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From:	General Secretariat of the Council
To:	Permanent Representatives Committee
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Subject:	Proposal for a Regulation amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products *- Outcome of proceedings*

Delegations will find attached the compromise text on the above mentioned proposal as approved by the Permanent Representatives Committee on 20 February 2019.

ANNEX

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

(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,

Whereas:

(1) Regulation (EC) No 469/2009 of the European Parliament and of the Council[1] 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 2001/83/EC of the European Parliament and of the Council[2]or Directive 2001/82/EC of the European Parliament and of the Council[3], may be the subject of a supplementary protection certificate under the terms and conditions provided for in Regulation (EC) No 469/2009.

(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.

(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, and their active ingredients, in particular in countries outside the EU ('third countries') where protection does not exist or has expired.

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1 Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152, 16.6.2009, p. 1).

2 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p.67).

3 Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

(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 makers of generics and biosimilars established in the Union from making in the Union, even for the purpose of exporting to third country markets in which protection does not exist or has expired. Likewise, they are prevented from making for the purpose of storing for a limited period before the expiry of the certificate. This makes it more difficult for those makers 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 export and for the purpose of entering the market of a Member State until the protection provided by the certificate has expired, by contrast with makers located in third countries where protection does not exist or has expired.

(5) This puts makers of generics and biosimilars established in the Union at a significant competitive disadvantage compared 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 certificate holders is guaranteed in relation to the Union market.

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

(6a) The timely entry of generics and biosimilars onto the Union market is important, notably to increase competition, to reduce prices and to ensure both the sustainability of national healthcare systems and better access to affordable medicines by patients in the EU. The importance of such timely entry has been 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 production of generics and biosimilars for export and storage, while recalling that intellectual property rights remain one of the cornerstones of innovation, competitiveness and growth in the internal market.

(7) The aim of this Regulation is to promote the competitiveness of the Union, 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 medicinal products or products for the purpose of export to third country markets where protection does not exist or has expired, thereby also helping these makers to compete effectively in those third country markets. The Regulation should also allow these makers to make and store medicinal products or 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 (EU 'Day-one' entry), thereby helping these makers to compete effectively in the Union immediately after protection has expired. It should also complement the efforts of the Union's trade policy to ensure open markets for Union-based makers of medicinal products or products. Over time, the 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 common interest in the Union would be promoted as, through the reinforcement of Union-based supply chains for medicines, and by allowing storing in view of entry onto the Union market upon expiry of the certificate, medicines would become more accessible to patients in the Union after the expiry of the certificate.

(8) In these specific and limited circumstances, and in order to create a level playing field between Union-based makers and third country makers, it is appropriate to restrict the protection conferred by a certificate so as to allow making for the exclusive purpose of export to third countries and any related acts in the Union strictly necessary for making or for the actual export itself, where such acts would otherwise require the consent of a certificate holder (‘related acts’). For instance, such acts could include the possession, supply, offering to supply, import, using or synthesis of an active ingredient for the purpose of making a medicinal product containing that product, or temporary storage of the product or advertising for the exclusive purpose of export to third country destinations.The exception should also apply to related acts performed by third parties who are in a contractual relationship with the maker.

(9) This 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.

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

(11) By limiting the scope of the exception to the making for the purpose of export outside the Union or to the making for the purpose of storing, and to acts strictly necessary for such making or for the actual export or the actual storing itself, the exception introduced by this Regulation should not conflict with the normal exploitation of the product or medicinal product containing that product in the Member State where 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 certificate. In addition, the exception should not unreasonably prejudice the legitimate interests of the certificate holder, whilst taking account of the legitimate interests of third parties.

(12) Effective and proportionate safeguards should accompany the exception in order to increase transparency, to help the holder of a certificate to enforce its protection in the Union, to 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.

(13) To this end, 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 medicinal product containing that product for the purpose of export or storing is done (this includes the possibility of the person itself directly doing the making). Namely, the maker should provide certain information to the authority which granted the certificate in the Member State where the making is to take place. A common notification form should be provided for this purpose. The information should be provided before the making starts for the first time in that Member State, or before any related act prior to that making, whichever is the earlier. It should be updated as and when appropriate. 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 and has informed the holder of the certificate granted in that Member State. Should making take place in more than one Member State, a notification should be required in each of these Member States. In the interests of transparency, the authority should be required to publish, as soon as possible, the information it receives, 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 once-off fee. This fee should be set at a level which does not exceed the administrative cost of processing notifications and updates.

