in a position to build up production capacity until the protection provided by the certificate has lapsed, by contrast with manufacturers located in third countries where protection does not exist or has expired.

exporting to third country markets in which such protection does not exist or has expired. A further unintended consequence is that the protection conferred by the certificate makes it more difficult for those manufacturers to enter the Union market immediately after expiry of the certificate, given that they are not in a position to build up production capacity until the protection provided by the certificate has lapsed, by contrast with manufacturers located in third countries where protection does not exist or has expired.

Amendment 5

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) This puts manufacturers of generics and biosimilars established in the Union at a significant competitive disadvantage compared with manufacturers based in third countries that offer less or no protection.	(5) This puts manufacturers of generics and biosimilars established in the Union at a significant competitive disadvantage compared with manufacturers based in third countries that offer less or no protection***, which also leads to higher prices for medical products***.

Amendment 6

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) The aim of this Regulation is to ensure that manufacturers established in the Union are able to compete effectively in those third country markets where supplementary protection does not exist or has expired. It is intended to complement the efforts of the Union's trade policy to ensure open markets for Union-based manufacturers of medicinal products. Indirectly, it is also intended to put those manufacturers in a better position to enter the Union market immediately after expiry	(7) The aim of this Regulation is to ensure that manufacturers established in the Union are able to compete effectively in those third country markets where supplementary protection does not exist or has expired***, and to ensure the entry of generics and biosimilar medicines onto the Union market from Day-1 after the expiry of the relevant supplementary protection certificate, thus fostering access to medicines***. It is intended to complement the efforts of the Union's

of the relevant supplementary protection certificate. It would also help to serve the aim of fostering access to medicines in the Union by helping to ensure a swifter entry of generic and biosimilar medicines onto the market after expiry of the relevant certificate.	trade policy to ensure open markets for Union-based manufacturers of medicinal products. It is also intended to put those manufacturers in a better position to enter the Union market immediately after expiry of the relevant supplementary protection certificate***, namely the Day-1 entry***. It would also help to serve the aim of fostering access to medicines in the Union ***and thereby help to prevent shortages of certain medicines,*** by helping to ensure a swifter entry of generic and biosimilar medicines onto the market after expiry of the relevant certificate.

Amendment 7

Proposal for a regulation
Recital 8

Text proposed by the Commission	*Amendment*
(8) In ***those*** specific and limited circumstances, ***and in order to create a level playing field between Union-based manufacturers and third country manufacturers,*** it is appropriate to restrict the protection conferred by a supplementary protection certificate so as to ***allow making for the exclusive purpose of*** export to third countries ***and any related acts*** strictly necessary for ***making or for the actual export itself.***	(8) In ***these*** specific and limited circumstances, it is appropriate to restrict the protection conferred by a supplementary protection certificate***, but not any other intellectual property right, in order to eliminate the aforementioned, unintended side effects of the*** supplementary protection certificate so as to ***enable a level-playing field between Union-based manufacturers and those in third countries. This would enable manufacturing exclusively for (i)*** export to third countries***, as well as for any other acts that are*** strictly necessary for ***this manufacturing and (ii) entry onto the Union market as soon as the supplementary protection certificate expires***.

Amendment 8

Proposal for a regulation
Recital 9

Text proposed by the Commission	*Amendment*
(9) That exception should cover the	(9) That exception should cover the

making of the product, including the product which corresponds to the medicinal product protected by a supplementary protection certificate in the territory of a Member State, for the exclusive purpose of export to third countries, as well as any upstream or downstream acts by the maker or by third parties in a contractual relationship with the maker, where such acts would otherwise require the consent of the certificate-holder, and are strictly necessary for making for the purpose of export ***or*** for the actual export itself. For instance, such acts may include the supply and import of active ingredients for the purpose of making the medicinal product to which the product covered by the certificate corresponds, or temporary storage of the product or advertising for the exclusive purpose of export to third country destinations.	making of the product, including the product which corresponds to the medicinal product protected by a supplementary protection certificate in the territory of a Member State, for the exclusive purpose of export to third countries ***and to prepare for Day-1 entry onto the Union market*** as well as any upstream or downstream acts by the maker or by third parties in a contractual relationship with the maker, where such acts would otherwise require the consent of the certificate-holder, and are strictly necessary for making for the purpose of export***,*** for the actual export itself ***and for Day-1 entry***. For instance, such acts may include the supply and import of active ingredients for the purpose of making the medicinal product to which the product covered by the certificate corresponds, or temporary storage of the product or medicinal product, advertising for the exclusive purpose of export to third country destinations ***or Day-1 Entry***.

