



**2018/0161(COD)**

3.12.2018

# **OPINION**

of the Committee on International Trade

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: Lola Sánchez Caldentey

PA\_Legam

## AMENDMENTS

The Committee on International Trade 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 2 a (new)

*Text proposed by the Commission*

*Amendment*

***(2 a) 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; and amending Regulation (EC) No 469/2009 so as to allow the production of generics and biosimilars for export and storage does not conflict with intellectual property rights, which remain one of the cornerstones of innovation, competitiveness and growth in the Member States. The proposal does not interfere with the duration of market exclusivity rights during the 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. The proposal takes into account the concerns expressed by the European Parliament and by the Council regarding that 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 2

#### Proposal for a regulation

### Recital 3

*Text proposed by the Commission*

(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 third countries where protection does not exist or has expired.

*Amendment*

(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.

*Justification*

*Clarification of the countries to which the regulation applies.*

### Amendment 3

**Proposal for a regulation**

**Recital 3 a (new)**

*Text proposed by the Commission*

*Amendment*

***(3a) Pharmaceuticals are one of the pillars of healthcare rather than a mere object of trade. Insufficient access to essential medicinal products and high prices of innovative medicines pose a serious threat to the sustainability of national health care systems, and a serious threat to patients.***

### Amendment 4

**Proposal for a regulation**

**Recital 3 b (new)**

*Text proposed by the Commission*

*Amendment*

***(3b) The Council, in its conclusions on strengthening the balance in the pharmaceutical systems in the Union and its Member States, has underlined the importance of timely availability of***

*generics and biosimilars in order to facilitate patients' access to pharmaceutical therapies and to improve the sustainability of national health systems.*

## Amendment 5

### Proposal for a regulation

#### Recital 4

*Text proposed by the Commission*

(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.

*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 *within* the Union from manufacturing, *with a view* to enter the Union market immediately after expiry of the certificate *and/or export to countries outside the Union ('third countries')* in *which* protection does not exist or has expired, 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.

## Amendment 6

### Proposal for a regulation

#### Recital 7

*Text proposed by the Commission*

(7) The aim of this Regulation is to ensure that manufacturers established in the Union are able to compete effectively

*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.

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. 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, *i.e. 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.

## Amendment 7

### Proposal for a regulation

#### Recital 8

##### *Text proposed by the Commission*

(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 the actual export itself.

##### *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, **and to offer better access to generic and biosimilar medicines to Union citizens**, it is appropriate to **overcome the above mentioned unintended effects deriving from** a supplementary protection certificate so as to **enable (i) the making exclusively for** export to third countries **and (ii) entry onto the Union market immediately after expiry of the relevant supplementary protection certificate, as well as** and any related acts strictly necessary for **that** making or for the actual export **or that entry onto the Union market** itself.

## Amendment 8

### Proposal for a regulation

## Recital 9

*Text proposed by the Commission*

(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*.

*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 *countries outside the Union ('third countries') and to prepare for Day-1 entry in 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 *markets in countries outside the Union ('third countries') or Day-1 entry in the Union's market*.

## Amendment 9

### Proposal for a regulation

#### Recital 11

*Text proposed by the Commission*

(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

*Amendment*

(11) By limiting the scope of the exception to making for the *purposes of day-1 entry* and 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 conflict with normal exploitation of the product in the Member State where

certificate is in force, nor unreasonably prejudice the legitimate interests of the certificate-holder, taking account of the legitimate interests of third parties.

the certificate is in force, nor prejudice the legitimate interests of the certificate-holder, taking account of the legitimate interests of third parties. ***In this regard, the Commission’s study<sup>1a</sup> states that “neither the production for export, nor the production for stockpiling purposes run counter to the legal objectives of the SPC system”, and “arguably the only effect of prohibiting stockpiling would be to boost the business opportunities of non-EU companies to the disadvantage of generic manufacturers established here.”***

## Amendment 10

### Proposal for a regulation Recital 12

#### *Text proposed by the Commission*

(12) Safeguards should accompany the exception ***in order to increase transparency, to help*** the holder of a supplementary protection 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.***

#### *Amendment*

(12) ***Reasonable, proportionate and appropriate*** safeguards should accompany the exception, ***for the exclusive purpose of helping*** the holder of a supplementary protection certificate to ***check compliance with the conditions set out hereunder, but without affecting fair competition among companies. The safeguards should ensure the necessary confidentiality and protection of commercially sensitive information of the applicant, in compliance with existing EU legislation and recommendations, such as Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on trade secrets and the EMA/HMA Guidance Document on the identification of commercially confidential information and personal data.***