(13a) The maker should also inform the certificate holder, through appropriate and documented means, of the intention to make a product or 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 is limited to what is necessary and appropriate for the certificate holder to assess whether the rights conferred by the certificate are being respected, and does not include confidential or commercially sensitive information. The information to the certificate holder may be provided by making use of the same common notification form, and the information provided should be updated as and when appropriate.

(13b) Regarding related acts prior to the making, if any, the notification should list the name of the Member State where the first related act, which would otherwise require the consent of a certificate holder, is to take place, as this information is relevant to the timing of the notification.

(13c) If the local marketing authorisation, or equivalent, in a specific third country, for a given medicinal product, is published after the notification is made, the notification should be promptly updated to include the reference number of that marketing authorisation, as soon as it is publicly available. If the reference number of the granted authorisation is pending publication, the maker should be required to provide, in the notification, that reference number as soon as it is publicly available.

(13d) For reasons of proportionality, failure to comply with these requirements regarding a third country would only affect exports to that country, and exports to such third country would thus not benefit from the exception. 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, subject to any limitations or exemptions in that country. A notification to an authority and the corresponding information to the certificate holder may be provided already during the period between the entry into force of the Regulation and the date on which the exception itself becomes applicable.

(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 in the Union, including the exporter and the person doing the storing, through appropriate and documented means, in particular contractual means, that the product or medicinal product containing that product is covered by the exception introduced by this Regulation and is intended for the purpose of export or storing, as applicable. 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, while paying due regard to the general obligation, set out in Directive 2004/48/EC of the European Parliament and of the Council[4], not to engage in abusive litigation.

(15) Furthermore, in respect of products to be exported, this Regulation should impose labelling requirements on the maker, in order to facilitate, by means of a logo, identification of the product or medicinal product containing that product as being exclusively intended for the purpose of export to third countries. The making for the purposes of export and related acts should only fall outside the protection conferred by a certificate if the product or medicinal product containing that product is labelled in this manner. This labelling obligation would be without prejudice to labelling requirements of third countries.

(16) Any act not covered by the exception introduced by this Regulation will remain within the scope of the protection conferred by a certificate. Any diversion onto the Union market, during the term of the certificate, of any product or medicinal product containing that product made within the terms of the exception, will remain prohibited.

[4] 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).

(17) This Regulation is without prejudice to the respect of other intellectual property rights that may protect other aspects of a medicinal product. 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[5] and Regulation (EU) No 608/2013 of the European Parliament and of the Council[5]. Furthermore, this Regulation does not affect the rules on the unique identifier provided for by Directive 2001/83/EC of the European Parliament and of the Council as amended by Directive 2011/62/EU and as provided for by Commission Delegated Regulation (EU) 2016/161[6]. The maker ensures that the medicinal product made pursuant to point (a)(i) of paragraph 2 does not bear an active unique identifier within the meaning of Directive 2011/62/EU. However, the requirement to affix an active unique identifier applies to medicinal products to be placed on the market of a Member State upon expiry of the corresponding certificate.

(18) This Regulation does not affect the application of Directives 2001/83/EC and 2001/82/EC, in particular the requirements related to the manufacturing authorisation of medicinal products manufactured for export. This includes compliance with the principles and guidelines of good manufacturing practices for medicinal products and the use of active substances that have been manufactured in accordance with good manufacturing practices for active substances and distributed in accordance with good distribution practices for active substances.

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5 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).

6 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).

(19) To safeguard the rights of certificate holders, the exception should not apply to a certificate that has already taken effect at the date of entry into force of the Regulation. In order to ensure that the rights of certificate holders are not excessively restricted, the exception provided for in this Regulation should apply to certificates that are applied for on or after the day of the entry into force of this Regulation. At the same time, in order to safeguard the aim of this Regulation, and since a certificate takes effect at the end of the lawful term of the basic patent, which can be a relatively long time after the date of filing of the application for the certificate, it is justified to bring within the scope of the Regulation, over a certain period of time, a certificate that was applied for before the entry into force of this Regulation, but has not yet taken effect before that entry into force, and irrespective of whether or not that certificate has been granted before the entry into force of the Regulation. Therefore, the exception should apply, as from 1 July 2022, to a certificate that takes effect as from that entry into force. This 'certain period of time' for each individual certificate that takes effect after that entry into force should ensure that the exception is applied, on a progressive basis, to such a certificate, depending on its date of taking effect and its duration. Such application of the exception would allow the holder of a granted certificate that has not yet taken effect by the date of the entry into force of the Regulation a reasonable period of transition to adapt to the changed legal context, while at the same time ensuring that makers of generics and biosimilars can benefit effectively, without excessive delay, from the exception.

