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DRAFT OPINION

of the Committee on the Environment, Public Health and Food Safety

for the Committee on Legal Affairs

on the 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
(COM(2018)0317 – C8-0217/2018 – 2018/0161(COD))

Rapporteur for opinion: Tiemo Wölken

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SHORT JUSTIFICATION

In line with the European Parliaments position on EU options for improving access to medicines (2016/2057(INI)), the rapporteur welcomes the proposal for a regulation amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products.

Currently EU-based manufacturers of generics and/or biosimilar face problems on the EU Single Market which put them at a disadvantage compared to manufacturers located outside of the Union.

The rapporteur therefore intends to restore the level playing field between EU-based generic and biosimilar manufacturers and non EU-based ones, boosting the competitiveness of EU-based generic and biosimilar manufacturers especially in respect to the export to those countries where no supplementary protection certificate is in place, as well as facilitating Day-1 entry within the Union. For this, the rapporteur not only supports a manufacturing waiver for export, but also supports introducing a stockpiling waiver, giving generic and/or biosimilar manufacturers more incentives to manufacture within the Union and not in third countries.

The prices of new medicines have increased during the past decades to the point of sometimes being unaffordable for many European citizens, limiting their "right to benefit from medical treatment", as stated in the Charter of Fundamental Rights of the EU. The entry of generics and biosimilar onto the EU market is important for reducing prices, ensuring sustainability of healthcare systems, whilst also having a positive effect on national health budgets. The faster entry into the EU market gives European citizens faster access to affordable medicinal products. The introduction of the SPC Manufacturing Waiver helps to reduce barriers to access to medicines, including shortages of essential and other medicines. Producing within the EU can lead to enhanced security and quality of supply, reduced counterfeits and uncertainty due to import reliance.

Introducing the manufacturing and stockpiling waver will also strengthen the generic and biosimilar sector in Europe, and reinforce the EU's position as a hub for pharmaceutical innovation and manufacture, especially in the field of biosimilars, creating jobs and ensuring expertise remains within the Union.

AMENDMENTS

The Committee on the Environment, Public Health and Food Safety calls on the Committee on Legal Affairs, as the committee responsible, to take into account the following amendments:

Amendment 1

Proposal for a regulation
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) The timely entry of generics and biosimilars onto the Union market is important for increasing competition, reducing prices and ensuring the sustainability of healthcare systems.

Or. en

Amendment 2

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) The absence of any exception in Regulation (EC) No 469/2009 to the protection conferred by a supplementary protection certificate has had the unintended consequence of preventing manufacturers of generics and biosimilars established in the Union from manufacturing, even for the exclusive purpose of exporting to ***third country*** markets in which such protection does not exist or has expired. A further unintended consequence is that the protection conferred by the certificate makes it more difficult for those manufacturers to enter the Union market immediately after expiry of the certificate, given that they are not in a position to build up production capacity until the protection provided by the certificate has lapsed, by contrast with manufacturers located in third countries where protection does not exist or has expired.	(4) The absence of any exception in Regulation (EC) No 469/2009 to the protection conferred by a supplementary protection certificate has had the unintended consequence of preventing manufacturers of generics and biosimilars established in the Union from manufacturing, even for the exclusive purpose of exporting to markets in which such protection does not exist or has expired. A further unintended consequence is that the protection conferred by the certificate makes it more difficult for those manufacturers to enter the Union market immediately after expiry of the certificate, given that they are not in a position to build up production capacity until the protection provided by the certificate has lapsed, by contrast with manufacturers located in third countries where protection does not exist or has expired.

Or. en

Amendment 3

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) The aim of this Regulation is to ensure that manufacturers established in the Union are able to compete effectively in those ***third*** country markets where supplementary protection does not exist or has expired. It is intended to complement the efforts of the Union's trade policy to ensure open markets for Union-based manufacturers of medicinal products. Indirectly, it is also intended to put those manufacturers in a better position to enter the Union market immediately after expiry of the relevant supplementary protection certificate. It would also help to serve the aim of fostering access to medicines in the Union by helping to ensure a swifter entry of generic and biosimilar medicines onto the market after expiry of the relevant certificate.	(7) The aim of this Regulation is to ensure that manufacturers established in the Union are able to compete effectively in those country markets where supplementary protection does not exist or has expired. It is intended to complement the efforts of the Union's trade policy to ensure open markets for Union-based manufacturers of medicinal products. Indirectly, it is also intended to put those manufacturers in a better position to enter the Union market immediately after expiry of the relevant supplementary protection certificate***, namely the Day-1 entry***. It would also help to serve the aim of fostering access to medicines in the Union by helping to ensure a swifter entry of generic and biosimilar medicines onto the market after expiry of the relevant certificate.

