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***I
REPORT

on the proposal for a regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast)
(COM(2023)0231 – C9-0146/2023 – 2023/0130(COD))

Committee on Legal Affairs

Rapporteur: Tiemo Wölken

(Recast – Rule 110 of the Rules of Procedure)

Symbols for procedures

*	Consultation procedure
***	Consent procedure
***I	Ordinary legislative procedure (first reading)
***II	Ordinary legislative procedure (second reading)
***III	Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.
By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

CONTENTS

Page

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast)
(COM(2023)0231 – C9-0146/2023 – 2023/0130(COD))

(Ordinary legislative procedure – recast)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2023)0231),

– having regard to Article 294(2) and Article 114(1) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0146/2023),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 27 September 2023[1],

– having regard to the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts[2],

– having regard to Rules 110 and 59 of its Rules of Procedure,

– having regard to the report of the Committee on Legal Affairs (A9-0022/2024),

A. whereas, according to the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission, the Commission proposal does not include any substantive amendments other than those identified as such in the proposal and whereas, as regards the codification of the unchanged provisions of the earlier acts together with those amendments, the proposal contains a straightforward codification of the existing texts, without any change in their substance;

1. Adopts its position at first reading hereinafter set out, taking into account the recommendations of the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

[1] OJ C, C/2023/865, 08.12.2023, ELI: http://data.europa.eu/eli/C/2023/865/oj.
[2] OJ C 77, 28.3.2002, p. 1.

Amendment 1

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) Pharmaceutical research plays a decisive role in the continuing improvement in public health.	(2) Pharmaceutical research plays a decisive role in the continuing improvement in public health. ***Medicinal products, in particular those that are the result of long, costly research will not continue to be developed in the Union unless they are covered by favourable rules that provide for sufficient protection to encourage such research. However, it is difficult to establish a direct link between such favourable rules and Union competitiveness because while such rules make Union markets more attractive, medicines' geographical origin and authorised medicines from third countries are equally eligible to receive all Union incentives, just as Union based innovative companies can equally benefit from incentives in third countries.***

Amendment 2

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) Medicinal products, in particular those that are the result of long, costly research will not continue to be developed in the Union unless they are covered by favourable rules that provide for sufficient protection to encourage such research.	***deleted***

Amendment 3

Proposal for a regulation
Recital 8

Text proposed by the Commission	*Amendment*
(8) One of the conditions for the grant of a certificate should be that the product is protected by the basic patent, in the sense that the product should fall within the scope of one or more claims of that patent, as interpreted by the person skilled in the art ***by*** the description of the patent ***on its*** filing date. This should not necessarily require that the active ingredient of the product be explicitly identified in the claims***.*** Or, in the event of a combination product, this should not necessarily require that each of its active ingredients be explicitly identified in the claims, provided that each ***of them*** is specifically identifiable in the light of all the information disclosed by that patent.	(8) One of the conditions for the grant of a certificate should be that the product is protected by the basic patent, in the sense that the product should fall within the scope of one or more claims of that patent, as interpreted by the person skilled in the art ***in light of*** the description ***and drawings*** of the patent***, on the basis of that person's general knowledge in the relevant field and of the prior art at the*** filing date ***or priority date of the basic patent***. This should not necessarily require that the active ingredient of the product be explicitly identified in the claims or, in the event of a combination product, this should not necessarily require that each of its active ingredients be explicitly identified in the claims, provided that each ***active ingredient*** is specifically identifiable in the light of all the information disclosed by that patent***, on the basis of the prior art at the filing date or priority date of the basic patent***.

Amendment 4

Proposal for a regulation
Recital 9

Text proposed by the Commission	*Amendment*
(9) To avoid overprotection, it should be provided that no more than one certificate, whether national or unitary, may protect the same product in a Member State. Therefore it should be required that the product, or any ***therapeutically equivalent*** derivative such as salts, esters, ethers, isomers, mixtures of isomers, complexes or biosimilars, should not have already been the subject of a prior certificate, ***either alone or in combination with one or more additional active***	(9) To avoid overprotection, it should be provided that no more than one certificate, whether national or unitary, may protect the same product in a Member State. Therefore it should be required that the product, or any derivative such as salts, esters, ethers, isomers, mixtures of isomers, complexes or biosimilars, should not have already been the subject of a prior certificate, whether for the same therapeutic indication or for a different

ingredients, whether for the same therapeutic indication or for a different one.	one.

