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NOTE

From:	Presidency
To:	Delegations
No. prev. doc.:	13749/18
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Subject:	Proposal for a Regulation amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medical products - Revised presidencial text

In preparation for the Intellectual Property Working Party meeting on 28 November 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 on 7 November, and taking into account the subsequent written comments from delegations.

Changes compared to the previous Presidency compromise text (13749/18) are highlighted using **bold underlined** for additions and ~~**strikethrough**~~ for deletions.

Overview of the changes made in this third revised Presidency compromise text:

- **Definition of maker (Article 1(f))**

This definition has been amended, in line with drafting suggestions from delegations, including to avoid a cross-reference to Article 4(2)(a)(i), which some delegations considered confusing. In the same vein, recital (13) is also aligned to the new wording.

- **Article of Regulation (EC) No 469/2009 being amended (Article 5)**

Article 4 of Regulation (EC) 469/2009 covers the subject matter of protection (setting out which products are concerned – namely taking into account the scope of the related marketing authorisation). Article 5 relates to the effects of an SPC (setting out which acts are concerned – currently defined as being identical to the rights conferred by the related patent, including any limitations and obligations).

As the proposed measure would introduce an exception to the effects of an SPC (namely, that some acts will no longer be prohibited by an SPC, if certain conditions are met), a number of delegations request that the Commission text be amended, so that the waiver is introduced to Article 5 rather than Article 4. This would also clarify that there is no intention to alter the scope of the SPC right, but only some of its effects.

The Presidency has accepted this amendment, as it would also clarify that there is no intention to alter the scope of the right conferred by the SPC, but only some of its effects.

- **Scope of the exception (Article 5(2)(a)(i))**

A number of delegations continue to call for extending the exception to include making for **stockpiling** purposes. They argue that this would further improve the competitiveness of EU-based Generics/Biosimilars ('G/Bs') (namely faster entry into the EU market as of day one after the expiry of the SPC) and facilitate access to medicines to EU patients. Some of these delegations have come forward with a joint proposal to introduce stockpiling, either throughout the whole period of the certificate, or during the final 12 months prior to the expiry of a certificate.

However, other delegations strongly oppose stockpiling. These Member States argue that stockpiling would increase the risk of illicit diversion of G/Bs and, in general, that the interest of the originator industry and consequently the protection of SPC right holders in the EU would be unnecessarily undermined.

In light of this divergence of positions, the Presidency takes the view that introducing stockpiling, thus going substantially beyond the scope of the Commission proposal, will not result in agreement on a Trilogue mandate in Council. In addition, the Presidency would like to recall that the export waiver should also make medicines more accessible in the Union after expiry of SPC protection and, to this end, proposes to introduce new drafting into recital (7).

This new language in recital (7) also clarifies, as called for by some delegations, that the Regulation is in the 'common interest' of the Union.

Some delegations call for the exception to apply to **intra-EU exports** (namely from 'protected' Member States to 'unprotected' ones) in addition to third countries. This suggestion, which is opposed by other delegations, is not taken on board, as it would encourage a form of fragmentation in the single market, would lead to problems with the logo, and would potentially increase the risk of illicit diversion onto protected Union markets.

Finally, one delegation has called to remove **veterinary medicines** from the scope of the exception. Such a carve-out would however be problematic, as medicines can have dual-use for both humans and animals; moreover it is often only at a certain point in time that the second 'use' is identified. In line with the existing text of Regulation (EC) No 469/2009, it is therefore suggested that no carve-out be introduced.

- **Requirements regarding export countries (Article 5(2)(a)(i))**

Some delegations propose to require that the exception shall only apply for the purpose of export to third countries '*in which SPC or similar protection does not exist or has expired*' (i.e. repeating in the operative part the text that appears in several recitals). While noting that it is obviously not the intention of the proposal to encourage the infringement of IP rights in third countries, the Presidency has not included this suggestion as, inter alia, it is not the role of a court in the Union to investigate the legal situation of the product to be exported in third countries, where infringement criteria are not necessarily identical to those in a Member State of the Union. That role should be left to courts in the countries concerned.