Or. en

Amendment 4

Proposal for a regulation
Recital 8

Text proposed by the Commission	*Amendment*
(8) In ***those*** specific and limited circumstances, ***and in order to create a level playing field between Union-based manufacturers and third country manufacturers,*** it is appropriate to ***restrict the protection conferred by a*** supplementary protection certificate so as to ***allow making for the exclusive purpose of*** export to third countries ***and any related acts*** strictly necessary for ***making or for***	(8) In ***these*** specific and limited circumstances, it is appropriate to ***eliminate the aforementioned, unintended side effects of the*** supplementary protection certificate so as to ***enable a level-playing field between Union-based manufacturers and those in third countries. This would enable manufacturing exclusively for (i)*** export to third countries ***or to countries where the***

the actual export itself.	***supplementary protection has expired, as well as for any other acts that are*** strictly necessary for ***this manufacturing and (ii) entry onto the Union market as soon as the supplementary protection certificate expires***.

Or. en

Amendment 5

Proposal for a regulation
Recital 9

Text proposed by the Commission	*Amendment*
(9) That exception should cover the making of the product, including the product which corresponds to the medicinal product protected by a supplementary protection certificate in the territory of a Member State, for the exclusive purpose of export to third countries, as well as any upstream or downstream acts by the maker or by third parties in a contractual relationship with the maker, where such acts would otherwise require the consent of the certificate-holder, and are strictly necessary for making for the purpose of export ***or*** for the actual export itself. For instance, such acts may include the supply and import of active ingredients for the purpose of making the medicinal product to which the product covered by the certificate corresponds, or temporary storage of the product or advertising for the exclusive purpose of export to third country destinations.	(9) That exception should cover the making of the product, including the product which corresponds to the medicinal product protected by a supplementary protection certificate in the territory of a Member State, for the exclusive purpose of export to third countries ***or countries where no supplementary protection certificate is in place and to prepare for Day-1 entry on the Union's market***, as well as any upstream or downstream acts by the maker or by third parties in a contractual relationship with the maker, where such acts would otherwise require the consent of the certificate-holder, and are strictly necessary for making for the purpose of export***,*** for the actual export itself ***and for Day-1 entry***. For instance, such acts may include the supply and import of active ingredients for the purpose of making the medicinal product to which the product covered by the certificate corresponds, or temporary storage of the product or advertising for the exclusive purpose of export to third country destinations.

Or. en

Amendment 6

Proposal for a regulation
Recital 11

Text proposed by the Commission	*Amendment*
(11) ***By limiting*** the scope of the exception to making for the purpose of export outside the Union and acts strictly necessary for such making or for the actual export itself, the exception introduced by this Regulation will not ***unreasonably*** conflict with normal exploitation of the product in the Member State where the certificate is in force, nor ***unreasonably*** prejudice the legitimate interests of the certificate-holder, taking account of the legitimate interests of third parties.	(11) The scope of the exception ***is limited*** to making ***for Day-1 entry and*** for the purpose of export outside the Union ***or to countries where no supplementary protection certificate is in place*** and acts strictly necessary for such making or for the actual export itself, the exception introduced by this Regulation will not conflict with normal exploitation of the product in the Member State where the certificate is in force, nor prejudice the legitimate interests of the certificate-holder, taking account of the legitimate interests of third parties.

Or. en

Amendment 7

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) To this end, this Regulation should impose a once-off duty on the person making the product for the exclusive purpose of export, requiring that person to provide certain information to the authority which granted the supplementary protection certificate in the Member State where the making is to take place. The information should be provided before the making is intended to start for the first time in that Member State. 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	(13) To this end, this Regulation should impose a once-off duty on the person making the product for the exclusive purpose of export, requiring that person to provide certain information to the authority which granted the supplementary protection certificate in the Member State where the making is to take place. The information should be provided before the making is intended to start for the first time in that Member State. 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. The once-off duty to provide information to the authority should apply in each Member State where making is to take place, both as regards the making in that Member State, and as regards related acts, whether performed in that or another Member State, related to that making. ***The authority should be required to publish that information, in the interests of transparency and for the purpose of informing the holder of the certificate of the maker's intention.***	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. The once-off duty to provide information to the authority should apply in each Member State where making is to take place, both as regards the making in that Member State, and as regards related acts, whether performed in that or another Member State, related to that making.

