European Parliament
2019-2024

TEXTS ADOPTED

P9_TA(2024)0097

Unitary supplementary certificate for medicinal products

European Parliament legislative resolution of 28 February 2024 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.

P9_TC1-COD(2023)0127

Position of the European Parliament adopted at first reading on 28 February 2024 with a view to the adoption of Regulation (EU) 2024/... 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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 118, first paragraph, thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

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1 OJ C […], […], p. […].
2 OJ C […], […], p. […].

Whereas:

(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 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.*** **[Am. 1]**

(2) The period that elapses between the filing of an application for a patent for a new medicinal product and the authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.

(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. **[Am. 2]**

(3) Uniform patent and supplementary certificate protection within the internal market, or at least a significant part thereof, should feature amongst the legal instruments which pharmaceutical undertakings have at their disposal.

(4) In its Communication of 25 November 2020 entitled ‘Making the most of the EU’s innovative potential – An intellectual property action plan to support the EU’s recovery and resilience’[3], the Commission highlighted the need to tackle the remaining fragmentation of the Union’s intellectual property system. In that Communication, the Commission noted that, for medicinal products and plant protection products, supplementary protection is only available at national level. At the same time, there is a centralised procedure for granting European patents, as well as a centralised procedure for obtaining marketing authorisations for medicinal products. In addition, the 'unitary patent' as laid down in Regulation (EU) No 1257/2012 of the European Parliament and of the Council[4] enters into force in June 2023 in respect of the Member States having ratified the Agreement on a Unified Patent Court (‘UPC’).

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3 COM(2020)760 final.

4 Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection (OJ L 361, 31.12.2012, p. 1).

(5) Regulation (EU) No 1257/2012 has created the possibility to provide unitary patents. However, Regulation (EU) No 1257/2012 does not provide for a unitary supplementary protection certificate (‘unitary certificate’).

(6) In the absence of a unitary certificate, a unitary patent could only be extended by applying for several national certificates in each Member State where protection is sought, preventing the holder of a unitary patent from obtaining unitary protection during the whole combined protection period conferred by that unitary patent and subsequently by these certificates. Therefore, a unitary certificate for medicinal products should be created, that would allow a unitary patent to be extended in a unitary manner. Such a unitary certificate should be applied for on the basis of a unitary basic patent and a centralised authorisation; it would have the same legal effects as national certificates in all Member States in which that basic patent has unitary effect. The main feature of such a unitary certificate should be its unitary character.

(7) A unitary certificate should provide uniform protection and have equal effect in all Member States where the basic patent it relies upon has unitary effect. Consequently, a unitary certificate should only be transferred or revoked, or expire, in respect of all those Member States.

(8) Regulation [COM(2023) 231] replaces Regulation (EC) No 469/2009 of the European Parliament and of the Council[5], and includes new provisions establishing a centralised procedure for the examination of supplementary protection certificates for medicinal products.

(9) Considering that products authorised under procedures other than the centralised one should still be able to enjoy supplementary protection, and that certain Member States have not yet joined the unitary patent system, certificates granted by national patent offices should remain available.

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

(10) To avoid discrimination between applicants for certificates under Regulation [COM(2023) 231] and for unitary certificates under this Regulation, and distortions of the internal market, the same substantive rules should apply, with appropriate adaptations, to certificates under Regulation [COM(2023) 231] and to unitary certificates, in particular as regards the conditions for grant of a certificate, as well as the duration and effects of a certificate.

(11) In particular, the duration of the protection granted by a unitary certificate should be identical to the duration provided for as regards national certificates under Regulation [COM(2023) 231]; namely, the holder of both a unitary patent and a unitary certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains an authorisation to be placed on the market in the Union. Since the unitary certificate would take effect at the expiry of the basic patent, and in order to take into account discrepancies in national practices regarding the date of expiry of a patent which may result in 1-day differences, this Regulation should clarify when exactly the protection conferred by a unitary certificate should take effect.

(12) Regulation (EU) No 2017/1001 of the European Parliament and of the Council[6] has established, under its Article 2, a European Union Intellectual Property Office (‘the Office’). In the interest of the internal market, and due to the autonomous nature of the unitary certificate, its examination and grant procedure should be carried out by a single examining authority. This can be achieved by the Office being given the task of examining both applications for unitary certificates in accordance with this Regulation and Regulation [COM(2023) 221] and centralised applications for certificates under Regulations [COM(2023) 231] and [COM(2023) 223]. To ensure consistency with this Regulation, Regulation (EU) No 2017/1001 should be amended.

(13) A unitary certificate for a medicinal product should be based only on a centralised marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council[7] or Regulation (EU) 2019/6 of the European Parliament and of the Council[8] only. These authorisations refer to human medicinal and veterinary medicinal products respectively. Such an authorisation, unlike national authorisations, relates to the same medicinal product throughout the Union, and this would thus facilitate the examination of applications for unitary certificates.

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6 Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark (OJ L 154, 16.6.2017, p. 1).

7 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

8 Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

(14) An applicant should also be allowed to lodge a ‘combined application’ that would also include the designation of Member States, other than those in which the basic patent has unitary effect, in which the grant of national certificates would be requested as set out in Regulation [COM(2023) 231]. Such a combined application should undergo a single examination procedure.

(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. **[Am. 3]**

(15) In such an event, double protection by both a unitary certificate and a national certificate – whether obtained on the basis of a national application or of a centralised application – should be excluded in any Member State.

(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~~***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*** ~~on its~~ 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 ~~of them~~***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***. **[Am. 4]**

(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. **[Am. 5]**

(18) Within the limits of the protection conferred by the basic patent, the protection conferred by a unitary certificate should extend only to the product, namely the active ingredient or combinations thereof, covered by the authorisation to place it on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the unitary certificate.

(19) To ensure balanced protection, however, a unitary certificate should entitle its holder to prevent a third party from manufacturing not only the product identified in the unitary certificate but also therapeutically equivalent derivatives of that product, such as salts, esters, ethers, isomers, mixtures of isomers or complexes, as well as biosimilars, even where such derivatives are not explicitly mentioned in the product description on the unitary certificate. There is therefore a need to consider that the protection conferred by the unitary certificate extends to such equivalent derivatives, within the limits of the protection conferred by the basic patent.

(20) As a further measure to ensure that no more than one certificate may protect the same product in any Member State, the holder of more than one patent for the same product should not be granted more than one certificate for that product. However, where two patents protecting the product are held by two holders, one certificate for that product should be allowed to be granted to each of those holders, where they can demonstrate that they are not economically linked. Furthermore, no certificate should be granted to the proprietor of a basic patent in respect of a product which is the subject of an authorisation held by a third party, without that party's consent.

(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. **[Am. 6]**

(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~~***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. **[Am. 7]**

(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. **[Am. 8]**

(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 ~~its entry into the Union~~***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.
[Am. 9]

(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. **[Am. 10]**

(23) To ensure alignment with the rules applicable to unitary patents, a unitary certificate as an object of property should be dealt with, in its entirety and in all Member States in which it has effect, as a national certificate of the Member State determined in accordance with the law that applies to the basic patent.

(24) To avoid discrimination between applicants for national certificates under Regulation [COM(2023) 231] and applicants for unitary certificates under this Regulation, an extension of the duration of a certificate as defined by Article 36 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council[9] should also be available for unitary certificates. For this purpose that Regulation should be amended.

(25) To guarantee a fair and transparent process, ensure legal certainty and reduce the risk of subsequent validity challenges, third parties should have the possibility, after the publication of the unitary certificate application, to submit within 3 months observations to the Office while the centralised examination is being performed. These third parties allowed to submit observations should also include Member States. This, however, should not affect the rights of third parties to initiate subsequent invalidity proceedings before the Office. These provisions are necessary to ensure involvement of third parties both before and after the grant of certificates.

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9 Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).

(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. **[Am. 11]**

(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. **[Am. 12]**

(27) The Office should examine the application for a unitary certificate and issue an examination opinion. That opinion should state the reasons for which it is positive or negative.

(28) To safeguard third parties' procedural rights and ensure a complete system of remedies, third parties should be able to challenge an examination opinion, by initiating opposition proceedings within a short duration following the publication of that opinion, and that opposition may result in that opinion being amended.

(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. **[Am. 13]**

(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. **[Am. 14]**

(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. **[Am. 15]**

(32) Any person may challenge the validity of a unitary certificate by lodging with the Office an application for a declaration of invalidity.