Amendment 5

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) Where the marketing authorisation submitted in support of the application for a certificate for a biological medicinal product identifies that product by means of its International Nonproprietary Name (INN), the protection conferred by the certificate should extend to all ***therapeutically equivalent products*** having the same International Nonproprietary Name as the product referred to in the marketing authorisation, irrespective of possible minor differences between a subsequent biosimilar and the product authorised, which are usually unavoidable given the nature of biological products.	(13) Where the marketing authorisation submitted in support of the application for a certificate for a biological medicinal product identifies that product by means of its International Nonproprietary Name (INN), the protection conferred by the certificate should extend to all ***biosimilar*** having the same International Nonproprietary Name as the product referred to in the marketing authorisation, irrespective of possible minor differences between a subsequent biosimilar and the product authorised, which are usually unavoidable given the nature of biological products.

Amendment 6

Proposal for a regulation
Recital 24

Text proposed by the Commission	*Amendment*
(24) The Office should have the possibility to charge a fee for the centralised application for a certificate and for an application for the extension of duration of certificates in the case of paediatric medicinal products, as well as other procedural fees such as a fee for opposition or appeal. The fees charged by the Office should be laid down by an implementing act.	(24) The Office should have the possibility to charge a fee for the centralised application for a certificate and for an application for the extension of duration of certificates in the case of paediatric medicinal products ***in accordance with Article 86 of Directive (EU) .../... [2023/0132(COD)],*** as well as other procedural fees such as a fee for opposition or appeal. The fees charged by the Office should be laid down by an implementing act.

Amendment 7

Proposal for a regulation
Recital 30

Text proposed by the Commission	*Amendment*
(30) The examination of a centralised application for a certificate should be conducted, under supervision of the Office, by an examination panel including one member of the Office as well as two examiners employed by the national patent offices. This would ensure that optimal use be made of expertise in supplementary protection certificates matters, located today at national offices only. To ensure an optimal quality of the examination, suitable criteria should be laid down in respect of the participation of specific examiners in the centralised procedure, in particular as regards qualification and conflicts of interest.	(30) The examination of a centralised application for a certificate should be conducted, under supervision of the Office, by an examination panel including one member of the Office as well as two examiners employed by the national patent offices. This would ensure that optimal use be made of expertise in supplementary protection certificates ***and related patent*** matters, located today at national offices only. To ensure an optimal quality of the examination, ***the Office and the competent national authorities should make sure that designated examiners have the relevant expertise and sufficient experience in the assessment of supplementary protection certificates. Additional*** suitable criteria should be laid down in respect of the participation of specific examiners in the centralised procedure, in particular as regards qualification and conflicts of interest.

Amendment 8

Proposal for a regulation
Recital 32 a (new)

Text proposed by the Commission	*Amendment*
	(32a) To guarantee an effective protection of innovation, in certain urgent situations, including where the expiry of the basic patent is imminent, an expedited examination procedure might be necessary, notwithstanding the possibility for third parties to submit observations and make use of other remedies provided for in this Regulation. Therefore, a mechanism for applicants to request an expedited examination procedure should

be provided.

Amendment 9

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) After the completion of the examination of a centralised application, and after the time limits for appeal and opposition have expired, or, the case being, after a final decision on the merits has been issued, the opinion should be transmitted to the respective national patent offices of the designated Member States.	(33) After the completion of the examination of a centralised application, and after the time limits for appeal and opposition have expired, or, the case being, after a final decision on the merits has been issued, the opinion should be transmitted to the respective national patent offices of the designated Member States. ***The Office shall ensure the transmission takes place within a timeframe allowing national patent offices to grant the certificate or reject the application, as applicable, before the expiry of the basic patent.***

Amendment 10

Proposal for a regulation
Recital 38

Text proposed by the Commission	*Amendment*
(38) Where the applicant or another party is adversely affected by a decision of the Office, the applicant or that party should have the right, subject to a fee, to file within 2 months an appeal against the decision, before a Board of Appeal of the Office. This also applies to the examination opinion, that may be appealed by the applicant. Decisions of that Board of Appeal should, in turn, be amenable to actions before the General Court, which has jurisdiction to annul or to alter the contested decision. In case of a combined application including a request for a unitary certificate, a common appeal may be filed.	(38) ***To safeguard procedural rights and ensure a complete system of remedies,*** where the applicant or another party is adversely affected by a decision of the Office, the applicant or that party should have the right, subject to a fee, to file within 2 months an appeal against the decision, before a Board of Appeal of the Office. This also applies to the examination opinion, that may be appealed by the applicant. Decisions of that Board of Appeal should, in turn, be amenable to actions before the General Court, which has jurisdiction to annul or to alter the contested decision. In case of a combined application including a request for a unitary certificate, a common appeal may

be filed.

Amendment 11

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) When appointing members of the Boards of Appeal in matters regarding centralised applications for certificates, their prior experience in supplementary protection certificate or patent matters should be taken into account.	(39) When appointing members of the Boards of Appeal in matters regarding centralised applications for certificates, their ***relevant expertise, independence and sufficient*** prior experience in supplementary protection certificate or patent matters should be taken into account.