## Amendment 11

### Proposal for a regulation

## Recital 13

### *Text proposed by the Commission*

(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.***

### *Amendment*

(13) To this end, ***to the extent it intends to rely on the exception and in the interest of transparency***, the person *responsible* for the *making* (*'the maker'*), ***or any person acting on its behalf should provide a warning letter to the registered holder(s) of the certificate, at its (their) registered address(es). This letter should not include commercially sensitive information or confidential details of a company business plan, to limit any anti-competitive effects. To that end, the information required in the warning letter should notably comply with existing EU legislation and recommendations, such as Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on trade secrets and the EMA/HMA Guidance Document on the identification of commercially confidential information and personal data. For the same reasons, the warning letter and the information it contains should be treated as strictly confidential by the holder of the certificate and should not be used by the holder of the certificate for any other purpose than ensuring that the maker has complied with the scope and conditions of the exception.*** This Regulation should, ***additionally***, impose a once-off duty on the person making the product, 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 ***keep the notification and the information it contains confidential and specific measures should be taken to protect such confidentiality. The authority may only disclose the information to the holder of the certificate only if disclosure is ordered by a court (i) upon request from the holder of the certificate (and other persons entitled under national law to start an infringement action on the basis of the certificate), (ii) after the maker was given the opportunity to attend and to be heard, (iii) if the holder of the certificate has, in a justified and proportionate manner, provided evidence rendering plausible that the maker did not comply with the conditions for the exception to apply, and (iv) if the holder of the certificate and the court have taken appropriate measures to keep the notification and the information it contains confidential and avoid their disclosure to third parties. The maker should be required to inform the competent authority as well as the certificate holder of any changes to the information provided in the notifications.***

## Amendment 12

### Proposal for a regulation Recital 14

*Text proposed by the Commission*

(14) In addition, this Regulation should impose certain due diligence requirements

*Amendment*

(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, through appropriate means, in particular contractual means, that the 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.

on the maker as a condition for the exception to operate. The maker should be required to inform *the undertakings* within its supply chain, through appropriate means, in particular contractual *or documented* means, that the product is covered by the exception introduced by this Regulation and is intended for the exclusive purpose of export *or Day-1 entry*. 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.

## Amendment 13

### Proposal for a regulation

#### Recital 17

##### *Text proposed by the Commission*

(17) 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<sup>41</sup> **and** Regulation (EU) No 608/2013 of the European Parliament and of the Council<sup>42</sup> .

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<sup>41</sup> 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).

<sup>42</sup> Regulation (EU) No 608/2013 of the European Parliament and of the Council of

##### *Amendment*

(17) 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<sup>41</sup>, Regulation (EU) No 608/2013 of the European Parliament and of the Council<sup>42</sup> **and the unique identifier established in Commission Delegated Regulation (EU) 2016/161**.

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<sup>41</sup> 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).

<sup>42</sup> 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).

12 June 2013 concerning customs enforcement of intellectual property rights (OJ L 181, 29.6.2013, p. 15).

#### Amendment 14

##### Proposal for a regulation Recital 19

*Text proposed by the Commission*

(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.***

*Amendment*

(19) In order to ***boost the potential benefits for patients and for generics and biosimilars' producers established in the Union, the entry into force of*** the exception provided for in this Regulation should ***be within a reasonable timeframe so as*** to ensure that holders of supplementary protection certificates ***are able to adapt to the waiver***, the exception ***provided should become applicable to certificates for which the basic patent expires*** after ***the*** entry into force ***of this*** Regulation, which ***allows*** 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.

#### Amendment 15

##### Proposal for a regulation Recital 21

*Text proposed by the Commission*

(21) It is necessary and appropriate for the achievement of the basic objective, of providing a level playing field for generic and biosimilar manufacturers with their competitors in third country markets where

*Amendment*

(21) It is necessary and appropriate for the achievement of the basic objective, of providing a level playing field for generic and biosimilar manufacturers 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 supplementary protection 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.

## Amendment 16

### Proposal for a regulation Recital 22

#### *Text proposed by the Commission*

(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.

protection does not exist or has expired, *and to improve access to medicines for the Union citizens*, to lay down rules *enabling the making of* the product in question during the term of the certificate, and also to impose certain information 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.

