



**2023/0127(COD)**

13.10.2023

**\*\*\*I**

## **DRAFT REPORT**

on the proposal for a regulation of the European Parliament and of the Council on the unitary supplementary certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013  
(COM(2023)0222 – C9-0148/2023 – 2023/0127(COD))

Committee on Legal Affairs

Rapporteur: Tiemo Wölken

### ***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 unitary supplementary certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013 (COM(2023)0222 – C9-0148/2023 – 2023/0127(COD))**

**(Ordinary legislative procedure: first reading)**

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2023)0222),
  - having regard to Article 294(2) and Article 118, first paragraph, of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0148/2023),
  - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
  - having regard to Rule 59 of its Rules of Procedure,
  - having regard to the report of the Committee on Legal Affairs (A9-0000/2023),
1. Adopts its position at first reading hereinafter set out;
  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.

### **Amendment 1**

#### **Proposal for a regulation**

##### **Recital 1**

*Text proposed by the Commission*

(1) 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

*Amendment*

(1) 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.

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 14 a (new)**

*Text proposed by the Commission*

*Amendment*

*(14a) To avoid unnecessary an administrative and financial burden both for the pharmaceutical industry and for the national authorities and the Office, certain streamlining measures should be introduced. Electronic applications for unitary and combined applications for supplementary protection certificates should be made possible. An application submitted to the Office should follow the 'digital by default' principle and hence be submitted to the Office in electronic form. Applications should be assessed based on the file submitted by the applicant in accordance with this Regulation.*

Or. en

## **Amendment 3**

### **Proposal for a regulation Recital 21**

*Text proposed by the Commission*

(21) 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*

(21) 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 4**

**Proposal for a regulation**  
**Recital 21 a (new)**

*Text proposed by the Commission*

*Amendment*

***(21a) 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 pharmaceutical systems in the Union and its Member States.***

Or. en

## Amendment 5

### Proposal for a regulation Recital 22

#### *Text proposed by the Commission*

(22) Regulation [COM(2023) 231] provides for an exception according to which, under narrowly defined circumstances and subject to various safeguards, the protection conferred by a national supplementary protection certificate for medicinal products does not extend to a product that would be manufactured in the Union by a person other than the holder of that certificate, where it is manufactured for the purpose of being exported to **a** third country, or of being stored in the Union in view of **its entry into the Union** market upon expiry of the certificate. To avoid discrimination between applicants for certificates under Regulation [COM(2023) 231] and for unitary certificates under this Regulation, similar rights and limitations should be conferred by certificates under Regulation [COM(2023) 231] and by unitary certificates, and therefore that exception should also be available in respect of unitary certificates. The reasons for the introduction for the waiver and the conditions for its application should be applicable for unitary certificates.

#### *Amendment*

(22) Regulation [COM(2023) 231] provides for an exception according to which, under narrowly defined circumstances and subject to various safeguards, the protection conferred by a national supplementary protection certificate for medicinal products does not extend to a product that would be manufactured in the Union by a person other than the holder of that certificate, where it is manufactured for the purpose of being exported to a third country **market where protection does not exist or has expired** or of being **made and** stored in the Union in view of **entering the market of any Member State** upon expiry of the **corresponding** certificate (**'EU day-one entry'**) **and any acts related thereto**. To avoid discrimination between applicants for certificates under Regulation [COM(2023) 231] and for unitary certificates under this Regulation, similar rights and limitations should be conferred by certificates under Regulation [COM(2023) 231] and by unitary certificates, and therefore that exception should also be available in respect of unitary certificates. The reasons for the introduction for the waiver and the conditions for its application should be applicable for unitary certificates.

Or. en

## Amendment 6

### Proposal for a regulation Recital 22 a (new)

***(22a) 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 7**

### **Proposal for a regulation**

#### **Recital 26**

(26) The examination of an application for a unitary 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

(26) The examination of an application for a unitary 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 procedure, in particular as regards qualification and conflicts of interest.

protection certificates ***and related patent*** matters, located today at national offices only. To ensure an optimal quality of the examination, ***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 procedure, in particular as regards qualification and conflicts of interest.

Or. en

## Amendment 8

### Proposal for a regulation Recital 31

#### *Text proposed by the Commission*

(31) When appointing members of the Boards of Appeal in matters regarding applications for unitary certificates, their prior experience in supplementary protection certificate or patent matters should be taken into account.

