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NOTE

From:	Presidency
To:	Delegations
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Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicine products - Presidency revised text

In preparation for the Intellectual Property Working Party meeting on 12 October 2018, delegations will find in the Annex a revised text of the above proposal prepared by the Presidency in the light of the discussions held in the Intellectual Property Working Party between June and September 2018, and taking into account the written comments from delegations (WK 11113/2018, WK 11115/2018).

Changes compared to the text of the Commission proposal are highlighted using **bold underlined** for additions and ~~**strikethrough**~~ for deletions.

Overview of the major changes made:

- **Scope of the exception granted by the waiver**

Some delegations advocated extending the exception provided by the waiver to include the production for **stockpiling**. The main argument put forward for such an extension was that producers should be allowed to enter the EU market as of day one after the expiry of the SPC.

However, several other delegations strongly opposed such an extension. They argued that the interest of the originator industry and consequently the protection of SPC right holders in the EU must not be undermined by the waiver. These delegations are therefore in favour of strictly restricting the exception to the export to third countries outside the EU in which no SPC or other protection is in place, as is suggested in the Commission proposal.

The Presidency has taken careful note of the different views and concerns expressed on this question so far.

Taking into account the different positions, it seems to the Presidency that in order to overcome the concerns expressed regarding the interests of SPC right holders, the proposal has to remain moderate and be limited to removing the possible competitive disadvantage generic manufacturers might face when intending to do business *outside the EU*.

The Presidency therefore proposes a revised text, which does not go beyond the scope of the original Commission proposal in this regard, as it would be very difficult to get general agreement on the scope if it were extended as suggested.

Like the Commission proposal, the revised text is intended to be clear that the exception is tailor-made for export purposes only and will not change the rights of SPC holders inside the EU (see Article 4(2)(a)(i) and recitals (4), (8), (9) and (10), which remained largely unchanged). The revised text clarifies that export to 'third countries' means 'countries outside the EU' (see changes in recital 3).

- **Subject matter of the waiver and coherence of terminology**

The revised text aims to provide more **coherence** throughout the text as regards the use of the **terms 'product'** and **'medicinal product'**. In order to bring the text into line with the definitions of these terms in points (a) and (b) of Article 1 of Regulation (EC) No 469/2009 and to clarify the subject matter of the waiver, changes were made in particular in point (i) of Article 4(2)(a) and in recitals (7), (8) and (9).

Some delegations wanted an exhaustive list of what can be considered a **related act**, whereas several other delegations cautioned against overcomplicating the text. Therefore no such list was added, but some further clarifications were inserted in recital (9).

- **Notification to the authority, informing the SPC holder and the public**

The revised text extends the **deadline for the notification** to the authority (Article 4(2)(b)) to **3 months** before the start of the making. Furthermore, it specifies that the notification must also precede any related act taking place prior to that making. Recital (13) clarifies that only the making (not the related acts) needs to be notified.

The revised text takes on board the idea of providing a **standard form** for the information to be notified to the authority (see Article 2(3a), recital (13) and new Annex -I).

The suggestion made by several delegations to provide for an obligation of the maker to **inform the SPC holder** has also been incorporated in the revised text (Article 4, new paragraph 2(ba)). However, in order to prevent the disclosure of sensitive information to the SPC holder, which could create an unjustified competitive advantage for the SPC holder, it is suggested that not all of the information that the maker has to submit to the authority needs to be provided to the SPC holder. It is suggested that the maker should not be required to communicate to the SPC holder the place of the making or the third countries to which export is intended (Article 4(3)(b) and (f). The SPC holder would be informed about the name and address of the maker, the SPC number and the intended start of the making (Article 4(3)(a)(c) and (e)), as these are considered the essential information for the SPC holder to assess whether there is an infringement of his certificate. To prevent this information obligation from causing an unnecessary burden for the maker, the SPC holder merely has to be informed in writing, and no special form is required (see recital (13a)).

The **publication obligation** (Article 11(4)) has been adapted in light of the changes made to the notification obligation and the introduction of an obligation to inform the SPC holder. The information to be published has been limited to 'certain elements' of the information provided to the authority, namely the name and address of the maker and the SPC number (i.e. the information required by Article 4(3)(a) and (c); see also the clarification in recital (13)) . The deadline for the publication has been removed, as its main purpose was to ensure that the SPC holder was informed in a timely manner; under the revised Presidency text this would now be ensured by the obligation to inform the SPC holder directly. This change also aims to accommodate the concerns expressed about any possibility that the authority could incur liability as a result of late publication.