#### *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, *the right to health care in Article 35 of the Charter by making medicines more accessible to EU patients, the principle of proportionality in Article 52 of the Charter, point (a) of Article 6 TFEU on the right to health protection for European citizens, while allowing a reasonable predictability for applicants and other relevant market players, by confining the exception to certificates for which the basic patent expires after the entry into force of this Regulation and by imposing certain conditions on the application of the exception.*

## Amendment 17

### Proposal for a regulation

#### Article 1 – paragraph 1 – point 1

Regulation (EC) No 469/2009

Article 4 – paragraph 2

#### *Text proposed by the Commission*

2. The certificate referred to in paragraph 1 shall not confer protection against a particular act against which the basic patent conferred protection if, with respect to that particular act, the following conditions are met:
- (a) the act comprises:
- (i) making for the exclusive purpose of export to third countries; or
- (ii) any related act that is strictly necessary for that making or for the actual export itself;
- (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;
- (c) *the maker ensures that a logo, in the form set out in Annex -I, is affixed to the outer packaging of the product or, if there is no outer packaging, to its immediate packaging;*

#### *Amendment*

2. The certificate referred to in paragraph 1 shall not confer protection against a particular act against which the basic patent conferred protection if, with respect to that particular act, the following conditions are met:
- (a) the act comprises:
- (i) making for *either*:
- a.* the exclusive purpose of export to countries *outside the European Union ('third countries')* where no protection for the medicinal product exists or has expired; or
- b.* *the exclusive purpose of selling or offering to sell in the Union market immediately after expiry of the certificate;*
- (ii) any related act that is strictly necessary for that making, **storing**, or for the actual export itself;
- (iia) importing for the purposes of (i)*
- (b) the authority referred to in Article 9(1) of the Member State where 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 **60** days before the intended start date of making in that Member State;
- (c) *The certificate holder is informed, in writing, by the maker, that a notification has been sent pursuant to paragraph 2(b) and is provided with the information listed in of paragraph 3 (c) of this article no later than 60 days before the start date of making in that Member State and in advance of any related act*

*prior to that making that would otherwise be prohibited by the protection conferred by a certificate; the SPC holder should keep the warning letter and the information it contains strictly confidential and should not use them for any other purpose than ensuring that the maker has complied with the scope*

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

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

*If the information referred to in point (b) of the first subparagraph changes, the maker shall notify the authority referred to in Article 9(1) before these changes take effect. The notification and the information it contains should be kept confidential. The authority may only disclose the information to the SPC holder if disclosure is ordered by a court.*

## Amendment 18

### Proposal for a regulation

#### Article 1 – paragraph 1 – point 1

Regulation (EC) No 469/2009

Article 4 – paragraph 3

#### *Text proposed by the Commission*

3. The information for the purposes of paragraph 2(b) shall be as follows:

- (a) the name and address of the maker;
- (b) ***the address, or addresses, of the premises where the making is to take place in*** the relevant Member State;
- (c) the number of the certificate granted in the relevant Member State, and identification of the product, by reference to the proprietary name used by the holder of that certificate;
- (d) ***the number of the authorisation granted in accordance with Article 40(1) of Directive 2001/83/EC or Article 44(1)***

#### *Amendment*

3. The information for the purposes of paragraph 2(b) shall be ***treated as strictly confidential and be*** as follows:

- (a) the name and address of the maker;
- (b) the relevant Member State ***where the making is to take place;***
- (c) the number of the certificate granted in the relevant Member State, and identification of the product, by reference to the proprietary name used by the holder of that certificate;

*of Directive 2001/82/EC for the manufacture of the corresponding medicinal product or, in the absence of such authorisation, a valid certificate of good manufacturing practice as referred to in Article 111(5) of Directive 2001/83/EC or Article 80(5) of Directive 2001/82/EC covering the premises where the making is to take place;*

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

(f) *an indicative list of the intended third country or third countries to which the product is to be exported.*

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

## Amendment 19

### Proposal for a regulation

#### Article 1 – paragraph 1 – point 1

Regulation (EC) No 469/2009

Article 4 – paragraph 5

*Text proposed by the Commission*

5. *Paragraph 2* shall apply in the case only of certificates granted on or after [OP: please insert the date of the first day of the third month that follows the month in which this amending Regulation is published in the Official Journal].’;

*Amendment*

5. *The exception set out in paragraph 2* shall apply in the case only of certificates *for which the basic patent expires* after [OP: please insert the date of the first day of the third month that follows the month in which this amending Regulation is published in the Official Journal)];

## Amendment 20

### Proposal for a regulation

#### Article 1 – paragraph 1 – point 2

Regulation (EC) No 469/2009

Article 11 – paragraph 4

*Text proposed by the Commission*

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.

