Introduction of SPC Manufacturing and Stockpiling Waiver

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 (SPC) for medicinal products** was published in the Official Journal of the European Union on 11 June 2019. This regulation, which introduces an exception to the protection conferred by an SPC for products, or medicinal products containing those products, manufactured for export purposes and/or stockpiling purposes, will enter into force across all Member States on 01 July 2019.

The background to the Regulation is essentially set out in recitals 4 and 5 of the Regulation:-

> *(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 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.*

As stated in Recitals 8 and 9, the aim of the Regulation is

> *… to promote the competitiveness of the Union, …, 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 Union immediately after protection has expired ('EU day-one entry').

(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.

The exception will apply only where:

- generics or biosimilars are produced exclusively for export to third countries where protection of the original medicine does not exist or has expired or for stockpiling purposes during the last six months of the validity of the SPC;
- the maker has provided the information required by the regulation to both the authorities of the member state of production and to the holder of the SPC at least three months in advance (the standard form provided for notification is included in Annex Ia overleaf));
- the maker has duly informed all those involved in the commercialisation of the product;
- the maker has affixed to the packaging of the product the specific logo provided for by the regulation indicating clearly that it is only for export.

This manufacturing waiver will apply to all new SPCs filed on or after 1 July 2019. An SPC already in effect by 01 July 2019 will not be affected by this waiver. However, for SPCs filed before 01 July 2019 but that are not yet in effect by this date, the manufacturing waiver will initially not apply but will become applicable three years after the waiver enters into force, i.e. July 2022.

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

ANNEX -Ia

Standard form for notification pursuant to points (b) and (c) of Article 5(2)

<table>
<tr><td>Tick the appropriate box</td><td colspan="2">☐ New notification
☐ Update of an existing notification</td></tr>
<tr><td>(a) Name and address of the maker</td><td colspan="2"></td></tr>
<tr><td>(b) Purpose of making</td><td colspan="2">☐ Export
☐ Storing
☐ Export and storing</td></tr>
<tr><td rowspan="2">(c) Member State in which making is to take place and Member State in which first related act (if any) prior to making is to take place</td><td>Member State of making</td><td></td></tr>
<tr><td>(Member State of first related act (if any))</td><td></td></tr>
<tr><td rowspan="2">(d) Number of certificate granted in the Member State of making and number of certificate granted in Member State of first related act (if any) prior to making</td><td>Certificate of Member State of making</td><td></td></tr>
<tr><td>(Certificate of Member State of first related act (if any))</td><td></td></tr>
<tr><td rowspan="3">(e) For medicinal products to be exported to third countries, reference number of marketing authorisation, or the equivalent of such authorisation, in each third country of export</td><td colspan="2"></td></tr>
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