Amendment 9

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(10) The exception should not cover placing ***the*** product made for the exclusive purpose of export on the market in the Member State where a supplementary protection certificate is in force, either directly or indirectly after export, nor should it cover re-importation of the product to the market of a Member State in which a certificate is in force. Moreover, it should not cover any act or activity for the purpose of import of medicinal products, or parts of medicinal products, into the Union merely for the purposes of repackaging and re-exporting.	(10) The exception should not cover placing ***a medicinal*** product made for the exclusive purpose of export ***or Day-1 entry*** on the market in the Member State where a supplementary protection certificate is in force, either directly or indirectly after export nor should it cover re-importation of the ***medicinal*** product to the market of a Member State in which a certificate is in force. Moreover, it should not cover any act or activity for the purpose of import of medicinal products, or parts of medicinal products, into the Union merely for the purposes of repackaging and re- exporting***, i.e. their re-export from third countries to the Union***.

Amendment 10

Proposal for a regulation
Recital 11

Text proposed by the Commission	*Amendment*
(11) ***By limiting the*** scope of the exception to making for the purpose of export outside the Union and acts strictly necessary for such making or for the actual export itself, the exception introduced by this Regulation will not ***unreasonably*** conflict with normal exploitation of the product in the Member State where the certificate is in force, nor ***unreasonably*** prejudice the legitimate interests of the certificate-holder, taking account of the legitimate interests of third parties.	(11) ***The*** scope of the exception ***is limited*** to making ***for Day-1 entry and*** for the purpose of export outside the Union and ***to*** acts strictly necessary for such making or for the actual export itself, ***and therefore*** the exception introduced by this Regulation will not conflict with normal exploitation of the product ***or medicinal product*** in the Member State where the certificate is in force, nor prejudice the legitimate interests of the certificate-holder, taking account of the legitimate interests of third parties.

Amendment 11

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) ***Safeguards*** should accompany the exception ***in order to increase transparency, to help*** the holder of a supplementary protection certificate to ***enforce its protection in the Union and to reduce the risk of illicit diversion onto the Union market during the term*** of the ***certificate***.	(12) ***Reasonable and proportionate safeguards*** should accompany the exception***, for the exclusive purpose of helping*** the holder of a supplementary protection certificate to ***check compliance with the conditions set out hereunder. Those safeguards should not negatively affect competition among companies and should allow the exception to work effectively with no disruption on the main objectives*** of the ***exception. At the same time the safeguards should also ensure the necessary confidentiality and protection of commercially sensitive information of the applicant***.

Amendment 12

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) To this end, ***this Regulation should impose a once-off duty on*** the person ***making the product for the exclusive purpose of export, requiring that person to provide certain information*** to the authority which granted the supplementary protection certificate in the Member State ***where the making is to take place***. ***The*** information ***should be provided*** before the making is intended to start for the first time in that Member State. The making and related acts, including those performed in Member States other than the one of making in cases where the product is protected by a certificate in those other Member States too, should only fall within the scope of the exception where the maker has sent this notification to the competent industrial property authority (or other designated authority) of the Member State of making. The once-off duty to provide information to the authority should apply in each Member State where making is to take place, both as regards the making in that Member State, and as regards related acts, whether performed in that or another Member State, related to that making. ***The authority should be required to publish that information, in the interests of transparency and for the purpose of informing the holder of the certificate of the maker's intention.***	(13) To this end and ***to the extent it intends to rely on the exception and in the interest of transparency,*** the person ***responsible*** for the ***making ('the maker'), or any*** person ***acting on its behalf should*** provide***, on a confidentiality basis, a notification to the registered holder(s) of the certificate, at its (their) registered address(es). The maker should also provide*** to the authority which granted the supplementary protection certificate in the Member State***, a notification with certain*** information before the making is intended to start for the first time. The making and related acts, including those performed in Member States other than the one of making in cases where the product is protected by a certificate in those other Member States too, should only fall within the scope of the exception where the maker has sent this notification to the competent industrial property authority (or other designated authority) of the Member State of making. The once-off duty to provide information to the authority should apply in each Member State where making is to take place, both as regards the making in that Member State, and as regards related acts, whether performed in that or another Member State, related to that making.

