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**NOTE**

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| From: | Presidency |
| To: | Delegations |
| N° prev. doc.: | 12208/25; 13278/25; 13282/25 |
| N° Cion doc.: | 8851/23, 8869/23, 8887/23, 8894/23 |
| Subject: | Supplementary Protection Certificate (SPCs)<br>- Presidency steering note |

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 a steering note from the Presidency accompanying the partial revised text of the SPC proposals set out in documents 13278/25 and 13282/25.

**Annex to WK 12452/2025**

# Supplementary Protection Certificate proposals

## Steering note accompanying the new partially revised Presidency texts concerning the USPC proposal for medicinal products and the recast proposal for medicinal products (doc. 13278/25 and doc. 13282/25)

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## I. Introduction

The Danish Presidency would like to thank delegations for their valuable input at the last IP Working Party on 5 September, as well as for the written comments submitted thereafter. Based on the discussions and comments received, the Danish Presidency has amended the partial revised Presidency text concerning the **unitary SPC proposal for medicinal product** – please see doc. **13278/25**.

In order to keep the package character of the four SPC proposals and following a call from some of the non-UPC Member State not to overlook centralised and combined SPC applications, the **recast proposal on medicinal products** has also been reviewed and amended (doc. **13282/25**, incorporating changes introduced in the USPC proposal, along with the necessary adjustments to render the Regulation operable.

The revised texts contain a selected number of articles, focusing on the same provisions as those in the previous Presidency text.

The Presidency is looking to **discuss both partially revised texts** with delegations at the upcoming IP Working Party on Friday, 3 October 2025.

This accompanying note provides an overview of the changes that have been made to both proposals, grouping together the corresponding articles. Changes made to the USPC proposal are presented first, followed by those made in the recast proposal. The order of the articles follows that of the USPC proposal.

Several **key questions** concerning **the managing office** and the **granting and rejection of SPCs** remain unresolved. A number of delegations indicated they would have a preference for the EPO to be designated as the managing office. Some delegations, in a position paper (WK 10989/2025) and in the written comments (see WK 11385/2025), asked for the network to be embedded in the EPO. On that basis, we would invite delegations to reflect on a number of questions when commenting on the revised Presidency texts. This includes especially choices on the managing office and the setup and role of the network:

- Which organisation should be assigned the role of the managing office?
- What role should the managing office assume; merely administrative or should it be involved in the substantive examination?
- Should the managing office be the same for centralised applications and unitary SPCs?
- Would delegations be able to accept a network as in the current compromise text, i.e., an independent entity not attached to a specific body?

- Should the network's opinion/recommendation be binding or non-binding? Should the answer to this question be the same for the recast and unitary SPC proposals?
- If the managing office should be a body set up outside the legal framework of EU law, overseeing both the granting and rejection of unitary SPC applications, delegations are encouraged to reflect on how such an intuitional setup could be implemented.
- Delegations are invited to present views on a language system should the EPO be made the managing office, as well as on a separate Regulation to be adopted by unanimity.

These and other, more specific questions can be found in part II of this note, and delegations are kindly asked to **consider and address** them at the upcoming Working Party meeting on 3 October. In addition, delegations are invited to express their **general views on the concerned article**. Where possible, delegations are encouraged to provide **specific drafting suggestions**.

## II. Overview of the textual changes and related questions

### USPC: Article 3 – Conditions for obtaining a unitary certificate, Article 4 – Scope of protection, Article 6 – Entitlement to the unitary certificate / Recast: Article 20 – Centralised applications

These are introductory articles to which **no changes** have been made in the **USPC proposal** since the previous version.

In the **recast proposal**, Article 20 corresponds to the above-mentioned provisions in the USPC proposal. Only **minor linguistic changes** have been applied, such as in the title and in references to the EUIPO, which have been replaced by 'managing office'. The question of which body should ultimately assume this role for centralised applications remains open and is put for discussion of delegations under the article relating to the managing office.