- **Notification (Article 5(2)(b) and (ba)) and Publication (Article 11(4))**

Some delegations ask for a further streamlining of **information to be provided** to SPC holders and competent authorities/patent offices. In addition, some delegations call for publication of all the information provided to patent offices. At the same time however, delegations have diverging views about *what* information must be provided (some wishing to reduce or eliminate the communication of sensitive information, some calling for more details to be communicated to the SPC holder, and others calling for the inclusion of some details on related acts). Some delegations call for a deletion of the update requirement.

On this point, the Presidency would like to recall that the two notification regimes – information to the SPC holder and notification to the competent authority – serve different purposes.

Information to the SPC holder aims to provide the latter with the information needed to enforce its SPC. It should not contain commercially sensitive information relating, for example, to export countries, as this could potentially have the unwanted effect of negatively affecting competition. Notification to the authority/patent office aims to improve transparency and facilitate the provision of evidence in case of investigations or litigation.

Therefore, the Presidency suggests to maintain the two different regimes, whereby more information is provided to patent offices, subject to the latter's obligation to keep part of that information confidential.

To facilitate the task of the patent offices, a clearer distinction between information to be published and information not to be published is proposed in the standard notification form (Annex –I).

The revised compromise text extends, from one to three months, the **deadline for notification** to the competent authority and for informing the right holder in respect of related acts, in order to have a harmonised timeframe for all notifications, as requested by several delegations.

The maker should now inform the right holder 'through appropriate and documented means', rather than just 'in writing'. This aligns the text to the language in Article 5(4). Recital (13a) is also adjusted in this regard.

- **Application in time (Article 5(5) and Recital 19)**

In the discussions so far, very diverging views, have been expressed about which SPCs, according to their status (i.e. applied for, granted, or in effect) at the time of entry into force of the Regulation, should be covered, or not covered, by the exception. To seek to overcome this significant divergence of views, the Presidency has sought to develop a new approach, which, while building on the already discussed options, addresses the issue from a new angle, as follows:

The exception would be applicable to both the following situations:

1) SPCs that are applied for *after* the entry into force of the Regulation.

2) From 1 July 2024 (i.e. five years after the entry into force of the Regulation, assuming entry into force on 1 July 2019[1]), to SPCs which have been applied for *before* the entry into force of this Regulation but which only enter into effect *after* the entry into force of this Regulation.

This approach would result in the exception not affecting any SPC already in effect *before* the Regulation comes into force (indeed, this is now explicitly clarified in the Article and in a new sentence inserted into recital (19)).

Secondly, and as called for by several delegations, introducing the exception on the basis of the *date of filing of the application* rather than the *date of grant* of the certificate would promote uniformity, limiting the risk of fragmentation in the internal market[2]. Under this approach in the Presidency compromise, the SPC grant date is not referred to and the exception will apply, or not, for a specific medicine, irrespective of the grant dates of the related SPCs in the different Member States (and of course exclusively in respect of certificates entering into effect after the Regulation comes into force).

Situation 2 takes into account the reality that SPCs generally enter into effect a relatively long period after filing. While it might affect some SPCs already granted (but not yet in effect) at the date of entry into force of the Regulation, it would do so only after 1 July 2024 (namely five years after the entry into force of the Regulation). Therefore, certain SPCs will be subject to the exception only from a certain point in time of their 'life', namely after 1 July 2024. This is the meaning of 'progressive basis' and 'depending on its date of entry into effect and its duration' in recital (19).

