Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products (Text with EEA relevance)

REGULATION (EU) 2019/933 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 May 2019

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[(2)],

Whereas:

(1) Regulation (EC) No 469/2009 of the European Parliament and of the Council[(3)] 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 2001/82/EC[(4)] or 2001/83/EC[(5)] of the European Parliament and of the Council, may, under the terms and conditions provided for in that Regulation, be the subject of a supplementary protection certificate (‘certificate’).

(2) By providing for a period of supplementary protection, 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 might 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 making of generics and especially of biosimilars, and in the making of their active ingredients, in particular in countries outside the Union (‘third countries’) in which protection does not exist or has expired.

(4) The absence in Regulation (EC) No 469/2009 of any exception to the protection conferred by the certificate has had the unintended consequence of preventing makers of

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generics and biosimilars established in the Union from making generics and biosimilars in the Union, even for the purpose of export to third-country markets in which protection does not exist or has expired. Likewise, makers are prevented from making generics and biosimilars for the purpose of storing them for a limited period before the expiry of the certificate. Those circumstances make it more difficult for those makers, in contrast to makers located in third countries where protection does not exist or has expired, to enter the Union market immediately after expiry of the certificate, given that they are not in a position to build up production capacity for the purpose of export or for the purpose of entering the market of a Member State until the protection provided by that certificate has expired.

(5) Those circumstances put makers of generics and biosimilars established in the Union at a significant competitive disadvantage in comparison with makers based in third countries that offer less or no protection. The Union should strike a balance between restoring a level playing field between those makers and ensuring that the essence of the exclusive rights of holders of certificates (‘certificate holders’) is guaranteed in relation to the Union market.

(6) Without intervention, the viability of makers of generics and biosimilars established in the Union could be threatened, with consequences for the Union's pharmaceutical industrial base as a whole. That situation could affect the fully effective functioning of the internal market through the loss of potential new business opportunities for makers of generics and biosimilars, thereby possibly diminishing related investments and hampering job creation within the Union.

(7) The timely entry of generics and biosimilars into the Union market is important, particularly in order to increase competition, to reduce prices and to ensure that national healthcare systems are sustainable and that patients in the Union have better access to affordable medicines. The importance of such timely entry was underlined by the Council in its conclusions of 17 June 2016 on strengthening the balance in the pharmaceutical systems in the Union and its Member States. Regulation (EC) No 469/2009 should, therefore, be amended so as to allow the making of generics and biosimilars for export and storing, while bearing in mind that intellectual property rights remain one of the cornerstones of innovation, competitiveness and growth in the internal market.

(8) The aim of this Regulation is to promote the competitiveness of the Union, thereby 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 products, or medicinal products containing those products, for the purpose of export to third-country markets in which protection does not exist or has expired, thereby also helping those makers to compete effectively in those third-country markets. This Regulation should also allow such makers to make and store products, or medicinal products containing those products, in a Member State for a defined period pending the expiry of the certificate, for the purpose of entering the market of any Member State upon expiry of the corresponding certificate, thereby helping those makers to compete effectively in the

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Union immediately after protection has expired ('EU day-one entry'). This Regulation should also complement the efforts of the Union's trade policy to ensure open markets for makers of products, or medicinal products containing those products, established in the Union. Over time, this 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 general interest of the Union would be promoted given that, by reinforcing Union-based supply chains for medicines and by allowing storing with a view to entry into the Union market upon expiry of the certificate, medicines would become more accessible to patients in the Union after the expiry of the certificate.

(9) In those specific and limited circumstances, and in order to create a level playing field between makers established in the Union and third-country makers, it is appropriate to provide for an exception to the protection conferred by a certificate so as to allow the making of a product, or a medicinal product containing that product, for the purpose of export to third countries or of storing, and any related acts in the Union strictly necessary for that making or for the actual export or the actual storing, where such acts would otherwise require the consent of a certificate holder ('related acts'). For instance, such related acts could include: possessing; offering to supply; supplying; importing; using or synthesising an active ingredient for the purpose of making a medicinal product; or temporary storing or advertising for the exclusive purpose of export to third-country destinations. That exception should also apply to related acts performed by third parties who are in a contractual relationship with the maker.

(10) The exception should apply to a product, or a medicinal product containing that product, protected by a certificate. It should cover the making of the product protected by a certificate in the territory of a Member State and the making of the medicinal product containing that product.

(11) The exception should not cover placing a product, or a medicinal product containing that product, which is made for the purpose of export to third countries or of storing with a view to EU day-one entry, on the market of a Member State where a certificate is in force, either directly or indirectly after export, nor should it cover re-importation of such a product, or medicinal product containing that product, into the market of a Member State in which a certificate is in force. Moreover, it should not cover any act or activity carried out for the purpose of import of products, or medicinal products containing those products, into the Union merely for the purposes of repackaging and re-exporting. In addition, the exception should not cover any storing of products, or medicinal products containing those products, for any purposes other than those set out in this Regulation.

