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NOTE

From:	General Secretariat of the Council
To:	Delegations
N° prev. doc.:	12208/25, 13278/25, 13282/25, WK 12452/2025
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Subject:	Supplementary Protection Certificates (SPCs) - Informal comparative table

With a view to facilitating the discussions at the meeting of the Working Party on Intellectual Property on 3 October 2025, delegations will find attached an informal compartive table of the partial Presidency revised texts of the SPC proposals set out in documents 13278/25 and 13282/25.

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Unitary Supplementary Protection Certificates (unitary SPCs) - doc. 13278/25	**Supplementary Protection Certificate for medicinal products (recast) – doc. 13282/25**
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.	

Unitary Supplementary Protection Certificates (unitary SPCs) - doc. 13278/25	Supplementary Protection Certificate for medicinal products (recast) – doc. 13282/25
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 certifcate[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.	
Article 7	
The unitary certificate as an object of property[2]	

[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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Unitary Supplementary Protection Certificates (unitary SPCs) - doc. 13278/25	Supplementary Protection Certificate for medicinal products (recast) – doc. 13282/25
Article 10	*Article 20*
Lodging of an application for a unitary certificate	***~~Scope of the~~ eCentralised 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.
	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.
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.	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 8	*Article 7*
Application for a unitary certificate	***Application for a 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.	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.

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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.	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 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.	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 unitary certificate already granted shall be lodged not later than 2 years before the expiry of the unitary certificate.	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 9	*Article 8*
Content of the application for a unitary certificate	***Content of the application for a certificate***
1. The application for a unitary certificate shall contain the following:	1. The application for a certificate shall contain the following:
(a) a request for the grant of a unitary certificate, stating the following information:	(a) a request for the grant of a certificate, stating in particular:
(i) the name, address, seat or ~~**primary**~~**principal** place of business of the applicant;	(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;	(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;	(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;	(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[3] of the European Parliament and of the Council or Article 35 of Regulation (EU) 2019/6;	(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[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.	(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:	(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;	(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.	(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.

[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).

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	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.
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.	(…)[4]
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]
4. The applications referred to in this Article shall be filed by using specific application forms.	(…)[4]
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.	

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

Unitary Supplementary Protection Certificates (unitary SPCs) - doc. 13278/25	Supplementary Protection Certificate for medicinal products (recast) – doc. 13282/25
(new) ***Article 9a***	*(new)* ***Article 21a***
Network of competent national authorities[5]	***Network of competent national authorities***[6]
1. Competent national authorities shall cooperate within a network of competent national authorities ("network") ~~to~~ that examines applications for unitary certificates and for extensions of the duration of unitary certificates for the purpose of preparing a recommendation[7] **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].**	**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**[7] **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].**

[5] 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."

[6] 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."

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

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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.	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.	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.	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.
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.	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.	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.	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.

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(new) ***Article 9b***	*(new)* ***Article 21b***
Managing office	***Managing office***
The [European Patent Office] shall act as the managing office. It shall provide ~~administrative~~ 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:	**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;	**(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;	**(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 ~~admissibility~~ formal requirements of the applications in accordance with Article 11;	**(c) performing a preliminary assessment of the formal requirements of the applications in accordance with Article 22;**
(d) transmitting to the examining members[8] referred to in Article 17(1) the recommendation, as well as any comments or statements of disagreement regarding the recommendation;	**(d) transmitting to the network the recommendation, as well as any comments or statements of disagreement regarding the recommendation;**
(e) establishing and maintaining the register and database;	**(e) establishing and maintaining the register and database;**
(f) transmitting communications to the applicants, certificate holders and third parties;	**(f) transmitting communications to the applicants, certificate holders and third parties;**
(g) collecting and distributing fees.	**(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].	**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].**

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

Unitary Supplementary Protection Certificates (unitary SPCs) - doc. 13278/25	Supplementary Protection Certificate for medicinal products (recast) – doc. 13282/25
(new) ***Article 9c***	*(new)* ***Article 21c***
Rapporteur and co-rapporteurs	***Rapporteur and co-rapporteurs***
For each application, the managing office shall designate from the network one competent national authority as rapporteur and ~~one~~ two as co-rapporteurs 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).~~	**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 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;	
(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)***	*(new)* ***Article 21d (OPTION 1)***
Criteria for the designation of the granting office, rapporteur and co-rapporteurs	***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 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	**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**

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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].	**State[9], 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.	**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[10] ~~and~~ that is subject to the following conditions:	**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[10] that is subject to the requirement that**
(a) ~~the competent national authority~~ the rapporteur and the two co-rapporteurs shall be from a Member State in which the basic patent has unitary effect; and	**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).**
(b) the rapporteur ~~or the~~ and at least one co-rapporteur ~~is a competent national authority~~ 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].	**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.**

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

[10] 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.

