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NOTE

From:	Presidency
To:	Delegations
No. prev. doc.:	12208/25; 13278/25
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Subject:	Supplementary Protection Certificates (SPCs) Proposal for a Regulation on the Supplementary Protection Certificates for medicinal products (recast) - Partial revised text

In view of the Council Working Party on Intellectual Property on 3 October 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 above-mentioned proposal.

Changes compared to the Commission proposal (doc. 8894/23) are highlighted in **bold underlined** or in ~~strikethrough~~.

This partial revised text is to be read in conjunction with the partial revised text on the proposal for a Regulation on the unitary SPCs (doc. 13278/25) and with the Presidency steering note outlining the main amendments and the underlying reasoning for the changes made (WK 12452/2025).

ANNEX

2023/0130 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on the supplementary protection certificate for medicinal products (recast)

Partial revised Presidency text

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Article 7

Application for a certificate

1. The application for a 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 the basic patent is granted, the application for a certificate shall be lodged within 6 months of the date on which the patent is granted.

3. The application for an extension of the duration may be lodged at the same time when lodging the application for a certificate or when the application for the certificate is pending and the appropriate requirements of Article 8(1), point (d), or Article 8(2), respectively, are fulfilled.

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

Article 8

Content of the application for a certificate

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

(a) a request for the grant of a certificate, stating in particular:

(i) the name**,** ~~and~~ address**, seat or principal 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;

(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 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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(d) where the application for a 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.

1a. A centralised application in accordance with Chapter 3 shall, in addition to the information referred to in paragraph 1, contain the designation of the Member States in which certificates are sought.

(…)[1]

Articles 9 to 19

(will be addressed later)

Chapter III
Centralised procedure for certificates

Article 20

~~Scope of the c~~Centralised applications

1. Where the basic patent is a European patent, including a unitary patent, and the authorisation to place the product on the market has been granted through the centralised procedure under Regulation (EC) No 726/2004 or Regulation (EU) 2019/6, the procedure in this Chapter shall apply.

[1] The revision of paragraphs 2, 3 and 4 of Article 8 will be addressed at a later stage.

2. When the conditions under paragraph 1 are met, the filing of national applications shall be prohibited, in respect of the same product, in those Member States in which that basic patent is in force.

3. A centralised application shall be lodged with the ~~European Union Intellectual Property Office established by Article 2 of Regulation (EU) 2017/1001 ('the Office')~~ **managing office referred to in Article 21b**.

4. Articles 1 to 7 and 13 to 18 shall apply to centralised applications.

5. The centralised application shall be lodged by using a specific application form **and shall contain the information referred to in Article 8(1) and 8(1a)**.

The Commission is empowered to adopt implementing acts laying down rules on the application form to be used to lodge a centralised application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 56.

Article 21
Content of the centralised application
(deleted)

~~The centralised application shall contain the following:~~

~~(a) designation of the Member States in which certificates are sought under the centralised procedure;~~ *(moved to new paragraph (1a) of Article 8)*

~~(b) the information referred to in Article 8(1).~~ *(moved to Article 20(5))*

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(new) ***Article 21a***

Network of competent national authorities[2]

1. **Competent national authorities shall cooperate within a network of competent national authorities ("network") that examines centralised applications and applications for extensions of the duration for the purpose of preparing a recommendation**[3] **on the grant of national certificates or on the rejection of the application in accordance with Article 32 or on the grant or rejection of an extension of the duration, in accordance with Article 33. In case of combined applications referred to in Article 39, the network shall also perform the tasks set out in Regulation [COM(2023) 222].**

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 21b 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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[2] It 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 USPC Regulation. Participation in the network should be voluntary. For centralised and combined applications, the examination within the network should be conducted by all competent national authorities participating in the network. In case of USPC applications, only competent national authorities of the Member States in which the basic patent has unitary effect should take part in the examination procedure in accordance with Article 17(1) of the USPC proposal."

[3] 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 56.**

(new) ***Article 21b***

Managing office

The [EPO/EUIPO] shall act as the managing office. It shall provide procedural support to the network by performing, in particular, the following administrative tasks relating to centralised applications and related applications for extensions of duration established under this Chapter:

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

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

(c) **performing a preliminary assessment of the formal requirements of the applications in accordance with Article 22;**

(d) **transmitting to the network the recommendation, as well as any comments or statements of disagreement regarding the recommendation;**

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(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 39, the managing office shall also perform the tasks set out in [Article 9b of] Regulation [COM(2023) 222].

(new) ***Article 21c***

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 21d.