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### USPC: Article 8 – Application for a unitary certificate / Recast: Article 7 – Application for a certificate

**Minor linguistic** changes have been made **in both Regulations** to clarify that SPC applications may be lodged either by the holder of the basic patent or by their successor in title.

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### USPC: Article 9 – Content of the application for a unitary certificate / Recast: (new) Article 8– Content of the application for a certificate

**No changes** have been made to the **USPC Regulation, except an editorial adjustment**.

In the **recast proposal**, the provision concerning the content of the centralised application was set out in Article 21. To streamline the text and for ease of cross-referencing, Article 21 has been deleted, and its content is now reflected in **Article 8**, where a new paragraph 1a has been added. This paragraph states that the centralised application should contain information on the

Member States for which protection is sought ("designated Member State") – an element not applicable to the USPC.

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## USPC: Article 9a / Recast: (new) Article 21a – Network of competent national authorities

In the **USPC proposal, no changes have been made** in this article for now. However, a recital has been added to clarify that there is only one network that convenes in different constellations, depending on whether it is assessing an application for a unitary SPC or a centralised or combined SPC application.

In the **recast proposal**, the text from the USPC proposal has been **carried over** with relevant amendments, e.g., replacing 'unitary application' with 'centralised application'.

**The timeframe** for changes to the participation of competent national authorities in the network is currently proposed to take effect after six months **in both proposals**. This timeframe **could be amended,** as any of the other timeframes in the proposals.

An open question remains as to whether the network should be embedded within the structures of the managing office or operate as a floating entity, i.e., not be embedded within an existing organisation but functioning as an independent network of Member States. This question will be revisited when covering the article concerning the *tasks* of the network further below.

***Question:*** *Delegations are kindly requested to confirm whether they can support the six-month timeframe currently suggested for changes to the participation of competent national authorities in the network to take effect.*

## USPC: Article 9b / Recast: (new) Article 21b - Managing Office

In the **USPC proposal**, it is now stated that the **EPO will be acting as managing office**, alongside some **minor linguistic changes**.

Assigning the role of the managing office to the EPO reflects the preference expressed by several delegations. Under the Presidency revised text, the role of the EPO is purely procedural, e.g., receiving applications and conducting a preliminary assessment of the formal requirements. This preliminary assessment would be clerical in nature, e.g., checking that all relevant information has been completed and attached. It would not involve any form of substantive examination of the application.

A question linked to this article concerns the scope of the managing office's tasks. At the last Working Party, some delegations argued that the managing office should be given a more substantive role in the process, including issuing and granting USPCs. This will be addressed under the article related to the granting office further below.

In the **recast proposal**, the wording from the UPSC proposal has been **carried over** with the necessary operability amendments.

***Question:*** *Delegations are invited to indicate whether they could agree with the EPO being assigned the role of the managing office for USPCs, as well as for centralised and combined SPC applications.*

*Considering that the EPO is a non-EU body, delegations are encouraged to reflect, preferably in concrete drafting suggestions, how such role could be enacted.*

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## USPC: Article 9c / Recast: (new) Article 21c – Rapporteur and co-rapporteurs

In the **USPC proposal** the number of co-rapporteurs has been **increased from two to three**. This change addresses the concerns raised by some delegations regarding situations in which the rapporteur and co-rapporteur disagree on whether to grant or reject an SPC application. With three parties involved, decisions can be made by majority.

This article has been **carried over** into the **recast proposal** with the amendments required to make it operable.

## USPC: Article 9d – Granting Office

In the **USPC proposal**, this article has **not been amended for the time being** due to the fact that, at the most recent IP Working Party, there did not appear to be a clear majority in favour of any of the options regarding which body should be assigned the role of the granting office. This question therefore needs to be revisited.

At the latest Working Party, several delegations expressed support for designating the EPO as the granting office for USPCs. They argued that this approach would avoid the decision being classified as an EU act, thereby ensuring that any invalidity actions would fall under the jurisdiction of the UPC.