#### *Amendment*

(31) When appointing members of the Boards of Appeal in matters regarding applications for unitary certificates, their ***relevant expertise and sufficient*** prior experience in supplementary protection certificate or patent matters should be taken into account.

Or. en

## Amendment 9

### Proposal for a regulation Recital 33

#### *Text proposed by the Commission*

(33) The Office should have the possibility to charge a fee for the application for a unitary certificate and for an application for the extension of duration of a unitary certificate ***in the case of***

#### *Amendment*

(33) The Office should have the possibility to charge a fee for the application for a unitary certificate and for an application for the extension of duration of a unitary certificate ***for*** paediatric

paediatric medicinal products, as well as other procedural fees such as those for oppositions, appeals and invalidity. The fees charged by the Office should be laid down by an implementing act.

medicinal products *in accordance with Article 86 of Directive (EU) ... [2023/0132 (COD)]*, as well as other procedural fees such as those for oppositions, appeals and invalidity. The fees charged by the Office should be laid down by an implementing act.

Or. en

## Amendment 10

### Proposal for a regulation Recital 35

#### *Text proposed by the Commission*

(35) To ensure transparency, a register should be set up that can serve as a single access point providing information on applications for unitary certificates as well as granted unitary certificates and their status. The register should be available in all official languages of the Union.

#### *Amendment*

(35) To ensure transparency, a register should be set up that can serve as a single access point providing information on applications for unitary certificates as well as granted unitary certificates and their status. 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 generics 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 11

### 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 12

### Proposal for a regulation

#### Article 2 – paragraph 1 – point 9 a (new)

*Text proposed by the Commission*

*Amendment*

***(9a) ‘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 13

### Proposal for a regulation

#### Article 3 – paragraph 1 – point b

*Text proposed by the Commission*

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Regulation (EU) 2019/6, or with the centralised procedure under Regulation (EC) No 726/2004;

*Amendment*

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

Or. en

## Amendment 14

### Proposal for a regulation

#### Article 5 – paragraph 3 – introductory part

*Text proposed by the Commission*

3. By way of derogation from paragraph 1, the unitary certificate shall not confer protection against certain acts which would otherwise require the consent of the unitary certificate holder, if all of the following conditions are met:

*Amendment*

3. By way of derogation from paragraph 1 ***and in accordance with Regulation (EU) 2019/933***, the unitary certificate shall not confer protection against certain acts which would otherwise require the consent of the unitary certificate holder, if all of the following conditions are met:

Or. en

## Amendment 15

### Proposal for a regulation

#### Article 5 – paragraph 3 – point a – point i

*Text proposed by the Commission*

(i) ***the*** making ***of*** a product, or a medicinal product containing that product,

*Amendment*

(i) making a product, or a medicinal product containing that product, for the

for the purpose of export to third countries;

purpose of export to third countries; **or**

Or. en

## Amendment 16

### Proposal for a regulation

#### Article 5 – paragraph 3 – 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 17

### Proposal for a regulation

#### Article 5 – paragraph 3 – point a – point iii

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

(iii) **the** making, no earlier than 6 months before the expiry of the **unitary** 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 **that** certificate; **or**

Or. en

## Amendment 18

### Proposal for a regulation

#### Article 5 – paragraph 3 – 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 **unitary** 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 19**

**Proposal for a regulation**

**Article 5 – paragraph 3 – 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 20**

**Proposal for a regulation**

**Article 8 – paragraph 4 a (new)**

*Text proposed by the Commission*

*Amendment*

**4a. The application for a unitary certificate shall be lodged electronically, using the formats made available by the Office.**

Or. en

**Amendment 21**

**Proposal for a regulation**

**Article 8 – paragraph 4 b (new)**

*Text proposed by the Commission*

*Amendment*

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

Or. en

## **Amendment 22**

### **Proposal for a regulation**

#### **Article 9 – 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);**

Or. en

## **Amendment 23**

### **Proposal for a regulation**

#### **Article 9 – paragraph 1 – point d b (new)**

*Text proposed by the Commission*

*Amendment*

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

Or. en

## **Amendment 24**

### **Proposal for a regulation**

#### **Article 10 – paragraph 1**

*Text proposed by the Commission*

The application for a unitary certificate and, where applicable, the application for an extension of the duration of a unitary certificate, shall be lodged with the Office.

*Amendment*

The application for a unitary certificate and, where applicable, the application for an extension of the duration of a unitary certificate, shall be lodged ***in electronic form*** with the Office.

