European Parliament
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Plenary sitting

A9-0019/2024

31.1.2024

***I
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 (A9-0019/2024),

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	*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	(1) Pharmaceutical research plays a decisive role in the continuing improvement in public health ***and in ensuring the Union's competitiveness***. Medicinal products, in particular those that are the result of long, costly research will not continue to be developed in the Union

that provide for sufficient protection to encourage such research.	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 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) 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 3

Proposal for a regulation
Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) To avoid unnecessary 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. Applications 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 on the basis of the file submitted by the applicant in accordance with this Regulation.

Amendment 4

Proposal for a regulation
Recital 16

Text proposed by the Commission	*Amendment*
(16) 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.	(16) 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 5

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) To avoid overprotection, it should be provided that no more than one certificate, whether national or unitary,	(17) 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 ingredients,*** whether for the same therapeutic indication or for a different one.	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 one.

Amendment 6

Proposal for a regulation
Recital 20 a (new)

Text proposed by the Commission	*Amendment*
	(20a) For the purposes of ensuring a broad supply of products protected by supplementary protection certificates, holders of unitary supplementary protection certificates are encouraged to exercise their rights under such certificates in a way that allows the supply of products in markets where they do not have the intention to launch any product. In that respect, holders might reach voluntary agreements to licence the unitary supplementary protection certificate rights in those markets. The objective is to allow the supply of products by licensees where the holders of unitary supplementary protection certificates decide not to put any product on the market.

Amendment 7

Proposal for a regulation
Recital 21

Text proposed by the Commission	*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 therapeutically equivalent products 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.	(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 ***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.

Amendment 8

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 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 9

Proposal for a regulation
Recital 22

Text proposed by the Commission	*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, 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.	(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.

Amendment 10

Proposal for a regulation
Recital 22 a (new)

Text proposed by the Commission	*Amendment*
	(22a) 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 the 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 11

Proposal for a regulation
Recital 26

Text proposed by the Commission	*Amendment*
(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.	(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 ***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.

Amendment 12

Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission	*Amendment*
	(26a) 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 under this Regulation. Therefore, a mechanism for applicants to request an expedited examination procedure should be provided.

Amendment 13

Proposal for a regulation
Recital 29

Text proposed by the Commission	*Amendment*
(29) After the completion of the examination of a unitary certificate 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 Office should implement the examination opinion by granting a unitary certificate or rejecting the application, as applicable.	(29) After the completion of the examination of a unitary certificate 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 Office should implement ***without undue delay*** the examination opinion by granting a unitary certificate or rejecting the application, as applicable.

Amendment 14

Proposal for a regulation
Recital 30

Text proposed by the Commission	*Amendment*
(30) 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 the designation of additional Member States with a view to the grant of national certificates, a common appeal may be filed.	(30) ***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 the designation of additional Member States with a view to the grant of national certificates, a common appeal may be filed.

Amendment 15

Proposal for a regulation
Recital 31

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

Amendment 16

Proposal for a regulation
Recital 33

Text proposed by the Commission	*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 ***in the case of*** 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.	(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 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.

Amendment 17

Proposal for a regulation
Recital 35

Text proposed by the Commission	*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.	(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 in the register should not be used in relation 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 18

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.

Amendment 19

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 Regulation (EU) 2019/6, or with the centralised procedure under Regulation (EC) No 726/2004;	(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)], with*** Regulation (EU) 2019/6, or with the centralised procedure under Regulation (EC) No 726/2004***, as appropriate***;

Amendment 20

Proposal for a regulation
Article 3 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
Where two or more applications, whether national or centralised applications for certificates, or applications for unitary certificates, concerning the same product and submitted by two or more holders of different patents are pending in a given Member State, one certificate or unitary certificate for that product may be granted to each of those holders, where they are not economically linked, by a competent national authority or by the Office, as applicable.	Where two or more applications, whether national or centralised applications for certificates, or applications for unitary certificates, concerning the same product and submitted by two or more holders of different patents are pending in a given Member State, one certificate or unitary certificate for that product may be granted to each of those holders, where they are not economically linked, by a competent national authority or by the Office, as applicable. ***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 21

Proposal for a regulation
Article 5 – paragraph 3 – introductory part

Text proposed by the Commission	*Amendment*
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:	3. By way of derogation from paragraph 1 ***and in accordance with Regulation (EU) .../... [2023/0130(COD)]***, 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 22

Proposal for a regulation
Article 5 – paragraph 3 – 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 23

Proposal for a regulation
Article 5 – paragraph 3 – 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 24

Proposal for a regulation
Article 5 – paragraph 3 – point a – point iii

Text proposed by the Commission	*Amendment*
(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;	(iii) making, no earlier than 6 months before the expiry of the unitary 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 25

Proposal for a regulation
Article 5 – paragraph 3 – 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 ***unitary*** 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 26

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.