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(new) Article 9e (OPTION 2)	*(new)* ***Article 21d (OPTION 2)***
Criteria for the designation of the granting office, rapporteur and co-rapporteurs	***Criteria for the designation of the 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[11] that is subject to the following conditions:	**1. The managing office shall designate the rapporteur and co-rapporteurs based on a rotation mechanism[11] that is subject to the requirement that**
(a) the rapporteur and the two co-rapporteurs shall be from Member States in which the basic patent has unitary effect;	**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).**
(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].	**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.**
Article 11	*Article 22*
~~Examination of the a~~Admissibility of ~~an~~ applications ~~for a unitary certificate~~	***~~Examination of the~~ Admissibility of ~~a centralised~~ applications***
1. **In providing administrative support to the network,** ~~T~~the **managing** office shall ~~examine~~ **perform a preliminary assessment of** the following:	1. **In providing administrative support to the network,** ~~T~~the **managing** ~~O~~office shall ~~examine~~ **perform a preliminary assessment of** the following:

[11] See footnote 7.

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(a) whether the application for a unitary certificate ~~complies with~~ **contains the ~~formal requirements~~ information**[12] **set out in** Article 9;	(a) whether the ~~centralised~~ application ~~complies with Article 21~~ **contains the information**[13] **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 application complies with Article 8;	(b) whether the ~~centralised~~ application complies with Article 7;
(c) whether the application fee referred to in Article 31(1) has been paid within the prescribed period.	(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** office shall ~~request~~ **invite** the applicant to take the measures necessary to satisfy those requirements, and shall set a deadline for such compliance.	2. Where the ~~centralised~~ application does not satisfy the requirements referred to in paragraph 1, the **managing** ~~O~~**o**ffice 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.~~	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.~~

[12] 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 9(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".

[13] 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".

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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~~**.	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~~.
~~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	*Article 23*
Publication of ***~~the~~*** ***applications***	***Publication of*** ***~~the centralised~~*** ***applications***
~~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~~** in the Register **applications for a unitary certificate and applications for an extension of the duration of certificates, where applicable upon expiry of the deadline set under Article 11(2).** **~~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.~~**	**The managing office shall publish in the Register** ~~If the~~ centralised application**s** ~~complies with Article 22, or if an~~ **and** application**s** 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,~~ **where applicable upon expiry of the deadline set under Article 22(2)**.

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Article 13 (of the Commission proposal)	*Article 24*
Examination of the application for a unitary certificate	***Examination of the centralised application***
(deleted / replaced by Articles 17, 17a to 17c)	*(deleted / replaced by new Articles 25a -25d)*
Article 14	*Article 25*
Observations by third parties	***Observations by third parties***
1. ~~**Within 3 months after publication of the application in the Register,**~~ Any natural or legal person may submit written observations to the **managing** office ~~concerning the eligibility for supplementary protection **compliance of**~~ **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 **in accordance**~~ **comply with Articles 3(1) and 6(2)**.	1. Any natural or legal person may submit written observations to the **managing** ~~O~~**o**ffice ~~concerning the eligibility for supplementary protection of~~ **on whether the application and** the product to which ~~the application~~ **it** relates **comply with Articles 3(1) and 6(2)** in one or more of the **designated** Member States ~~designated therein~~.
2. A natural or legal person that has submitted written observations in accordance with paragraph 1 shall not be a party to the proceedings.	2. A natural or legal person that has submitted the written observations in accordance with paragraph 1 shall not be a party to the proceedings.
3. Third party observations shall be submitted within 3 months after publication of the application in the Register.	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 and state the grounds on which they are based.	4. Any observations by a third party shall be submitted in writing in one of the official languages of the Union[14] 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.**	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.**

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

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Article 15 (of the Commission proposal)	*Article 26*
Opposition	***Opposition***
(deleted)	*(deleted)*
(new) ***Article 17***[15]	*(new)* ***Article 25a***[16]
General principles of the examination procedure	***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").	**1. All competent national authorities participating in the network shall take part in the examination procedure in accordance with Articles 25b to 25d.**
2. In case of a combined application referred to in Article 32, ~~the examination procedure shall also be conducted by those~~ all competent national authorities in the network shall be examining members ~~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.	**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.**
4. The network shall endeavour to reach consensus when examining the applications.	**3. 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.	**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.**