Other delegations have favoured assigning the responsibility for granting and rejecting USPCs to the EUIPO, in line with the joint proposal of the Polish and Danish Presidencies (doc. 10909/25).

A number of delegations have also supported the Presidency's latest proposal (doc. 12208/25), under which a decision on a USPC would be taken by a single Member State and would, pursuant to the USPC Regulation, acquire SPC protection across the remaining UPC contracting countries. The legal services of both the Council and the Commission have confirmed that this would constitute a legally sound solution, compliant with Union law.

There is **no equivalent article** in the **recast proposal** as the granting and rejection of centralised SPC applications is conducted by the individual Member States for which protection is sought ("designated Member States").

***Question:*** *With regard to the USPC proposal, delegations are invited indicate whether they have a preference regarding which body should be assigned the task of granting USPCs, as well as combined applications.*

## USPC: Article 9e – Criteria for the designation of the granting office, rapporteur and co-rapporteur / Recast (new) Article 21d – Criteria for the designation of the rapporteur and co-rapporteurs

At the most recent IP Working Party, a number of delegations expressed a wish to **amend the criteria for designating the rapporteur** in the **USPC proposal**, favouring a mechanism based solely on a rotation system over the Presidency's proposal based primarily on the applicant's residence or principal place of business.

To address the comments made, **two options** are being put forward for discussion for **both the USPC and the recast proposal**, with the latter slightly amended to reflect the different structure of the centralised process. In the **recast proposal**, this appears as a new article.

**Option 1 – The Presidency's previous proposal with minor amendments**

- In the **USPC proposal**, the rapporteur would be designated according to the applicant's residence or principal place of business. The co-rapporteur would continue to be selected via a rotation system, with the number of co-rapporteurs increased from two to three. The rapporteur and at least one of the co-rapporteurs should be from the Member States that conduct substantive examinations. For combined applications, one co-rapporteur should be from a Member State for which a centralised SPC application is sought.
- In the **recast proposal**, the same approach would apply, with the exception that it would only apply to the rapporteur and co-rapporteurs (but not, as in the USPC proposal, also to the granting office), as the granting would be carried out by those Member States for which a centralised SPC is sought.

**Option 2 (new) – Rotation system**

- In the **USPC proposal**, both the rapporteur and the co-rapporteurs would be designated on the basis of a rotation system. The remainder of the article would mirror option 1: the rapporteur and at least one of the co-rapporteurs should be from Member States that conduct substantive examinations. For combined applications, one co-rapporteur should be from a Member State for which a centralised SPC application is sought. The details of the rotation mechanism could be further elaborated in an implementing act.

- The wording in the **recast proposal** is largely identical, with relevant adjustments made to reflect the centralised procedure.

***Question:*** *Delegations are invited to indicate which option they prefer for both Regulations.*

## USPC: Article 8 – Application for a unitary certificate / Recast: Article 7 – Application for a certificate

In both the **USPC proposal** and the **recast proposal**, **wording has been added** to clarify that an application for a certificate can be lodged by the holder of the basic patent or by their successor in title.

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## USPC: Article 11 / Recast: Article 22 – Admissibility of applications

In both the **USPC proposal** and the **recast proposal**, both the **title and the text of the article have been amended** to clarify that the preliminary assessment of the application by the managing office is just an act of administrative support to check the completeness of the application. To that end, e.g., the phrase 'examination of…' has been removed to clarify that the admissibility assessment does not constitute an examination of substantive elements.

In **both Regulations**, **a recital will be added** to explain the nature of the admissibility assessment, i.e., that it does not involve any substantive examination.

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## USPC: Article 12 / Recast: Article 23 – Publication of applications

The **USPC proposal** has been **reworded** to state that the managing office shall publish USPC applications and applications for extensions for paediatric pharmaceuticals in the register after the expiry of the deadline that has to be granted to the applicant for correcting or completing the application, if the initial application has failed to meet the formal admissibility requirements.