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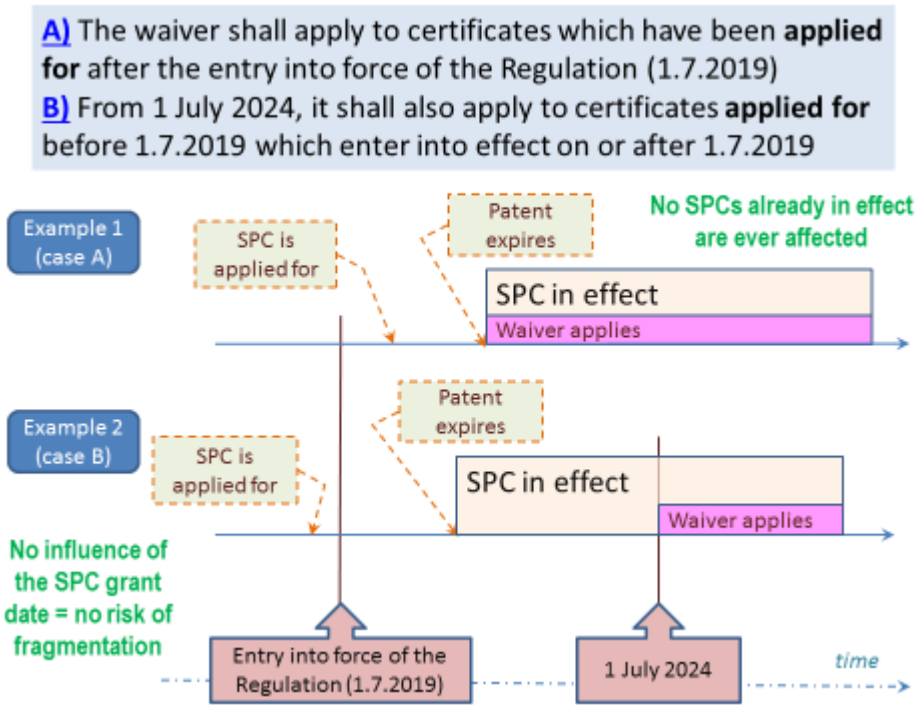
1 The 1.7.2024 date will of course change slightly, to align to exactly five years after the actual entry into force date.

2 Fragmentation could only occur if, in respect of a given product, a rightholder files SPC applications on different dates in different Member States, some before the date of entry into force of the Regulation and some after it.

Finally, 2024 leaves a reasonable period of time to all stakeholders to adjust to the new legal situation, while introducing the waiver in a manner that will be economically useful in view of the patent cliff of the coming decade, since all 5-year SPCs coming into effect after the entry into force of the Regulation will be subject, at some point in their lifetime (as of 1 July 2024), to the exception.

The approach can be illustrated in visual form as follows:



- **Fee for notification (Article 12)**

Further to the request of some delegations, Article 12(2) and recital (13) now lay down that authorities may impose a once-off fee for the notification to the authority. This would reimburse authorities for any costs and burdens that some delegations fear may arise from the new regime. A new addition to Article 5(2)(d) stipulates that the payment of such a fee, where it exists, is a pre-condition for the exception to apply.

- **Aim (Recital 7)**

It is now clarified that the aim of the Regulation is the competitiveness of the Union, not of just one sector of the pharmaceutical industry. This will be achieved by allowing generic and biosimilar medicines to be made for the exclusive purpose of export.

In addition, reference is now made to how the Regulation will promote the 'common interest' in the Union, as medicines would become, to some extent, more accessible to patients in the Union after the expiry of a certificate.

- **Recital 8**

The example of 'logistics operators' has been removed, in line with the request of some delegations.

- **Recital 11**

It is now stated that the essence of the right conferred by an SPC (exclusive right of a SPC holder to place its product on the EU market during the SPC term) is being fully respected, since it is not affected by the waiver.

- **Recital 17**

As regards the unique identifier in recital (17) related to Implementing Regulation (EU) 2016/161 laying down rules for the safety features appearing on the packaging of medicinal products for human use, which is one of the major safeguards preventing illicit medical products coming on the EU market, the language of the recital is slightly adjusted, to clarify the relationship with Directive 2001/83/EC.

- **Recital 22**

The recital on the Charter remains unchanged, and the substance of new drafting suggestions received from delegations has been incorporated, where possible, into other recitals (notably recitals (7) and (19)).