Amendment 12

Proposal for a regulation
Recital 41 a (new)

Text proposed by the Commission	*Amendment*
	(41a) The timely entry of generics and biosimilars onto the Union market is important, in particular to increase competition, to reduce prices and to ensure both the sustainability of national healthcare systems and better access to affordable medicines for patients in the Union. The importance of such timely entry was 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. On the other hand, it should be borne in mind that intellectual property rights remain one of the cornerstones of innovation, competitiveness and growth in the internal market.

Amendment 13

Proposal for a regulation
Recital 45

Text proposed by the Commission	*Amendment*
(45) In ***those*** specific and limited circumstances, and in order to create a level playing field between makers ***established in the Union and third-country*** makers, it is appropriate to ***provide for an exception to*** the protection conferred by a certificate so as to allow ***the*** making ***of a product, or a medicinal product containing that product,*** for the purpose of export to third countries ***or of storing,*** and any related acts in the Union strictly necessary for ***that*** making or for the actual export ***or the actual storing ('related acts')*** , where such acts would otherwise require the consent of ***the*** certificate holder. For instance, such ***related*** acts could include the ***possessing***, offering to supply, ***supplying, importing***, using or ***synthesising*** of an active ingredient for the purpose of making a medicinal product***. They could also consist of*** temporary ***storing*** or advertising ***of the product*** 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.	(45) In ***those*** specific and limited circumstances, and in order to create a level playing field between ***Union-based*** makers ***and third country*** makers, the protection conferred by a ***supplementary protection*** certificate ***in accordance to Regulation (EU) 2019/933*** should be restricted, 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, related acts could include the***, possession, supply***, offering to supply, ***import***, use 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.

Amendment 14

Proposal for a regulation
Recital 60

Text proposed by the Commission	*Amendment*
(60) To ensure transparency, a register should be set up that can serve as a single access point providing information on applications for certificates under the centralised procedure, including on certificates granted on that basis by competent national authorities, which should share with the Office any related information. The register should be	(60) To ensure transparency, a register should be set up that can serve as a single access point providing information on applications for certificates under the centralised procedure, including on certificates granted on that basis by competent national authorities, which should share with the Office any related information. The register should be

available in all official languages of the Union.	available in all official languages of the Union. ***However, the information provided in the register should not be used in regards to practices of patent linkage and no regulatory or administrative decisions related to generics or biosimilars, such as marketing authorisations, pricing and reimbursement decisions or tender bids to the existence of the SPC, should be based on information provided for in the register.***

Amendment 15

Proposal for a regulation
Article 2 – paragraph 1 – point 12 a (new)

Text proposed by the Commission	*Amendment*
	(12a) 'economically linked' means, in respect of different holders of two or more basic patents protecting the same product, that one holder, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with another holder.

Amendment 16

Proposal for a regulation
Article 3 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC, Regulation (EC) No 726/2004 or Regulation (EU) 2019/6, as appropriate;	(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive .../... [2023/0132(COD)***]***, Regulation (EC) No 726/2004 or Regulation (EU) 2019/6, as appropriate;

Amendment 17

Proposal for a regulation
Article 3 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for that product may be issued to each of those holders, where they are not economically linked.	3. The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for that product may be issued to each of those holders, where they are not economically linked. ***The same principle shall apply mutatis mutandis to applications submitted by the holder concerning the same product for which one or more certificates or unitary certificates have been previously granted to other different holders of different patents.***

Amendment 18

Proposal for a regulation
Article 5 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
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 the certificate holder, if all of the following conditions are met:	2. By way of derogation from paragraph 1***, and in accordance with Regulation (EU).../... [2023/0130(COD)]***, the certificate shall not confer protection against certain acts which would otherwise require the consent of the certificate holder, if all of the following conditions are met:

Amendment 19

Proposal for a regulation
Article 5 – paragraph 2 – point a – point i

Text proposed by the Commission	*Amendment*
(i) the making of a product, or a medicinal product containing that product, for the purpose of export to third countries;	(i) the making of a product, or a medicinal product containing that product, for the purpose of export to third countries; ***or***

Amendment 20

Proposal for a regulation
Article 5 – paragraph 2 – point a – point ii

Text proposed by the Commission	*Amendment*
(ii) any related act that is strictly necessary for ***the*** making**,** in the Union**,** ***referred to in point (i),*** or for the actual export;	(ii) any related act that is strictly necessary for ***that*** making in the Union or for the actual export ***itself***; ***or***

Amendment 21

Proposal for a regulation
Article 5 – paragraph 2 – point a – point iii

Text proposed by the Commission	*Amendment*
(iii) ***the*** making, no earlier than 6 months before the expiry of the certificate, ***of*** 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 ***corresponding*** certificate;	(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***

Amendment 22

Proposal for a regulation
Article 5 – paragraph 2 – point a – point iv

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

Amendment 23

Proposal for a regulation
Article 8 – paragraph 1 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) if applicable, the consent of the third party referred to in Article 6(2) of this Regulation.