Amendment 13

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(14) In addition, this Regulation should impose certain due diligence requirements on the maker as a condition for the exception to operate. The maker should be required to inform persons within its supply chain, through appropriate means,	(14) In addition, this Regulation should impose certain due diligence requirements on the maker as a condition for the exception to operate. The maker should be required to inform persons within its supply chain, through appropriate ***and***

in particular contractual means, that the product is covered by the exception introduced by this Regulation and is intended for the exclusive ***purpose*** of export. A maker who failed to comply with these due diligence requirements would not benefit from the exception, nor would any third party performing a related act in the same or a different Member State where a certificate conferring protection for the product was in force, and the holder of the relevant certificate would therefore be entitled to enforce its rights under the certificate	***documented*** means, in particular contractual means, that the product is covered by the exception introduced by this Regulation and is intended for the exclusive ***purposes*** of export ***and/or day-1 entry***. A maker who failed to comply with these due diligence requirements would not benefit from the exception, nor would any third party performing a related act in the same or a different Member State where a certificate conferring protection for the product was in force, and the holder of the relevant certificate would therefore be entitled to enforce its rights under the certificate.

Amendment 14

Proposal for a regulation
Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) The notification to the SPC Holder should not include commercially sensitive information and confidential details of a company business plan, to limit any anti-competitive effects. To that end, the information required in the notification should notably comply with existing Union law and recommendations, such as Directive (EU) 2016/943 of the European Parliament and of the Council[1a] and the EMA/HMA Guidance Document on the identification of commercially confidential information and personal data. For the same reasons, the notification and the information it contains should be treated as strictly confidential by the holder of the certificate and should not be used by the holder of the certificate for any other purpose than ensuring that the maker has complied with the scope and conditions of the exception.

[1a] Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1)

Amendment 15

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) Furthermore, this Regulation should impose labelling requirements on the maker, in order to facilitate, by means of a logo, identification of the product as a product exclusively intended for the purpose of export to third countries. The making and related acts should only fall outside the protection conferred by a supplementary protection certificate if the product is labelled in this manner. This labelling obligation would be without prejudice to labelling requirements of third countries.	***deleted***

Amendment 16

Proposal for a regulation
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) The notification to the authority which granted the supplementary protection certificate and the information it contains should be kept confidential. Specific measures should be taken to protect such confidentiality. The authority may only disclose the information if disclosure is ordered by a court under specific circumstances.

Amendment 17

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(19) In order to ensure that holders of supplementary protection certificates already in force are not deprived of their acquired rights, the exception provided for in this Regulation should only apply to certificates that are granted ***on or*** after ***a specified*** date ***after*** entry into force, irrespective of when the application for the certificate was first lodged. The date specified should allow a reasonable time for applicants and other relevant market players to adjust to the changed legal context and to make appropriate investment and manufacturing location decisions in a timely way. ***The date should also allow sufficient time for public authorities to put in place appropriate arrangements to receive and publish notifications of the intention to make, and should take due account of pending applications for certificates.***	(19) In order to ensure that holders of supplementary protection certificates already in force are not deprived of their acquired rights, the exception provided for in this Regulation should only apply to certificates that are granted ***after the*** date ***of*** entry into force ***of this regulation***, irrespective of when the application for the certificate was first lodged. The date specified should allow a reasonable time for applicants and other relevant market players to adjust to the changed legal context and to make appropriate investment and manufacturing location decisions in a timely way.

