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From:	Presidency and the incoming Romanian 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 medicinal products - Revised Presidency text

Further to the views expressed at the Competitiveness Council on 29 November 2018, the discussions held in the meeting of the Intellectual Property Working Party on 28 November 2018, and drawing on written comments from delegations on the room document presented at that Working Party meeting (WK 14701/2018 INIT), delegations will find at Annex to this note a revised text of the above proposal prepared jointly by the Presidency and the incoming Romanian Presidency.

This revised text will be submitted for discussion in the Intellectual Property Working Party at its meeting on Tuesday, 8 January 2019, with a view to transmitting a compromise text as soon as possible to the Committee of Permanent Representatives for approval of a negotiating mandate for trilogue negotiations with the European Parliament.

Changes compared to the previous Presidency compromise text (14647/18) are highlighted using **bold underlined** for additions and ~~**strikethrough**~~ for deletions.

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

- **Definition of 'maker' and of 'product, or medicinal product containing that product'**

The definition of 'maker' has been further refined (Article 1(f)), following further drafting suggestions from delegations, to clarify that the maker can only be one person, namely the person responsible for the production. Recital 13 is also adjusted, to confirm that 'on whose behalf' also includes the possibility that the person itself may also directly be the person who does the making.

The definition describes that the making is of 'a product or a medicinal product containing that product'. This language reflects the preference expressed by a number of delegations during the negotiation on the Regulation. For the purpose of consistency of terminology, this formluation is now introduced into Article 5(2)(a)(i) as well. Likewise, Recital 9 is also aligned.

For the purpose of consistency of terminology, but above all of legal certainty, a new definition is now introduced (Article 1(g)), using the agreed language that had been in Recital 9 up to now. With this change, there can thus be no misunderstanding between the new language being introduced (product/medicinal product containing that product) and the previous language used in Regulation (EC) 469/2009.

- **Scope of the exception**

The decision on the issue of stockpiling has been reserved for COREPER level. Recital 7 currently states that the Regulation is in the common interest of the Union, and that the export waiver will, to some extent, make medicines more accessible in the Union after expiry of SPC protection.

A number of delegations wish to expand the exception, so that its scope also include stockpiling. These delegations consider that this would further improve the competitiveness of EU-based Generics and Biosimilars, due to the faster entry of these medicines onto the EU market as of day-one after the expiry of the SPC, and the facilitation of faster access for EU patients. Some of these delegations have stated that their final view on whether to call for stockpiling will be contingent on the decision on application in time (Article 5(5)), while several of these delegations have come forward with a joint proposal to introduce stockpiling during the final 12 months prior to the expiry of a certificate.

Other delegations strongly oppose stockpiling, arguing that it would increase the risk of illicit diversion onto the EU market of generic and biosimilar medicines, and that the interest of originators and of research into innovative medicines in the EU would be undermined.

A few delegations call for the exception to apply to intra-EU exports (from 'protected' Member States to 'unprotected' ones) in addition to third countries. However, allowing this could increase the risk of diversion of generics and biosimilars onto protected Union markets, could have an impact on originators in unprotected Union markets, and more generally, could lead to more fragmentation in the single market.

- **Notification**

For some delegations, their final view on notification-related issues will be subject to the decisions reached on scope (stockpiling) and application in time.

On foot of lengthy discussions, written inputs from delegations, and detailed consideration of frequently diverging demands, the Presidency revised text proposes a compromise package on the notification and information obligations that seeks to meet the request of many delegations in favour of simplification of the regime. That compromise also aims at eliminating any additional burden on competent authorities (patent offices).

The newly re-drafted notification requirement covers all information that certificate holders need for them to be able to ensure and monitor compliance in relation to the rights conferred by their certificates, whilst avoiding the disclosure of confidential or commercially sensitive information. The information to be provided to the patent office in the Member State of making, and to the SPC holder in that Member State, is therefore now identical, and, in the interest of fair competition, all this information is to be published by that authority as soon as possible (albeit without the fixed deadlines). These changes in turn make possible important further streamlining and simplification of the text (notably merging (previous) Article 5(2)(ba) into Article 5(2)(b), and simplifying Article 5(2)(bb), which now becomes Article 5(2)(ba)).

However, such streamlining requires important adjustments to the information actually notified (under Article 5(3)), a subject on which there have been many requests by delegations. Sensitive information, such as the premises of manufacture is now deleted from the notification/information obligation (point (b) of Article 5(3)), while other relevant information is added, namely details of the Member State in which the first prior related act, if any, is to take place and of the corresponding certificate concerned (see changes in points (b) and (c) of Article 5(3)), as this act is relevant for the timing of the notification in accordance with Article 5(2)(b). Obviously, in the event that there were no prior related acts (before the making), then such information would not be required. The date of notification shall also now be published (Article 11), and as such will replace the notification of the 'intended' start date of manufacture, which was a somewhat problematic concept for some delegations (former point (e) of Article 5(3)). In any event, it remains the case that no making or prior related act can take place during the three months following the date of the notification.

