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NOTE

From:	Presidency
To:	Delegations
No. prev. doc.:	13278/25; 13282/25
No. Cion doc.:	8869/23
Subject:	Supplementary Protection Certificates (SPCs): Proposal for a Regulation on the unitary Supplementary Protection Certificates for medicinal products - Partial revised text

In view of the Council Working Party on Intellectual Property on 20 October 2025, delegations will find in the Annex a Presidency revised text on a number of articles of the above-mentioned proposal.

Changes compared to the Commission proposal (doc. 8894/23) are highlighted in **bold underlined** or in ~~strikethrough~~. Changes compared to the previous revised Presidency text (doc. 13278/25) are indicated in grey shade and ~~double strikethrough~~.

This partial revised text is to be read in conjunction with the partial revised text on the proposal for a Regulation on SPCs for medicinal products (recast) (doc. 13924/25) and with the Presidency discussion paper set out in WK 13518/2025.

ANNEX

Article 1 (to be addressed later)

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[1] ('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~~ **pursuant to** Regulation (EU) No 1257/2012;

(5) 'basic patent' means a ~~unitary~~**European** patent **with unitary effect** 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~~ **in an application for** a unitary certificate **or in a combined application (in accordance with Article 32**;

(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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[1] 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')~~ **lodged** 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.

Article 3

Conditions for obtaining a unitary certificate

1. A unitary certificate shall be granted by the ~~Office~~ **granting office referred to in Article 9d** 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 Regulation (EU) 2019/6, or with the centralised procedure under Regulation (EC) No 726/2004;

(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.

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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 **granting** office, as applicable.

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. *(paragraph 2 to be discussed at a later stage)* 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, 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:

(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;

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

(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;

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

(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;

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(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.

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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[2].

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.

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[2] 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).

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 (to be addressed later)

Article 8

Application for a unitary certificate

1. The application for a unitary certificate shall be lodged **by the holder of the basic patent** ~~**or the successor in title of that holder**~~ 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.

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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, address, seat or ~~**primary**~~**principal** place of business of the **holder of the basic patent (“**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;

(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[3] 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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[3] 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).

(ca) where a basic patent has been granted in respect of a product that is the subject of an authorisation held by a third party, the consent of that party that a unitary certificate for that product shall be granted to the holder of the basic patent;

(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.

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.

PUBLIC

(new) ***Article 9a***

Network of competent national authorities[4]

1. **Competent national authorities shall cooperate within a network of competent national authorities ("network") that examines applications for unitary certificates and for extensions of the duration of unitary certificates for the purpose of preparing a recommendation**[5] **on the grant or rejection of a unitary SPC in accordance with Articles 17a and 17b. In case of combined applications referred to in Article 32, the network shall also perform the tasks set out in Regulation [COM(2023) 231].**

2. **All competent national authorities shall be entitled to participate in the network. Competent national authorities shall notify the managing office referred to in Article 9b of their participation in the network.**

3. **Each competent national authority shall be part of the network upon the notification under paragraph 2 and shall perform the tasks conferred upon it pursuant to this Regulation in respect of applications filed after said notification.**

4. **Competent national authorities shall notify the managing office of any changes regarding their participation in the network, including the termination of such participation. Changes to the participation shall take effect [6 months] after the receipt of such a notification. Competent national authorities shall complete any tasks that are pending at the moment of the change in participation.**

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[4] It is suggested to clarify in a recital that only one single network is established for both the USPC proposals and the recast proposals and that this network convenes in different constellations depending on whether it assesses a unitary SPC application, or a centralised or combined application:
"Competent national authorities should cooperate in a single network to conduct the examination procedures under this Regulation and the recast Regulation. Participation in the network should be voluntary. In case of unitary SPC applications only competent national authorities of the Member States in which the basic patent has unitary effect should take part in the examination procedure [see Article 17(1) of this Regulation]. For centralised and combined applications, the examination within the network should be conducted by all competent national authorities in accordance with Article 25a(1) of the recast Regulation."

[5] To streamline the text, a definition of recommendation could be inserted in Article 2.

5. **Competent national authorities shall ensure that examiners performing tasks within the network possess the required qualification in the relevant technical field or in law. They shall be impartial in the exercise of their duties and shall declare any actual or perceived conflict of interest.**

6. **The managing office shall produce a yearly report on the network's work, including on the involvement of each competent national authority.**

7. **The Commission is empowered to adopt implementing acts laying down the rules of procedure of the network. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.**

(new) ***Article 9b***

Managing office

The [European Patent Office] shall act as the managing office. It shall provide procedural support to the network by performing, in particular, the following administrative tasks relating to the grant of unitary certificates and to the extension of the duration of unitary certificates established under this Regulation:

(a) **maintaining and publishing a list of competent national authorities participating in the network;**