Amendment 24

Proposal for a regulation
Article 8 – paragraph 1 – point d b (new)

Text proposed by the Commission	*Amendment*
	(db) information on any direct public financial support received for research related to the development of the product.

Amendment 25

Proposal for a regulation
Article 11 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The authority referred to in Article 9(1) shall publish, ***as soon as possible***, notification of the fact that a certificate has been granted . The notification shall contain all of the following information:	1. The authority referred to in Article 9(1) shall publish, ***without undue delay***, notification of the fact that a certificate has been granted. The notification shall contain all of the following information:

Amendment 26

Proposal for a regulation
Article 11 – paragraph 1 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) information on any direct public financial support received for research related to the development of the product.

Amendment 27

Proposal for a regulation
Article 15 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the certificate was granted contrary to Article 3;	(a) the certificate was granted contrary to Article 3 ***or 6(2)***;

Amendment 28

Proposal for a regulation
Article 16 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Any person may submit an application for revocation of the extension of the duration granted under this Chapter to the body responsible under national law for the revocation of the corresponding basic patent.	2. Any person may submit an application for revocation of the extension of the duration granted under this Chapter to the body responsible under national law for the revocation of the corresponding basic patent ***or before a competent court of a Member State***.

Amendment 29

Proposal for a regulation
Article 18 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Full transparency shall be ensured throughout the whole appeal proceeding, which shall be open, whenever possible, to public participation.

Amendment 30

Proposal for a regulation
Article 20 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where the basic patent is a European patent, including a unitary	1. Where the basic patent is a European patent, including a unitary

patent, and the authorisation to place the product on the market has been granted through the centralised procedure under Regulation (EC) No 726/2004 or Regulation (EU) 2019/6, the procedure in this Chapter shall apply.	patent, and the authorisation to place the product on the market has been granted***, as appropriate, in accordance with Directive .../... [2023/0132(COD)],*** through the centralised procedure under Regulation (EC) No 726/2004 or Regulation (EU) 2019/6, the procedure in this Chapter shall apply.

Amendment 31

Proposal for a regulation
Article 23 – paragraph 1

Text proposed by the Commission	*Amendment*
If the centralised application complies with Article 22, or if an application for an extension of the duration of certificates complies with Article 33(2), the Office shall publish the application, without undue delay***, in the Register***.	If the centralised application complies with Article 22, or if an application for an extension of the duration of certificates complies with Article 33(2), the Office shall publish the application, ***in the Register*** without undue delay ***and no later than five working days after***.

Amendment 32

Proposal for a regulation
Article 24 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Office shall assess the application on the basis of all the conditions in Article 3(1) for each of the designated Member States.	1. The Office shall assess the application on the basis of all the conditions in Articles 3(1) and ***(3) and Article 6(2)*** for each of the designated Member States.

Amendment 33

Proposal for a regulation
Article 24 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where the centralised application for a certificate and the product to which it	2. Where the centralised application for a certificate and the product to which it

relates comply with Article 3(1) in respect of all or some of the designated Member States, the Office shall adopt a reasoned positive examination opinion in respect of such Member States. The Office shall notify that opinion to the applicant.	relates comply with Article 3(1) and ***(3) and Article 6(2)*** in respect of all or some of the designated Member States, the Office shall adopt a reasoned positive examination opinion in respect of such Member States. The Office shall notify that opinion to the applicant ***and publish the opinion on the dedicated register without undue delay***.

Amendment 34

Proposal for a regulation
Article 24 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the centralised application for a certificate and the product to which it relates does not comply with Article 3(1) in respect of all or some of the designated Member States, the Office shall adopt a reasoned negative examination opinion in respect of such Member States. The Office shall notify that opinion to the applicant.	3. Where the centralised application for a certificate and the product to which it relates does not comply with Article 3(1) and ***(3) and Article 6(2)*** in respect of all or some of the designated Member States, the Office shall adopt a reasoned negative examination opinion in respect of such Member States. The Office shall notify that opinion to the applicant ***and publish the opinion on the dedicated register without undue delay***.

Amendment 35

Proposal for a regulation
Article 24 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. The Office shall adopt an examination opinion within 6 months after publication of the centralised application in the Register. Without prejudice to Articles 25, 26 and 28 of this Regulation, whenever duly justified for reasons of urgency, the applicant may submit a request for an expedited procedure. Where the request for an expedited examination procedure is deemed justified, the Office shall adopt an examination opinion within 4 months

from the publication of the application for a unitary certificate.

Amendment 36

Proposal for a regulation
Article 25 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Whenever the expedited procedure applies in accordance with to Article 24 (5a), observations shall be submitted within six weeks after publication of the application in the Register.