Most diverging views have been expressed on the requirement to notify third country export destinations (point (f) of Article 5(3)). This point, therefore has now been re-engineered, to essentially remove confidential and sensitive details of future export intentions. Instead, the maker must now provide the reference number of the corresponding marketing authorisation (or equivalent) obtained in the third country of export in respect of a given medicinal product, so that the country in question is identifiable. The maker must provide this information in the notification if it is already publicly available, or by means of an update to the notification if it is only delivered later, but at the latest prior to the actual export itself. Such marketing authorisation would show that the medicinal product is genuinely intended for placing on the market in that country. If such an authorisation is granted, but not published, the maker can then choose between communicating either the reference number or the name of the third country of export, before starting to export to that country. During the period between grant and publication of the authorisation, the manufacturer can start to export if the name of the country of export has been included in the notification. As a failsafe transparency measure, in the unlikely event of no marketing authorisation or equivalent regime existing in a given third country, then only the name of that intended country of export would have to be notified. In the absence of any information in relation to a specific third country, exports to that country would then not be covered by the waiver.

An additional provision clarifies that incorrect or missing information related to a third country affects only exports to that country (new paragraph (3b) of Article 5), i.e. it does not invalidate the waiver as a whole. Recitals 13 and 13a explain the rationale of all these changes, and Recital 13 also clarifies that updates to the notification (under renumbered point (ba) of Article 5(2)), in respect of information on a marketing authorisation in a third country that only becomes publicly available in that country after the original notification is filed, should be provided promptly.

The standard notification form (Annex –I) is now made more user-friendly. While its principal vocation is for notification to the patent office (under Article 5(3a)), the text now states that a maker may also choose, if it wishes, to use this form to comply with the obligation of providing the required information through appropriate and documented means to the certificate holder (Recital 13a).

- **Logo**

The provision on the logo (point (c) of Article 5(2)) is adjusted, to confirm that the logo should be affixed to both the outer packaging and immediate packaging.

- **Application in time**

This is a key issue in the negotiation, and on which a decision will need to be taken at COREPER level.

Building on the broad consensus in the Working Party in favour of the Presidency's conception of the 'structure' of the entry into application of the waiver (Article 5(5) and Recital 19) as proposed in the previous compromise text (document 14647/18 of 22 November 2018), this concept is maintained in this form in the new Presidency revised text, meaning that the basis on which the exception applies is the date of the filing of the application for the certificate. This approach reduces to the minimum any risk of disparities in the legal situation of the applicant for a given product with regard to whether the waiver applies/does not apply to it, and such disparities would only be possible if a right holder filed its SPC application on different dates in different Member States, some before the date of the entry into force of the Regulation, and some after it. A new Recital 19a is added to provide further clarification on this point.

Regarding more specifically when the waiver should begin to apply, all delegations agree that SPCs applied for after the Regulation enters into force should fall within the scope of the waiver (cf. Article 5(5) first sentence). In addition, an overwhelming majority of delegations now accept that the waiver should also apply, from a fixed date (to be decided in COREPER), to certificates applied for before the entry into force of the Regulation and which enter into effect after the Regulation itself enters into force (cf. Article 5(5) second sentence). The views expressed at the Competitiveness Council on 29 November 2018 however showed that there is no overall consensus so far on what that date should be.

A large number of delegations call for a start of application in 2021, though many of these delegations are prepared to show flexibility and accept a date in the course of 2022. Other delegations support the previous Presidency proposed date (1 July 2024). A few delegations would prefer a much later entry into application.

In the face of potential blocking minorities on the two main sides of the argument, the Presidency revised text therefore now proposes a compromise date of 1 January 2023, which would be adjusted in the final Regulation to the date corresponding to 3.5 years after the date of entry into force of the Regulation. This would still leave 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 years, since both the average-length SPC coming into effect after the entry into force of the Regulation (i.e. 3.5 years) and, by extension all full five-year SPCs, will be subject, at some point in their lifetime (i.e. as of 1 January 2023), to being covered by the exception.

- **Fees**

For the avoidance of doubt, it is clarified that a proportionate fee may also be levied by the authority in respect of administrative costs arising from processing updates to a notification (Article 12(2) and Recital 13).

- **Recital 8**

A minor clarification is introduced to the first citation of related acts, confirming that they refer of course to acts carried out ‘in the Union’.