(19a) An applicant for a certificate might be expected to file an application at around the same date in each Member State of filing. However due to differences in national procedures for examination of applications, the date of grant might vary significantly from one Member State to another, thereby creating disparities in the legal situation of the applicant in the different Member States where the certificate is applied for. Introducing the exception on the basis of the date of filing of the application for a certificate would therefore promote uniformity and limit this risk of disparities.

(20) The Commission should carry out a regular 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[7], 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 on the one hand, exports to outside the Union, and on the other, the effects of storing on swifter entry of generic and especially biosimilar medicines onto markets in the Union as soon as possible after a certificate lapses. Such regular evaluation should also address the effects of this Regulation on making within the Union by generic and biosimilar makers based in the Union. In this context, it would be important to ascertain whether making that was previously taking place outside of the Union would be 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 . It should also study the impact of the exception on research and production of innovative medicines in the Union by holders of certificates and consider the balance between the different interests at stake, notably public health, public expenditure and, in this context, access to medicines within the Union. It should also study whether the period foreseen for making for the purpose of storing is sufficient to achieve the objective of EU Day-one entry, including its effects on public health.

(21) It is necessary and appropriate for the achievement of the basic objective, of providing a level playing field for makers of generics and biosimilars with their competitors in third country markets where protection does not exist or has expired, to lay down rules enabling the making of the product in question during the term of the certificate, and also to provide certain information and labelling obligations on makers using 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.

(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, and the right to health care under Article 35, of the Charter. The Regulation should maintain the core rights of the certificate, by confining the exception provided for in this Regulation to the making of a product or a medicinal product containing that product only for the purpose of export outside the Union or for the purpose of storing it during a limited period of time in view of entry onto the Union market upon expiry of the protection, and to the acts strictly necessary for such making or for the actual export or storing itself. This exception does not go beyond what is necessary and appropriate in the light of the overall objective of this Regulation, which is to promote the competitiveness of the Union by avoiding delocalisations and allowing Union-based makers of generics and biosimilars to compete, on the one hand, on fast-growing, global markets where protection does not exist or has already expired, and on the other, on the Union market upon expiry of the certificate. Indeed, it is necessary to benefit from those positive economic effects arising from the exception, as otherwise the Union would risk substantially weakening its position as a hub for pharmaceutical development and manufacturing. It is therefore appropriate to introduce that exception in order to increase the competitive position of Union-based makers of generics and biosimilars in third countries whose markets are in any event open to competition, whilst leaving the scope and duration of the protection granted by the certificate in the Union untouched. The appropriateness of the measure is further ensured by providing for appropriate safeguards regulating the use of the exception. The Regulation should allow sufficient time for public authorities to put in place the necessary arrangements to receive and publish notifications,

HAVE ADOPTED THIS REGULATION

Article 1 – Amendment of Regulation (EC) No 469/2009

Regulation (EC) No 469/2009 is amended as follows:

(-1) in Article 1, the following point is added:

‘(f) ‘maker’ means 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 to third countries or for the purpose of storing, is done;’

(1) Article 5 is replaced by the following:

‘Article 5 – Effects of the certificate

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 the same obligations.

2. By way of derogation from paragraph 1, the certificate referred to in paragraph 1 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 comprise:

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

(ii) any related act that is strictly necessary for that making in the Union or for the actual export itself; or

(iii) making, no earlier than 6 months before the expiry of the certificate, a product, or a medicinal product containing that product, for the purpose of storing it in the Member State of making in order to place that product, or a medicinal product containing that product, on the market of Member States after the expiry of the certificate;or

(iv) any related act that is strictly necessary for the making in the Union as referred to in point (iii), or for the actual storing itself, provided that such related act is carried out no earlier than 6 months before the expiry of the certificate.

(b) the maker, through appropriate and documented means, notifies the authority referred to in Article 9(1) of the Member State where that making is to take place and informs the certificate holder of the information listed in paragraph 3 no later than three months before the start date of making in that Member State, or no later than three months before the first related act prior to that making that would otherwise be prohibited by the protection conferred by a certificate, whichever is the earlier;

(ba) if the information listed in paragraph 3 changes, the maker shall notify the authority referred to in Article 9(1) and shall inform the certificate holder, before these changes take effect;

(c) 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 -I, is affixed to the outer packaging of the product or of the medicinal product containing that product, referred to in paragraph 2(a)(i), and, where feasible, to its immediate packaging;

(d) the maker complies with the requirements of paragraph 4 and, if applicable, of Article 12(2).

2a. The exception referred to in paragraph 2 shall not apply to any act or activity for import of medicinal products, or parts thereof, into the Union merely for the purpose of repackaging and re-exporting or storing.

2b. The information provided to the certificate holder shall be 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.