This wording has been **carried over** into the **recast proposal**, with the necessary amendments to ensure operability.

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## USPC: Article 13 – Examination of the application for a unitary certificate / Recast: Article 24 – Examination of the centralised application

**Deleted** in the **USPC proposal**, as in the previous version (as it has been replaced by Articles 17, 17a-17c).

Now also **deleted** in the **recast proposal** / **replaced by Articles 25a-25d**.

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## USPC: Article 14 / Recast: Article 25 – Observations by third parties

**No changes** have been made to the **USPC proposal** at this stage.

However, once a final decision is taken regarding which organisation will serve as the managing office, the wording concerning the **languages** in which applications may be submitted will have to be amended. For example, if the EPO is chosen, the permissible languages for submitting applications would be English, German, and French.

Once the language regime is established, a follow-up question arises as to whether **third party observations** should be **automatically translated** into the national languages of other Member States with the possibility for Member States to opt-out from this translation requirement, or whether Member States should actively request translations via an opt-in system.

At the latest Working Party, some delegations expressed a preference for **longer timeframes** in relation to the examination process. There is also scope to amend other timeframes, including those applicable to third-party observations and related procedures.

The **recast proposal** has been **reworded** to reflect the USPC proposal, with the necessary operability adaptations.

***Questions:***

*1.) Delegations are invited to indicate whether they would prefer third-party observations to be translated into their national languages, either through an opt-in or opt-out model.*

*2.) Furthermore, delegations are invited to express their preference regarding the timeframe for submitting third-party observations.*

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## USPC: Article 15 / Recast: Article 26 – Opposition

**Deleted** in the **USPC proposal**, as in the previous version.

Now also **deleted** in the **recast proposal**.

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## USPC: Article 17 / Recast: (new) Article 25a – General principles of the examination procedure

**No major changes** have been made to the **USPC proposal**, only a consequential amendment adjusting the provision on combined applications (Article 17(2)) to the composition of the network proposed for the examination of centralised applications, i.e., all members of the network participating in the examination (see Article 25a(1) of the recast proposal).

This is a **new article** in the **recast proposal**, where the wording from the USPC Regulation has been **carried over**, with the necessary operability amendments.

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## USPC: Article 17a / Recast: (new) Article 25b - Examination by the network

In the **USPC proposal**, besides some linguistic adjustments, the **only change** made thus far **concerns the timeframe** for examining members to submit comments following receipt of the rapporteur's recommendation. This has been **extended from one month to three months**, reflecting feedback from some delegations at the last IP Working Party. In addition, **minor linguistic adjustments** have been made.

In the **recast proposal**, this is a new article, with the wording **carried over** from the USPC proposal and adapted for operability.

However, **two key questions** remain open, both linked to the articles concerning the managing office:

- Should the network's decision to the issuing body for USPCs **be binding**?
- Should the **network be embedded within the EPO**, or should it operate as a **floating entity**?

As mentioned above, some delegations have expressed a preference for designating the EPO as the granting office for USPCs, while others favour assigning the EUIPO the responsibility for granting and rejecting USPCs. Others have supported the Presidency's previous proposal whereby a decision on an USPC would be taken by a Member State and would, pursuant to the USPC Regulation, acquire legal effect in the remaining UPC contracting countries.

If the EPO is tasked with granting USPCs/rejecting USPC applications, one way to regulate this could be to make the **network's recommendation binding on the EPO**. This would effectively leave the actual **decision-making power** in the hands of the **Member States that participate in the network**. Some delegations have raised concerns that a binding opinion from a network of Member States could be interpreted as an EU act, thereby making it appealable before the CJEU rather than UPC, which would contradict the Coreper mandate.

In the **recast proposal,** the network's opinion **would remain non-binding**, thereby granting Member States the discretion to reject a centralised application. While it is anticipated that Member States would generally follow the network's opinion, they would retain the option to overrule it for their territory.

Once a decision is reached on these questions, the structure under which the network operates will need to be amended accordingly in this and other related articles.