ANNEX

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[3],

Acting in accordance with the ordinary legislative procedure,

[3] OJ C , , p. .

Whereas:

(1) Regulation (EC) No 469/2009 of the European Parliament and of the Council[4] 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[5] or Directive 2001/82/EC of the European Parliament and of the Council[6], 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 countries outside the EU ('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 makers of generics and biosimilars established in the Union from making in the Union, 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 makers 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 makers located in third countries where protection does not exist or has expired.

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4 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).

5 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).

6 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).

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

(6) Without any intervention, the viability of makers of generics and biosimilars **established** 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 promote the competitiveness **of the Union** ~~makers of generics and biosimilars established in the Union~~, enhancing growth and job creation in the internal market and contributing to a wider supply of products under uniform conditions, **by** ~~This will~~ **allowing makers of generics and biosimilars established in the Union to make in the Union medicinal products or products for the exclusive purpose of export** to third country markets where protection does not exist or has expired**, thus also helping these makers to compete effectively in those third country markets**. It should also complement the efforts of the Union's trade policy to ensure open markets for Union-based makers of medicinal products or **products** ~~active ingredients~~. **Over time, the Regulation should benefit the entire pharmaceutical sector in the Union, by allowing all players, including newcomers, to reap the benefits of the new opportunities opening up in the fast-changing global pharmaceutical market. Furthermore, the common interest in the Union would be promoted, as medicines would become, to some extent, more accessible to patients in the Union after the expiry of the certificate.**

(8) In these specific and limited circumstances, and in order to create a level playing field between Union-based makers and third country makers, it is appropriate to restrict the protection conferred by a 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, where such acts would otherwise require the consent of a certificate-holder ('related acts'). For instance, such acts may include the possession, supply, import, or making of **products** ~~active ingredients~~ for the 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. 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.

(9) This exception should apply to a product, or a product to be placed on the market as a medicinal product, protected by a certificate ('a product or a medicinal product containing that product'). It should cover the making of the product and the product resulting from that making which is protected by a certificate in the territory of a Member State.

(10) The exception should not cover placing the product or medicinal product containing that product, made for the exclusive purpose of export, on the market in the Member State where a 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. It should not cover temporary storage of the product or medicinal product containing that product for any purposes other than those set out in this Regulation.

(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 should not ~~unreasonably~~ conflict with **the** normal exploitation of the product or medicinal product containing that product in the Member State where the certificate is in force, **namely with the core exclusive right of the certificate holder to make that product for the purpose of placing it on the Union market during the term of the certificate**. **In addition, the exception should not** ~~**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 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 duty on the person **that makes a** ~~making the~~ product or medicinal product containing that product for the exclusive purpose of export, requiring that person **(or a person on whose behalf that making is done, if that person is different)** to provide certain information to the authority which granted the 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 starts for the first time in that Member State, or before any related act prior to that making, whichever is the earlier. It 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 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, but may be requested by a court or other competent authority. **Member States should be allowed to require that notifications be subject to the payment of a once-off fee. This fee should be set at a level which does not exceed the administrative cost of processing notifications.**

(13a) The maker should also inform the certificate holder, **through appropriate and documented means** ~~in writing~~, of the intention to make a product or medicinal product containing that 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 or medicinal product containing that 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 or medicinal product containing that product as being exclusively intended for the purpose of export to third countries. The making and related acts should only fall outside the protection conferred by a certificate if the product or medicinal product containing that 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 certificate. ~~This includes the~~ **Any** illicit diversion onto the Union market, during the term of the certificate, of any product or medicinal product containing that product made within the terms of the exception**, will remain prohibited**.

(17) **This Regulation is without prejudice to the respect of other intellectual property rights that may protect other aspects of a medicinal product.** 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[7] and Regulation (EU) No 608/2013 of the European Parliament and of the Council[8]. Furthermore, this Regulation does not affect the rules on the unique identifier provided for **by Directive 2001/83/EC of the European Parliament and of the Council and by ~~in~~** Commission Delegated Regulation (EU) 2016/161. **According to Directive 2001/83/EC, medicinal products produced exclusively for export do not need to bear unique identifiers.**

(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.