As was suggested by several delegations, the revised text includes, for discussion, an **update obligation**: the maker must inform the authority and the SPC holder of changes in (certain elements of) the information provided to them, and the authority has to update the information it publishes (see changes in Article 4(2)(bb), the additional phrase in Article 11(4), and recital (13a)).

- **Safeguards/prevention of re-import**

As regards the safeguards for preventing illicit diversion or re-import to the EU market, a clarification was inserted in recital (17) to the effect that the **unique identifier** for the verification of the authenticity of medicinal products provided for by Implementing Regulation (EU) 2016/161, which is one of the major safeguards preventing illicit medical products coming on the EU market, fully applies and is unaffected by the current proposal.

Moreover, further specifications for the **logo** to be put on the outer packaging of (medicinal) product covered by the SPC waiver were included in the description of the logo in Annex -II (previous Annex -I).

- **Application in time**

In the discussions held so far, hugely diverging views were expressed about which SPCs should be covered by the exception (**application in time**). To allow for an open discussion, the revised text puts forward three alternatives on this point (Article 4(5)) for delegations to consider.

ANNEX

2018/0161 (COD)

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Acting in accordance with the ordinary legislative procedure,

[1] OJ C , , p. .

Whereas:

(1) Regulation (EC) No 469/2009 of the European Parliament and of the Council[2] provides that any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83/EC of the European Parliament and of the Council[3] or Directive 2001/82/EC of the European Parliament and of the Council[4], may be the subject of a supplementary protection certificate under the terms and conditions provided for in Regulation (EC) No 469/2009.

(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.

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

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[2] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152, 16.6.2009, p. 1).

[3] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p.67).

[4] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

(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 **producers** ~~established in the Union~~ from manufacturing **in the Union**, 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.

(5) This puts ~~manufacturers of~~ generics and biosimilars **producers** ~~established~~ in the Union at a significant competitive disadvantage compared with manufacturers based in third countries that offer less or no protection.

(6) Without any intervention, the viability of ~~the~~ manufacture**rs** of generics and biosimilars in the Union could be under threat, with consequences for the Union's pharmaceutical industrial base as a whole.

(7) The aim of this Regulation is to ~~ensure that manufacturers established~~ **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 these producers** ~~are able~~ to compete effectively in ~~those~~ third country markets where ~~supplementary~~ protection does not exist or has expired. It ~~is intended to~~ **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 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.~~

(8) In ~~those~~ **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. **This 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 a certificate.**

(9) That exception should cover the making of the product **and the product resulting from that making**~~, including the product~~ which ~~corresponds to the medicinal product~~ **is** protected by a ~~supplementary protection~~ certificate in the territory of a Member State, for the exclusive purpose of export **of that product or 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 purpose of making ~~the~~ **a** medicinal product ~~to which the product covered by the certificate corresponds~~**containing that product**, or temporary storage of the product or advertising for the exclusive purpose of export to third country destinations. **The exception should also apply to related acts performed by third parties, such as logistics operators, who are in a contractual relationship with the maker.**

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

(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~~ **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.

(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.

(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. **A common notification form should be provided for this purpose.** The information should be provided before the making ~~is intended to~~ start**s** for the first time in that Member State**, and before any related act prior to that making, and should be updated as and when 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 certificate granted in that Member State**. **Only the making should be notified, not the related acts. Should making take place in more than one Member State, a notification should be required in each of these Member States.** ~~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 **certain elements of** that information, in the interests of transparency ~~and for the purpose of informing the holder of the certificate of the maker's intention~~. **Certain confidential or commercially sensitive information notified to the authority should not be published, but may be requested by a court or other competent authority.**

(13a) The maker should also inform the certificate holder, in writing, of the intention to make a product pursuant to the exception. This information should be updated as and when appropriate.

(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 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.

(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.

(16) Any act not covered by the exception introduced by this Regulation will remain within the scope of the protection conferred by a supplementary protection certificate. This includes **the illicit diversion onto the Union market, during the term of the certificate, of** any product **– including for any use as a medicinal product –** made within the terms of the exception ~~and illicitly diverted onto the Union market during the term of the certificate~~.