(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~~***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. **[Am. 16]**

(34) Annual fees in respect of unitary certificates (also known as renewal fees) should be paid to the Office, which should retain a part of them to cover the expenses generated by carrying out tasks in relation to the grant of unitary certificates while the remaining part would be shared with those Member States in which unitary certificates have effect.

(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.*** **[Am. 17]**

(36) For the tasks conferred on the Office under this Regulation, the languages of the Office should be all official languages of the Union, to enable actors across the Union to easily apply for unitary certificates or submit third party observations and result in optimal transparency for all stakeholders across the Union. The Office should accept verified translations, into one of the official languages of the Union, of documents and information. The Office may, if appropriate, use verified machine translations.

(37) Financial provision should be made to ensure competent national authorities that participate in the centralised procedure are adequately remunerated for their participation.

(38) The necessary set-up costs related to the tasks conferred to the Office, including the costs of new digital systems, should be financed from the Office's accumulated budgetary surplus.

(39) To ensure that Regulation (EU) No 608/2013 of the European Parliament and of the Council[10] also covers unitary certificates, that Regulation should be amended.

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10 Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003.

(40) In order to supplement certain non-essential elements of this Regulation, the power to adopt acts, in accordance with Article 290 of the Treaty on the Functioning of the European Union, should be delegated to the Commission in respect of: (i) specifying the content and form of the notice of appeal and the content and the form of the Boards of Appeal's decision, (ii) specifying the details concerning the organisation of the Boards of Appeal in proceedings relating to certificates, (iii) specifying the rules on the means of communication, including the electronic means of communication, to be used by the parties to proceedings before the Office and the forms to be made available by the Office, (iv) setting out the detailed arrangements for oral proceedings, (v) setting out the detailed arrangements for the taking of evidence, (vi) setting out the detailed arrangements for notification, (vii) specifying the details regarding the calculation and duration of time limits and (viii) setting out the detailed arrangements for the resumption of proceedings. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.[11] In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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11 Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making (OJ L 123, 12.5.2016, p. 1).

(41) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards: (i) the application forms to be used; (ii) rules on procedures relating to the filing, and procedures regarding the way in which examination panels examine centralised applications and prepare examination opinions, as well as the issuance of examination opinions by the Office, (iii) the criteria in the ways the examination panels are to be set up, and the criteria for the selection of examiners, (iv) the amounts of the applicable fees to be paid to the Office, (v) specifying the maximum rates for costs essential to the proceedings and actually incurred by the successful party, and (vi) rules on the financial transfers between the Office and Member States, the amounts of these transfers, and the remuneration to be paid by the Office regarding the participation of competent national authorities. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[12].

(42) The Commission should regularly report on the operation of this Regulation, in coordination with that required in Regulation [COM(2023) 231]. The Commission should regularly evaluate the impact of unitary supplementary protection on access to medicines.

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12 Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

(43) This Regulation respects fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union (‘the Charter’). The rules in this Regulation should be interpreted and applied in accordance with those rights and principles. In particular, this Regulation seeks to ensure full respect for the right to property and the right to health care and the right to an effective remedy in Articles 17 and 35 and 47 of the Charter. This also applies to the above-mentioned exception, which maintains the core rights of the certificate, by being limited to the making of a product, or a medicinal product containing that product, only for the purpose of export outside the Union or for the purpose of storing for a limited period of time with a view to entry into the Union market upon expiry of the protection, and to the acts strictly necessary for such making or for the actual export or the actual storing. In the light of those fundamental rights and principles, the exception does not go beyond what is necessary and appropriate in the light of its overall objective, which is to promote the competitiveness of the Union by avoiding relocation and allowing makers of generics and biosimilars established in the Union to compete, on the one hand, on fast-growing global markets where protection does not exist or has already expired, and on the other, on the Union market upon expiry of the certificate.

(44) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States but can rather, by reason of the autonomous nature of the unitary certificate being independent from national systems, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(45) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725[13] and delivered an opinion on XXX [OP, please add reference once available].

(46) Provision should be made for appropriate arrangements to facilitate a smooth implementation of the rules provided for in this Regulation. To allow for sufficient time for the Office to prepare the operational set-up and launch of the procedure to be used for the grant of unitary certificates, as set out in this Regulation, the application of this Regulation should be deferred,

HAVE ADOPTED THIS REGULATION:

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13 Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

Article 1

Subject matter

This Regulation lays down rules on the unitary supplementary protection certificate (‘unitary certificate’) for medicinal products protected by a European patent with unitary effect and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Regulation (EC) No 726/2004, or Regulation (EU) 2019/6.

Article 2

Definitions

For the purposes of this Regulation the following definitions shall apply:

(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;

(2) ‘product’ means the active ingredient or combination of active ingredients of a medicinal product;

(3) 'European patent' means a patent granted by the European Patent Office (‘EPO’) under the rules and procedures laid down in the European Patent Convention[14] ('EPC');

(4) ‘unitary patent’ means a European patent which benefits from unitary effect in those Member States participating in the enhanced cooperation laid down in Regulation (EU) No 1257/2012;

(5) 'basic patent' means a unitary patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a unitary certificate;

(6) 'application for an extension of the duration' means an application for an extension of the duration of a unitary certificate pursuant to Article 20(3) of this Regulation and Article 36 of Regulation (EC) No 1901/2006;

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14 Convention on the Grant of European Patents of 5 October 1973, as revised on 17 December 1991 and on 29 November 2000.

(7) 'maker' means the person, established in the Union, on whose behalf the making of a product, or a medicinal product containing that product, for the purpose of export to third countries or for the purpose of storing, is carried out;

(8) 'centralised application' means an application made before the European Union Intellectual Property Office (‘the Office’) pursuant to Chapter III of Regulation [COM(2023) 231] with a view to the grant of certificates, for the product identified in the application, in the designated Member States;

(9) ‘competent national authority’ means the national authority that is competent, in a given Member State, for the grant of certificates and for the rejection of applications for certificates.

(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. **[Am. 18]**

Article 3

Conditions for obtaining a unitary certificate

1. A unitary certificate shall be granted by the Office on the basis of a basic patent if, in each of the Member States in which that basic patent has unitary effect, at the date of the application, all of the following conditions are fulfilled:

(a) the product is protected by that basic patent in force;

(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***; **[Am. 19]**

(c) the product has not already been the subject of a certificate, nor of a unitary certificate;

(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

2. The holder of more than one patent for the same product shall not be granted more than one certificate or unitary certificate for that product for any given Member State.

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.*** **[Am. 20]**

Article 4

Scope of the protection

Within the limits of the protection conferred by the basic patent, the protection conferred by a unitary certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the unitary certificate.

Article 5

Effects of the unitary certificate

1. The unitary certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations, in all Member States in which the basic patent has unitary effect.

2. A unitary certificate shall have a unitary character. It shall provide uniform protection and shall have equal effect in all Member States in which the basic patent has unitary effect. The unitary certificate may only be limited, transferred or revoked, or lapse, in respect of all those Member States.

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: **[Am. 21]**

   (a) the acts comprise any of the following:

      (i) the making of a product, or a medicinal product containing that product, for the purpose of export to third countries; ***or*** **[Am. 22]**

(ii) any related act that is strictly necessary for ~~the~~***that*** making~~,~~ in the Union~~, referred to in point (i),~~ or for the actual export ***itself***; ***or*** **[Am. 23]**

(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; ***or*** **[Am. 24]**

(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 ~~unitary~~ certificate. **[Am. 25]**

(b) the maker, through appropriate and documented means, notifies the Office, and the competent industrial property office of the respective Member State, and informs the unitary certificate holder, of the information referred to in paragraph 6 no later than 3 months before the start date of the making in that Member State, or no later than 3 months before the first related act, prior to that making, that would otherwise be prohibited by the protection conferred by a unitary certificate, whichever is the earlier;

(c) if the information referred to in paragraph 6 of this Article changes, the maker notifies the Office and the competent industrial property office of the respective Member State, and informs the certificate holder, before those changes take effect;

(d) in the case of products, or medicinal products containing those products, made for the purpose of export to third countries, the maker ensures that a logo, in the form set out in Annex I, is affixed to the outer packaging of the product, or the medicinal product containing that product, referred to in point (a)(i) of this paragraph, and, where feasible, to its immediate packaging;

(e) the maker complies with paragraph 10 of this Article and, if applicable, with Article 31(4).