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[7] 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).

[8] 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).

(19) ~~In order to ensure that the rights of holders of supplementary protection certificates are not unduly restricted, the exception provided for in this Regulation should only apply to certificates that are applied for after the entry into force of this Regulation, as well as to certificates that enter into effect five years after the entry into force of this Regulation, irrespective of when these certificates were granted. It is necessary to ensure a timely entry into force of this Regulation, given that, as from 2020, patents will expire in third countries for many high-turnover medicinal products that are protected by certificates in the Union, thus opening up considerable new opportunities in global markets that makers of generics and biosimilars established in the Union should be able to seize. At the same time, given that the period of time between the granting and entry into effect of a certificate is approximately five years on average, These timing arrangements should allow a reasonable time for certificate holders to adjust to the changed legal context and to make appropriate investment decisions in a timely way, while ensuring that the economic benefits of the exception can be effectively reaped by makers of generics and biosimilars.~~

In order to ensure that the rights of certificate holders are not unduly restricted, the exception provided for in this Regulation should apply to certificates that are applied for on or after the day of the entry into force of this Regulation. In order to safeguard the rights of certificate holders, the exception should not apply to a certificate that has already entered into effect at the date of entry into force of the Regulation. At the same time, in order to safeguard the aim of this Regulation, and since a certificate enters into effect a relatively long time after its date of filing, it is justified to bring within the scope of the Regulation, over a certain period of time, a certificate that was applied for before the entry into force of this Regulation, but has not yet entered into effect before that entry into force, and irrespective of whether or not that certificate has been granted before the entry into force of the Regulation. Therefore, the exception should apply, as from five years from that entry into force, to a certificate that enters into effect as from that entry into force. This 'certain period of time' for each individual certificate that enters into effect after that entry into force should ensure that the exception is applied, on a progressive basis, to such a certificate, depending on its date of entry into effect and its duration. Such application of the exception would allow the holder of a granted certificate that is not yet in effect by the date of the entry into force of the Regulation a reasonable period of transition to adapt to the changed legal context, while at the same time ensuring that makers of generics and biosimilars can benefit effectively, without excessive delay, from the exception.

(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[9], 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 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 makers of generic and biosimilar 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 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.

[9] 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 certificate, by confining the exception provided for in this Regulation to the making of a product or a medicinal product containing that product only for the purpose of export outside the Union and to the acts strictly necessary for such making or for the actual export itself. This exception does not go beyond what is necessary and appropriate in the light of the overall objective of this Regulation, which is to promote the competitiveness of the Union by avoiding delocalisations and allowing Union-based makers of generics and biosimilars to compete on fast-growing, global markets where protection does not exist or has already expired. Indeed, it is necessary to benefit from those positive economic effects arising from the exception, as otherwise the Union would risk substantially weakening its position as a hub for pharmaceutical development and manufacturing. It is therefore appropriate to introduce that exception in order to increase the competitive position of Union-based makers of generics and biosimilars in third countries whose markets are in any event open to competition, whilst leaving the scope and duration of the protection granted by the certificate in the Union untouched. The appropriateness of the measure is further ensured by providing for appropriate safeguards regulating the use of the exception. The Regulation should allow sufficient time for public authorities to put in place the necessary arrangements to receive and publish notifications,

HAVE ADOPTED THIS REGULATION:

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

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

(0) in Article 1, the following point is added:

(f) **‘**‘maker’ means **any** person **established in the Union** ~~doing the making referred to in Article 4(2)(a)(i), for the exclusive purpose of export to third countries, or the person~~ **that makes 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 **a** ~~the~~ person **established in the Union** on whose behalf that making is done **if that person is different to the person doing that making**.’;

(1) Article ~~4~~ **5** is replaced by the following:

*‘Article ~~4~~ **5** – **Effects of the certificate*** ~~*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.~~