Amendment 18

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) The Commission should carry out an evaluation of this Regulation. Pursuant to paragraph 22 of the Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making of 13 April 2016[43], that evaluation should be based on the five criteria of effectiveness, efficiency, relevance, coherence and added value and should provide the basis for impact assessments of possible further measures.	(20) The Commission should carry out an evaluation of this Regulation. Pursuant to paragraph 22 of the Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making of 13 April 2016[43], that evaluation should be based on the five criteria of effectiveness, efficiency, relevance, coherence and added value and should provide the basis for impact assessments of possible further measures.

The evaluation should take into account exports to outside the Union and the ability of generics and especially biosimilars to enter markets in the Union ***as soon as possible*** after a certificate lapses. In particular, this evaluation should review the effectiveness of the exception in the light of the aim to restore a global level playing field for generic and biosimilar firms in the Union and a swifter entry of generic and especially biosimilar medicines onto the market after a certificate lapses. It should also study the impact of the exception on research and production of innovative medicines by holders of certificates in the Union and consider the balance between the different interests at stake, including those of public health.	The evaluation should take into account exports to outside the Union and the ability of generics and especially biosimilars to enter markets in the Union ***on Day-1*** after a certificate lapses. In particular, this evaluation should review the effectiveness of the exception in the light of the aim to restore a global level playing field for generic and biosimilar firms in the Union and a swifter entry of generic and especially biosimilar medicines onto the market after a certificate lapses. It should also study the impact of the exception on research and production of innovative medicines by holders of certificates in the Union and consider the balance between the different interests at stake, including ***access to medicines and above all*** those of public health.
[43] OJ L 123, 12.5.2016, p. 1.	[43] OJ L 123, 12.5.2016, p. 1.

Amendment 19

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(21) It is necessary and appropriate for the achievement of the basic objective***,*** of providing a level playing field for generic and biosimilar manufacturers with their competitors in third country markets where protection does not exist or has expired, to lay down rules ***restricting the exclusive right of a supplementary protection certificate holder to make*** the product in question during the term of the certificate***, and also to impose certain information and labelling obligations on makers wishing to take advantage of those rules***. This Regulation complies with the principle of proportionality, and does not go beyond what is necessary in order to achieve the objectives pursued, in accordance with Article 5(4) of the Treaty	(21) It is necessary and appropriate for the achievement of the basic objective of providing a level playing field for generic and biosimilar manufacturers with their competitors in third country markets where protection does not exist or has expired, to lay down rules ***enabling the making of*** the product in question during the term of the certificate. This Regulation complies with the principle of proportionality, and does not go beyond what is necessary in order to achieve the objectives pursued, in accordance with Article 5(4) of the Treaty on European Union.

on European Union.

Amendment 20

Proposal for a regulation
Recital 22

Text proposed by the Commission	*Amendment*
(22) This Regulation respects fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union. In particular, this Regulation seeks to ensure full respect for the right to property in Article 17 of the Charter by maintaining the core rights of the supplementary protection certificate, ***by confining*** the exception ***to certificates granted on or*** after ***a specified date after*** entry into force of this Regulation and by imposing certain conditions on the application of the exception**,**	(22) This Regulation respects fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union ***(Charter)***. In particular, this Regulation seeks to ensure full respect for the right to property ***laid down*** in Article 17 of the Charter by maintaining the core rights of the supplementary protection certificate***, by confining*** the exception ***to certificates granted after the date of*** entry into force of this Regulation**.**, as well as ***the right to health care provided for in Article 35 of the Charter by making medicines more accessible to EU patients, the principle of proportionality set out in Article 52 of the Charter and the right to health protection for European citizens sert out in point (a) of Article 6 TFEU.***

Amendment 21

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EU) No 469/2009
Article 4 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. The certificate referred to in paragraph 1 shall not confer protection against ***a particular act*** against which the basic patent conferred protection if, with respect to ***that*** particular ***act***, the following conditions are met:	2. The certificate referred to in paragraph 1 shall not confer protection against ***certain acts*** against which the basic patent conferred protection if, with respect to ***those*** particular ***acts***, the following conditions are met:

Amendment 22

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EU) No 469/2009
Article 4 – paragraph 2 – point a – point i