Or. en

**Amendment 25**

**Proposal for a regulation**

**Article 10 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***The applicant shall seek to ensure that exchanges of data and information are made available in electronic formats and shall protect the commercially confidential nature of the information exchanged and be without prejudice to the provisions on regulatory protection.***

Or. en

**Amendment 26**

**Proposal for a regulation**

**Article 12 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

If the application for a unitary certificate complies with Article 11(1), or if an application for an extension of the duration of a unitary certificate complies with Article 9(3), the Office shall publish the application in the Register.

If the application for a unitary certificate complies with Article 11(1), or if an application for an extension of the duration of a unitary certificate complies with Article 9(3), the Office shall publish the application in the Register ***without undue delay***.

Or. en



## Amendment 27

### Proposal for a regulation Article 13 – 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 all Member States in which the basic patent has unitary effect.

#### *Amendment*

1. The Office shall assess the application on the basis of all the conditions in Article **3 and Article 6(2)**, for all Member States in which the basic patent has unitary effect.

Or. en

## Amendment 28

### Proposal for a regulation Article 13 – paragraph 2

#### *Text proposed by the Commission*

2. Where the application for a unitary certificate and the product to which it relates comply with Article **3(1)** for each of the Member States referred to in paragraph 1, the Office shall issue a reasoned positive examination opinion in respect of the grant of a unitary certificate. The Office shall notify that opinion to the applicant.

#### *Amendment*

2. Where the application for a unitary certificate and the product to which it relates comply with Article **3 and Article 6(2)** for each of the Member States referred to in paragraph 1, the Office shall issue a reasoned positive examination opinion in respect of the grant of a unitary certificate. The Office shall notify that opinion to the applicant **via the register and publish it on the Register without undue delay.**

Or. en

## Amendment 29

### Proposal for a regulation Article 13 – paragraph 3

#### *Text proposed by the Commission*

3. Where the application for a unitary certificate and the product to which it

#### *Amendment*

3. Where the application for a unitary certificate and the product to which it

relates does not comply with Article **3(1)** in respect of one or more of those Member States, the Office shall issue a reasoned negative examination opinion on the grant of a unitary certificate. The Office shall notify that opinion to the applicant.

relates does not comply with Article **3 and Article 6(2)** in respect of one or more of those Member States, the Office shall issue a reasoned negative examination opinion on the grant of a unitary certificate. The Office shall notify that opinion to the applicant.

Or. en

## **Amendment 30**

### **Proposal for a regulation Article 13 – paragraph 5**

#### *Text proposed by the Commission*

5. The Commission is empowered to adopt implementing acts laying down rules on procedures relating to the filing, and procedures regarding the way in which examination panels examine applications for unitary certificates and prepare examination opinions, as well as the issuance of examination opinions by the Office. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

#### *Amendment*

5. The Commission is empowered to adopt implementing acts laying down rules on procedures relating to the filing, and procedures regarding the way in which examination panels examine applications for unitary certificates and prepare examination opinions, as well as the issuance of examination opinions by the Office **in electronic form**. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

Or. en

## **Amendment 31**

### **Proposal for a regulation Article 14 – paragraph 1**

#### *Text proposed by the Commission*

1. Any natural or legal person may submit written observations to the Office concerning the eligibility for supplementary protection of the product to which the application relates, in one or more of the Member States in which the

#### *Amendment*

1. Any natural or legal person may submit written observations to the Office concerning the eligibility for supplementary protection of the product to which the application relates, in one or more of the Member States in which the

basic patent has unitary effect.

basic patent has unitary effect. ***Such written observations shall be submitted electronically.***

Or. en

## Amendment 32

### Proposal for a regulation Article 14 – paragraph 4

*Text proposed by the Commission*

4. Any observations by a third party shall be submitted ***in writing*** in one of the official languages of the Union and state the grounds on which they are based.

*Amendment*

4. Any observations by a third party shall be submitted ***electronically*** in one of the official languages of the Union and state the grounds on which they are based.

Or. en

## Amendment 33

### Proposal for a regulation Article 15 – 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 34

### Proposal for a regulation Article 15 – paragraph 6

*Text proposed by the Commission*

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

*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.

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 35

### Proposal for a regulation Article 15 – 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 36

### Proposal for a regulation Article 15 – paragraph 10

*Text proposed by the Commission*

*Amendment*

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

10. 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.