4. Paragraph 3 shall not apply to any act or activity carried out for the import of products, or medicinal products containing those products, into the Union merely for the purpose of repackaging, re-exporting or storing.

5. The information provided to the unitary certificate holder for the purposes of paragraph 3, points (b) and (c), shall be used exclusively for the purposes of verifying whether the requirements of this Regulation have been met and, where applicable, initiating legal proceedings for non-compliance.

6. For the purposes of paragraph 3, point (b), the maker shall provide all of the following information:

(a) the name and address of the maker;

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

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

(d) the number of the unitary certificate having effect in the Member State of making, and the number of the certificate or unitary certificate granted in the Member State of the first related act, if any, prior to that making;

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

7. For the purposes of the notifications to the Office and to the competent industrial property office referred to in paragraph 3, points (b) and (c), the maker shall use the standard form for notification set out in Annex II.

8. Failure to provide the information referred to in paragraph 6, point (e), with regard to a third country shall only affect exports to that third country, and those exports shall not benefit from the exception laid down in paragraph 3.

9. The maker shall ensure that medicinal products made pursuant to paragraph 3, point (a)(i), do not bear an active unique identifier within the meaning of Delegated Regulation (EU) 2016/161[15].

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15 Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 9.2.2016, p. 1).

10. The maker shall ensure, through appropriate and documented means, that any person in a contractual relationship with the maker that performs acts falling under paragraph 3, point (a), is fully informed and aware of all of the following:

(a) that those acts are subject to paragraph 3;

(b) that the placing on the market, import or re-import of the product, or the medicinal product containing that product, referred to in paragraph 3, point (a)(i), or the placing on the market of the product, or the medicinal product containing that product, referred to in paragraph 3, point (a)(iii), could infringe the unitary certificate referred to in that paragraph where, and for as long as, that certificate applies.

Article 6

Entitlement to the unitary certificate

1. The unitary certificate shall be granted to the holder of the basic patent or to the successor in title of that holder.

2. Notwithstanding paragraph 1, where a basic patent has been granted in respect of a product that is the subject of an authorisation held by a third party, a unitary certificate for that product shall not be granted to the holder of the basic patent without the consent of that third party.

Article 7

The unitary certificate as an object of property

A unitary certificate or an application for a unitary certificate as an object of property shall be treated in its entirety, in each Member State in which the basic patent has unitary effect, in accordance with the national law applicable to the basic patent as an object of property.

Article 8

Application for a unitary certificate

1. The application for a unitary certificate shall be lodged within 6 months of the date on which the authorisation referred to in Article 3(1), point (b), to place the product on the market as a medicinal product was granted.

2. Notwithstanding paragraph 1, where the authorisation to place the product on the market is granted before unitary effect is attributed to the basic patent, the application for a unitary certificate shall be lodged within 6 months of the date on which unitary effect is attributed to the basic patent.

3. The application for an extension of the duration may be lodged at the same time when lodging the application for a unitary certificate or when the application for the unitary certificate is pending and the appropriate requirements of Article 9(1), point (d), or Article 9(2), respectively, are fulfilled.

4. The application for an extension of the duration of a unitary certificate already granted shall be lodged not later than 2 years before the expiry of the unitary certificate.

4a. The application for a unitary certificate shall be lodged electronically, using the formats made available by the Office. **[Am. 26]**

Article 9

Content of the application for a unitary certificate

1. The application for a unitary certificate shall contain the following:

(a) a request for the grant of a unitary certificate, stating the following information:

(i) the name and address of the applicant;

(ii) if the applicant has appointed a representative, the name and address of that representative;

(iii) the number of the basic patent and the title of the invention;

(iv) the number and date of the first authorisation to place the product on the market, as referred to in Article 3(1), point (b) and, if this authorisation is not the first authorisation for placing the product on the market in the Union, the number and date of that authorisation;

(iva) information on any direct public financial support received for research related to the development of the product for which the SPC is requested;
[Am. 27]

(b) a copy of the authorisation to place the product on the market, as referred to in Article 3(1), point (b), in which the product is identified, containing in particular the number and date of the authorisation and the summary of the product characteristics listed in Article 11 of Directive 2001/83/EC of the European Parliament and of the Council[16] or Article 35 of Regulation (EU) 2019/6;

(c) where the authorisation referred to in point (b) is not the first authorisation for placing the product on the market as a medicinal product in the Union, information regarding the identity of the product thus authorised and the legal provision under which the authorisation procedure took place, together with a copy of the notice publishing the authorisation in the appropriate official publication or, in the absence of such a notice, any other document proving that the authorisation has been issued, the date on which it was issued and the identity of the product authorised.

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

(d) where the application for a unitary certificate for a medicinal product includes a request for an extension of the duration:

(i) a copy of the statement indicating compliance with an agreed completed paediatric investigation plan as referred to in Article 36(1) of Regulation (EC) No 1901/2006;

(ii) where necessary, in addition to the copy of the authorisation to place the product on the market as referred to in point (b), proof of possession of authorisations to place the product on the market of all other Member States, as referred to in Article 36(3) of Regulation (EC) No 1901/2006;

(da) where applicable, the consent of the third party referred to in Article 6(2) of this Regulation. **[Am. 28]**

2. Where an application for a unitary certificate is pending, an application for an extension of the duration in accordance with Article 8(3) shall include the documents referred to in paragraph 1, point (d) of this Article and a reference to the application for a certificate already lodged.

3. The application for an extension of the duration of a unitary certificate already granted shall contain the documents referred to in paragraph 1, point (d), and a copy of the certificate already granted.

4. The applications referred to in this Article shall be filed by using specific application forms.

The Commission is empowered to adopt implementing acts laying down rules on the application form to be used. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

Article 10

Lodging of an application for a unitary certificate

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.
[Am. 29]

Article 11

Examination of the admissibility of an application for a unitary certificate

1. The Office shall examine the following:

   (a) whether the application for a unitary certificate complies with Article 9;

   (b) whether the application complies with Article 8;

   (c) whether the application fee referred to in Article 31(1) has been paid within the prescribed period.

2. Where the centralised application does not satisfy the requirements referred to in paragraph 1, the Office shall request the applicant to take the measures necessary to satisfy those requirements, and shall set a deadline for such compliance.

3. Where the fee referred to in paragraph 1, point (c), has not been paid or has not been paid in full, the Office shall inform the applicant accordingly.

4. If the applicant does not satisfy the requirements referred to in paragraph 1 within the deadline referred to in paragraph 2, the Office shall reject the application for a unitary certificate.

Article 12

Publication of the application

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***. **[Am. 30]**

Article 13

Examination of the application for a unitary certificate

1. The Office shall assess the application on the basis of all the conditions in ~~Article 3(1)~~***Articles3 and 6(2)***, for all Member States in which the basic patent has unitary effect. **[Am. 31]**

2. Where the application for a unitary certificate and the product to which it relates comply with ~~Article 3(1)~~***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***. **[Am. 32]**

3. Where the application for a unitary certificate and the product to which it relates does not comply with ~~Article 3(1)~~***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***. **[Am. 33]**

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.*** **[Am. 34]**

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. **[Am. 35]**

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. **[Am. 36]**

Article 14

Observations by third parties

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.*** **[Am. 37]**

2. A natural or legal person that has submitted the written observations in accordance with paragraph 1 shall not be a party to the proceedings.

3. Third party observations shall be submitted within 3 months after publication of the application in the Register.

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. **[Am. 38]**

4. Any observations by a third party shall be submitted ~~in writing~~***electronically*** in one of the official languages of the Union and state the grounds on which they are based. **[Am. 39]**

5. Any observations by a third party shall be notified to the applicant. The applicant may comment on the observations within a time limit set by the Office.

Article 15

Opposition

1. Within a period of 2 months following the publication of the examination opinion in respect of an application for a unitary certificate, any person (‘opponent’) may file with the Office a notice of opposition to that opinion.

2. Opposition may only be filed on the grounds that one or more of the conditions set out in Article 3 are not fulfilled for one or more of the Member States in which the basic patent has unitary effect.

3. Opposition 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 opposition fee has been paid.

4. The notice of opposition shall contain:

(a) the references of the unitary certificate application against which opposition is filed, the name of its holder, and the identification of the product;

(b) the particulars of the opponent and, where applicable, of its representative;

(c) a statement of the extent to which the examination opinion is opposed, and of the grounds on which the opposition is based;

(ca) any evidence the opponent relies on in support of the opposition. **[Am. 40]**

5. The opposition shall be examined by an opposition panel set up by the Office in accordance with the rules applicable to examination panels as referred to in Article 17. However, the opposition panel shall not include any examiner previously involved in the examination panel that examined the unitary certificate application.

