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NOTE

From:	Presidency
To:	Delegations
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Subject:	Supplementary Protection Certificates (SPCs) - Partial revised text

In view of the Council Working Party on Intellectual Property on 5 September 2025, delegations will find in the Annex a Presidency revised text on a number of articles relating to the institutional set-up and the examination procedure of the SPC proposals.

This partial revised text takes as basis the text of the proposal on unitary SPCs for medicinal products. Changes compared to the Commission proposal (doc. 8869/23) are highlighted in **bold underlined** or in ~~strikethrough~~. The proposed architecture is intended to apply coherently across all four SPC legislative proposals. If approved, the changes will therefore be transposed to the other SPC proposals with the appropriate adaptations.

This partial revised text is to be read in conjunction with the steering note outlining the main amendments and the underlying reasoning for the changes made (WK 10552/2025).

ANNEX

Unitary Supplementary Protection Certificates (unitary SPCs)

Partial revised Presidency text

(based on the text of the proposal for unitary SPCs for medicinal products - 2023/0127(COD))

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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.

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.

(…)[1]

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.

(…)[2]

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.

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[1] The revision of Article 5 will be addressed at a later stage.
[2] The revision of Article 7 will be addressed at a later stage.

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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.

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 place of business 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;

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(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.

(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] 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).

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.

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

Network of competent national authorities

1. Competent national authorities shall cooperate within a network of competent national authorities ("network") to examine applications for unitary certificates and for extensions of the duration of unitary certificates for the purpose of preparing a recommendation[4] 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] To streamline the text, a definition of recommendation could be inserted in Article 2.

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 pending at the moment of the change in participation.**

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

[TBD] shall act as the managing office. It shall provide administrative support to the network by performing, in particular, the following 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 admissibility of applications in accordance with Article 11;**

(d) transmitting to the examining members[5] referred to in Article 17(1) the recommendation, as well as any comments or statements of disagreement regarding the recommendation;

(e) establishing and maintaining the register and database;

(f) transmitting communications to 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 Regulation [COM(2023) 231].

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

Rapporteur and co-rapporteur

For each application, the managing office shall designate from the network one competent national authority as rapporteur and one as co-rapporteur in accordance with the criteria set out in Article 9e. In complex cases, upon request of the rapporteur or the co-rapporteur, an additional co-rapporteur shall be designated by the managing office in accordance with the criteria set out in Article 9e(3).

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

Granting office

The competent national authority designated as rapporteur 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;

[5] 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***

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.

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-rapporteur and, where the conditions under paragraph 1 are not fulfilled, the rapporteur, based on a rotation mechanism[6] and subject to the following conditions:

(a) the competent national authority shall be from a Member State in which the basic patent has unitary effect; and

(b) the rapporteur or the co-rapporteur is a competent national authority not making use of the exemption set out in Article 10(5) of Regulation [COM(2023) 231].

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[6] 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 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.

Article 11

Examination of the admissibility of an application for a unitary certificate

1. **In providing administrative support to the network,** ~~T~~the **managing** office shall assess the following:

   (a) whether the application for a unitary certificate complies with **the formal requirements set out in** 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 **managing** office shall ~~request~~ **invite** 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 **managing** office shall ~~reject~~ **forward** the application ~~for a unitary certificate~~ **and its assessment of admissibility of the application to the granting office.**

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5. **If the granting office finds that the requirements referred to in paragraph 1 are met, it shall inform the managing office for the purpose of publishing the application in accordance with Article 12.**

6. **If the granting office finds that the requirements referred to in paragraph 1 are not met, it shall reject the application for a unitary certificate in accordance with Article 18.**

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 **managing** office shall publish the application in the Register. **The managing office shall also publish the application in the Register, if the granting office, following the procedure in Article 11(5) finds that the requirements refered to in Article 11(1) are met.**

Article 13 (of the Commission proposal)

Examination of the application for a unitary certificate

(deleted)

Article 14

Observations by third parties

1. **Within 3 months after publication of the application in the Register,** ~~A~~**a**ny natural or legal person may submit written observations to the **managing** office concerning the ~~eligibility for supplementary protection~~ **compliance of the application and** of the product to which the application relates~~, in one or more of the Member States in which the basic patent has unitary effect~~ **in accordance with Articles 3(1) 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 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 month from the expiry of the deadline referred to in paragraph 1 or one month from the receipt of the observations, whichever is later.**

Article 15 (of the Commission proposal)

Opposition

(deleted)

(new) ***Article 17***[7]

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, the examination procedure shall also be conducted by those competent national authorities of Member States that are designated in the application in accordance with Article 21(a) of Regulation [COM(2023) 231].**

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

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

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. 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.**

2. **The rapporteur and co-rapporteur(s) shall, within [6] months after publication of the application in the register, prepare a recommendation, to either:**

(a) grant a unitary certificate where the application for a unitary certificate and the product to which it relates comply with 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 this Regulation.

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

3. **The managing office shall transmit the recommendation to the examining members. Any examining member may, within [one] month from the transmission of the recommendation, submit comments or a reasoned statement of disagreement to the managing office. The managing office shall, without undue delay, transmit any comments and any statements of disagreement received to the rapporteur, the co-rapporteur(s) and to the other examining members.**

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4. **If no statements of disagreement are received within the time limit referred to in paragraph 3, 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-rapporteur may revise the 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 recommendation or the reasons for not following the statements of disagreement to the examining members.**

3. **If no further statements of disagreement are submitted from a majority of the examining members within [one] month from the transmission under paragraph 2 the granting office shall proceed to adopt a final decision pursuant to Article 18.**

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

5. **If a majority[8] 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.**

[8] Majority to be defined. Delegations are invited to share their preference.

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

Consultation of the applicant

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

2. Before any decision is taken that may adversely affect the applicant, the applicant shall be invited to submit comments within [2] months. The rapporteur and co-rapporteur may consult the examining members on the comments submitted by the applicant.

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 inform the network and the managing office of the decision.**

(*new*) ***Article 18a***

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 decsion 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).**

2. **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-rapporteur** 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 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].

[9] The text corresponds to Article 15(2) of Regulation (EC) No 469/2009.

(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].

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.

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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.