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

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

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(new) ***Article 17a***	*(new)* ***Article 25b***
Examination by the network	***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.	**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 after publication of the application in the register, prepare a recommendation, to either:	**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 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	**(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 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.	**(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.**
When preparing the recommendation, they shall consider any third party observations submitted and any related comments received from the applicant.	**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~~ three] months 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 to the network any comments and any statements of disagreement received ~~to the rapporteur, the co-rapporteur(s) and to the other examining members~~.	**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.**

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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.	**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 17b***	(*new*) ***Article 25c***
Procedure for disagreement	***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 recommendation based on the statements. Otherwise, they shall provide reasons for not following the statements of 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 examining members.	**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 ~~from~~ or supported by 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.	**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 examining members 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 granting office shall proceed to adopt a final decision pursuant to Article 18.	**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 competent national authorities of the designated Member States for processing in accordance with Article 32.**

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5. <u>If a majority[17] 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.</u>	
(*new*) ***<u>Article 17c</u>***	(*new*) ***<u>Article 25d</u>***
<u>Consultation of the applicant and right to be heard</u>	***<u>Consultation of the applicant and right to be heard</u>***
<u>1. The rapporteur and co-rapporteurs may, at any stage of the procedure, invite the applicant to submit comments</u> ~~at any stage of the procedure~~<u>. Any comments received shall be shared with the examining members.</u>	**<u>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.</u>**
<u>2.</u> ~~Before any decision is taken that may adversely affect the applicant,~~ <u>The rapporteur and co-rapporteurs shall, before transmitting to the examining members any recommendation to reject the application, invite the applicant</u> ~~shall be invited~~ <u>to submit comments within [2] months.</u> ~~The rapporteur and the co-rapporteur may consult the examining members on the comments submitted by the applicant.~~ <u>Any comments received shall be transmitted to the examining members.</u>	**<u>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.</u>**
<u>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.</u>	**<u>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.</u>**
<u>4. In case of combined applications, any comments received under paragraphs 1 , 2 or 3 shall be transmitted to all members of the network.</u>	

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

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Article 18	*Article 32*
Grant of a unitary certificate or rejection of the application for a unitary certificate	~~***National implementation of a centralised examination opinion***~~ ***Grant of a certificate or rejection of the application in designated Member States***
~~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. ~~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:**
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.	**(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;**
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.	**(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.**

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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.	**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. 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~~ transmit the decision to the network and the managing office ~~of the decision~~.	
	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.~~
(*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:	

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(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[18]	*Article 33*
Grant of an extension of the duration of a unitary certificate	***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.
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**	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).

[18] Please note: To facilitate the comparison of the texts, Article 19(2) of the unitary SPC text has been moved down to be displayed next to the corresponding provision of Article 33(4) of the recast proposal.

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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.**	
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.**	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. ~~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**.	
2. ~~Third parties may also submit observations in respect of an application for an extension of the duration of a unitary certificate.~~	4. ~~Third parties may also submit observations in respect of a centralised application for an extension of the duration of certificates.~~
Article 22	*Article 15*
Invalidity of the unitary certificate	***Invalidity of the certificate***
1. The unitary certificate shall be invalid in any of the following events:	1. The certificate shall be invalid in any of the following events:
(a) the certificate was granted contrary to Article 3;	(a) the certificate was granted contrary to Article 3;
(b) the basic patent has lapsed before its lawful term expires;	(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.	(c) the basic patent is revoked or limited to the extent that the product for which the 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.

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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[19].	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, or before a competent court of a Member State.
(new) ***Article 28***[20]	
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[21].	
Article 32	*Article 39*
Combined applications	***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.	1. A centralised application may ~~also~~ include a request for the grant of a unitary certificate, as defined in Regulation [COM(2023) 222][22] ('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~~

[19] The text corresponds to Article 15(2) of Regulation (EC) No 469/2009.
[20] Suggested new Article 28 is meant to replace Articles 28, 29 and 30 of the initial Commission proposal.
[21] Provision inspired by Article 18 of Regulation (EC) No 469/2009.
[22] Regulation of the European Parliament and of the Council concerning the unitary supplementary protection certificate for medicinal products [COM(2023) 222].

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	~~appeal procedure, where it has been filed against an opinion or decision in respect of both the centralised application and the unitary certificate application~~.
	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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