Text proposed by the Commission	*Amendment*
(i) making for the exclusive purpose of export to third countries; or	(i) making for the exclusive purpose***(s)*** of export to third countries ***where no supplementary protection certificate is in place; or***

Amendment 23

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EU) No 469/2009
Article 4 – paragraph 2 – point a – point i a (new)

Text proposed by the Commission	*Amendment*
	(ia) making for the purpose of entering the Union market on Day-1 after the expiry of the supplementary protection certificate; or

Amendment 24

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EU) No 469/2009
Article 4 – paragraph 2 – point a – point ii

Text proposed by the Commission	*Amendment*
(ii) any related act that is strictly necessary for that making or for the actual export itself;	(ii) any related act that is strictly necessary for that making***, storing*** or for the actual export itself;

Amendment 25

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EU) No 469/2009

Article 4 – paragraph 2 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) the act excludes any act or activity for the purpose of import of medicinal products, or parts thereof, into the Union merely for the purpose of repackaging and re-exporting.

Amendment 26

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EU) No 469/2009
Article 4 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) the authority referred to in Article 9(1) of the Member State where that making is to take place ('the relevant Member State') is notified by the person doing the making ('the maker') of the information listed in paragraph 3 no later than ***28*** days before the intended start date of making in that Member State;	(b) the authority referred to in Article 9(1) of the Member State where that making is to take place ('the relevant Member State') notified by the person doing the making ('the maker') of the information listed in paragraph 3 no later than ***60*** days before the intended start date of making in that Member State;

Amendment 27

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EU) No 469/2009
Article 4 – paragraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) the certificate holder is also informed, in writing, by the maker, that a notification has been sent pursuant to point (b) of paragraph 2 with the information listed in points (a), (c) and (f) of paragraph 3 no later than 60 days before the start date of making in that Member State and in advance of any related act prior to that making that would otherwise be prohibited by the protection

conferred by a certificate;

Amendment 28

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EU) No 469/2009
Article 4 – paragraph 2 – point b b (new)

Text proposed by the Commission	*Amendment*
	(bb) the notification to the certificate holder shall not contain any confidential or commercially sensitive information.

Amendment 29

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EU) No 469/2009
Article 4 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) the maker ensures that a logo, in the form set out in Annex -I, is affixed to the outer packaging of the product or, if there is no outer packaging, to its immediate packaging;	***deleted***

Amendment 30

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EU) No 469/2009
Article 4 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) the maker ensures that the medicinal product manufactured under point (a) of paragraph 2 of this article does not bear an active Unique Identifier as per Articles 3(d) and 4 of Commission Delegated Regulation 2016/161/EU[1a]. Where appropriate, competent authorities

	shall have access to the data in the repositories mandated by Directive 2011/62/EU and Delegated Regulation 2016/161/EU to ensure that the maker complies with its obligations.
	[1a] Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 9.2.2016, p. 1)

Amendment 31

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EU) No 469/2009
Article 4 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The information for the purposes of paragraph 2***(b)*** shall be ***as follows:***	3. The information for the purposes of ***point (b) of*** paragraph 2, ***which must be treated in a strictly confidential manner by all parties,*** shall be:
(a) the name and address of the maker;	(a) the name and address of the maker;
(b) the address, or addresses, of the premises where the making is to take place in the relevant Member State;	(b) ***the relevant Member State*** where the making is ***taking*** place;
(c) the number of the certificate granted in the relevant Member State, and identification of the product, by reference to the proprietary name used by the holder of that certificate;	(c) the number of the ***relevant*** certificate granted in the relevant Member State, and identification of the product, by reference to the proprietary name used by the holder of that certificate;
(d) the number of the authorisation granted in accordance with Article 40(1) of Directive 2001/83/EC or Article 44(1) of Directive 2001/82/EC for the manufacture of the corresponding medicinal product or, in the absence of such authorisation, a valid certificate of good manufacturing practice as referred	

to in Article 111(5) of Directive 2001/83/EC or Article 80(5) of Directive 2001/82/EC covering the premises where the making is to take place;	
(e) the intended start date of making in the relevant Member State;	
(f) an indicative list of the intended third country or third countries to which the product is to be exported.	(f) an indicative list of the intended third country or third countries to which the product is to be exported.