Amendment 27

Proposal for a regulation
Article 9 – paragraph 1 – point a – point iv a (new)

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

Amendment 28

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) of this Regulation.

Amendment 29

Proposal for a regulation
Article 10 – paragraph 1

Text proposed by the Commission	*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 with the Office.	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. ***The Office shall put the necessary arrangements in place in order to ensure that exchanges of data and information are done electronically and that the commercially confidential nature of the information exchanged is protected. Such arrangements shall be without prejudice to the provisions on regulatory protection.***

Amendment 30

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 and no later than five working days after the application was lodged***.

Amendment 31

Proposal for a regulation
Article 13 – 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 all Member States in which the basic patent has unitary effect.	1. The Office shall assess the application on the basis of all the conditions in ***Articles 3 and 6(2)***, for all Member States in which the basic patent has unitary effect.

Amendment 32

Proposal for a regulation
Article 13 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. Where the application for a unitary certificate and the product to which it relates comply with ***Articles 3 and 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 electronic platform and publish it in the Register without undue delay***.

Amendment 33

Proposal for a regulation
Article 13 – paragraph 3

Text proposed by the Commission	*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.	3. Where the application for a unitary certificate and the product to which it relates does not comply with ***Articles 3 and 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 ***via the electronic platform and publish it in the Register without undue delay***.

Amendment 34

Proposal for a regulation
Article 13 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Office shall translate the examination opinion in the official languages of all designated Member States. The Office may use verified machine translation to that effect.	4. The Office shall translate the examination opinion in the official languages of all designated Member States. The Office may use verified machine translation to that effect***. The Office shall publish the examination opinion in the Register as soon as possible after it is issued***.

Amendment 35

Proposal for a regulation
Article 13 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Commission is empowered to adopt implementing acts laying down rules on procedures relating to the filing, and	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.	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.

Amendment 36

Proposal for a regulation
Article 13 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. The Office shall issue an examination opinion within six months of publication of the application for a unitary certificate. Without prejudice to Articles 14, 25 and 28, 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 issue an examination opinion within four months from the publication of the application for a unitary certificate.

Amendment 37

Proposal for a regulation
Article 14 – paragraph 1

Text proposed by the Commission	*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.	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. ***Such written observations shall be submitted to***

	the Office electronically.

Amendment 38

Proposal for a regulation
Article 14 – paragraph 3 – subparagraph 2 (new)

Text proposed by the Commission	*Amendment*
	Whenever the expedited procedure applies in accordance with Article 13(5a), observations shall be submitted within six weeks after publication of the application in the Register.

Amendment 39

Proposal for a regulation
Article 14 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	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.

Amendment 40

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.

Amendment 41

Proposal for a regulation
Article 15 – 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 ***as soon as practicable after the filing of the notice of opposition***, unless these deficiencies have been remedied before expiry of the opposition filing period referred to in paragraph 1.

Amendment 42

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

Amendment 43

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.

Amendment 44

Proposal for a regulation
Article 15 – paragraph 12

Text proposed by the Commission	*Amendment*
12. If the opposition panel considers that at least one ground for opposition prejudices the maintenance of the examination opinion, it shall adopt an amended opinion, and the Office shall ***mention this*** in the Register.	12. If the opposition panel considers that at least one ground for opposition prejudices the maintenance of the examination opinion, it shall adopt an amended opinion, and the Office shall ***publish its full decision*** in the Register.

Amendment 45

Proposal for a regulation
Article 15 – 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 46

Proposal for a regulation
Article 15 – paragraph 12 b (new)

Text proposed by the Commission	*Amendment*
	12b. All exchanges between the Office, the holder and the opponent shall take place electronically.