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~~***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. **[Am. 41]**

7. The decision to reject an opposition as inadmissible shall be communicated to the holder of the unitary certificate application, together with a copy of the notice of opposition.

8. A notice of opposition shall be inadmissible where a previous appeal relating to the same subject matter and cause of action has been adjudicated on its merits by the Office, and the decision of the Office on that appeal has acquired the authority of a final decision.

9. Where the opposition is not rejected as inadmissible, the Office shall promptly transmit the notice of opposition to the applicant, and shall publish it in the Register. If several notices of opposition have been filed, the Office shall promptly communicate them to the other opponents.

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.*** **[Am. 42]**

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. **[Am. 43]**

11. If the opposition panel considers that no ground for opposition prejudices the maintenance of the examination opinion, it shall reject the opposition, and the Office shall mention this in the Register.

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~~***publish its full decision*** in the Register. **[Am. 44]**

12a. ***Full transparency shall be ensured throughout the whole opposition proceeding, which shall be open, whenever possible, to public participation.*** **[Am. 45]**

12b. ***All exchanges between the Office, the holder and the opponent shall take place electronically.*** **[Am. 46]**

13. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the details of the procedure for filing and examining an opposition.

Article 16

Role of competent national authorities

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 ***based on relevant expertise and sufficient experience required for the centralised examination procedure***. **[Am. 47]**

2. The Office and the competent national authority shall conclude an administrative agreement before that competent national authority is appointed as participating office as referred to in paragraph 1.

The agreement shall specify the rights and obligations of the parties, in particular the formal undertaking by the competent national authority concerned to comply with this Regulation as regards the examination of applications for unitary certificates.

3. The Office may appoint a competent national authority as a participating office as referred to in paragraph 1 for 5 years. That appointment may be extended for further periods of 5 years.

4. The Office shall, before appointing a competent national authority, or extending its appointment, or before any such appointment expires, hear the competent national authority concerned.

5. Each competent national authority appointed under this Article shall provide the Office with a list identifying the individual examiners who are available for participation in examination, opposition and invalidity proceedings. Each such competent national authority shall update that list in the event of a change.

Article 17
Examination panels

1. The assessments under Articles 13, 15, 19 and 23 shall be conducted by an examination panel including one member of the Office as well as two examiners as referred to in Article 16(1) from two different participating competent national authorities, under supervision of the Office.

2. Examiners shall be impartial in the exercise of their duties and shall declare to the Office any real or perceived conflict of interest upon their designation.

3. When setting up an examination panel, the Office shall ensure the following:

(a) ~~geographical balance amongst the participating offices~~***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***; **[Am. 48]**

(aa) where possible, geographical balance amongst the participating offices; **[Am. 49]**

(b) the respective workload of the examiners is taken into account;

(c) ***that there is*** 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]. **[Am. 50]**

4. The Office shall publish a yearly an overview of the number of procedures, including those for examination, opposition, appeal and invalidity, each competent national authority participated in.

5. The Commission is empowered to adopt implementing acts to determine the criteria in the ways the panels are to be set up and the criteria for the selection of examiners. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

Article 18

Grant of a unitary certificate or rejection of the application for a unitary certificate

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:*** ~~:~~ **[Am. 51]**

(a) where the examination opinion is positive, the Office shall grant a unitary certificate;

(b) where the examination opinion is negative, the Office shall reject the application for a unitary certificate.

The Office shall inform the applicant of its decision without undue delay. **[Am. 52]**

Article 19

Grant of an extension of the duration of a unitary certificate

1. After ensuring that the application for an extension of the duration of a unitary certificate complies with Article 9(3), the Office shall assess that application on the basis of the conditions laid down in Article 36 of Regulation (EC) No 1901/2006.

2. Third parties may also submit observations ***or oppositions*** in respect of an application for an extension of the duration of a unitary certificate. **[Am. 53]**

3. Where the application for an extension of the duration complies with the conditions referred to in paragraph 1, the Office shall grant an extension of the duration of the unitary certificate.

4. Where the application for an extension of the duration does not comply with the conditions referred to in paragraph 1, the Office shall reject that application.

Article 20

Duration of the unitary certificate

1. The unitary certificate shall take effect at the end of the lawful term of the basic patent, namely on the twentieth anniversary of the filing date of the application for that patent, for a period equal to the period which elapsed between the date on which the application for the basic patent was lodged and the date of the first authorisation to place the product on the market in the Union, reduced by a period of 5 years.

2. The duration of the unitary certificate may not exceed 5 years from the date on which it takes effect.

3. The periods laid down in paragraphs 1 and 2 shall be extended by 6 months in the case where Article 36 of Regulation (EC) No 1901/2006 applies. In that case, the duration of the period laid down in paragraph 1 of this Article may be extended only once.

Article 21

Expiry of the unitary certificate

The unitary certificate shall lapse in any of the following events:

(a) at the end of the period provided for in Article 20;

(b) if the unitary certificate holder surrenders it;

(c) if the annual fee laid down in accordance with Article 31(3) is not paid in time;

(d) if and as long as the product covered by the unitary certificate may no longer be placed on the market following the withdrawal of the appropriate authorisation to place on the market in accordance with Regulation (EC) No 726/2004 or Regulation (EU) 2019/6.

For the purposes of the first subparagraph, point (d), the Office may decide on the lapse of the certificate either of its own motion or at the request of a third party.

Article 22

Invalidity of the unitary certificate

The unitary certificate shall be invalid in any of the following events:

(a) the certificate was granted contrary to ~~Article 3~~***Articles 3 and 6(2)***; **[Am. 54]**

(b) the basic patent has lapsed before its lawful term expires;

(c) the basic patent is revoked or limited to the extent that the product for which the unitary certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.

Article 23

Application for a declaration of invalidity

1. Any person may file with the Office an application for a declaration of invalidity of a unitary certificate.

2. An application for a declaration of invalidity may only be filed on the grounds that one or more of the conditions set out in Article 22 are not fulfilled for one or more of the Member States in which the basic patent has unitary effect.

3. An application for a declaration of invalidity shall be filed ~~in writing,~~***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. **[Am. 55]**

4. The application for a declaration of invalidity shall contain:

   (a) the references of the unitary certificate against which that application is filed, the name of its holder, and the identification of the product;

   (b) the particulars of the person referred to in paragraph 1 (‘applicant’) and, where applicable, of its representative;

   (c) a statement of the grounds on which the application for a declaration of invalidity is based.

5. The application for a declaration of invalidity shall be examined by an invalidation panel set up by the Office in accordance with the rules applicable to examination panels. However, the invalidation panel shall not include any examiner previously involved in the examination panel that examined the unitary certificate application, nor, the case being, any examiner involved in possible related opposition proceedings, nor in related appeal proceedings.

6. An application for a declaration of invalidity shall be inadmissible where an application relating to the same subject matter and cause of action, and involving the same parties, has been adjudicated on its merits, either by the Office or by a competent court as referred to in Article 24, and the decision of the Office or that court on that application has acquired the authority of a final decision.

7. If the invalidation panel notes that the application for a declaration of invalidity does not comply with paragraphs 2, 3 or 4, it shall reject that application as inadmissible, and communicate this to applicant.

8. The decision to reject an application for a declaration of invalidity as inadmissible shall be communicated to the holder of the unitary certificate, together with a copy of that application.

9. Where the application for a declaration of invalidity is not rejected as inadmissible, the Office shall promptly transmit that application to the holder of the unitary certificate, and shall publish it in the Register. If several applications for a declaration of invalidity have been filed, the Office shall promptly communicate them to the other applicants.

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

11. If the examination of the application for a declaration of invalidity reveals that the one or more of the conditions set out in Article 22 are met, the unitary certificate shall be declared invalid. Otherwise the application for a declaration of invalidity shall be rejected. The outcome shall be mentioned in the Register.

12. The unitary certificate shall be deemed not to have had, as from the outset, the effects specified in this Regulation, to the extent that it has been declared invalid.

13. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the details of the procedure governing the declaration of invalidity.

Article 24

Counterclaim for the invalidity of a certificate

1. A counterclaim for a declaration of invalidity may only be based on the grounds for invalidity set out in Article 22.

2. The competent court of a Member State shall reject a counterclaim for a declaration of invalidity if a decision taken by the Office relating to the same subject matter and cause of action and involving the same parties has already become final.