- **Recital 13**

Aside from the changes set out above, this recital takes on board the request of some delegations to further spell out the implications of the existing language that the exception only applies for the purpose of exports to third countries where SPC or similar protection does not exist or has expired (Recitals 3, 4, 7, 21 and 22). The Presidency revised text therefore now proposes that reference be made (in Recital 13) to the responsibility of the maker to ensure that protection does not exist or has expired in a country of export, subject to any limitations or exemptions in that country (e.g. such as a local 'Bolar' exemption or special local pharmaceutical regulatory requirements). In addition, Recital 13 has been adjusted to clarify, as requested by some delegations, that a notification may be filed before the date on which the exception enters into application.

- **Recital 14**

This recital now recalls that, in the event that the conditions of the waiver are not respected by the maker, the certificate holder, in enforcing its legitimate rights under the certificate, should respect the general obligation of not initiating abusive litigation (as set out in Article 3(2) of Directive 2004/48/EC on the enforcement of intellectual property rights). Recital 14 also clarifies that the maker must, as part of the obligation vis-à-vis the supply chain, explicitly inform also the exporter that the production under the waiver is for the exclusive purposes of export.

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[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 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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[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).

(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, enhancing growth and job creation in the internal market and contributing to a wider supply of products under uniform conditions, by 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. 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 **in the Union** 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 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 who are in a contractual relationship with the maker.

(9) This exception should apply to a product, or a **medicinal** product **containing that 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 **and the making of the medicinal product containing that product**.

(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 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 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**n information obligation** ~~duty~~ on the **maker, namely the** person **established in the Union,** ~~that makes~~ **on whose behalf the making of** a product or medicinal product containing that product for the exclusive purpose of export~~,~~ **is done (this includes the possibility of the person itself directly doing the making).** ~~requiring that person (or a person on whose behalf that making is done, if that person is different)~~ ~~to~~ **Namely, the maker should** 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. **In the interests of transparency,** ~~T~~**t**he authority should be required to publish**, as soon as possible,** ~~certain elements of that~~ **the** information **it receives, together with the date of notification 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, **and updates to 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 **and updates**.

(13a) The maker should also inform the certificate holder, through appropriate and documented means, of the intention to make a product or medicinal product containing that product pursuant to the exception~~.~~ **, by providing the certificate holder with the same information as notified to the authority. That information is limited to what is necessary and appropriate for the certificate holder to assess whether the rights conferred by the certificate are being respected, and does not include confidential or commercially sensitive information. The information to the certificate holder may be provided by making use of the same common notification form, and the information provided should be updated as and when appropriate.** ~~This information should be updated as and when appropriate.~~

(13b) Regarding related acts prior to the making, if any, the notification should list the name of the Member State where the first related act, which would otherwise require the consent of a certificate holder, is to take place, as this information is relevant to the timing of the notification.

(13c) If the local marketing authorisation, or equivalent, in a specific third country, for a given medicinal product, is published after the notification is made, the notifcation should be promptly updated to include the reference number of that marketing authorisation, at the latest before the actual export of the medicinal product to that third country takes place. If a marketing authorisation or equivalent mechansim applies, but the reference number of the granted authorisation is not published or is pending publication, the maker should be required to provide, in the notification, either that reference number or the name of the third country of export. As a failsafe, if no marketing authorisation or equivalent applies in that country, the maker should then be required to provide, in the interests of transparency, the name of the third country of export.

(13d) For reasons of proportionality, failure to comply with these requirements regarding a third country would only affect exports to that country, and exports to such third country would thus not benefit from the exception. It should be the responsibility of the maker established in the Union to verify that protection does not exist or has expired in a country of export, subject to any limitations or exemptions in that country. A notification to an authority and the corresponding information to the certificate holder may be provided during the period following the entry into force of the Regulation and the date on which the exception itself becomes applicable.

(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 **in the Union**, **including the exporter,** 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**, while paying due regard to the general obligation, set out in Directive 2004/48/EC of the European Parliament and of the Council[5], not to engage in abusive litigation.**

(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.

[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).**

(16) Any act not covered by the exception introduced by this Regulation will remain within the scope of the protection conferred by a certificate. 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~~[6] and Regulation (EU) No 608/2013 of the European Parliament and of the Council[7]. 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 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.

~~[6] 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).~~

[7] 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) **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.** In order to ensure that the rights of certificate holders are not **excessively** ~~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 **1 January 2023** ~~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.

(19a) An applicant for a certificate might be expected to file an application at around the same date in each Member State of filing. However due to differences in national procedures for examination of applications, the date of grant might vary significantly from one Member State to another, thereby creating disparities in the legal situation of the applicant in the different Member States where the certificate is applied for. Introducing the exception on the basis of the date of filing of the application for a certificate would therefore promote uniformity and limit this risk of disparities.

(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 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.