(12) By limiting the scope of the exception to making for the purpose of export outside the Union or to making for the purpose of storing, and to acts strictly necessary for such making or for the actual export or the actual storing, the exception provided for in this Regulation should not conflict with the normal exploitation of the product, or the medicinal product containing that product, in the Member State in which 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

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certificate. In addition, that exception should not unreasonably prejudice the legitimate interests of the certificate holder, whilst taking account of the legitimate interests of third parties.

(13) Effective and proportionate safeguards should apply in relation to the exception in order to increase transparency, to help the holder of a certificate enforce its protection in the Union and check compliance with the conditions set out in this Regulation, and to reduce the risk of illicit diversion onto the Union market during the term of the certificate.

(14) This Regulation should impose an information obligation on the maker, namely the person established in the Union, on whose behalf the making of a product, or a medicinal product containing that product, for the purpose of export or storing, is carried out. It is possible that the maker directly carries out the making. That information obligation should consist of requiring the maker to provide certain information to the competent industrial property office, or another designated authority, which granted the certificate ('the authority') in the Member State where the making is to take place. A standard form for notification should be provided for this purpose. The information should be provided before the making of a product, or a medicinal product containing that product, starts for the first time in that Member State, or before any related act prior to that making, whichever is the earlier. The information should be updated as and when appropriate. The making of a product, or a medicinal product containing that product, and the related acts, including those performed in Member States other than the one of making in cases where the product is also protected by a certificate in those other Member States, should only fall within the scope of the exception where the maker has sent the notification to the authority of the Member State of making, and where the maker has informed the holder of the certificate granted in that Member State. Where making takes place in more than one Member State, a notification should be required in each of those Member States. In the interests of transparency, the authority should be required to publish, as soon as possible, the information received, together with the date of notification of that information. Member States should be allowed to require that notifications, and updates to notifications, be subject to the payment of a one-off fee. That fee should be set at a level which does not exceed the administrative cost of processing notifications and updates.

(15) The maker should also inform the certificate holder, through appropriate and documented means, of the intention to make a product, or a 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 should be limited to what is necessary and appropriate for the certificate holder to assess whether the rights conferred by the certificate are being respected, and should not include confidential or commercially sensitive information. The standard form for notification could also be used to inform the certificate holder, and the information provided should be updated as and when appropriate.

(16) With regard to related acts, if any, prior to the making of a product, or a medicinal product containing that product, the notification should indicate the name of the

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Member State in which the first related act which would otherwise require the consent of a certificate holder is to take place, as that information is relevant for the timing of the notification.

(17) If a local marketing authorisation, or the equivalent of such authorisation, in a specific third country, for a given medicinal product, is published after the authority is notified, the notification should be promptly updated to include the reference number of that marketing authorisation, or the equivalent of such authorisation, as soon as it is publicly available. If the reference number of that marketing authorisation, or the equivalent of such authorisation, is pending publication, the maker should be required to provide, in the notification, that reference number as soon as it is publicly available.

(18) For reasons of proportionality, failure to comply with the requirement regarding a third country should only affect exports to that country, and exports to that country should, thus, not benefit from the exception provided for in this Regulation. 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, or whether that protection is subject to any limitations or exemptions in that country.

(19) A notification to the authority and the corresponding information to the certificate holder could be provided during the period between the date of entry into force of this Regulation and the date on which the exception provided for in this Regulation becomes applicable for the relevant certificate.

(20) This Regulation should impose certain due diligence requirements on the maker as a condition to use the exception. The maker should be required to inform persons within its supply chain in the Union, including the exporter and the person carrying out the storing, through appropriate and documented means, in particular contractual means, that the product, or the medicinal product containing that product, is covered by the exception provided for in this Regulation and that the making is intended for the purpose of export or storing. A maker who fails to comply with those due diligence requirements should not benefit from the exception, nor should any third party performing a related act in the Member State of making or in a different Member State in which a certificate conferring protection for the product is in force. The holder of the relevant certificate would, therefore, be entitled to enforce its rights under the certificate, while having due regard to the general obligation, provided for in Directive 2004/48/EC of the European Parliament and of the Council[(6)], not to engage in abusive litigation.

(21) This Regulation should impose labelling requirements on the maker in respect of products, or medicinal products containing those products, to be exported, in order to facilitate, by means of a logo, identification of such products or such medicinal products as being exclusively intended for the purpose of export to third countries. Making for the purpose of export and related acts should only fall within the scope of the exception if the product, or the medicinal product containing that product, is labelled in the manner provided for in this Regulation. That labelling obligation should be without prejudice to labelling requirements of third countries.

(22) Any act not covered by the exception provided for in this Regulation should remain within the scope of the protection conferred by a certificate. Any diversion onto the