Amendment 37

Proposal for a regulation
Article 26 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Opposition may only be filed on the grounds that one or more of the conditions set out in Article 3 are not fulfilled for one or more of the designated Member States.	2. Opposition may only be filed on the grounds that one or more of the conditions set out in Article 3 ***or 6*** are not fulfilled for one or more of the designated Member States.

Amendment 38

Proposal for a regulation
Article 26 – paragraph 4 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) any evidence the opponent relies on in support of the opposition.

Amendment 39

Proposal for a regulation
Article 26 – paragraph 6

Text proposed by the Commission	*Amendment*
6. If the opposition panel notes that the notice of opposition does not comply with paragraphs 2, 3 or 4, it shall reject the opposition as inadmissible, and communicate ***this to*** opponent, unless these deficiencies have been remedied before expiry of the opposition filing period referred to in paragraph 1.	6. If the opposition panel notes that the notice of opposition does not comply with paragraphs 2, 3 or 4, it shall reject the opposition as inadmissible, and communicate ***its decision as well as the reasoning for its decision to the*** opponent, unless these deficiencies have been remedied before expiry of the opposition filing period referred to in paragraph 1.

Amendment 40

Proposal for a regulation
Article 26 – paragraph 9

Text proposed by the Commission	*Amendment*
9. The Office shall issue a decision on the opposition within 6 months, unless the complexity of the case requires a longer period.	9. The Office shall issue a decision on the opposition ***including a detailed reasoning for that decision*** within 6 months, unless the complexity of the case requires a longer period.

Amendment 41

Proposal for a regulation
Article 26 – paragraph 9 a (new)

Text proposed by the Commission	*Amendment*
	9a. In cases where several oppositions have been filed against an examination opinion, the Office shall deal with the oppositions jointly and issue one single decision in regards to all oppositions filed.

Amendment 42

Proposal for a regulation
Article 26 – paragraph 10

Text proposed by the Commission	*Amendment*
10. If the opposition panel considers that no ground for opposition prejudices the maintenance of the examination opinion, it shall reject the opposition, and the Office shall mention this in the Register.	10. If the opposition panel considers that no ground for opposition prejudices the maintenance of the examination opinion, it shall reject the opposition and ***notify the opponent of its decision,*** and the Office shall mention this in the Register.

Amendment 43

Proposal for a regulation
Article 26 – paragraph 12 a (new)

Text proposed by the Commission	*Amendment*
	12a. Full transparency shall be ensured throughout the whole opposition proceeding, which shall be open, whenever possible, to public participation.

Amendment 44

Proposal for a regulation
Article 27 – paragraph 1

Text proposed by the Commission	*Amendment*
1. On a request made to the Office, any competent national authority may be appointed by the Office as a participating office in the examination procedure. Once a competent national authority is appointed in accordance with this Article, that authority shall designate one or more examiners to be involved in the examination of one or more centralised applications.	1. On a request made to the Office, any competent national authority may be appointed by the Office as a participating office in the examination procedure. Once a competent national authority is appointed in accordance with this Article, that authority shall designate one or more examiners to be involved in the examination of one or more centralised applications***, on the basis of their relevant expertise and of their experience in the field***.

Amendment 45

Proposal for a regulation
Article 28 – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
(a) ***geographical balance amongst the participating offices***;	(a) ***relevant expertise and sufficient experience in the examination of patents and supplementary protection certificates, ensuring, in particular, that at least one examiner has a minimum of five years of experience in the examination of patents and supplementary protection certificates***;

Amendment 46

Proposal for a regulation
Article 28 – paragraph 3 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) where possible, geographical balance amongst the participating offices;

Amendment 47

Proposal for a regulation
Article 28 – paragraph 3 – point c

Text proposed by the Commission	*Amendment*
(c) no ***more than one*** examiner employed by a competent national authority making use of the exemption ***laid down*** in Article 10(5).	(c) ***that there is*** no examiner employed by a competent national authority making use of the exemption ***set out*** in Article 10(5) ***of this Regulation***.

Amendment 48

Proposal for a regulation
Article 29 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Notice of appeal shall be filed in writing at the Office within 2 months of the date of notification of the decision. The notice shall be deemed to have been filed only when the fee for appeal has been paid. In case of an appeal, a written statement	3. Notice of appeal shall be filed in writing at the Office within 2 months of the date of notification of the decision. The notice shall be deemed to have been filed only when the fee for appeal has been paid. In case of an appeal, a written statement

setting out the grounds of appeal shall be filed within ***4*** months of the date of notification of the decision***.***	setting out the grounds of appeal***, including corresponding evidence relied on,*** shall be filed within ***3*** months of the date of notification of the decision

Amendment 49

Proposal for a regulation
Article 29 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Any reply to statement of the grounds of appeal shall be submitted in writing within three months from the date of the notification of the statement of the grounds of appeal. Where applicable, the Office shall set a date for an oral hearing within three months after the filing of the reply to the grounds of appeal or within six months of the filing of grounds of appeal, whichever is earlier. The Office shall issue a written decision within three months of the oral hearing or of the filing of the reply to the statement of grounds of appeal, as applicable.