(b) **receiving and publishing applications for unitary certificates, as well as applications for extensions of duration, and transmitting applications to the network;**

(c) ~~**performing a preliminary assessment of the formal requirements of the applications in accordance with Article 11**~~ **verifying that the application fee [referred to in Article 31(1)] has been paid and informing the rapporteur and co-rapporteurs of the payment;**

(d) transmitting to the examining members[6] referred to in Article 17(1) the draft recommendation prepared by the rapporteur and co-rapporteurs in accordance with Art 17a(2), as well as any comments or statements of disagreement regarding the draft recommendation;

(e) establishing and maintaining the register and data base;

(f) transmitting communications ~~to~~ between the rapporteur, co-rapporteurs or the network and the applicants, certificate holders and third parties;

(g) collecting and distributing fees.

In cases of combined applications referred to in Article 32, the managing office shall also perform the tasks set out in [Chapter III/Article 21b of] Regulation [COM(2023) 231].

(new) ***Article 9c***

Rapporteur and co-rapporteurs

For each application, the managing office shall designate from the network one competent national authority as rapporteur and two as co-rapporteurs in accordance with the criteria set out in Article 9e.

(new) ***Article 9d***

Granting office

The ~~competent national authority designated as rapporteur~~ [TBC] shall ~~also~~ assume the role of the granting office. The granting office shall, in accordance with Articles 18 and 19, be responsible for:

(a) the grant of the unitary certificate;

(b) the grant of an extension of the duration of a unitary certificate;

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[6] To streamline the text, a definition of "examining members" could be inserted in Article 2.

(c) the rejection of the application for a unitary certificate;

(d) the rejection of the application for an extension of the duration of a unitary certificate.

~~*(new) Article 9e (OPTION 1)*~~

~~***Criteria for the designation of the granting office, rapporteur and co-rapporteurs***~~

~~**1. Where the applicant – or, in case of a joint application, one of the applicants – has, on the date of filing of the application for a unitary certificate, its residence or principal place of business in a Member State in which the basic patent has unitary effect, the competent national authority of that Member State shall be assigned the roles of rapporteur and granting office, provided that it participates in the network and it does not make use of the exemption set out in Article 10(5) of Regulation [COM(2023) 231].**~~

~~**2. If two or more applicants of a joint application fulfil the criterion in paragraph 1, that paragraph shall apply to the applicant amongst them mentioned first in the application.**~~

~~**3. The managing office shall designate the co-rapporteurs and, where the conditions under paragraph 1 are not fulfilled, the rapporteur, based on a rotation mechanism that is subject to the following conditions:**~~

~~**(a) the rapporteur and the two co-rapporteurs shall be from a Member State in which the basic patent has unitary effect; and**~~

~~**(b) the rapporteur and at least one co-rapporteur shall be from a Member State not making use of the exemption set out in Article 10(5) of Regulation [COM(2023) 231].**~~

~~**By way of derogation from paragraph 3(a), in case of combined applications, one co-rapporteur shall be from a Member State designated in accordance with Article 8(1a) of Regulation [COM(2023) 231].**~~

(new) ***Article 9e*** ~~***(OPTION 2)***~~

Criteria for the designation of the ~~***granting office,***~~ ***rapporteur and co-rapporteurs***

The managing office shall designate the rapporteur, also acting as the granting office, and co-rapporteurs based on a rotation mechanism[7] that is subject to the following conditions:

(a) the rapporteur and the two co-rapporteurs shall be from Member States in which the basic patent has unitary effect;

(b) the rapporteur and at least one co-rapporteur shall be from a Member State not making use of the exemption set out in Article 10(5) of Regulation [COM(2023) 231].

By way of derogation from point (a), in case of combined applications, one co-rapporteur shall be from a Member State designated in accordance with Article 8(1a) of Regulation [COM(2023) 231].

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 with the **managing** office.

(new) ***Article 10a*** *(former Article 12)*

Publication of ~~***the***~~ ***application***s

~~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), t~~**T**he **managing** office shall publish ~~**the application**~~ **applications for a unitary certificate,** ~~**and**~~ **applications for an extension of the duration of certificates**~~**,**~~ **and combined applications as referred in Article 32, without undue delay,** in the Register ~~**where applicable upon expiry of the deadline set under Article 11(2)**~~**and upon publication transmit them to the examining members.**

[7] The purpose of the rotation mechanism is to ensure a fair distribution of the examination workload among the national offices. The details of the rotation mechanism, if supported by delegations, will have to be further elaborated and could be established by means of implementing act..