3. If the counterclaim is brought in a legal action to which the holder of the unitary certificate is not already a party, that holder shall be informed thereof and may be joined as a party to the action in accordance with the conditions applicable before the competent court.

4. The competent court of a Member State with which a counterclaim for a declaration of invalidity of the unitary certificate has been filed shall not proceed with the examination of the counterclaim, until either the interested party or the court has informed the Office of the date on which the counterclaim was filed. The Office shall record that information in the Register. If an application for a declaration of invalidity of the unitary certificate had already been filed before the Office before the counterclaim was filed, the court shall be informed thereof by the Office and stay the proceedings until the decision on the application is final or the application is withdrawn.

5. Where the competent court of a Member State has given a judgment which has become final on a counterclaim for a declaration of invalidity of a unitary certificate, a copy of the judgment shall be sent to the Office without delay, either by the court or by any of the parties to the national proceedings. The Office or any other interested party may request information about such transmission. The Office shall mention the judgment in the Register and shall take the necessary measures to comply with its operative part.

6. The competent court hearing a counterclaim for a declaration of invalidity may stay the proceedings on application by the holder of a unitary certificate and after hearing the other parties and may request the defendant to submit an application for a declaration of invalidity to the Office within a time limit which it shall determine. If the application is not made within the time limit, the proceedings shall continue; the counterclaim shall be deemed withdrawn. Where the competent court of a Member State stays the proceedings it may order provisional and protective measures for the duration of the stay.

Article 25

Revocation of an extension of the duration of a unitary certificate for a medicinal product

1. The Office may revoke an extension of the duration if it was granted contrary to Article 36 of Regulation (EC) No 1901/2006.

2. Any person may submit an application for revocation of the extension of the duration to the Office.

Article 26

Notification of lapse or invalidity

1. Where the unitary certificate lapses in accordance with Article 21, point (b), (c) or (d), or is invalid in accordance with Article 22 and 23, the Office shall promptly publish a notification thereof.

2. Where the extension of the duration is revoked in accordance with Article 25, the Office shall promptly publish a notification thereof.

Article 27

Conversion

1. Where the unitary effect of the basic patent is revoked while the application for a unitary certificate is still pending, the holder of that application may, subject to a fee, request the conversion of that application into a centralised application for certificates.

2. Where the unitary effect of the basic patent is revoked after the unitary certificate has been granted, the holder of that certificate may, subject to a fee, request the conversion of that unitary certificate into national certificates.

3. A request for conversion may be filed with the Office within 3 months after notification of the revocation of the unitary effect of the basic patent.

4. A request for conversion, as well as its outcome, shall be published in the Register.

5. The Office shall check whether the conversion requested fulfils the conditions set out in this Article, together with the formal conditions specified in the implementing act adopted pursuant to paragraph 8. If the conditions governing the request are not fulfilled, the Office shall notify the applicant of the deficiencies. If the deficiencies are not remedied within a period to be specified by the Office, the Office shall reject the request for conversion. Where the conversion fee has not been paid within the relevant period of 3 months, the Office shall inform the applicant that the request for conversion is deemed not to have been filed.

6. Where a request under paragraph 1 complies with paragraph 5, the Office shall convert the application for a unitary certificate into a centralised application for certificates designating the Member States in which the basic patent had unitary effect. In the event of a combined application, the designation of the Member States in which the basic patent had unitary effect shall be added to the designation of other Member States already included in the combined application.

7. Where a request under paragraph 2 complies with paragraph 5, the Office shall transmit the request for conversion to the competent national authorities of each Member State in which the basic patent had unitary effect and for which the request has been found admissible. The competent national authorities shall take decisions accordingly.

8. The Commission shall adopt implementing acts specifying the details to be contained in a request for conversion of the for a unitary certificate or unitary certificate into a centralised application for certificates or national certificates. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

Article 28

Appeals

1. Any party to proceedings under this Regulation, adversely affected by a decision of the Office, including the adoption of an examination opinion, may appeal the decision to the Boards of Appeal.

2. The filing of the appeal shall have suspensive effect. A decision of the Office that has not been contested shall take effect on the day following the date of expiry of the appeal period referred to in paragraph 3.

3. Notice of appeal shall be filed ~~in writing~~***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 4***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. **[Am. 56]**

4. Following an examination of admissibility of the appeal, the Boards of Appeal shall decide on the merits of the appeal.

5. Where an appeal results in a decision which is not in line with the examination opinion, the decision of the Boards ~~may~~***shall*** annul or alter the opinion. **[Am. 57]**

6. An action may be brought before the General Court of the European Union against a decision of the Boards of Appeal in relation to appeals, within 2 months of the date of notification of that decision, on grounds of infringement of an essential procedural requirement, infringement of the Treaty on the Functioning of the European Union, infringement of this Regulation or of any rule of law relating to their application or misuse of power. The action shall be open to any party to proceedings before the Board of Appeal adversely affected by its decision. The General Court shall have jurisdiction to annul or to alter the contested decision.

7. The decisions of the Boards of Appeal shall take effect on the day following the date of expiry of the period referred to in paragraph 6 or, if an action has been brought before the General Court within that period, as from the date following the day of dismissal of such action or of dismissal of any appeal filed with the Court of Justice of the European Union against the decision of the General Court. The Office shall take the necessary measures to comply with the judgement of the General Court or, in the event of an appeal against that judgement, the Court of Justice.

8. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the content and form of the notice of appeal referred to in paragraph 3, the procedure for the filing and examination of an appeal and the content and the form of the Boards of Appeal's decision referred to in paragraph 4.

Article 29

Boards of Appeal

1. In addition to the powers conferred upon it by Article 165 of Regulation (EU) 2017/1001, the Boards of Appeal instituted by that Regulation shall be responsible for deciding on appeals against decisions of the Office taken on the basis of Article 25(1).

2. A Board of Appeal in matters regarding unitary certificates shall consist of three members, at least two of whom are legally qualified. Where the Board of Appeal considers that the nature of the appeal so requires, it may call up to two further members for that case.

3. There shall be no Grand Board as referred to in Article 165(2), (3) and (4), and Article 167(2) of Regulation (EU) 2017/1001 in matters regarding unitary certificates. Decisions taken by a single member as under Article 165(2) of Regulation (EU) 2017/1001 shall not be possible.

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.*** **[Am. 58]**

4a. Article 166(9) of Regulation (EU) 2017/1001 shall apply to Boards of Appeal in matters regarding unitary certificates. **[Am. 59]**

Article 30

Delegation of power regarding the Boards of Appeal

The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the details concerning the organisation of the Boards of Appeal in proceedings relating to unitary certificates under this Regulation.

Article 31

Fees

1. The Office shall charge a fee for an application for a unitary certificate, and for an application for the extension of the duration of a unitary certificate.

2. The Office shall charge a fee for appeals, for oppositions, for applications for a declaration of invalidity and for conversions.

3. The unitary certificate shall be subject to the payment of annual maintenance fees to the Office.

4. The notifications referred to in Article 5(3), points (b) and (c), shall be subject to the payment of a fee to the Office.

5. The Commission is empowered to adopt implementing acts determining the amounts of the fees charged by the Office, the time limits within which they have to be paid, and the ways in which they are to be paid. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

Article 32

Combined applications

An application for a unitary certificate may be included in a combined centralised application in which the applicant also requests the grant of national certificates, in the designated Member States, in accordance with the centralised procedure under Regulation [COM(2023) 231]. In that case, Article 39 of that Regulation shall apply.

An applicant shall submit an application for a combined centralised application electronically to the Office and in the formats made available by the Office. **[Am. 60]**

Article 33

Languages

1. All documents and information sent to the Office in respect of the procedures under this Regulation shall be in one of the official languages of the Union.

2. For the tasks conferred on the Office under this Regulation, the languages of the Office shall be all the official languages of the Union in accordance with Council Regulation No 1[17].

Article 34

Communications to the Office

1. Communications addressed to the Office ~~may~~***shall*** be effected by electronic means. The Executive Director shall determine ~~to what extent and~~ under which technical conditions those communications ~~may~~***are to*** be submitted ~~electronically~~. **[Am. 61]**

2. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the rules on the means of communication, including the electronic means of communication, to be used by the parties to proceedings before the Office and the forms to be made available by the Office.

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17 Council Regulation No 1 determining the languages to be used by the European Economic Community (OJ 17, 6.10.1958, p. 385).

