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Committee on Legal Affairs

2018/0161(COD)

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DRAFT 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 ...[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 Environment, Public Health and Food Safety (A8-0000/2018),

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 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	(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

[1] Not yet published in the Official Journal.

third countries where protection does not exist or has expired.	***countries outside the EU (‘***third countries***’)*** where protection does not exist or has expired.

Or. en

Amendment 2

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, even for the exclusive purpose of exporting to third country markets in which 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.

Or. en

Amendment 3

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.

Or. en

Amendment 4

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 ***promote the competitiveness of generics and biosimilars producers*** in the Union***, enhancing growth and job creation in the internal market and contributing to a wider supply of products under uniform conditions. This will help those producers*** to compete effectively in third country markets where protection does not exist or has expired. It ***should also*** complement the efforts of the Union's trade policy to ensure open markets for Union-based manufacturers of medicinal products ***or active ingredients***. Indirectly, it ***should*** put those manufacturers in a better position to enter the Union market immediately after expiry of the relevant supplementary protection certificate.

Or. en

Amendment 5

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 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. ***The exception should apply to products to be placed on the market as medicinal products, as well as to products which are active ingredients of a medicinal product or combinations thereof, protected by the relevant supplementary protection certificate.***

Or. en

Amendment 6

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	(9) That exception should cover the making of the product ***and of*** the product ***resulting from such making,*** which ***is*** protected by a certificate in the territory of a Member State, for the exclusive purpose of export ***of that product or of a medicinal product containing that product*** 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 possession,*** supply and import of active ingredients for the

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.

purpose of making ***a*** medicinal product ***containing that*** product, or temporary storage of the product or advertising for the exclusive purpose of export to third country destinations.

Or. en

Amendment 7

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 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 products ***or*** medicinal products, into the Union merely for the purposes of repackaging and re-exporting.

Or. en

Amendment 8

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	(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.	this Regulation ***should*** 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.

Or. en

Amendment 9

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***	(13) To this end, this Regulation should impose a 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. ***A standard form should be used for the purpose of communicating such information.*** The information should be provided before the making is intended to start for the first time in that Member State***, and before any related act prior to that making, and should be updated as appropriate***. 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 ***and has informed the holder of the supplementary protection certificate granted*** in that Member State ***as regards the making. Only the making should be notified, not the*** related acts. ***Should making take place in more than one***

informing the holder of the certificate of the maker's intention.	Member State, ***a notification should be required in each of those Member States***. The authority should be required to publish ***certain elements of*** that information, in the interests of transparency***. Certain confidential or commercially sensitive information notified to the authority should not be published. Only a court or other competent authority should be able to request such information***.

Or. en

Amendment 10

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 covered by the exception. This information should be updated as appropriate.

Or. en

Amendment 11

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	(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

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.	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.
	Or. en

Amendment 12

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, this Regulation does not affect the rules on the unique identifier provided for in Commission Delegated Regulation (EU) 2016/161.***
[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 12 June 2013 concerning customs enforcement of intellectual property rights (OJ L 181, 29.6.2013, p. 15).	[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).

[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).

Or. en

Amendment 13

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 ***for which the basic patent expired on or after 1 January 2023***. The date specified ***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. That date*** should ***also*** 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.

Or. en

Amendment 14

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 ***for which the basic patent expired*** on or after ***1 January 2023*** and by imposing certain conditions on the application of the exception,

Or. en

Amendment 15

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) 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 a particular act which ***otherwise require the consent of the certificate holder***, the following conditions are met:

Or. en

Amendment 16

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) 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 ***a product, or a product to be placed on the market as a medicinal product,*** for the exclusive purpose of export to third countries; or

Or. en

Amendment 17

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) 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’) is notified by the person doing the making ***referred to in point (a)(i) of paragraph 2*** (‘the maker’) of the information listed in paragraph 3 no later than ***three months*** 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 owing to the protection conferred by that certificate;***

Or. en

Amendment 18

Proposal for a regulation
Article 1 – paragraph 1 – point 1

Regulation (EC) No 469/2009
Article 4 – paragraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(b a) the certificate holder is informed, in writing, by the maker, of the information listed in points (a),(c), (e) and (f) of paragraph 3 no later than three months 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 owing to the protection conferred by that certificate;

Or. en

Amendment 19

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

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

Or. en

Amendment 20

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

Text proposed by the Commission	*Amendment*
	(b c) if the information referred to in point (b) of paragraph 2 changes, the maker shall notify the authority referred to in Article 9(1) of the relevant Member

	State before these changes take effect. If the changes relate to the information to be provided pursuant to point (ba) of paragraph 2, the maker shall also inform the certificate holder of these changes.

Or. en

Amendment 21

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EC) 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;	(c) the maker ensures that a logo, in the form set out in Annex ***-II***, is affixed to the outer packaging of the product ***referred to in point (a)(i) of paragraph 2*** or, if there is no outer packaging, to its immediate packaging;

Or. en

Amendment 22

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

Text proposed by the Commission	*Amendment*
(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 ***its international non***-proprietary name***, if available***;

Or. en

Amendment 23

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

Text proposed by the Commission	*Amendment*
(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;	***deleted***

Or. en

Amendment 24

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

Text proposed by the Commission	*Amendment*
(e) the intended start date of making in the relevant Member State;	(e) the ***earliest*** intended start date of making in the relevant Member State;

Or. en

Amendment 25

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

Text proposed by the Commission	*Amendment*
	3a. 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.

Or. en

Amendment 26

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

Text proposed by the Commission	*Amendment*
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:	4. 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)(ii) are fully informed and aware of the following:

Or. en

Amendment 27

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

Text proposed by the Commission	*Amendment*
(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.	(b) that the placing on the market, import or re-import of the product ***referred to in point (a)(i) of paragraph 2***might infringe the certificate referred to in paragraph ***2*** where, and as long as, that certificate applies.

Or. en

Amendment 28

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 third month that follows the month in which this amending Regulation is published in the Official Journal)];***	5. Paragraph 2 shall apply in the case only of certificates ***for which the basic patent expired*** on or after ***1 January 2023***.

Or. en

Amendment 29

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) of the relevant Member State*** shall ***publish the information listed in points (a) and (c) of Article 4(3)***. ***It shall also publish any changes to that information that are notified in accordance with the first sentence of point (bc) of article 4(2).***

Or. en

Amendment 30

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

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

Or. en

Amendment 31

Proposal for a regulation
Annex

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 intended third country or third countries to which the product is to be exported

Or. en

Amendment 32

Proposal for a regulation
Annex II

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

Or. en

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.