Article 11

~~Examination of the a~~Admissibility of ~~an~~ applications ~~for a unitary certificate~~

1. **~~In providing administrative support to the network,~~Once** ~~T~~the **managing** office **has confirmed that the application fee referred to in Article 31(1) has been paid, the rapporteur and the co-rapporteurs** shall ~~examine~~ **~~perform a preliminary assessment of~~ assess** the following:

   (a) whether the application for a unitary certificate **contains the information set out in** Article 9; **and**

   (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 rapporteur and the co-rapporteurs find that** the ~~centralised~~ application does not satisfy the requirements referred to in paragraph 1, ~~the **managing** office shall request **invite**~~ the applicant **shall be given the opportunity** to take the measures necessary to satisfy those requirements~~, and shall set a deadline for such compliance~~**[within one month]**.

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 (to reflect the sequence in the procedure,
Article 12 has been placed – as new Article 10a – before Article 11)

Article 13 (of the Commission proposal)

Examination of the application for a unitary certificate

(deleted / replaced by Articles 17, 17a to 17c)

Article 14

Observations by third parties

1. Any natural or legal person may submit written observations to the **managing** office ~~concerning the eligibility for supplementary protection~~ **on whether the application and** ~~of~~ the product to which ~~the application~~ **it** relates~~, in one or more of the Member States in which the basic patent has unitary effect~~ **comply with Articles 3(1), 3(2) and 6(2)**.

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

3. Third party observations shall be submitted within **[**~~3~~ **two]** months after publication of the application in the Register.

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

5. **The managing office shall notify the applicant of** ~~A~~**a**ny observations by a third party ~~shall be notified to the applicant~~ **without undue delay.** The applicant may comment on the observations within ~~a time limit set by the Office~~ **[**~~one~~ **two] months from the expiry of the deadline referred to in paragraph 1 or one month from the receipt of the observations, whichever is later.**

6. **The managing office shall, without undue delay, transmit to the examining members any third party observations and any comments from the applicant received in accordance with paragraph 5.**

Article 15 (of the Commission proposal)

Opposition

(deleted)

PUBLIC

(new) ***Article 17***[8]

General principles of the examination procedure

1. **Within the network, only competent national authorities of the Member States in which the basic patent has unitary effect shall take part in the examination procedure in accordance with Articles 17a to 17c ("examining members").**

2. **In case of a combined application referred to in Article 32, all competent national authorities in the network shall be examining members.**

3. **The examination procedure shall generally be conducted in writing. However, plenary meetings of the network to be held online shall be convened by the managing office for the purpose of discussing cases referred to in Article 17b.**

4. **The network shall endeavour to reach consensus when examining the applications.**

5. **The Commission is empowered to adopt implementing acts laying down the rules of procedure regarding the examination of applications by the network including on plenary meetings. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 55.**

(new) ***Article 17a***

Examination by the network

~~**1. Upon the publication of the application in accordance with Article 12, the managing office shall transmit the application to the examining members.**~~ *(first sentence integrated in Article 10a (former Article 12)* ~~**The managing office shall also, without undue delay, transmit to the examining members any third party observations and any comments from the applicant received in accordance with Article 14.**~~ *(second sentence moved to Article 14)*

2. **The rapporteur and co-rapporteurs shall, within [~~six~~ three] months after publication of the application in the register, or in case third party observation have been**

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[8] Suggested new Articles 17, 17a, 17b and 17c replace Articles 13, 16 and 17 of the initial Commission proposal.

submitted, within [three] months after the receipt of any related comments of the applicant [submitted in accordance with Article 14(5)], prepare a draft recommendation, to either:

(a) grant a unitary certificate where the application for a unitary certificate and the product to which it relates comply with the requirements set out in this Regulation; or

(b) reject the application for a unitary certificate where the application for a unitary certificate or the product to which it relates does not comply with the requirements set out in this Regulation.

When preparing the draft recommendation, they shall consider any third party observations submitted and any related comments received from the applicant.

3. **The managing office shall transmit the draft recommendation to the examining members. Any examining member may, within [~~three~~ two] months from the transmission of the draft recommendation, submit comments or a reasoned statement of disagreement to the managing office. The managing office shall, without undue delay, transmit to the network any comments and any statements of disagreement received.**

4. **If no statements of disagreement are received within the time limit referred to in paragraph 3, the recommendation shall be considered approved by the network and the granting office shall proceed to adopt a final decision pursuant to Article 18.**

(*new*) ***Article 17b***

Procedure for disagreement

1. **Where one or more statements of disagreements have been submitted in accordance with Article 17a(3), the rapporteur and the co-rapporteurs may revise the draft recommendation based on the statements. Otherwise, they shall provide reasons for not following the statements of disagreement.**

2. **The managing office shall transmit the revised draft recommendation or the reasons for not following the statements of disagreement to the examining members.**

3. **If no further statements of disagreement are submitted or supported by a majority of the examining members within [one month][two months] from the transmission under paragraph 2 the recommendation shall be considered approved by the network and the granting office shall proceed to adopt a final decision pursuant to Article 18.**