(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[5] and Regulation (EU) No 608/2013 of the European Parliament and of the Council[6]. **Furthermore, this Regulation does not affect the rules on the unique identifier provided for in Commission Delegated Regulation (EU) 2016/161.**

(18) This Regulation does not affect the application of Directives 2001/83/EC and 2001/82/EC, in particular the requirements related to the manufacturing authorisation of medicinal products manufactured for export. This includes compliance with the principles and guidelines of good manufacturing practices for medicinal products and the use of active substances that have been manufactured in accordance with good manufacturing practices for active substances and distributed in accordance with good distribution practices for active substances.

(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**]**[7].

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[5] 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).

[6] 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).

[7] *The wording of recital 19 depends on the final text of Article 4(5). The recital will be revised later, as necessary, depending on the choices made as regards the application in time - please see the alternatives put for discussion in Article 4(5).*

(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[8], 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 **in the Union** by holders of certificates ~~in the Union~~ and consider the balance between the different interests at stake, including those of public health.

(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.

[8] OJ L 123, 12.5.2016, p. 1.

(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**][applied for][that entered into force]**[9] on or after a specified date after entry into force of this Regulation and by imposing certain conditions on the application of the exception,

HAVE ADOPTED THIS REGULATION:

Article 1 – Amendment of Regulation (EC) No 469/2009

Regulation (EC) No 469/2009 is amended as follows:

(1) Article 4 is replaced by the following[10]:

'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.

[9] *The wording depends on the final text of Article 4(5) - please see the alternatives put for discussion in Article 4(5).*

[10] *One delegation proposed that the exception should be to Article 5 of Regulation 469/2009 rather than to Article 4.*

2. The certificate referred to in paragraph 1 shall not confer protection against a particular act **which would otherwise require the consent of the certificate holder** ~~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 **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

(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')~~ **referred to in paragraph 2(a)(i) ('the maker')** of the information listed in paragraph 3 no later than ~~28 days~~ **three months** before the ~~intended~~ 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**;

(ba) the certificate holder is informed, in writing, by the maker, of the information listed in points [(a), (c) and (e)] 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 by the protection conferred by a certificate;**

(bb) If the information referred to in paragraph 2(b) changes, the maker shall notify the authority referred to in Article 9(1) before these changes take effect. If the changes relate to the information to be provided pursuant to paragraph 2(ba), the maker shall also inform the certificate holder of these changes.

(c) the maker ensures that a logo, in the form set out in Annex -I**I**, is affixed to the outer packaging of the product **referred to in paragraph 2(a)(i),** 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 **its international nonproprietary name, if available** ~~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 **earliest** 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.

3a. Annex -I includes a standard form that shall be used by makers for notifications under paragraph 2(b);

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:

(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 **referred to in paragraph 2(a)(i)** might infringe the certificate referred to in ~~that~~ paragraph **2** where, and as long as, that certificate applies.

5. ***Initial COM proposal:***

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}*

Alternative 1:

Paragraph 2 shall apply in the case only of certificates ~~granted~~ **applied for** on or after *{OP: please insert the date of the **twentieth day** following that on which this amending Regulation is published in the Official Journal}*

Alternative 2:

Paragraph 2 shall apply in the case only of certificates ~~granted~~ **whose basic patent expired** on or after **1.1.2021 or** the first day of the **third month** that follows the month in which this amending Regulation is published in the Official Journal**, whichever is the later.**

(2) in Article 11, the following paragraph is added:

4. 'The ~~notification sent to an~~ authority ~~as~~ referred to in Article ~~4(2)(b)~~ **9(1)** shall ~~be published~~ **publish the information listed in points (a) and (c) of Article 4(3)** ~~by that authority within 15 days of receipt of the notification.~~ **It shall also publish any changes to this information notified in accordance with the first sentence of Article 4(2)(bb).**';

(3) the following Article is inserted:

'Article 21a – 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.';

(4) the Annex**es** to this Regulation ~~**is**~~ **are** inserted as Annex –I **and –II**.

Article 2 – Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX -II

Logo

This logo should appear in black colour and of such size as to be sufficiently visible.

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ANNEX -I

Form for notification pursuant to Article 4(2)(b)

(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	
(d)*	
(e) Earliest intended start date of making in the relevant Member State	
(f) Third country or countries to which the product is to be exported	

**point (d) of Artcile 4(2)(b) is suggested to be deleted in the revsied Presidency text; however, the numbering of paragraphs is kept for discussion purposes.*