Or. en

## Amendment 37

### Proposal for a regulation Article 15 – paragraph 13 a (new)

*Text proposed by the Commission*

*Amendment*

***13a. All exchanges between the Office, the holder and the opponent shall take place electronically.***

Or. en

## **Amendment 38**

**Proposal for a regulation**

**Article 16 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***1a. Once a national competent authority is appointed by the Office as a participating office, it shall appoint its designated examiners based on relevant expertise and whether they have sufficient experience for the centralised examination procedure.***

Or. en

## **Amendment 39**

**Proposal for a regulation**

**Article 17 – 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;***

Or. en

## **Amendment 40**

**Proposal for a regulation**

**Article 17 – 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 set out in Article 10(5) of Regulation [COM(2023) 231].

*Amendment*

(c) ***that there is*** no examiner employed by a competent national authority making use of the exemption set out in Article 10(5) of Regulation [COM(2023) 231].

Or. en

**Amendment 41**

**Proposal for a regulation**

**Article 18 – paragraph 1 – introductory part**

*Text proposed by the Commission*

After the period during which an appeal or an opposition may be filed has expired without any appeal nor opposition being filed, or after a final decision on the merits has been issued, the Office shall take one of the following decisions:

*Amendment*

***No later than three months*** after the period during which an appeal or an opposition may be filed has expired without any appeal nor opposition being filed, or after a final decision on the merits has been issued, the Office shall take one of the following decisions:

Or. en

**Amendment 42**

**Proposal for a regulation**

**Article 18 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

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

Or. en

## Amendment 43

### Proposal for a regulation Article 19 – paragraph 2

*Text proposed by the Commission*

2. Third parties may also submit observations in respect of an application for an extension of the duration of a unitary certificate.

*Amendment*

2. Third parties may also submit observations ***or oppositions*** in respect of an application for an extension of the duration of a unitary certificate.

Or. en

## Amendment 44

### Proposal for a regulation Article 22 – paragraph 1 – point c a (new)

*Text proposed by the Commission*

*Amendment*

***(ca) the centralised marketing authorisation has been withdrawn in accordance with Article 14 or there has been a suspension of marketing, a withdrawal from the market of a medicinal product or a withdrawal of a marketing authorisation by the marketing authorisation holder in accordance with Article 24 [revised Regulation (EC) No 726/2004].***

Or. en

## Amendment 45

### Proposal for a regulation Article 22 – paragraph 1 – point c b (new)

*Text proposed by the Commission*

*Amendment*

***(cb) the medicinal product is not placed on all Member States market covered by the unitary certificate or combined centralised supplementary protection***

*certificate; where a medicinal product is not placed on a Member State market covered by the unitary certificate or the combined centralised supplementary protection certificate, the applicant shall waive the supplementary protection certificate rights for markets where the medicinal product has not been launched.*

Or. en

## Amendment 46

### Proposal for a regulation Article 23 – paragraph 3

*Text proposed by the Commission*

3. An application for a declaration of invalidity shall be filed ***in writing***, and shall specify the grounds on which it is made. It shall not be considered as duly filed until the related fee has been paid.

*Amendment*

3. An application for a declaration of invalidity shall be filed ***electronically*** and shall specify the grounds on which it is made. It shall not be considered as duly filed until the related fee has been paid.

Or. en

## Amendment 47

### Proposal for a regulation Article 28 – 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 ***electronically*** 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 the supporting evidence for those grounds***, shall be filed ***electronically*** within 4 months of the date of notification of the decision.



## **Amendment 48**

### **Proposal for a regulation Article 28 – paragraph 5**

*Text proposed by the Commission*

5. Where an appeal results in a decision which is not in line with the examination opinion, the decision of the Boards ***may*** annul or alter the opinion.

*Amendment*

5. Where an appeal results in a decision which is not in line with the examination opinion, the decision of the Boards ***shall*** annul or alter the opinion.

## **Amendment 49**

### **Proposal for a regulation Article 29 – paragraph 4 a (new)**

*Text proposed by the Commission*

*Amendment*

***4a. The rules set out in Article 166(9) of Regulation (EU) 2017/1001 shall be respected.***

## **Amendment 50**

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

*Text proposed by the Commission*

*Amendment*

***An applicant shall submit an application for a combined centralised application electronically to the Office and in the formats made available by the Office.***

## Amendment 51

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

*Text proposed by the Commission*

*Amendment*

***The applicant shall be responsible for the accuracy of the information and documentation submitted in respect of its application.***

Or. en

## Amendment 52

### Proposal for a regulation Article 34 – paragraph 1

*Text proposed by the Commission*

*Amendment*

1. Communications addressed to the Office ***may*** be effected by electronic means. The Executive Director shall determine ***to what extent and*** under which technical conditions those communications ***may*** be submitted ***electronically***.