[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 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 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 person established in the Union on whose behalf that making is done if that person is different to the person doing that making.';~~

''maker' means the person established in the Union on whose behalf the making of a product or a medicinal product containing that product, for the exclusive purpose of export to third countries, is done;

(g) 'a product, or a medicinal product containing that product' means a product, or a product to be placed on the market as a medicinal product, protected by a certificate.';

(1) Article 5 is replaced by the following:

'Article 5 – Effects 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, 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 medicinal product containing that product**~~, or a product to be placed on the market as a medicinal product~~, for the exclusive purpose of export to third countries[9]; or

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

(b) **the maker, through appropriate and documented means, notifies** 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~~ **and informs the certificate holder** 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 months before ~~any~~ **the first** 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, 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 months 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** ~~bb~~) if the information **listed** ~~referred to~~ in paragraph **3** ~~2(b)~~ changes, the maker shall notify the authority referred to in Article 9(1) **and shall inform the certificate holder,** 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~~;

[9] *A number of delegations consider that stockpiling should also be included within the scope.*

(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), **and** ~~or, if there is no outer packaging,~~ to its immediate packaging;

(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 **Member State** ~~address, or addresses, of the premises~~ where the making is to take place ~~in the relevant Member State~~ **and the Member State where the first related act prior to that making is to take place**;

(c) the number of the certificate granted in the ~~relevant~~ Member State **of making, and the number of the certificate granted in the Member State of the first related act prior to that making**;

(d) (deleted)

(e) **(deleted)**~~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~~**for medicinal products, the reference number of the marketing authorisation or equivalent in each third country of export or, failing that, the name of that third country.**

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

3b. Failure to comply with the requirements of paragraph 3(f) in respect of a third country shall only affect exports to that country, and such exports would thus not benefit from the exception.

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 applied for on or after the entry into force of this Regulation.

From **1 January 2023**~~1 July 2024~~[10], 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**, as soon as possible,** the information listed in ~~points (a) and (c) of~~ Article 5(3)**, together with the date of notification of that information**. It shall also publish**, as soon as possible,** any changes to this information notified in accordance with ~~the first sentence of~~ Article 5(2)(b**a**~~b~~). ~~The remaining information notified under Article 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.~~';

[10] *Date to be replaced by the actual date of entry into force of the Regulation, plus ~~five~~ **3.5** years.*

(**3** ~~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**s** referred to in Article 5(2)(b) **and (ba)** be subject to the payment of a fee.';

(**4** ~~3~~) the following Article is inserted:

'Article 21a – Evaluation

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

(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*

Logo

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

Form for notification pursuant to Article 5(2)(b)

<table>
<tr><td colspan="3"><s>Information that shall be published by the authority</s></td></tr>
<tr><td><u>Tick the appropriate box</u></td><td colspan="2">☐ <u>New notification</u>
☐ <u>Update of an existing notification</u></td></tr>
<tr><td>(a) Name and address of the maker</td><td colspan="2"><u>…</u></td></tr>
<tr><td rowspan="2"><u>(b) Member State where making is to take place and Member State where first related act prior to making is to take place</u></td><td><u>Member State of making:</u></td><td><u>…</u></td></tr>
<tr><td><u>Member State of first related act:</u></td><td><u>…</u></td></tr>
<tr><td rowspan="2">(c) Number of <s>the</s> certificate granted in the <s>relevant</s> Member State <u>of making and number of certificate granted in Member State of first related act prior to making</u></td><td><u>Certificate of Member State of making</u></td><td><u>…</u></td></tr>
<tr><td><u>Certificate of Member State of first related act</u></td><td><u>…</u></td></tr>
<tr><td colspan="3"><s>Information that shall not be published by the authority</s></td></tr>
<tr><td><s>(b) Address(es) of the premises where the making is to take place in the relevant Member State</s></td><td colspan="2"></td></tr>
<tr><td>(d)<s>*</s> (deleted)</td><td colspan="2"></td></tr>
<tr><td>(e)* <u>(deleted)</u><s> Intended start date of making in the relevant Member State</s></td><td colspan="2"></td></tr>
<tr><td rowspan="3">(f) <s>Third country or countries to which the product or medicinal product is to be exported</s> <u>for medicinal products, reference number of marketing authorisation or equivalent in each third country of export, or name of third country of export</u></td><td colspan="2"><u>…</u></td></tr>
<tr><td colspan="2"><u>…</u></td></tr>
<tr><td colspan="2"><u>…</u></td></tr>
</table>

**point (d) of Article 5(3) has been deleted; however, for ease of reference during discussions, the numbering of paragraphs, both in the form above and in Article 5, is retained, but will be adjusted before adoption of the Regulation. In addition, the current points (a) to (f) will be re-numbered at the jurists-linguists stage (i.e. meaning that current point (f) will become point (d)). These changes will also be carried through in Article 5.*