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ERRATUM

to the report

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))

Committee on Legal Affairs

Rapporteur: Luis de Grandes Pascual
A8-0039/2019

Draft legislative resolution

Amendment 1 should read:

Amendment 1

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(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.	(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, ***while at the same time ensuring access to medicines within the Union***.

Amendment 2 should read:

Amendment 2

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2 a) The timely entry of generics and biosimilars onto the Union market is important as regards increasing competition, reducing prices and ensuring the sustainability of healthcare systems. Amending Regulation (EC) No 469/2009 so as to allow the production of generics and biosimilars for export and storage to make it possible for them to enter the Union market when the patent expires should not conflict with intellectual property rights, which remain one of the cornerstones of innovation, competitiveness and growth in the Member States. This Regulation should not interfere with the duration of market exclusivity rights during the term of a patent, which is underscored by the fact that immediate import is allowed after expiry, but represents a competitive disadvantage for the European generic medicines industry. This Regulation should take into account the concerns expressed by the European Parliament and by the Council regarding the increasing number of examples of market failure in a number of Member States, where patients´ access to effective and affordable essential medicines is endangered by very high and unsustainable price levels.

Amendment 15 should read:

Amendment 15

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 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***.	(13) To this end, this Regulation should impose a duty on the ***maker, namely the legal*** person ***established in the Union, on whose behalf the*** making ***of a product or medicinal product containing that*** product***,*** for the ***purpose*** of export ***to third countries or of placing on the Union market after the expiry of the certificate, is carried out, including the possibility of the legal person itself directly doing the making***, where***by*** that person ***is required*** to provide certain information to the authority which granted the supplementary protection certificate in the Member State where the making is to take place. ***It is 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 it is subject to any limitations or exemptions in that country. A common notification form for the notification of the authority should be provided for that purpose.*** The information should be provided before the making is intended to start for the first time in that Member State. The making 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 supplementary protection certificate granted about the name and address of the maker and the number of the certificate*** in that Member State. ***The making should be notified***. ***Should making take place in more than one*** Member State, ***a notification should be required in each of those Member States***. The authority should be required to publish ***the certificate number of the relevant product or medicinal product***, in the

interests of transparency***. Certain confidential or commercially sensitive information notified to the authority should not be published, but could be provided, if so requested by a court or other competent authority only***.

Amendment 21 should read:

Amendment 21

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(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[43], 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 by holders of certificates in the Union and consider the balance between the different interests at stake, including those of public health.	(20) The Commission should carry out ***a regular*** evaluation of this Regulation. ***Given the paramount importance of access to and affordability of medicinal products for public health and public expenditure, a regular evaluation cycle of this Regulation is justified.*** 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[43], 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 ***the impact of the SPC system on access to affordable medicines as well as the waiver, including*** 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***. Such regular evaluation should also address the effects of this Regulation on manufacturing within the Union by Union established makers for reasons of stockpiling with a view to Day1 entry into the Union market when a certificate lapses. In this context, it would be important to ascertain whether manufacturing previously taking place***

outside of the Union, has been moved to within its territory. 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 ***and examine the case for a possible extension of the scope of the exception granted by the waiver so as to allow Union-based manufacturers of generics and biosimilars to manufacture for stockpiling purposes***. It should also study the impact of the exception ***and its possible extension*** on research and production of innovative medicines by holders of certificates in the Union and consider the balance between the different interests at stake, including ***access to medicines within the Union and*** those of public health.

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[43] OJ L 123, 12.5.2016, p. 1.

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[43] OJ L 123, 12.5.2016, p. 1.

Amendment 26 should read:

Amendment 26

Proposal for a regulation
Article 1 – paragraph 1 – point 1 a (new)
Regulation (EC) No 469/2009
Article 5

Present text	*Amendment*
	(1a) Article 5 is replaced by the following:
Article 5	**‘**Article 5
Effects of the certificate	Effects of the certificate
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	***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

same obligations.

the same obligations.

2. By way of derogation from paragraph 1, the certificate shall not confer protection against certain acts 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 acts comprises:

(i) making a product, or a medicinal product containing that product, for the purpose of export to third countries; or

(ii) making a product, or a medicinal product containing that product, for the purpose of storing it in the Member State of making, during the final 2 years of validity of the certificate referred to in paragraph 1, in order to place that product on the market of Member States as from day 1 after the expiry of the certificate in those Member States;

(iii) the act excludes any act or activity for import of medicinal products, or parts thereof, onto the Union merely for the purpose of repackaging and re-exporting.