1. Communications addressed to the Office ***shall*** be effected by electronic means. The Executive Director shall determine under which technical conditions those communications ***are to*** be submitted.

Or. en

## Amendment 53

### Proposal for a regulation Article 35 – paragraph 1 – point i a (new)

*Text proposed by the Commission*

*Amendment*

***(ia) information on any direct public financial support received for research related to the development of the product;***

Or. en

## Amendment 54

### Proposal for a regulation

#### Article 35 – paragraph 1 – point m

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

(m) where applicable, the filing of an opposition, and the outcome of the opposition proceedings, including where applicable a summary of the revised examination opinion;

##### *Amendment*

(m) where applicable, the filing of an opposition, ***its status*** and the outcome of the opposition proceedings, including where applicable a summary of the revised examination opinion;

Or. en

## Amendment 55

### Proposal for a regulation

#### Article 35 – paragraph 1 – point n

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

(n) 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*

(n) 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 56

### Proposal for a regulation

#### Article 35 – paragraph 8 a (new)

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

##### *Amendment*

***8a. By way of derogation from Article 35(7), 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 57**

### **Proposal for a regulation Article 36 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2a. For the purpose of this database the Office shall make public the format for the electronic submission of acts in accordance with Articles 10, 14, 15 and 28 on applications, oppositions, observations and appeals.**

Or. en

## **Amendment 58**

### **Proposal for a regulation Article 40 – paragraph 1**

*Text proposed by the Commission*

*Amendment*

1. Decisions of the Office under this Regulation shall include examination opinions and shall state the reasons on which they are based. They shall be based only on reasons or evidence on which the parties concerned have had an opportunity to present their comments. Where oral proceedings are held before the Office, the decision may be given orally. Subsequently, the decision or opinion shall be notified *in writing* to the parties.

1. Decisions of the Office under this Regulation shall include examination opinions and shall state the reasons on which they are based. They shall be based only on reasons or evidence on which the parties concerned have had an opportunity to present their comments. Where oral proceedings are held before the Office, the decision may be given orally. Subsequently, the decision or opinion shall be notified *electronically* to the parties.

Or. en

## Amendment 59

### Proposal for a regulation Article 40 – paragraph 3

#### *Text proposed by the Commission*

3. Decisions of the Office under this Regulation which are open to appeal shall be accompanied by a written communication indicating that any notice of appeal is to be filed ***in writing*** at the Office within 2 months of the date of notification of the decision in question. That communication shall also draw the attention of the parties to the provisions laid down in Article 28. The parties may not plead any failure on the part of the Office to communicate the availability of appeal proceedings.

#### *Amendment*

3. Decisions of the Office under this Regulation which are open to appeal shall be accompanied by a written communication indicating that any notice of appeal is to be filed ***electronically*** at the Office within 2 months of the date of notification of the decision in question. That communication shall also draw the attention of the parties to the provisions laid down in Article 28. The parties may not plead any failure on the part of the Office to communicate the availability of appeal proceedings.

Or. en

## Amendment 60

### Proposal for a regulation Article 42 – 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 61

### Proposal for a regulation Article 46 – paragraph 2

*Text proposed by the Commission*

2. The application for re-establishment shall be filed ***in writing*** within 2 months of the removal of the obstacle to compliance with the time limit. The omitted act shall be completed within this period. The application shall only be admissible within the year immediately following the expiry of the unobserved time limit.

*Amendment*

2. The application for re-establishment shall be filed ***electronically*** within 2 months of the removal of the obstacle to compliance with the time limit. The omitted act shall be completed within this period. The application shall only be admissible within the year immediately following the expiry of the unobserved time limit.

Or. en

## Amendment 62

### Proposal for a regulation Article 56 – paragraph 1

*Text proposed by the Commission*

By ~~xxxxxx~~ [OP, please insert: five years after the date of application], and every five years thereafter, the Commission shall evaluate the implementation of this Regulation.

*Amendment*

By ... [OP, please insert: five years after the date of application], and every five years thereafter, the Commission shall evaluate the implementation of this Regulation ***and present a report on the main findings to the European Parliament and to the Council. Special emphasis shall be given to the effects of opposition under Article 15 and whether the possibility of opposition leads to significant delays in granting unitary certificates.***

Or. en