Amendment 50

Proposal for a regulation
Article 29 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Where an appeal before the Boards of Appeal of the Office results in a decision which is not in line with the examination opinion and is remitted to the Office, the decision of the Boards ***may*** annul or alter that opinion before transmitting it to the competent national authorities of the designated Member States.	5. Where an appeal before the Boards of Appeal of the Office results in a decision which is not in line with the examination opinion and is remitted to the Office, the decision of the Boards ***shall*** annul or alter that opinion before transmitting it to the competent national authorities of the designated Member States.

Amendment 51

Proposal for a regulation
Article 30 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Members of the Boards of Appeal in matters regarding centralised applications for certificates shall be appointed in accordance with Article 166 (5) of Regulation (EU) 2017/1001.	4. Members of the Boards of Appeal in matters regarding centralised applications for certificates shall be appointed in accordance with Article 166 (5) of Regulation (EU) 2017/1001. ***When appointing members of the Boards of Appeal in matters regarding centralised applications for certificates, their prior experience in supplementary protection certificate or patent matters should be taken into account.***

Amendment 52

Proposal for a regulation
Article 30 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Article 166(9) of Regulation (EU) 2017/1001 shall apply to Boards of Appeal in matters regarding centralised applications for certificates.

Amendment 53

Proposal for a regulation
Article 32 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Such transmission shall take place without undue delay within a timeframe allowing the competent national authorities of each designated Member State to grant or reject a certificate, as applicable, according to applicable national procedures, before the expiry of the basic patent.

Amendment 54

Proposal for a regulation
Article 32 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. The competent national authority shall inform the applicant of its decision without undue delay.

Amendment 55

Proposal for a regulation
Article 33 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Third parties may also submit observations in respect of a centralised application for an extension of the duration of certificates.	4. Third parties may also submit observations ***or an opposition*** in respect of a centralised application for an extension of the duration of certificates.

Amendment 56

Proposal for a regulation
Article 35 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Office shall develop, keep and maintain an electronic Register, providing up-to-date information regarding the status of all published centralised applications, and of all centralised applications for an extension of the duration of certificates.	1. The Office shall develop, keep and maintain an electronic***, searchable and public*** Register, providing up-to-date information regarding the status of all published centralised applications, and of all centralised applications for an extension of the duration of certificates.

Amendment 57

Proposal for a regulation
Article 35 – paragraph 2 – point j a (new)

Text proposed by the Commission	*Amendment*
	(ja) information on any direct public financial support received for research

related to the development of the product;

Amendment 58

Proposal for a regulation
Article 35 – paragraph 2 – point k

Text proposed by the Commission	*Amendment*
(k) the date and ***a summary of*** the examination opinion in respect of each of the designated Member States;	(k) the date and the examination opinion in respect of each of the designated Member States;

Amendment 59

Proposal for a regulation
Article 35 – paragraph 2 – point n

Text proposed by the Commission	*Amendment*
(n) where applicable, the filing of an opposition, and its outcome, including where applicable a summary of the revised examination opinion;	(n) where applicable, the filing of an opposition, ***its status*** and its outcome, including where applicable a summary of the revised examination opinion;

Amendment 60

Proposal for a regulation
Article 35 – paragraph 2 – point o

Text proposed by the Commission	*Amendment*
(o) where applicable, the filing of an appeal, and the outcome of the appeal proceedings, including where applicable a summary of the revised examination opinion;	(o) where applicable, the filing of an appeal, ***its status*** and the outcome of the appeal proceedings, including where applicable a summary of the revised examination opinion;

Amendment 61

Proposal for a regulation
Article 35 – paragraph 11 a (new)

Text proposed by the Commission	*Amendment*
	11a. By way of derogation of Article 35(9)(b) public authorities shall not use the information provided for in the register for practices of patent linkage and no regulatory or administrative decisions related to generics or biosimilar shall be based on information provided for in the register and be used for refusal, suspension, delay, withdrawal or revocation of marketing authorisation, pricing and reimbursement decisions or tender bids.

Amendment 62

Proposal for a regulation
Article 44 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Oral proceedings before an examination panel or opposition panel shall not be public.	***deleted***

Amendment 63

Proposal for a regulation
Article 44 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Oral proceedings before the Boards of Appeal, including delivery of the decision and, as the case may be, of a revised opinion, shall be public, unless the Boards of Appeal decide otherwise in cases where admission of the public could have serious and unjustified disadvantages, in particular for a party to the proceedings.	3. Oral proceedings before ***an examination panel, an opposition panel or*** the Boards of Appeal, including delivery of the decision and, as the case may be, of a revised opinion, shall be public, unless the ***examination panel, the opposition panel or the*** Boards of Appeal decide otherwise in cases where admission of the public ***to all or a part of the oral proceedings*** could have serious and unjustified disadvantages, in particular for a party to the proceedings.