*Amendment*

4. The *authority referred to in Article 9(1) shall keep the* notification referred to in Article 4 (2) (b) *and the information listed in paragraph 3 confidential and shall take appropriate measures to*

*preserve such confidentiality.*

*The authority shall only disclose the notification and the information it contains if such disclosure is ordered by a court having competence under national law to hear an infringement action based on the certificate. A court shall only order such disclosure if at least the following conditions are met:*

*(a) the person requesting the disclosure is the holder of the certificate (or a person entitled under national law to start an infringement action on the basis of the certificate*

*(b) the maker is given the opportunity to attend the proceedings and to be heard before the court;*

*(c) the holder of the certificate has, in a justified and proportionate manner, provided evidence rendering plausible that the maker did not comply with the conditions set out in paragraph 2;*

*(d) the holder of the certificate and the court have taken appropriate measures to keep the notification and the information it contains confidential and avoid their disclosure to third parties.*

## **Amendment 21**

### **Proposal for a regulation**

#### **Article 1 – paragraph 1 – point 3**

Regulation (EC) No 469/2009

Article 21a – paragraph 1 a (new)

*Text proposed by the Commission*

*Amendment*

*In the evaluation a specific chapter shall be dedicated to the effects of the entry into force of the amended Regulation on the development of local generic and biosimilar industry of third countries, particularly developing countries.*

**Amendment 22**

**Proposal for a regulation**

**Annex**

*Text proposed by the Commission*

*Amendment*

*[...]*

*deleted*

## PROCEDURE – COMMITTEE ASKED FOR OPINION

<b>Title</b>	Supplementary protection certificate for medicinal products
<b>References</b>	COM(2018)0317 – C8-0217/2018 – 2018/0161(COD)
<b>Committee responsible</b> Date announced in plenary	JURI 2.7.2018
<b>Opinion by</b> Date announced in plenary	INTA 2.7.2018
<b>Rapporteur</b> Date appointed	Lola Sánchez Caldentey 20.6.2018
<b>Discussed in committee</b>	5.11.2018
<b>Date adopted</b>	3.12.2018
<b>Result of final vote</b>	+: 20 –: 11 0: 1
<b>Members present for the final vote</b>	David Borrelli, David Campbell Bannerman, Santiago Fisas Aixelà, Eleonora Forenza, Karoline Graswander-Hainz, Christophe Hansen, Heidi Hautala, Nadja Hirsch, France Jamet, Jude Kirton-Darling, Bernd Lange, David Martin, Emmanuel Maurel, Anne-Marie Mineur, Godelieve Quisthoudt-Rowohl, Inmaculada Rodríguez-Piñero Fernández, Tokia Saïfi, Joachim Schuster, Adam Szejnfeld, Iuliu Winkler
<b>Substitutes present for the final vote</b>	Reimer Böge, Klaus Buchner, Sajjad Karim, Gabriel Mato, Ralph Packet, Frédérique Ries, Pedro Silva Pereira, Jarosław Wałęsa
<b>Substitutes under Rule 200(2) present for the final vote</b>	Birgit Collin-Langen, Jonás Fernández, Alojz Peterle, Kosma Złotowski

## FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

20	+
ECR	Kosma Złotowski
ENF	France Jamet
GUE/NGL	Eleonora Forenza, Emmanuel Maurel, Anne-Marie Mineur
NI	David Borrelli
PPE	Alojz Peterle, Adam Szejnfeld, Jarosław Wałęsa, Iuliu Winkler
S&D	Jonás Fernández, Karoline Graswander-Hainz, Jude Kirton-Darling, Bernd Lange, David Martin, Inmaculada Rodríguez-Piñero Fernández, Joachim Schuster, Pedro Silva Pereira
VERTS/ALE	Klaus Buchner, Heidi Hautala

11	-
ALDE	Nadja Hirsch, Frédérique Ries
ECR	David Campbell Bannerman, Sajjad Karim, Ralph Packet
PPE	Reimer Böge, Birgit Collin-Langen, Santiago Fisas Ayxelà, Christophe Hansen, Gabriel Mato, Godelieve Quisthoudt-Rowohl

1	0
PPE	Tokia Saïfi

Key to symbols:

+ : in favour

- : against

0 : abstention