Article 35

Register

1. As regards applications for unitary certificates for medicinal products, the Register set up under Article 35 of Regulation [COM(2023) 231][18] shall include, for each unitary certificate, or application for a unitary certificate, or application for an extension of the duration of a unitary certificate, the following information, as applicable:

(a) the name and address of the applicant or certificate holder;

(b) the name and business address of the representative, other than a representative as referred to in Article 38(3);

(c) the application as well as its date of lodging and date of publication;

(d) whether the application relates to a medicinal product or to a plant protection product;

(e) where applicable, an indication that the application includes an application for an extension of the duration;

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18 Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products [COM(2023) 231].

(f) the number of the basic patent;

(g) an identification of the product for which a unitary certificate is requested;

(h) the number and date of the authorisation to place the product on the market referred to in Article 3(1), point (b), and an identification of the product identified therein;

(i) the number and date of the first authorisation to place the product on the market in the Union;

(ia) information on any direct public financial support received for research related to the development of the product; **[Am. 62]**

(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; **[Am. 63]**

(k) where applicable, the number and the duration of the unitary certificate;

(l) where applicable, the date and a summary of the examination opinion relating to an application for an extension of the duration of a unitary certificate;

(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; **[Am. 64]**

(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; **[Am. 65]**

(o) where applicable, a mention that a certificate has lapsed or was declared invalid;

(p) where applicable, the filing of an application for a declaration of invalidity and, once available, the outcome of the related proceedings;

(q) where applicable, information relating to a request for conversion, and its outcomes;

(r) information on the payment of annual fees.

2. The Register shall contain changes to the information in paragraph 1, including transfers, each accompanied by the date of recording of such entry.

3. The Register and information referred to in paragraphs 1 and 2 shall be available in all official languages of the Union. The Office may use verified machine translation for the information to be published in the Register.

4. The Executive Director of the Office may determine that information other than those referred to in paragraphs 1 and 2 shall be entered in the Register.

5. The Office shall collect, organise, make public and store the information referred to in paragraphs 1 and 2, including any personal data, for the purposes laid down in paragraph 7. The Office shall keep the Register easily accessible for public inspection.

6. The Office shall provide certified or uncertified extracts from the Register on request and on payment of a fee.

7. The processing of the data concerning the entries set out in paragraphs 1 and 2, including any personal data, shall take place for the purposes of the following:

   (a) administering the applications and unitary certificates in accordance with this Regulation and the acts adopted pursuant to it;

(b) maintaining the Register and making it available for inspection by public authorities and economic operators;

(c) producing reports and statistics enabling the Office to optimise its operations and improve the functioning of the system.

8. All the data, including personal data, concerning the entries in paragraphs 1 and 2 shall be considered to be of public interest and may be accessed by any third party. For reasons of legal certainty, the entries in the Register shall be kept for an indefinite period of time.

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.
[Am. 66]

Article 36

Database

1. In addition to the obligation to keep a Register, the Office shall collect and store in an electronic database all the particulars provided by applicants or any other third party observations pursuant to this Regulation or acts adopted pursuant to it.

2. The electronic database may include personal data, beyond those included in the Register, to the extent that such particulars are required by this Regulation or by acts adopted pursuant to it. The collection, storage and processing of such data shall serve the purposes of:

   (a) administering the applications and/or certificate registrations as described in this Regulation and in acts adopted pursuant to it;

   (b) accessing the information necessary for conducting the relevant proceedings more easily and efficiently;

   (c) communicating with the applicants and other third parties;

   (d) producing reports and statistics enabling the Office to optimise its operations and improve the functioning of the system.

3. The Executive Director shall determine the conditions of access to the electronic database and the manner in which its contents, other than the personal data referred to in paragraph 2 of this Article but including those listed in Article 35, may be made available in machine-readable form, including the charge for such access.

4. Access to the personal data referred to in paragraph 2 shall be restricted and such data shall not be made publicly available unless the party concerned has given his express consent.

5. All data shall be kept indefinitely. However, the party concerned may request the removal of any personal data from the database after 18 months from the expiry of the unitary certificate or, the case being, the closure of the relevant inter partes procedure. The party concerned shall have the right to obtain the correction of inaccurate or erroneous data at any time.

Article 37

Transparency

1. Regulation (EC) No 1049/2001 of the European Parliament and of the Council[19] shall apply to documents held by the Office.

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19 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

2. The Management Board of the Office shall adopt detailed rules for applying Regulation (EC) No 1049/2001 in the context of this Regulation.

3. Decisions taken by the Office under Article 8 of Regulation (EC) No 1049/2001 may be challenged through the European Ombudsman or form the subject of an action before the Court of Justice of the European Union, under the conditions laid down in Articles 228 and 263 TFEU respectively.

4. The processing of personal data by the Office shall be subject to Regulation (EC) No 45/2001 of the European Parliament and of the Council[20].

Article 38

Representation

1. Natural or legal persons having neither their domicile nor their principal place of business or a real and effective industrial or commercial establishment in the European Economic Area shall be represented before the Office in accordance with this Article in all proceedings provided for by this Regulation, other than the filing of an application for a unitary certificate.

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20 Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

2. Natural or legal persons having their domicile or principal place of business or a real and effective industrial or commercial establishment in the Union may be represented before the Office by an employee.

   An employee of a legal person may also represent other legal persons which are economically linked with the legal person being represented by that employee.

   The second subparagraph also applies where those other legal persons have neither their domicile nor their principal place of business nor a real and effective industrial or commercial establishment within the Union.

   Employees who represent natural or legal persons shall, at the request of the Office or, where appropriate, of the party to the proceedings, file with the Office a signed authorisation for insertion in the files.

3. A common representative shall be appointed where there is more than one applicant or more than one third party acting jointly.

4. Only a practitioner established in the Union, entitled to act as a professional representative in patent matters before a national patent office or the European Patent Office, or a lawyer authorised to practise before the courts or tribunals of a Member State, may represent natural or legal persons before the Office.

Article 39

Supplementary Protection Certificates Division

A Supplementary Protection Certificate Division (‘SPC Division’) shall be set up within the Office and, in addition to the responsibilities under Regulations [COM(2023) 231] and [COM(2023) 223], shall be responsible for implementing the tasks set out in this Regulation and in Regulation [COM(2023) 221], including in particular:

(a) receiving and supervising the examination of applications for unitary certificates, applications for an extension of the duration of unitary certificates, appeals and observations by third parties;

(b) adopting examination opinions on behalf of the Office in relation to applications for unitary certificates, as well as in relation to applications for an extension of the duration of unitary certificates;

(c) deciding on oppositions against examination opinions;

(d) deciding on applications for a declaration of invalidity;

(e) processing conversion requests;

(f) maintaining the register and the database.

Article 40

Decisions and communications of the Office

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~~***electronically*** to the parties. **[Am. 67]**

2. Any decision, opinion, communication or notice from the Office under this Regulation shall indicate the SPC Division and the relevant panel as well as the name or the names of the examiners responsible. It shall be signed by these examiners, or, instead of a signature, carry a printed or stamped seal of the Office. The Executive Director may determine that other means of identifying the SPC Division and the name of the examiners responsible, or an identification other than a seal, may be used where decisions or other communications are transmitted by any technical means of communication.

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~~***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. **[Am. 68]**

Article 41

Oral proceedings

1. If the Office considers that oral proceedings would be expedient they shall be held either at the instance of the Office or at the request of any party to the proceedings.

~~2. Oral proceedings before an examination panel, opposition panel or invalidity panel shall not be public.~~ **[Am. 69]**

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. **[Am. 70]**

4. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by setting out the detailed arrangements for oral proceedings.

Article 42

Taking of evidence

1. In any proceedings before the Office, the means of giving or obtaining evidence shall include the following:

(a) hearing the parties;

(b) requests for information;

(c) the production of documents and items of evidence;

(d) hearing witnesses;

(e) opinions by experts;

(f) statements in writing sworn or affirmed or having a similar effect under the law of the State in which the statement is drawn up.

2. The relevant panel may commission one of its members to examine the evidence adduced.

3. If the Office or the relevant panel considers it necessary for a party, witness or expert to give evidence orally, it shall issue a summons to the person concerned to appear before it. ***Where an expert is summonsed, the Office or the relevant panel, as 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. **[Am. 71]**

4. The parties shall be informed of the hearing of a witness or expert before the Office. They shall have the right to be present and to put questions to the witness or expert.

