



2023/0130(COD)

13.10.2023

*****I**

DRAFT 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.

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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 2023¹,
 - having regard to the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts²,
 - having regard to Rules 110 and 59 of its Rules of Procedure,
 - having regard to the report of the Committee on Legal Affairs (A9-0000/2023),
- 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 Not yet published in the Official Journal.

² OJ C 77, 28.3.2002, p. 1.

Amendment 1

Proposal for a regulation Recital 2

Text proposed by the Commission

(2) Pharmaceutical research plays a decisive role in the continuing improvement in public health.

Amendment

(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. It is, however, 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.***

Or. en

Amendment 2

Proposal for a regulation Recital 3

Text proposed by the Commission

(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.***

Amendment

deleted

Amendment 3

Proposal for a regulation

Recital 5

Text proposed by the Commission

(5) That situation leads to a lack of protection which penalises pharmaceutical research and there is a risk that research centres situated in the Member States relocate to countries that offer greater protection.

Amendment

deleted

Or. en

Amendment 4

Proposal for a regulation

Recital 13

Text proposed by the Commission

(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.

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 **biosimilars** 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.

Or. en

Amendment 5

Proposal for a regulation

Recital 24

Text proposed by the Commission

(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.

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 ***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.

Or. en

Amendment 6

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 by 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 pharmaceutical systems in the Union and its Member States.

Or. en

Amendment 7

Proposal for a regulation Recital 45

Text proposed by the Commission

(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.

Amendment

(45) In *those* 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 *supplementary protection* certificate *in accordance with Regulation (EU) 2019/933* 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*, 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.

Or. en

Amendment 8

Proposal for a regulation Recital 60

Text proposed by the Commission

(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

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 available in all official languages of the Union.

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. ***However, the information provided for within the register should not be used in relation to practices of patent linkage, and no regulatory or administrative decisions related to generic or biosimilars should be based on information provided for in the register, such as marketing authorisations, pricing and reimbursement decisions or tender bids to the existence of the supplementary protection certificate.***

Or. en

Amendment 9

Proposal for a regulation

Article 2 – paragraph 1 – point 1

Text proposed by the Commission

(1) ‘medicinal product’ means any substance or combination of substances presented for treating or preventing disease in human beings ***or animals and*** any substance or combination of substances ***which*** may be administered to human beings ***or animals*** with a view to ***making a medical diagnosis or to*** restoring, correcting or modifying physiological functions ***in humans or in animals***;

Amendment

(1) ‘medicinal product’ means any substance or combination of substances ***that fulfils at least one of the following conditions:***

(a) any substance or combination of substances that is presented as having properties for treating or preventing disease in human beings; ***or***

(b) any substance or combination of substances that may be used in or administered to human beings with a view to ***either*** restoring, correcting or modifying physiological functions ***by exerting a pharmacological, immunological or***

metabolic action, or to making a medical diagnosis;

Or. en

Amendment 10

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.

Or. en

Amendment 11

Proposal for a regulation

Article 5 – paragraph 1

Text proposed by the Commission

Amendment

1. 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.

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.

Or. en

Amendment 12

Proposal for a regulation

Article 5 – paragraph 2 – introductory part

Text proposed by the Commission

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:

Amendment

2. By way of derogation from paragraph 1, **and in accordance with Regulation (EU) 2019/933**, 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:

Or. en

Amendment 13

Proposal for a regulation

Article 5 – paragraph 2 – point a – point i

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 14

Proposal for a regulation

Article 5 – paragraph 2 – point a – point ii

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 15

Proposal for a regulation

Article 5 – paragraph 2 – point a – point iii

Text proposed by the Commission

(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;

Amendment

(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**

Or. en

Amendment 16

Proposal for a regulation

Article 5 – paragraph 2 – point a – point iv

Text proposed by the Commission

(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.

Amendment

(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.

Or. en

Amendment 17

Proposal for a regulation

Article 5 – paragraph 2 – point a – point iv a (new)

Text proposed by the Commission

Amendment

(iva) any act in accordance with Article [85] of Directive (EU) .../... [2023/0132(COD)].

Or. en

Amendment 18

Proposal for a regulation

Article 7 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. The applicant shall be responsible for the accuracy and completeness of the information and documentation submitted in relation to its application.

Or. en

Amendment 19

Proposal for a regulation

Article 8 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(da) where applicable, the consent of the third party referred to in Article 6(2) of this Regulation;

Or. en

Amendment 20

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.