Or. en

Amendment 8

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(19) In order to ensure that holders of supplementary protection certificates already in force are not deprived of their acquired rights, the exception provided for in this Regulation should only apply to certificates that are granted ***on or after a specified date*** after entry into force, irrespective of when the application for the certificate was first lodged. The date specified should allow a reasonable time for applicants and other relevant market players to adjust to the changed legal context and to make appropriate investment and manufacturing location decisions in a timely way. ***The date should also allow sufficient time for public authorities to put in place appropriate arrangements to receive and publish notifications of the intention to make, and should take due account of pending applications for certificates.***	(19) In order to ensure that holders of supplementary protection certificates already in force are not deprived of their acquired rights, the exception provided for in this Regulation should only apply to certificates that are granted after entry into force, irrespective of when the application for the certificate was first lodged. The date specified should allow a reasonable time for applicants and other relevant market players to adjust to the changed legal context and to make appropriate investment and manufacturing location decisions in a timely way.

Or. en

Amendment 9

Proposal for a regulation
Recital 22

Text proposed by the Commission	*Amendment*
(22) This Regulation respects fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union. In particular, this Regulation seeks to ensure full respect for the right to property in Article 17 of the Charter by maintaining the core rights of the supplementary protection certificate, by confining the exception to certificates granted on or after a specified date after entry into force of this Regulation and by imposing certain conditions on the application of the exception,	(22) This Regulation respects fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union. In particular, this Regulation seeks to ensure full respect for the right to property in Article 17 of the Charter by maintaining the core rights of the supplementary protection certificate, by confining the exception to certificates granted on or after a specified date after entry into force of this Regulation and by imposing certain conditions on the application of the exception, ***as well as for Article 35 of the Charter of Fundamental Rights of the European Union and point (a) of Article 6 TFEU on the right to health protection for European citizens,***

Or. en

Amendment 10

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EU) No 469/2009
Article 4 – paragraph 2 – point a – point i

Text proposed by the Commission	*Amendment*
(i) making for the exclusive purpose of export to third countries; or	(i) making for the exclusive purpose of export to third countries or ***to countries where no supplementary protection certificate is in place; or***

Or. en

Amendment 11

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EU) No 469/2009
Article 4 – paragraph 2 – point a – point i a (new)

Text proposed by the Commission	*Amendment*
	(ia) making for the purpose of entering the Union's market on Day-1 after the expiry of the supplementary protection certificate; or

Or. en

Amendment 12

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EU) No 469/2009
Article 4 – paragrah 2 – point a – point ii

Text proposed by the Commission	*Amendment*
(ii) any related act that is strictly necessary for that making or for the actual export itself;	(ii) any related act that is strictly necessary for that making***, storing*** or for the actual export itself;

Or. en

Amendment 13

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EU) No 469/2009
Article 4 – paragraph 2 – point a – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	and excludes any act or activity for the purpose of import of medicinal products, or parts thereof, into the Union merely for the purpose of repackaging and re-

exporting.

Or. en

Amendment 14

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EU) No 469/2009
Article 4 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) the authority referred to in Article 9(1) of the Member State where that making is to take place ('the relevant Member State') is notified by the person doing the making ('the maker') of the information listed in paragraph 3 no later than ***28*** days before the intended start date of making in that Member State;	(b) the authority referred to in Article 9(1) of the Member State where that making is to take place ('the relevant Member State') is notified by the person doing the making ('the maker') of the information listed in paragraph 3 no later than ***14*** days before the intended start date of making in that Member State;

Or. en

Amendment 15

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EU) No 469/2009
Article 4 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) the maker ensures that medicinal products intended for export to third countries do not bear a unique identifier as set out in point (d) of Article 3 and Article 4 of the Commission Delegated Regulation (EU) 2016/161[*];

[*] Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the

	Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 9.2.2016, p. 1).

Or. en

Amendment 16

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EU) No 469/2009
Article 4 – paragraph 3 – point b

Text proposed by the Commission	*Amendment*
(b) ***the address, or addresses, of the premises*** where the making is ***to take*** place ***in the relevant Member State***;	(b) ***the relevant Member State*** where the making is ***taking*** place;

Or. en

Amendment 17

Proposal for a regulation
Article 1 – paragraph 1 – point 1
Regulation (EU) No 469/2009
Article 4 – paragraph 3 – point f

Text proposed by the Commission	*Amendment*
(f) an indicative list of the intended third country or third countries to which the product is to be exported.	***deleted***

Or. en

Amendment 18

Proposal for a regulation
Article 1 – paragraph 1 – point 2
Regulation (EU) No 469/2009
Article 11 – paragraph 4

Text proposed by the Commission	*Amendment*
(2) in Article 11, the following paragraph is added:	***deleted***
'4. The notification sent to an authority as referred to in Article 4(2)(b) shall be published by that authority within 15 days of receipt of the notification.; '	

Or. en