5. The Executive Director shall determine the amounts of expenses to be paid, including advances, as regards the costs of taking of evidence as referred to in this Article.

6. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by setting out the detailed arrangements for the taking of evidence.

Article 43
Notification

1. The Office shall, as a matter of course, notify those concerned of decisions, including opinions, summonses and of any notice or other communication from which a time limit is reckoned, or of which those concerned are to be notified under other provisions of this Regulation or of acts adopted pursuant to this Regulation, or of which notification has been ordered by the Executive Director.

2. Notification may be effected by different means, including electronic means. The details regarding electronic means shall be determined by the Executive Director.

3. Where notification is to be effected by public notice, the Executive Director shall determine how the public notice is to be given and shall fix the beginning of the 1-month period on the expiry of which the document shall be deemed to have been notified.

4. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by setting out the detailed arrangements for notification.

Article 44

Time limits

1. Time limits shall be laid down in terms of full years, months, weeks or days. Calculation shall start on the day following the day on which the relevant event occurred. The duration of time limits shall be no less than 1 month and no more than 6 months.

2. The Executive Director shall determine, before the commencement of each calendar year, the days on which the Office is not open for receipt of documents or on which ordinary post is not delivered in the locality in which the Office is located.

3. The Executive Director shall determine the duration of the period of interruption in the case of a general interruption in the delivery of post in the Member State where the Office is located or, in the case of an actual interruption of the Office's connection to admitted electronic means of communication.

4. If an exceptional occurrence, such as a natural disaster or strike, interrupts or interferes with proper communication from the parties to the proceedings to the Office or vice-versa, the Executive Director may determine that for parties to the proceedings having their residence or registered office in the Member State concerned or who have appointed a representative with a place of business in the Member State concerned all time limits that otherwise would expire on or after the date of commencement of such occurrence, as determined by the Executive Director, shall extend until a date to be determined by the Executive Director. When determining that date, the Executive Director shall assess when the exceptional occurrence comes to an end. If the occurrence affects the seat of the Office, such determination of the Executive Director shall specify that it applies in respect of all parties to the proceedings.

5. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by specifying the details regarding the calculation and duration of time limits.

Article 45

Correction of errors and manifest oversights

1. The Office shall correct any linguistic errors or errors of transcription and manifest oversights in its decisions, including opinions, or technical errors in publishing information in the Register, of its own motion or at the request of a party.

2. Where the Office has made an entry in the Register or taken a decision which contains an obvious error attributable to the Office, it shall ensure that the entry is cancelled or the decision is revoked. The cancellation of the entry in the Register or the revocation of the decision shall be effected within 1 year of the date on which the entry was made in the Register or that decision was taken, after consultation with the parties to the proceedings.

3. The Office shall keep records of any such corrections or cancellations.

4. Corrections and cancellations shall be published by the Office.

Article 46

Restitutio in integrum

1. The applicant for or holder of a unitary certificate, or any other party to proceedings before the Office under this Regulation, who, in spite of all due care required by the circumstances having been taken, was unable to comply with a time limit vis-à-vis the Office shall, upon application, have his rights re-established if the obstacle to compliance has the direct consequence, by virtue of the provisions of this Regulation, of causing the loss of any right or means of redress.

2. The application for re-establishment shall be filed ~~in writing~~***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. **[Am. 72]**

3. The application for re-establishment shall state the grounds on which it is based and shall set out the facts on which it relies. It shall not be deemed to be filed until the fee for re-establishment of rights has been paid.

4. The SPC Division, or where applicable the Boards of Appeal, shall decide upon the application.

5. This Article shall not be applicable to the time limits referred to in paragraph 2 of this Article, or in Article 15(1) and (3).

Article 47

Interruption of proceedings

1. Proceedings before the Office under this Regulation shall be interrupted:

(a) in the event of the death or legal incapacity of the applicant or of the person authorised by national law to act on behalf of the applicant. To the extent that that death or incapacity does not affect the authorisation of a representative appointed under Article 39, proceedings shall be interrupted only on application by such representative;

(b) in the event of the applicant being prevented, for legal reasons resulting from action taken against his property, from continuing the proceedings before the Office;

(c) in the event of the death or legal incapacity of the representative of the applicant, or of that representative being prevented, for legal reasons resulting from action taken against his property, from continuing the proceedings before the Office.

2. Proceedings before the Office shall be resumed as soon as the identity of the person authorised to continue them has been established.

3. The Commission is empowered to adopt delegated acts in accordance with Article 54 to supplement this Regulation by setting out the detailed arrangements for the resumption of proceedings before the Office.

Article 48

Costs

1. The losing party in opposition proceedings and proceedings for a declaration of invalidity, including in related appeal proceedings, shall bear the fees paid by the other party. The losing party shall also bear all costs incurred by the other party that are essential to the proceedings, including travel and subsistence and the remuneration of a representative, within the maximum rates set for each category of costs in the implementing act to be adopted in accordance with paragraph 7. The fees to be borne by the losing party shall be limited to the fees paid by the other party in those proceedings.

2. Where each party succeeds on some and fails on other heads, or if reasons of equity so dictate, the SPC Division or Board of Appeal shall decide a different apportionment of costs.

3. Where proceedings are terminated the costs shall be at the discretion of the SPC Division or Board of Appeal.

4. Where the parties conclude before the SPC Division or Board of Appeal a settlement of costs differing from that provided for in paragraphs 1 to 3, the body concerned shall take note of that agreement.

5. The SPC Division or Board of Appeal shall fix the amount of the costs to be paid pursuant to paragraphs 1 to 3 of this Article when the costs to be paid are limited to the fees paid to the Office and the representation costs. In all other cases, the registry of the Board of Appeal or SPC Division shall fix, on request, the amount of the costs to be reimbursed. The request shall be admissible only for the period of 2 months following the date on which the decision for which an application was made for the costs to be fixed becomes final and shall be accompanied by a bill and supporting evidence. For the costs of representation an assurance by the representative that the costs that have been incurred shall be sufficient. For other costs, it shall be sufficient if their plausibility is established. Where the amount of the costs is fixed pursuant to the first sentence of this paragraph, representation costs shall be awarded at the level laid down in the implementing act adopted pursuant to paragraph 7 of this Article and irrespective of whether they have been actually incurred.

6. Decisions on the fixing of costs adopted in accordance with paragraph 5 shall state the reasons on which they are based, and may be reviewed by a decision of the SPC Division or Board of Appeal on a request filed within 1 month of the date of notification of the awarding of costs. It shall not be deemed to be filed until the fee for reviewing the amount of the costs has been paid. The SPC Division or the Board of Appeal, as the case may be, shall take a decision on the request for a review of the decision on the fixing of costs without oral proceedings.

7. The Commission shall adopt implementing acts specifying the maximum rates for costs essential to the proceedings and actually incurred by the successful party. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

8. When specifying the maximum rates with respect to travel and subsistence costs, the Commission shall take into account the distance between the place of residence or business of the party, representative or witness or expert and the place where the oral proceedings are held, the procedural stage at which the costs have been incurred, and, as far as costs of representation are concerned, the need to ensure that the obligation to bear the costs may not be misused for tactical reasons by the other party. In addition, subsistence expenses shall be calculated in accordance with the Staff Regulations of Officials of the Union and the Conditions of Employment of Other Servants of the Union, laid down in Council Regulation (EEC, Euratom, ECSC) No 259/68[21]. The losing party shall bear the costs for one party in the proceedings only and, where applicable, one representative only.

Article 49

Enforcement of decisions fixing the amount of costs

1. Any final decision of the Office fixing the amount of costs shall be enforceable.

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21 Regulation (EEC, Euratom, ECSC) No 259/68 of the Council of 29 February 1968 laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Commission and instituting special measures temporarily applicable to officials of the Commission (OJ L 56, 4.3.1968, p. 1.)’

2. Enforcement shall be governed by the rules of civil procedure in force in the Member State in the territory of which it is carried out. Each Member State shall designate a single authority responsible for verifying the authenticity of the decision referred to in paragraph 1 and shall communicate its contact details to the Office, the Court of Justice and the Commission. The order for enforcement shall be appended to the decision by that authority, with the verification of the authenticity of the decision as the sole formality

3. When these formalities have been completed on application by the party concerned, the latter may proceed to enforcement in accordance with the national law, by bringing the matter directly before the competent authority.