4. **If a majority of the examining members submit or support further statements of disagreement within [one month][two months] from the transmission under paragraph 2 the rapporteur and co-rapporteurs shall refer the case for discussion in a plenary meeting, following which the managing office shall transmit the recommendation as approved by the network to the granting office which shall proceed to adopt a final decision pursuant to Article 18.**

~~5. If a majority of the examining members participating in the plenary meeting express their reasoned disagreement with the recommendation to reject the application for a unitary certificate, that application may be converted in accordance with Article 18a.~~

(*new*) ***Article 17c***

Consultation of the applicant and right to be heard

1. **The rapporteur and co-rapporteurs may, at any stage of the procedure, invite the applicant to submit comments. Any comments received shall be shared with the examining members.**

2. **The rapporteur and co-rapporteurs shall, before transmitting to the examining members any recommendation to reject the application, invite the applicant to submit comments within [2] months. Any comments received shall be transmitted to the examining members.**

3. **Before any decision is taken by the granting office that may adversely affect the applicant, the applicant shall~~, in accordance with national rules and procedures,~~ be given the opportunity to be heard.**

4. **In case of combined applications, any comments received under paragraphs 1 , 2 or 3 shall be transmitted to all members of the network.**

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:~~

~~(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.~~

1. Where the application for a unitary certificate and the product to which it relates meet the conditions laid down in this Regulation, the granting office shall grant the unitary certificate.

2. Where the application for a unitary certificate or the product to which it relates does not meet the conditions laid down in this Regulation, the granting office shall reject the application.

3. When deciding whether to grant the unitary certificate or reject the application for a unitary certificate, the granting office shall take utmost consideration of the recommendation and any related statements of disagreement or comments submitted by examining members in accordance with Articles 17a and 17b.

4. The granting office shall notify the applicant of the decision ~~and, where applicable, of the option of converting its application in accordance with Article 18a~~. [The granting office shall transmit the decision to the network and the managing office.]

~~*(new) Article 18a* *(Article 27 on Conversion to be addressed later)~~

~~***Conversion of the application***~~

~~**1. Where the granting office rejects an application for a unitary certificate, the applicant shall be entitled to request the conversion of the application for a unitary certificate into a centralised application:**~~

~~(a) in case the decision to reject deviates from a recommendation to grant the certificate, where no statements of disagreement regarding that recommendation have been submitted in accordance with Article 17a(3); or~~

~~(b) in case the decision to reject is taken despite a majority of the examining members participating in the plenary meeting having objected the rejection pursuant to Article 17b(5).~~

~~The request for conversion shall be filed with the managing office within [two months] of the rejecting decision having become final. The managing office shall transmit the converted application and a copy of the related file to the competent national authorities of the Member States concerned, which shall decide whether or not to grant national certificates in accordance with Regulation [COM(2023) 231].~~

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 **the relevant requirements set out in** Article 9~~(3)~~, ~~the Office~~ **the rapporteur and co-rapporteurs** shall assess that application on the basis of the conditions laid down in Article 36 of Regulation (EC) No 1901/2006. **The network shall be informed of this assessment.**

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

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

3a. Where the application does not satisfy the relevant requirements set out in Article 9, the granting office shall invite the applicant to take the measures necessary to satisfy those requirements, and shall set a deadline for such compliance.

4. ~~Where the application for an extension of the duration~~ **If the applicant** does not ~~comply with~~ **satisfy** the ~~conditions~~ **relevant requirements** ~~referred to in paragraph 1~~ **set out in**

Article 9 within the deadline referred to in paragraph 3a, the **granting** office shall reject ~~that~~ **the** application **for an extension**.

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.

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For the purposes of the first subparagraph, point (d), the **granting** ~~O~~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

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

   (a) the certificate was granted contrary to Article 3;

   (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.

2. Any person may submit an application or bring an action for a declaration of invalidity of the certificate before the body responsible under national law for the revocation of the corresponding basic patent[9].

Articles 23 to 27 (to be addressed later)

(new) ***Article 28***[10]

Appeals

The decisions of the granting office referred to in Articles 18 and 19 shall be open to appeal before the body competent for such actions under national law of the Member State of the granting office[11].

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[9] The text corresponds to Article 15(2) of Regulation (EC) No 469/2009.
[10] Suggested new Article 28 is meant to replace Articles 28, 29 and 30 of the initial Commission proposal.
[11] Provision inspired by Article 18 of Regulation (EC) No 469/2009.

Article 31 (to be addressed later)

Article 32

Combined applications

~~**An application for a**~~ **A** unitary certificate may be ~~**included in**~~ **applied for as part of** a combined ~~**centralised**~~ application in which the applicant also requests the grant of **one or more** 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.

Articles 34 to 56 (to be addressed later)

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