Or. en

Amendment 21

Proposal for a regulation

Article 11 – paragraph 1 – introductory part

Text proposed by the Commission

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:

Amendment

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:

Or. en

Amendment 22

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.

Or. en

Amendment 23

Proposal for a regulation

Article 15 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(ca) if the marketing authorisation has been withdrawn or revoked in accordance with Directive (EU) .../... [2023/0132(COD)].

Or. en

Amendment 24

Proposal for a regulation

Article 20 – paragraph 1

Text proposed by the Commission

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.

Amendment

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, ***as appropriate, in accordance with Directive (EU) .../... [EC2023/0132(COD)]***, through the centralised procedure under Regulation (EC) No 726/2004 or Regulation (EU) 2019/6, the procedure in this Chapter shall apply.

Or. en

Amendment 25

**Proposal for a regulation
Article 24 – paragraph 1**

Text proposed by the Commission

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.

Amendment

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

Or. en

Amendment 26

**Proposal for a regulation
Article 24 – paragraph 2**

Text proposed by the Commission

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.

Amendment

2. Where the centralised application for a certificate and the product to which it 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.

Or. en

Amendment 27

Proposal for a regulation Article 24 – paragraph 3

Text proposed by the Commission

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.

Amendment

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 it on the Register without undue delay.***

Or. en

Amendment 28

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.

Or. en

Amendment 29

Proposal for a regulation Article 26 – paragraph 6

Text proposed by the Commission

Amendment

6. If the opposition panel notes that

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.

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.

Or. en

Amendment 30

Proposal for a regulation Article 26 – paragraph 9

Text proposed by the Commission

9. The Office shall issue a decision on the opposition within 6 months, unless the complexity of the case requires a longer period.

Amendment

9. The Office shall issue a decision on the opposition ***including a detailed reasoning for its decision*** within 6 months, unless the complexity of the case requires a longer period.

Or. en

Amendment 31

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 respect of all oppositions filed.

Or. en

Amendment 32

Proposal for a regulation Article 26 – paragraph 10

Text proposed by the Commission

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.

Amendment

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

Or. en

Amendment 33

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

Text proposed by the Commission

(a) ***geographical balance amongst the participating offices;***

Amendment

(a) ***relevant expertise and sufficient experience in the examination of patents and supplementary protection certificates;***

Or. en

Amendment 34

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

Text proposed by the Commission

(c) no ***more than one*** examiner employed by a competent national authority making use of the exemption laid down in Article 10(5).

Amendment

(c) ***that there is*** no examiner employed by a competent national authority making use of the exemption laid down in Article 10(5).

Or. en

Amendment 35

Proposal for a regulation

Article 29 – paragraph 3

Text proposed by the Commission

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.

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

Or. en

Amendment 36

Proposal for a regulation

Article 29 – paragraph 5

Text proposed by the Commission

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.

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 ***shall*** annul or alter that opinion before transmitting it to the competent national authorities of the designated Member States.

Or. en

Amendment 37

Proposal for a regulation

Article 32 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. The Office shall inform the applicant of its decision without undue delay.

Or. en

Amendment 38

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 oppositions** in respect of a centralised application for an extension of the duration of certificates.

Or. en

Amendment 39

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;

Or. en

Amendment 40

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

Text proposed by the Commission

Amendment

(n) where applicable, the filing of an

(n) where applicable, the filing of an

opposition, and its outcome, including where applicable a summary of the revised examination opinion;

opposition, ***its status*** and its outcome, including where applicable a summary of the revised examination opinion;

Or. en

Amendment 41

Proposal for a regulation

Article 35 – paragraph 2 – point o

Text proposed by the Commission

(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;

Amendment

(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;

Or. en

Amendment 42

Proposal for a regulation

Article 35 – paragraph 11 a (new)

Text proposed by the Commission

Amendment

11a. By way of derogation from Article 35(9), point (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 biosimilars shall be based on information provided for in the register and be used for refusal, suspension, delay, withdrawal or revocation of marketing authorisations, pricing and reimbursement decisions or tender bids.

Or. en

Amendment 43

Proposal for a regulation

Article 45 – paragraph 3

Text proposed by the Commission

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.

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. ***Where an expert is summonsed it shall be verified that that expert 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.

Or. en

Amendment 44

Proposal for a regulation

Article 57 – paragraph 2

Text proposed by the Commission

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.

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 ***and present a report on the main findings to the European Parliament and to the Council.***

Or. en