4. Enforcement may be suspended only by a decision of the Court of Justice. However, the courts of the Member State concerned shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

Article 50

Amendment to Regulation (EU) 2017/1001

Regulation (EU) 2017/1001 is amended as follows:

(1) Article 151(1) is amended as follows:

(a) point (c) is replaced by the following:

‘(c) promoting convergence of practices and tools in the fields of trade marks and designs as well as supplementary protection certificates, in cooperation with the central industrial property offices in the Member States, including the Benelux Office for Intellectual Property;’

(b) the following points (f) and (g) are added:

'(f) the tasks referred to in Chapter III of Regulation [COM(2023) 231] and in Chapter III of Regulation [COM(2023) 223] as well as in Regulations [COM(2023) 222] and [COM(2023) 221];

(g) on the basis of requests for participation in the centralised examination procedure, and after giving the Commission an opportunity to comment on them, appointing, by concluding an agreement, those competent national authorities whose examiners will be able to participate in the centralised examination of centralised applications for certificates under Regulations [COM(2023) 231] and [COM(2023) 223], including opposition proceedings, and of applications for unitary certificates under Regulation [COM(2023) 222] and Regulation [COM(2023) 221], including opposition and invalidity proceedings;'

(2) in Article 152(1), the first subparagraph is replaced by the following:

‘The Office and the central industrial property offices of the Member States and the Benelux Office for Intellectual Property shall cooperate with each other to promote convergence of practices and tools in the field of trade marks, designs, and supplementary protection certificates..'

Article 51

Amendment to Regulation (EU) No 608/2013

Article 2(1) of Regulation (EU) No 608/2013 is amended as follows:

(1) points (f) and (g) are replaced by the following:

‘(f) a supplementary protection certificate for medicinal products as provided for in Regulation [COM(2023) 231] of the European Parliament and of the Council of ddddd concerning the supplementary protection certificate for medicinal products [OP, please insert the No and date of COM(2023) 231 once adopted, as well as its O.J. reference in the footnote];

(g) a supplementary protection certificate for plant protection products as provided for in Regulation [COM(2023) 223] of the European Parliament and of the Council of ddddd concerning the creation of a supplementary protection certificate for plant protection products [OP, please insert the No and date of COM(2023) 223 once adopted, as well as its O.J. reference in the footnote];;’

(2) the following points (m) and (n) are inserted:

‘(m) a unitary supplementary protection certificate for medicinal products as provided for in Regulation [COM(2023) 222] of the European Parliament and of the Council of ddddd on the unitary supplementary protection certificate for medicinal products and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013 [OP, please insert the No and date of COM(2023) 222 once adopted, as well as its O.J. reference in the footnote];

(n) a unitary supplementary protection certificate for plant protection products as provided for in Regulation [COM(2023) 221] of the European Parliament and of the Council of dddddd on the unitary supplementary protection certificate for plant protection products [OP, please insert the No and date of COM(2023) 221 once adopted, as well as its O.J. reference in the footnote]..’

Article 52

Amendment to Regulation (EC) No 1901/2006

Regulation (EC) No 1901/2006 is amended as follows:

(1) in Article 2, point (4) is replaced by the following:

‘(4) ‘paediatric use marketing authorisation’ means a marketing authorisation granted in respect of a medicinal product for human use which is not protected by a supplementary protection certificate or unitary supplementary protection certificate under Regulation [COM(2023) 231] or Regulation [COM(2023) 222], or by a patent which qualifies for the grant of the supplementary protection certificate, covering exclusively therapeutic indications which are relevant for use in the paediatric population, or subsets thereof, including the appropriate strength, pharmaceutical form or route of administration for that product;;’

(2) in Article 8, the first paragraph is replaced by the following:

‘In the case of authorised medicinal products which are protected either by a supplementary protection certificate or unitary supplementary protection certificate under Regulation [COM(2023) 231] or Regulation [COM(2023) 222], or by a patent which qualifies for the grant of the supplementary protection certificate, Article 7 of this Regulation shall apply to applications for authorisation of new indications, including paediatric indications, new pharmaceutical forms and new routes of administration.;’

(3) Article 36 is amended as follows:

(a) in paragraph 1, the first subparagraph is replaced by the following:

‘Where an application under Article 7 or 8 includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate or unitary supplementary protection certificate shall be entitled to a six-month extension of the periods referred to in Articles 13(1) and 13(2) of Regulation [COM(2023) 231] or Article 20(1) and 20(2) of Regulation [COM(2023) 222].;’

(b) in paragraph 4, the first sentence is replaced by the following:

‘Paragraphs 1, 2 and 3 shall apply to products that are protected by a supplementary protection certificate or unitary supplementary protection certificate under Regulation [COM(2023) 231] or Regulation [COM(2023) 222], or under a patent which qualifies for the grant of the supplementary protection certificate..’

Article 53

Financial provisions

1. The expenses incurred by the Office in carrying out the additional tasks given to it in accordance with this Regulation shall be covered by the procedural fees to be paid to it by applicants and by a fraction of the annual fees paid by the holders of unitary certificates, while the remainder of the annual fees shall be shared with the Member States in accordance with the number of unitary certificates having legal effect in each of them. The fraction of the annual fees to be shared with Member States shall initially be set at a certain value but shall be reviewed every 5 years, in such a manner as to achieve financial sustainability for the activities carried out by the Office under this Regulation as well as under Regulations [COM(2023) 231], [COM(2023) 223] and [COM(2023) 221].

2. For the purposes of paragraph 1, the Office shall keep an account of the annual fees paid to it by holders of unitary certificates in force in the respective Member States.

3. The expenses incurred by a competent national authority participating in proceedings under this Chapter shall be covered by the Office and shall be paid annually, on the basis of the number of proceedings in which that competent national authority was involved during the preceding year.

4. The Commission is empowered to adopt implementing acts laying down rules on the financial transfers between the Office and Member States, the amounts of those transfers, and the remuneration to be paid by the Office regarding the participation of competent national authorities referred to in paragraph 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.

5. Article 12 of Regulation (EU) No 1257/2012 shall apply to the annual fees due in respect of unitary certificates.

Article 54

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 15(13), 23(13), 28(8), 30, 34(2), 41(4), 42(6), 43(4), 44(5) and 47(3) shall be conferred on the Commission for an indeterminate period of time from XXX [OP please insert the date = date of entry into force].

3. The delegation of power referred to in Articles 15(13), 23(13), 28(8), 30, 34(2), 41(4), 42(6), 43(4), 44(5) and 47(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect on the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 15(13), 23(13), 28(8), 30, 34(2), 41(4), 42(6), 43(4), 44(5) or 47(3) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 55

Committee procedure

1. The Commission shall be assisted by a Committee on Supplementary Protection Certificates established by Regulation [COM(2023) 231]. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 56

Evaluation

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***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].*** **[Am. 73]**

Article 57

Entry into force and application

This Regulation shall enter into force on XXX [OP – please insert the date - the 20th day following its publication in the Official Journal of the European Union].

It shall apply from xxxxx [OP please insert first day of the 12th month after the date of entry into force].

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

Done at …,

For the European Parliament	*For the Council*
The President	*The President*

Annex I

Logo

This logo shall appear in black and in such a size as to be sufficiently visible.

Annex II

Standard form for notification pursuant to Article 5(3), points (b) and (c).

<table>
<tr><td>Tick the appropriate box</td><td colspan="2">☐ New notification
☐ Update of an existing notification</td></tr>
<tr><td>(a) Name and address of the maker</td><td colspan="2">…</td></tr>
<tr><td>(b) Purpose of making</td><td colspan="2">☐ Export
☐ Storing
☐ Export and storing</td></tr>
<tr><td rowspan="2">(c) Member State in which making is to take place and Member State in which first related act (if any) prior to making is to take place</td><td>Member State of making</td><td></td></tr>
<tr><td>(Member State of first related act (if any))</td><td></td></tr>
<tr><td rowspan="2">(d) Number of unitary certificate having effect in the Member State of making and number of certificate granted in Member State of first related act (if any) prior to making</td><td>Unitary certificate having effect in the Member State of making</td><td></td></tr>
<tr><td>(Certificate of Member State of first related act (if any))</td><td></td></tr>
<tr><td rowspan="3">(e) For medicinal products to be exported to third countries, reference number of marketing authorisation, or the equivalent of such authorisation, in each third</td><td colspan="2"></td></tr>
<tr><td colspan="2"></td></tr>
<tr><td colspan="2"></td></tr>
</table>

Tick the appropriate box	☐ New notification ☐ Update of an existing notification
country of export	