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

(a) the name and address of the maker;

(aa) an indication of whether the making is for the purpose of export, for the purpose of storing, or for the purpose of both export and storing;

(b) the Member State where the making and if applicable, also the storing is to take place and the Member State where the first related act, if any, prior to that making is to take place;

(c) the number of the certificate granted in the Member State of making, and the number of the certificate granted in the Member State of the first related act, if any, prior to that making;

(d) ***(deleted)***

(e) ***(deleted)***

(f) for medicinal products to be exported to third countries, the reference number of the marketing authorisation or equivalent in each third country of export , as soon as it is publicly available.

3a. For the purposes of notification to the competent authority under points (b) and (ba) of paragraph, the maker shall use the standard form contained in Annex -Ia.

3b. Failure to comply with the requirements of paragraph 3(f) in respect of a third country shall only affect exports to that country, and such exports would thus not benefit from the exception.

3c. The maker ensures that the medicinal product made pursuant to point (a)(i) of paragraph 2 does not bear an active unique identifier within the meaning of Commission Delegated Regulation (EU) 2016/161.

4. The maker shall ensure, through appropriate and documented means, that any person in a contractual relationship with the maker who performs 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 or the placing on the market of the product referred to in point (a)(iii) of paragraph 2 might infringe the certificate referred to in paragraph 2 where, and as long as, that certificate applies.

5. Paragraph 2 shall apply to certificates that are applied for on or after the entry into force of this Regulation.

Paragraph 2, shall also apply, to certificates that have been applied for before the entry into force of this Regulation and that take effect on or after the entry into force of this Regulation Paragraph 2 shall only apply to such certificates from 1 July 2022[7].

Paragraph 2 shall not apply to certificates that enter into effect before the entry into force of this Regulation.';

[7] *Date to be replaced by the actual date of entry into force of the Regulation, plus 3 years.*

(2) in Article 11, the following paragraph is added:

4. ‘The authority referred to in Article 9(1) shall publish, as soon as possible, the information listed in Article 5(3), together with the date of notification of that information. It shall also publish, as soon as possible, any changes to this information notified in accordance with Article 5(2)(ba).’;

(2a) Article 12 is replaced by the following:

‘***Article 12 – Fees***

1. Member States may require that the certificate be subject to the payment of annual fees.

2. Member States may require that the notifications referred to in Article 5(2)(b) and (ba) be subject to the payment of a fee.’;

[Note to translators: Paragraph 1 corresponds to the existing Article 12 of Regulation (EC) No 469/2009]

(3) the following Article is inserted:

‘***Article 21a – Evaluation***

No later than five years after the date referred to in Article 5(5), and every five years thereafter, the Commission shall carry out an evaluation of Articles 5(2) to (4) and 11 in order to assess whether the objectives of these provisions have been achieved, and present a report on the main findings to the European Parliament, the Council and the European Economic and Social Committee. In addition to evaluating the impact of the exception of making for the purpose of export, special account shall be taken of the effects of making for the purpose of storing with a view to ensuring EU Day-one entry, on access to medicines and on public health expenditure, and on whether the waiver and in particular the period foreseen in point (a)(iii) of Article 5(2) is sufficient to achieve the objectives mentioned in Article 5 including public health.’;

(4) the Annexes to this Regulation are inserted as Annexes -I and -Ia.

[Note: Numbering of Annexes to be checked by jurist linguists]

Article 2 – Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	For the Council
The President	The President

ANNEX -I

Logo

This logo should appear in black colour and of such size as to be sufficiently visible.

ANNEX -Ia

Form for notification pursuant to Article 5(2)(b) and (ba)

Tick the appropriate box		☐ New notification ☐ Update of an existing notification	
(a) Purpose of making		☐ Export ☐ Storing ☐ Export and storing	
(aa) Name and address of the maker		…	
(b) Member State where making is to take place and Member State where first related act (if any) prior to making is to take place		Member State of making:	…
		(Member State of first related act (if any))	…
(c) 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		Certificate of Member State of making	…
		(Certificate of Member State of first related act (if any))	…
(d)* (deleted)			
(e)* (deleted)			
(f) for medicinal products to be exported to third countries, reference number of marketing authorisation or equivalent in each third country of export		…	
		…	
		…	

*[*Note: points (d) and (e) of Article 5(3) have been deleted; however, for ease of reference in the neogotiations, the numbering of paragraphs, both in the form above and in Article 5, is retained, but will be adjusted before adoption of the Regulation. In addition, the current points (a) to (f) will be re-numbered at the jurists-linguists stage (i.e. meaning that current point (f) will become point (d)). These changes will also be carried through in Article.]*