Amendment 47

Proposal for a regulation
Article 16 – 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	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 applications for unitary certificates.	in accordance with this Article, that authority shall designate one or more examiners to be involved in the examination of one or more applications for unitary certificates ***based on relevant expertise and sufficient experience required for the centralised examination procedure***.

Amendment 48

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, 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 49

Proposal for a regulation
Article 17 – paragraph 3 – point a a (new)

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

Amendment 50

Proposal for a regulation
Article 17 – paragraph 3 – point c

Text proposed by the Commission	*Amendment*
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].	(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].

Amendment 51

Proposal for a regulation
Article 18 – paragraph 1

Text proposed by the Commission	*Amendment*
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:	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***, without undue delay:***

Amendment 52

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.

Amendment 53

Proposal for a regulation
Article 19 – paragraph 2

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

Amendment 54

Proposal for a regulation
Article 22 – 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 ***Articles*** 3 ***and 6(2)***;

Amendment 55

Proposal for a regulation
Article 23 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	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.

Amendment 56

Proposal for a regulation
Article 28 – 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 setting out the grounds of appeal shall be filed within ***4*** months of the date of notification of the decision.	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 evidence supporting those grounds,*** shall be filed ***electronically*** within ***three*** months of the date of notification of the decision. ***Any reply to the statement of grounds of appeal shall be submitted in writing no later than three months from the date of the filing of the statement of grounds of appeal. The Office shall, where applicable, fix a date for oral proceedings within three months of the filing of the reply or within six months following the filing of the statement of grounds of***

	appeal, whichever is earlier. The Office shall issue a written decision within three months of the date of the oral hearing or of the filing of the reply to the statement of grounds of appeal, as applicable.

Amendment 57

Proposal for a regulation
Article 28 – paragraph 5

Text proposed by the Commission	*Amendment*
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.	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 58

Proposal for a regulation
Article 29 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Members of the Boards of Appeal in matters regarding unitary 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 unitary 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 concerning applications for unitary certificates, due consideration shall be given to their previous experience in matters concerning supplementary protection certificates or patent law.***

Amendment 59

Proposal for a regulation
Article 29 – 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 unitary certificates.

Amendment 60

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 61

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.

Amendment 62

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;

Amendment 63

Proposal for a regulation
Article 35 – paragraph 1 – point j

Text proposed by the Commission	*Amendment*
(j) the date and ***a summary of*** the examination opinion of the Office in respect of each of the Member States in which the basic patent has unitary effect;	(j) the date and the examination opinion of the Office in respect of each of the Member States in which the basic patent has unitary effect;

Amendment 64

Proposal for a regulation
Article 35 – paragraph 1 – point m

Text proposed by the Commission	*Amendment*
(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;	(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;

Amendment 65

Proposal for a regulation
Article 35 – paragraph 1 – point n

Text proposed by the Commission	*Amendment*
(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;	(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;

Amendment 66

Proposal for a regulation
Article 35 – paragraph 8 a (new)

Text proposed by the Commission	*Amendment*
	8a. Public authorities shall not use information in the Register for practices of patent linkage. No regulatory or administrative decisions related to

	generics or biosimilars shall be based on information in the Register. Information in the Registger shall not be used for refusal, suspension, delay, withdrawal or revocation of marketing authorisations, pricing and reimbursement decisions or tender bids.

Amendment 67

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.

Amendment 68

Proposal for a regulation
Article 40 – paragraph 3

Text proposed by the Commission	*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 ***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	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.	appeal proceedings.

Amendment 69

Proposal for a regulation
Article 41 – paragraph 2

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

Amendment 70

Proposal for a regulation
Article 41 – 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 71

Proposal for a regulation
Article 42 – 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	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***

1 month, unless they agree to a shorter period.	***panel, as the case may be, shall verify 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.

Amendment 72

Proposal for a regulation
Article 46 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	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.

Amendment 73

Proposal for a regulation
Article 56 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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, the Council and the European Economic and Social Committee***. ***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 and to the effects of this Regulation on the recovery of research and development investments in the light of Directive (EU) XXX/XX***

[COM(2023)192].

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.

PROCEDURE – COMMITTEE RESPONSIBLE

Title	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		
References	COM(2023)0222 – C9-0148/2023 – 2023/0127(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	31.1.2024		

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