Amendment 64

Proposal for a regulation
Article 45 – paragraph 3

Text proposed by the Commission	*Amendment*
3. If the Office or the relevant panel considers it necessary for a party, witness or expert to give evidence orally, it shall issue a summons to the person concerned to appear before it. The period of notice provided in such summons shall be at least 1 month, unless they agree to a shorter period.	3. If the Office or the relevant panel considers it necessary for a party, witness or expert to give evidence orally, it shall issue a summons to the person concerned to appear before it. ***Where an expert is summonsed, the Office or the relevant panel, as applicable, shall verify that the person is free of any conflict of interest.*** The period of notice provided in such summons shall be at least 1 month, unless they agree to a shorter period.

Amendment 65

Proposal for a regulation
Article 57 – paragraph 2

Text proposed by the Commission	*Amendment*
2. By [OP, please insert: five years after the date of application], and every 5 years thereafter, the Commission shall also carry out an evaluation of the application of Chapter III.	2. By … [OJ: please insert: five years after the date of application], and every 5 years thereafter, the Commission shall also carry out an evaluation of the application of Chapter III***, and present a report on the main findings to the European Parliament, the Council and the European Economic and Social Committee***. ***The evaluation should assess in particular whether the objectives of the provisions in that Chapter have been achieved.***

ANNEX: ENTITIES OR PERSONS FROM WHOM THE RAPPORTEUR HAS RECEIVED INPUT

Pursuant to Article 8 of Annex I to the Rules of Procedure, the rapporteur declares that he has received input from the following entities or persons in the preparation of the report, until the adoption thereof in committee:

Entity and/or person
AstraZeneca
AnimalhealthEurope a.i.s.b.l.
Bristol-Myers Squibb Company
Bundesverband der Arzneimittel-Hersteller e.V.
Bundesverband der Pharmazeutischen Industrie e.V.
Deutsche Sozialversicherung Europavertretung
European Federation of Pharmaceutical Industries and Associations
EUIPO
Johnson & Johnson
MEDICINES FOR EUROPE
Pro Generika e.V.
S.A. Eli Lilly Benelux N.V.
Verband der Chemischen Industrie e.V.
Verband der forschenden Pharma-Unternehmen
WEMOS

The list above is drawn up under the exclusive responsibility of the rapporteur.

9.11.2023

LETTER OF THE COMMITTEE ON LEGAL AFFAIRS

Mr Adrián Vázquez Lázara
Chair
Committee on Legal Affairs
BRUSSELS

Subject: Opinion on the Proposal for a regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast) (COM(2023)0231 – C9-0146/2023 – 2023/0130(COD))

Dear Mr Chair,

The Committee on Legal Affairs has examined the proposal referred to above pursuant to Rule 110 on recasting of Parliament's Rules of Procedure.

Paragraph 3 of that Rule reads as follows:

"If the committee responsible for legal affairs considers that the proposal does not entail any substantive changes other than those identified as such in the proposal, it shall inform the committee responsible for the subject matter thereof.

In such a case, over and above the conditions laid down in Rules 180 and 181, amendments shall be admissible within the committee responsible for the subject-matter only if they concern those parts of the proposal which contain changes.

However, amendments to parts of the proposal which remain unchanged may, by way of exception and on a case-by-case basis, be accepted by the Chair of the committee responsible for the subject matter if he or she considers that this is necessary for pressing reasons relating to the internal logic of the text or because the amendments are inextricably linked to other admissible amendments. Such reasons must be stated in a written justification to the amendments."

Following the here attached opinion of the Consultative Working Party of the Legal Services of the Parliament, the Council and the Commission, which has examined the recast proposal, and in keeping with the recommendations of the Rapporteur, the Committee on Legal Affairs considers that the proposal in question does not include any substantive changes other than those identified as such and that, as regards the codification of the unchanged provisions of the earlier act with those substantive amendments, the proposal contains a straightforward codification of the existing text, without any change in its substance.

In conclusion, at its meeting of 7 November 2023, the Committee on Legal Affairs unanimously[1] decided to recommend that the Committee on Legal Affairs, as the committee responsible, proceed to examine the above proposal in accordance with Rule 110.