(b) the maker notifies the authority referred to in Article 9 (1) of the Member State where that making is to take place ('the relevant Member State') of the information listed in points (a), (b), (c), (e) and (f) of paragraph 3 no later than two months before the start date of making in that Member State;

(c) the maker informs the certificate holder, in writing, of the information listed in points (a) and (c) of paragraph 3, no later than two months before the start date of making in that Member State;

(d) the notification to the certificate holder does not contain any confidential or commercially sensitive information;

(e) the information provided by the maker to the certificate holder is treated as strictly confidential by the certificate

holder and is not published; in addition, the information provided to the certificate holder is used exclusively for the purposes of verifying whether the requirements of this Regulation have been met and, where applicable, initiating legal proceedings for non-compliance;

(f) in the case of products made for the purpose of export to third countries, the maker ensures that a logo, in the form set out in Annex -Ia, is affixed to the outer packaging of the product referred to in paragraph 2(a)(i) or, if the product forms part of a medicinal product, the outer packaging of the medicinal product;

(g) the maker ensures that the medicinal product manufactured pursuant to paragraph 2(a)(i) does not bear an active Unique Identifier as laid down in Articles 3(d) of Commission Delegated Regulation (EU) 2016/161. Where appropriate, the competent authority shall have access to the data in the repositories mandated by Directive 2011/62/EU and Delegated Regulation (EU) 2016/161 in order to verify compliance;

(h) the maker complies with the requirements of paragraph 4.

3. The information for the purposes of paragraph 2(b), which shall be treated in a strictly confidential manner by all parties, shall be as follows:

(a) the name and address of the maker;

(b) the Member State where the making and, if applicable, also the storage, is to take place;

(c) the number of the certificate granted in the Member State of making;

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

(e) an indicative list of the intended third country or third countries to which

the product is to be exported.

4. For the purposes of the notification under point (b) of paragraph 2, the maker shall use the standard form contained in Annex -I to this Regulation.

5. The authorities of the Member States referred to in Article 9(1) shall under no circumstances disclose any business sensitive information provided by the maker, neither to the certificate holder nor to the public.

6. 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) 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 point (a)(i) of paragraph 2 might infringe the certificate referred to in paragraph 1 where, and as long as, that certificate applies.

7. Paragraph 2 shall apply to certificates that are applied for on or after the entry into force of this Regulation. It shall also apply in the case of certificates for which the basic patent expired on or after 1 January 2021.

Amendment 27 should read:

Amendment 27

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

Text proposed by the Commission	*Amendment*
4. The ***notification sent to an***	4. The authority referred to in Article

authority as referred to in Article ***4(2)(b)*** shall be published by ***that*** authority ***within 15 days of receipt of the notification.;***	***9(1) of the relevant Member State*** shall ***publish without undue delay the information listed in point (c) of Article 5(3)***. ***The remaining information notified under Article 5 (3) shall not*** be published by ***the*** authority ***or made available for inspection by the public, but shall be provided by it, upon request, to a court or other competent authority for the purposes of any legal proceedings in which Article 5(2) is considered. The national authority shall take appropriate measures to preserve the confidentiality of that information.***

Amendment 28 should read:

Amendment 28

Proposal for a regulation
Article 1 – paragraph 1 – point 3
Regulation (EC) No 469/2009
Article 21a

Text proposed by the Commission	*Amendment*
Article 21a	Article 21a
Evaluation	Evaluation
No later than five years ***after the date referred to in Article 4(5), and*** every ***five years thereafter***, the Commission shall carry out an evaluation of Articles 4(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**.**;	Every ***three*** years, the Commission shall carry out an evaluation of ***the SPC manufacturing waiver pursuant to*** Articles 5(2) to (6) and 11 ***as well as of the SPC system regarding the ability of generics to enter the Union market and the access to medicines and public health,*** and present a report on the main findings to the European Parliament, the Council and the European Economic and Social Committee***. Special account shall be taken on the effects of stockpiling with a view to Day1 entry into the Union market when a certificate lapses***;

Between Amendments 28 and 29, the following Amendment is inserted:

Proposal for a regulation
Article 1 – paragraph 1 – point 4

Text proposed by the Commission	*Amendment*
(4) the Annex to this Regulation is inserted as Annex -I	(4) the Annex***es*** to this Regulation ***are*** inserted as Annex -I ***and -Ia.***

Amendment 29 should read:

Amendment 29

Proposal for a regulation
Annex
Regulation (EC) No 469/2009
Annex -I

Text proposed by the Commission	*Amendment*
Annex	Annex -***I***
Logo	***Standard form to be used by makers for notifications under point (b) of Article 5(2)***
	
	a. Name and address of the maker
	b. Address(es) of the premises where the making is to take place in the relevant Member State
	c. Number of the certificate granted in the relevant Member State, and identification of the product, by reference to its international non-proprietary name, if available;
	d. Earliest intended start date of making in the relevant Member State

e. Indicative list of the third country or third countries to which the product is intended to be exported

(Affects all language versions.)