(new) ***Article 21d (OPTION 1)***

Criteria for the designation of the 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 centralised application, its residence or principal place of business in a designated Member State[4], the competent national authority of that Member State shall be assigned the roles of rapporteur, provided that it participates in the network and that it does not make use of the exemption set out in Article 10(5).

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.

[4] "Designated Member State" as defined in Article 2(9).

3. **The managing office shall, from within the network, designate the co-rapporteurs and, where the conditions under paragraph 1 are not fulfilled, the rapporteur, based on a rotation mechanism[5] that is subject to the requirement that the rapporteur and at least one of the co-rapporteurs are competent national authorities not making use of the exemption set out in Article 10(5).**

4. **In case of combined applications, the rapporteur and one co-rapporteur shall be from Member States in which the basic patent has unitary effect.**

(new) ***Article 21d (OPTION 2)***

Criteria for the designation of the rapporteur and co-rapporteurs

1. **The managing office shall designate the rapporteur and co-rapporteurs based on a rotation mechanism[6] that is subject to the requirement that the rapporteur and at least one of the co-rapporteurs are competent national authorities not making use of the exemption set out in Article 10(5).**

2. **In case of combined applications, the rapporteur and one co-rapporteur shall be from Member States in which the basic patent has unitary effect.**

[5] 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.

[6] See footnote 6.

Article 22

~~Examination of the~~ Admissibility of ~~a centralised~~ applications

1. **In providing administrative support to the network,** ~~T~~the **managing** ~~O~~office shall ~~examine~~ **perform a preliminary assessment of** the following:

   (a) whether the ~~centralised~~ application ~~complies with Article 21~~ **contains the information**[7] **set out in paragraphs (1) and (1a) of Article 8 as regards centralised applications or in Article 33(2) as regards related applications for an extension of the duration of certificates**;

   (b) whether the ~~centralised~~ application complies with Article 7;

   (c) whether the application fee referred to in Article 34(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** ~~O~~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 Office shall reject the application.~~

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[7] Further clarifications could be provided in the recitals that the assessment shall not include any examinations of substantive criteria, such as whether the market authorisation referred to in the application is the first one in accordance with Article 8(1)(a)(iv). Such recital could be worded along the following lines:

"In order to ease the workload and streamline procedures, the managing office should provide administrative support to the network by conducting a preliminary assessment on whether the application contains all the information necessary for the application to be considered to be complete under this Regulation. That preliminary assessment should not include any examination of substantive criteria, such as whether the marketing authorisation referred to in the application is the first one. The managing office should give the applicant the opportunity to rectify any deficiencies. In such cases, the application should only be published after the expiry of the time limit set to rectify the deficiencies".

Article 23

Publication of ~~the centralised~~ application<u>s</u>

<u>The managing office shall publish</u> <u>in the Register</u> ~~If the~~ centralised application<u>s</u> ~~complies with Article 22, or if an~~ **<u>and</u>** application<u>s</u> for an extension of the duration of certificates ~~complies with Article 33(2), the Office shall publish the application, without undue delay, in the Register,~~ **<u>where applicable upon expiry of the deadline set under Article 22(2)</u>**.

Article 24

Examination of the centralised application

(deleted / replaced by new Articles 25a -25d)

Article 25

Observations by third parties

1. Any natural or legal person may submit written observations to the **<u>managing</u>** ~~O~~**<u>o</u>**ffice ~~concerning the eligibility for supplementary protection of~~ **<u>on whether the application and</u>** the product to which ~~the application~~ **<u>it</u>** relates **<u>comply with Articles 3(1) and 6(2)</u>** in one or more of the **<u>designated</u>** Member States ~~designated therein~~.

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 centralised 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[8] and state the grounds on which they are based.

5. **<u>The managing office shall notify the applicant of</u>** ~~A~~**<u>a</u>**ny observations by a third party ~~shall be notified to the applicant~~ **<u>without undue delay</u>**. The applicant may comment on the observations within ~~a time limit set by the Office~~ **<u>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.</u>**

[8] Language regime to clarify once the choice of the managing office has been made.

(new) ***Article 25a***[9]

General principles of the examination procedure

1. **All competent national authorities participating in the network shall take part in the examination procedure in accordance with Articles 25b to 25d.**

2. **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 25c.**

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

4. **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 56.**

(new) ***Article 25b***

Examination by the network

1. **Upon the publication of the centralised application in accordance with Article 23, the managing office shall transmit the application to the network. The managing office shall also, without undue delay, transmit to the network any third party observations and any comments from the applicant received in accordance with Article 25.**

2. **The rapporteur and co-rapporteurs shall, within [6] months of the publication of the application in the register, prepare a recommendation in respect of each designated Member State to either:**

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

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

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[9] Suggested new Articles 25a, 25b, 25c and 25d replace Articles 23, 27, 28 of the initial Commission proposal.