Amendment 32

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EU) No 469/2009
Article 11 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The notification sent to an authority as referred to in Article 4(2)***(b)*** shall be published by that authority within 15 days of receipt of the notification.;’	4. The notification sent to ***the SPC holder*** as referred to in ***point (b) of*** Article 4(***2)*** shall be ***treated as strictly confidential by the holder*** of the ***certificate and shall not be used by the holder of the certificate for any other purpose than ensuring that the maker has complied with the scope and conditions of the exception***; ***The authority referred to in Article 9(1) shall keep the notification referred to in point (b) of Article 4(2) and the information listed in paragraph 3 confidential and shall take appropriate measures to preserve such confidentiality.*** ***The authority shall only disclose the notification and the information it contains if such disclosure is ordered by a court having competence under national law to hear an infringement action based on the certificate. A court shall only order such disclose if at least the following conditions are met:*** ***(a) the person requesting the disclosure is the holder of the certificate (or a person entitled under national law to start an infringement action on the basis of the***

certificate;

(b) the maker is given the opportunity to attend the proceedings and to be heard before the court;

(c) the holder of the certificate has provided evidence rendering plausible that the maker did not comply with the conditions set out in Article 4(2);

(d) the holder of the certificate and the court have taken appropriate measures to keep the notification and the information it contains confidential and avoid their disclosure to third parties;

Amendment 33

Proposal for a regulation
Article 1 – paragraph 1 – point 4
Regulation (EU) No 469/2009
Annex -I

Text proposed by the Commission	*Amendment*
(4) the Annex to this Regulation is inserted as Annex -I.	***deleted***

Justification

There is no need to keep the proposed annex of the Commission should the labelling requirements fall, given that they are unnecessary. The Falsified Medicines Directive already imposes enough safeguards on the access of medicines to the market of the EU.

Amendment 34

Proposal for a regulation
Annex
Regulation (EU) No 469/2009
Annex

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

Justification

There is no need to keep the proposed annex of the Commission should the labelling

requirements fall, given that they are unnecessary. The Falsified Medicines Directive already imposes enough safeguards on the access of medicines to the market of the EU.

PROCEDURE – COMMITTEE ASKED FOR OPINION

Title	Supplementary protection certificate for medicinal products
References	COM(2018)0317 – C8-0217/2018 – 2018/0161(COD)
Committee responsible Date announced in plenary	JURI 2.7.2018
Opinion by Date announced in plenary	ENVI 2.7.2018
Rapporteur Date appointed	Tiemo Wölken 26.6.2018
Discussed in committee	11.10.2018
Date adopted	27.11.2018
Result of final vote	+: 57 –: 1 0: 0
Members present for the final vote	Margrete Auken, Pilar Ayuso, Zoltán Balczó, Ivo Belet, Paul Brannen, Nessa Childers, Birgit Collin-Langen, Seb Dance, Mark Demesmaeker, Stefan Eck, Bas Eickhout, Karl-Heinz Florenz, Elisabetta Gardini, Gerben-Jan Gerbrandy, Jens Gieseke, Julie Girling, Françoise Grossetête, Jytte Guteland, György Hölvényi, Anneli Jäätteenmäki, Karin Kadenbach, Kateřina Konečná, Urszula Krupa, Giovanni La Via, Jo Leinen, Peter Liese, Lukas Mandl, Jiří Maštálka, Valentinas Mazuronis, Joëlle Mélin, Susanne Melior, Rory Palmer, Massimo Paolucci, Piernicola Pedicini, Bolesław G. Piecha, John Procter, Julia Reid, Frédérique Ries, Michèle Rivasi, Annie Schreijer-Pierik, Davor Škrlec, Renate Sommer, Adina-Ioana Vălean, Jadwiga Wiśniewska
Substitutes present for the final vote	Nikos Androulakis, Christophe Hansen, Martin Häusling, Anja Hazekamp, Jan Huitema, Ulrike Müller, Alojz Peterle, Keith Taylor, Tiemo Wölken
Substitutes under Rule 200(2) present for the final vote	Martina Anderson, Edward Czesak, Jens Geier, Vladimír Maňka, Virginie Rozière

FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

57	+
ALDE	Gerben Jan Gerbrandy, Jan Huitema, Anneli Jäätteenmäki, Valentinas Mazuronis, Ulrike Müller, Frédérique Ries
ECR	Edward Czesak, Mark Demesmaeker, Urszula Krupa, Bolesław G. Piecha, John Procter, Jadwiga Wiśniewska
EFDD	Piernicola Pedicini
ENF	Joëlle Mélin
GUE/NGL	Martina Anderson, Stefan Eck, Anja Hazekamp, Kateřina Konečná, Jiří Maštálka
NI	Zoltán Balczó
PPE	Pilar Ayuso, Ivo Belet, Birgit Collin-Langen, Karl Heinz Florenz, Elisabetta Gardini, Jens Gieseke, Julie Girling, Françoise Grossetête, Christophe Hansen, György Hölvényi, Giovanni La Via, Peter Liese, Lukas Mandl, Alojz Peterle, Annie Schreijer Pierik, Renate Sommer, Adina Ioana Vălean
S&D	Nikos Androulakis, Paul Brannen, Nessa Childers, Seb Dance, Jens Geier, Jytte Guteland, Karin Kadenbach, Jo Leinen, Vladimír Maňka, Susanne Melior, Rory Palmer, Massimo Paolucci, Virginie Rozière, Tiemo Wölken
VERTS/ALE	Margrete Auken, Bas Eickhout, Martin Häusling, Michèle Rivasi, Davor Škrlec, Keith Taylor

1	-
EFDD	Julia Reid

0	0

Key to symbols:
+ : in favour
- : against
0 : abstention

PROCEDURE – COMMITTEE RESPONSIBLE

Title	Supplementary protection certificate for medicinal products		
References	COM(2018)0317 – C8-0217/2018 – 2018/0161(COD)		
Date submitted to Parliament	28.5.2018		
Committee responsible Date announced in plenary	JURI 2.7.2018		
Committees asked for opinions Date announced in plenary	INTA 2.7.2018	ENVI 2.7.2018	ITRE 2.7.2018
Not delivering opinions Date of decision	ITRE 19.6.2018		
Rapporteurs Date appointed	Luis de Grandes Pascual 24.9.2018		
Discussed in committee	10.10.2018	20.11.2018	10.12.2018
Date adopted	23.1.2019		
Result of final vote	+: –: 0:	21 2 0	
Members present for the final vote	Max Andersson, Marie-Christine Boutonnet, Jean-Marie Cavada, Mady Delvaux, Rosa Estaràs Ferragut, Enrico Gasbarra, Lidia Joanna Geringer de Oedenberg, Sajjad Karim, Sylvia-Yvonne Kaufmann, Gilles Lebreton, António Marinho e Pinto, Julia Reda, Evelyn Regner, Pavel Svoboda, József Szájer, Axel Voss, Francis Zammit Dimech, Tadeusz Zwiefka		
Substitutes present for the final vote	Luis de Grandes Pascual, Pascal Durand, Angelika Niebler, Virginie Rozière, Tiemo Wölken, Kosma Złotowski		
Substitutes under Rule 200(2) present for the final vote	Andrey Kovatchev, Lola Sánchez Caldentey		
Date tabled	29.1.2019		

FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

21	+
ALDE	Jean-Marie Cavada, António Marinho e Pinto
ECR	Kosma Złotowski
ENF	Marie-Christine Boutonnet, Gilles Lebreton
GUE/NGL	Lola Sánchez Caldentey
PPE	Rosa Estaràs Ferragut, Luis de Grandes Pascual, Pavel Svoboda, József Szájer, Francis Zammit Dimech, Tadeusz Zwiefka
S&D	Mady Delvaux, Enrico Gasbarra, Lidia Joanna Geringer de Oedenberg, Sylvia-Yvonne Kaufmann, Evelyn Regner, Tiemo Wölken
VERTS/ALE	Max Andersson, Pascal Durand, Julia Reda

2	-
ECR	Sajjad Karim
PPE	Axel Voss

0	0

Key to symbols:
+ : in favour
- : against
0 : abstention