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,** ~~T~~the certificate referred to in paragraph 1 shall not confer protection against a particular act 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 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[10]; or

(ii) any related act that is strictly necessary for that making in the Union 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 maker of the information listed in paragraph 3 no later than three months before the start date of making in that Member State, or **no later than three** ~~1~~ month**s** ~~**in advance of**~~ **before** any related act prior to that making that would otherwise be prohibited by the protection conferred by a certificate, whichever is the earlier;

(ba) the certificate holder is informed, **through appropriate and documented means** ~~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, or **no later than three** ~~1~~ month**s** ~~**in advance of**~~ **before** any related act prior to that making that would otherwise be prohibited by the protection conferred by a certificate, whichever is the earlier;

(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 to the certificate holder, the maker shall also inform the certificate holder before these changes take effect;

(c) the maker ensures that a logo, in the form set out in Annex -II, is affixed to the outer packaging of the product or product to be placed on the market as a medicinal product, referred to in paragraph 2(a)(i), or, if there is no outer packaging, to its immediate packaging;

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[10] *A number of delegations consider that stockpiling should also be included within the scope. Discussion reserved for COREPER.*

(d) the maker complies with the requirements of paragraph 4 **and, if applicable, of Article 12(2)**.

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;

(d) (deleted)

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

(f) the third country or third countries to which the product or medicinal 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 paragraph 2 where, and as long as, that certificate applies.

5. Paragraph 2 shall apply to certificates **that are** ~~which have been~~ applied for **on or** after the entry into force of this Regulation**.** ~~, as well as to certificates which have entered into effect on or after *(please insert the date of the first day of the month that follows the date of the entry into force of this Regulation, plus 5 years);*~~[11]

From 1 July 2024[12]**, paragraph 2 shall also apply to certificates that have been applied for before the entry into force of this Regulation and that enter into effect on or after the entry into force of this Regulation.**

Paragraph 2 shall not apply to certificates that enter into effect before the entry into force of this Regulation.';

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

4. 'The authority referred to in Article 9(1) shall publish the information listed in points (a) and (c) of Article ~~4~~ **5**(3). It shall also publish any changes to this information notified in accordance with the first sentence of Article ~~4~~ **5**(2)(bb). The remaining information notified under Article ~~4~~ **5**(3) shall not be published by the authority, but shall be provided by it, upon request, exclusively to a court or other competent authority.';

(3) the following Article is inserted:

'Article 21a – Evaluation

No later than five years after the date referred to in Article ~~4~~ **5** (5), and every five years thereafter, the Commission shall carry out an evaluation of Articles ~~4~~ **5**(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.';

~~[11] The previous Presidency text (12514/18) contained several alternatives for Article 4(5). In this paragraph the text changes are indicated in comparison to the initial Commission proposal.~~

[12] *Date to be replaced by the actual date of entry into force of the Regulation, plus five years.*

(4) Article 12 is replaced by the following:

'Article 12 – *Fees*

1. Member States may require that the certificate be subject to the payment of annual fees.

2. Member States may require that the notification referred to in Article 5(2)(b) be subject to the payment of a fee.';

(4 **5**) the Annexes to this Regulation are inserted as Annex –II and –I.

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.

ANNEX -I

Form for notification pursuant to Article ~~4~~ **5**(2)(b)

Information that shall be published by the authority	
(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	
Information that shall not be published by the authority	
(b) Address(es) of the premises where the making is to take place in the relevant Member State	
(d)~~*~~ *(deleted)*	
(e) Intended start date of making in the relevant Member State	
(f) Third country or countries to which the product **or medicinal product** is to be exported	

point (d) of Article ~~4~~ **5(2)(b) is deleted in the revised Presidency text; however, for ease of reference during discussions the numbering of paragraphs in the notification form is kept the same as in the Article.*

In addition, the current points (a) to (f) will be re-numbered at the jurists-linguists stage (e.g. meaning that current point (c) will become point (b)). These changes will also be carried through in the relevant articles.