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 network. Any member of the network may, within [three] months of 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 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 managing office shall transmit the recommendation to the competent national authority of each designated Member State, for processing in accordance with Article 32.**

(*new*) ***Article 25c***

Procedure for disagreement

1. **Where one or more statements of disagreements have been submitted in accordance with Article 25b(3), the rapporteur and the co-rapporteurs 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 network.**

3. **If no further statements of disagreement are submitted or supported by a majority of the members of the network within [one] month from the transmission under paragraph 2, the managing office shall transmit the recommendation to the competent national authorities of the designated Member States for processing in accordance with Article 32.**

4. **If a majority of the members of the network submit or support further statements of disagreement within [one] month 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 to the**

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competent national authorities of the designated Member States for processing in accordance with Article 32.

(*new*) ***Article 25d***

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 transmitted to the network.**

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

3. **Before any decision under Article 32 is taken that may adversely affect the applicant, the applicant shall, in accordance with applicable national rules and procedures, be given the opportunity to be heard.**

Article 26

Opposition

(deleted)

Articles 27 – 31

(deleted / replaced by new Articles 21a, 21b, and 25a-25d)

Article 32

~~***National implementation of a centralised examination opinion***~~

Grant of a certificate or rejection of the application in designated Member States

1. ~~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, t~~**T**he **managing** ~~O~~**o**ffice shall transmit the ~~examination opinion~~ **recommendation** and its translations to the competent national authority of each designated Member State.

1a. **Member States can inform the managing office if, by way of derogation, no translation of the recommendations is required into their national languages. The derogation shall continue to apply until the Member State informs otherwise.**

2. ~~In respect of a centralised application, where a positive examination opinion has been issued for one or more designated Member State, the competent national authority of each of those Member States shall grant a certificate in accordance with applicable national rules and procedures.~~ **The competent national authority of each designated Member State shall decide to:**

(a) grant the certificate, where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation;

(b) reject the application, where the application for a certificate or the product to which it relates do not meet the conditions laid down in this Regulation.

When deciding whether to grant the certificate or reject the application, the competent national authorities shall take utmost consideration of the recommendation of the network.

3. ~~By way of derogation from paragraph 2, a Member State may decide not to grant a certificate, where material circumstances, in that Member State, have changed since the filing of the centralised application in respect of one or more of the conditions laid down in Article 15(1), points (b) or (c), or Article 14, first paragraph, point (d). In such a case that Member State shall reject the application insofar as that Member State is concerned.~~

4. A certificate granted by a competent national authority under this Article shall be subject to Articles 4, 5, 11 and 12 to 19, and to the applicable national legislation.

5. ~~Where a negative examination opinion has been issued for one or more designated Member State, the competent national authority of each of those Member States shall issue a rejection decision according to its applicable national rules and procedures.~~

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Article 33

Centralised application for an extension of the duration of certificates

1. Where certificates for a given medicinal product have been granted through the centralised procedure, their holder may request an extension of the duration of those certificates by filing a centralised application for an extension of the duration of those certificates with the **managing ~~O~~o**ffice. That centralised application shall specify the designation of the Member States for which the extension is requested.

2. The centralised application for an extension of the duration of certificates shall be filed in accordance with Article 7(3) and (4), Article 8(1), **(1a),** point (d), Article 8(2), (3) and (4).

3. Articles 10, 11 and 17 shall apply, whereby references to 'the authority referred to in Article 9(1)' shall be understood as references to the **managing ~~O~~o**ffice.

4. ~~Third parties may also submit observations in respect of a centralised application for an extension of the duration of certificates.~~

Articles 34 to 38
(will be addressed later)

Article 39

Combined applications

1. A centralised application may ~~also~~ include a request for the grant of a unitary certificate, as defined in Regulation [COM(2023) 222][10] ('combined application').

2. The combined application shall undergo a single ~~centralised~~ examination procedure**, according to the rules set out in this Regulation and Regulation [COM(2023) 222]**~~, as well as a single opposition or appeal procedure, where it has been filed against an opinion or decision in respect of both the centralised application and the unitary certificate application~~.

[10] Regulation of the European Parliament and of the Council concerning the unitary supplementary protection certificate for medicinal products [COM(2023) 222].

3. The Member States for which the basic patent has unitary effect shall not be designated in the combined application for the parallel grant of national certificates. Any designation, in the combined application, of a Member State for which the basic patent has unitary effect shall be disregarded for the purpose of the examination of the combined application.

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