Yours sincerely,

Adrián Vázquez Lázara

Encl.: Opinion of the Consultative Working Party

[1] The following were present for the final vote: Adrián Vázquez Lázara (Chair), Marion Walsmann (Vice-Chair), Raffaele Stancanelli (Vice-Chair), Alessandra Basso, Patrick Breyer, Ilana Cicurel, Angel Dzhambazki, Ibán García Del Blanco, Heidi Hautala, Valérie Hayer (for Pierre Karleskind pursuant to Rule 209(7)), Gilles Lebreton, Maria-Manuel Leitão-Marques, Karen Melchior, Ludek Niedermayer (for Jiří Pospíšil pursuant to Rule 209(7)), Sabrina Pignedoli, Franco Roberti, René Repasi, Axel Voss, Javier Zarzalajos, Juan Ignacio Zoido Alvarez.

CONSULTATIVE WORKING PARTY
OF THE LEGAL SERVICES

Brussels, 26 September 2023

OPINION

FOR THE ATTENTION OF THE EUROPEAN PARLIAMENT
THE COUNCIL
THE COMMISSION

Proposal for a regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products
COM(2023)0231 of 27.4.2023 – 2023/0130(COD)

Having regard to the Inter-institutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts, and in particular to point 9 thereof, the Consultative Working Party consisting of the respective legal services of the European Parliament, the Council and the Commission met on 13 July 2023 for the purpose of examining the aforementioned proposal submitted by the Commission.

At that meeting[2], an examination of the proposal for a Regulation of the European Parliament and of the Council recasting 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 resulted in the Consultative Working Party's establishing, by common accord, as follows.

1. The following should have been marked with the grey-shaded type generally used for identifying substantive amendments:
- in recital 43, the deletion of the first sentence of recital 5 of Regulation (EU) 2019/933;
- in recital 59, the deletion of the first and second sentences of recital 27 of Regulation (EU) 2019/933;
- in Article 11(1), introductory wording, and in Article 11(2), the adding of the words '*as soon as possible*'.

2. The following should have been identified as formal adaptations:
- in the title of the act, the replacement of the word '*concerning*' with the word '*on*';
- in Article 8(1), point (d), the adding of the words '*for a medicinal product*';
- in Article 8(2), the replacement of the words '*extended duration*' with the words '*extension of the duration*'.

In consequence, examination of the proposal has enabled the Consultative Working Party to conclude, without dissent, that the proposal does not comprise any substantive amendments

[2] The Consultative Working Party worked on the basis of the English language version of the proposal, being the master-copy language version of the text under discussion.

other than those identified as such. The Working Party also concluded, as regards the codification of the unchanged provisions of the earlier act with those substantive amendments, that the proposal contains a straightforward codification of the existing legal text, without any change in its substance.

F. DREXLER Jurisconsult	E. FINNEGAN Jurisconsult	D. CALLEJA CRESPO Director-General

PROCEDURE – COMMITTEE RESPONSIBLE

Title	Supplementary protection certificate for medicinal products (recast)		
References	COM(2023)0231 – C9-0146/2023 – 2023/0130(COD)		
Date submitted to Parliament	27.4.2023		
Committee responsible Date announced in plenary	JURI 11.9.2023		
Committees asked for opinions Date announced in plenary	INTA 11.9.2023	ENVI 11.9.2023	IMCO 11.9.2023
Not delivering opinions Date of decision	INTA 24.5.2023	ENVI 17.7.2023	IMCO 23.5.2023
Rapporteurs Date appointed	Tiemo Wölken 19.7.2023		
Discussed in committee	7.11.2023	29.11.2023	
Date adopted	24.1.2024		
Result of final vote	+: –: 0:	23 0 0	
Members present for the final vote	Pascal Arimont, Gunnar Beck, Ilana Cicurel, Ibán García Del Blanco, Virginie Joron, Pierre Karleskind, Sergey Lagodinsky, Gilles Lebreton, Sabrina Pignedoli, Jiří Pospíšil, Franco Roberti, Raffaele Stancanelli, Adrián Vázquez Lázara, Axel Voss, Marion Walsmann, Tiemo Wölken		
Substitutes present for the final vote	Pascal Durand, Angelika Niebler, Witold Pahl, Nacho Sánchez Amor, Jana Toom		
Substitutes under Rule 209(7) present for the final vote	Benoît Biteau, Christian Ehler		
Date tabled	1.2.2024		

FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

23	+
ECR	Raffaele Stancanelli
ID	Gunnar Beck, Virginie Joron, Gilles Lebreton
NI	Sabrina Pignedoli
PPE	Pascal Arimont, Christian Ehler, Angelika Niebler, Witold Pahl, Jiří Pospíšil, Axel Voss, Marion Walsmann
Renew	Ilana Cicurel, Pierre Karleskind, Jana Toom, Adrián Vázquez Lázara
S&D	Pascal Durand, Ibán García Del Blanco, Franco Roberti, Nacho Sánchez Amor, Tiemo Wölken
Verts/ALE	Benoît Biteau, Sergey Lagodinsky

0	-

0	0

Key to symbols:
+ : in favour
- : against
0 : abstention