***Questions:***

*1.) Delegations are invited to express their views on whether they support the proposed extension of the timeframe for members of the network to submit comments.*

*2.) Delegations are encouraged to indicate their position on whether the network's decision should be binding for USPC applications, provided that the EPO is chosen as the granting authority.*

*3.) Delegations are also asked to state their preference on whether the network should be embedded within the EPO or operate as a floating entity.*

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*To be able to assess potential/any legal issues arising from Union law, delegations are encouraged to be as specific as possible, including any drafting suggestions on how an institutional setup could be structured in detail, with a view to ensuring that invalidity actions would fall under the jurisdiction of the UPC, in line with the Coreper mandate.*

*Delegations are invited to indicate concrete suggestions on the governance of the system in order to allow for an assessment of potential legal issues arising from Union law.*

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## USPC: Article 17b / Recast: (new) Article 25c – Procedure for disagreement

Only **minor linguistic** changes have been made to the **USPC proposal**. However, the **timeframe for the second round of submitting statements** of disagreement on a given recommendation – or for supporting previously submitted statements – is currently set at one month, though this **could potentially be extended**.

In the **recast proposal**, this is a new article, adopting the same wording as the USPC proposal, with the necessary operability amendments.

***Question:*** *Delegations are invited to indicate whether they can support the concept of the article and the current one-month timeframe.*

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## USPC: Article 17c / Recast: (new) Article 25d – Consultation of the applicant and the right to be heard

In the **USPC proposal**, the article has been amended to include the provision on 'the **right to be heard**'. The second paragraph introduces the applicant's right to be heard **before any recommendation to reject** an application is submitted to the network.

A new paragraph 3 has been introduced in both texts with general provision on **the right to be heard** before a **decision taken by the granting office**.

A timeframe of **two months** has been set for applicants to submit comments prior to the rejection of their application. This timeframe could **potentially be revised**.

This is a new article in the **recast proposal**. The wording from the USPC has been **carried over**, with the necessary operability amendments relevant to the recast framework. The timeframe for applicant to be heard is governed by national rules in the Member State for which an SPC is sought.

***Question:*** *Delegations are invited to indicate if they agree with the amended concept of the article and the two-month timeframe set out in the USPC proposal.*

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## USPC: Article 18 – Grant of a unitary certificate or rejection of the application for a unitary certificate / Recast: Article 32 – National implementation of a centralised examination recommendation

In the **USPC proposal,** only **minor linguistic changes** have been made for now.

In the **recast proposal**, the **wording differs** from that of the USPC proposal, as the granting of centralised applications is carried out by those Member States for which an SPC is sought.

The title has been amended from '…centralised examination opinion' to '…centralised examination recommendation'. Overall, the article has been **reworded to streamline and simplify the language.** It now includes a provision allowing Member States to opt-out of receiving translations from the original language of an SPC application into their national languages. This opt-out would remain in effect until the Member States inform the managing office of a change, meaning there is no need to indicate this preference for each application.

***Question:*** *With regard to the recast proposal, delegations are invited to indicate whether they can support the proposed opt-out model for translations, including for third party observations.*

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## USPC: Article 18a – Conversion of the application

This article applies exclusively to **USPC applications**. At the latest Working Party meeting, some delegations noted that the **conversion mechanism was not clearly defined**.

***Question:*** *Delegations are invited to share their views on the conversion mechanism more broadly.*

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## USPC: Article 19 – Grant of an extension of the duration of a unitary certificate / Recast: Article 33 – Centralised application for an extension of the duration of certificates

A **minor amendment** has been made to the **USPC proposal** to reflect that there are now two co-rapporteurs.

Only minor adjustments in the recast proposal.

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## USPC: Article 22 – Invalidity of the unitary certificate

**No changes** have been made to the **USPC proposal**. Not yet drafted for recast.

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## USPC: Article 28 – Appeals

**No changes** have been made to the **USPC proposal.** Not yet drafted for recast

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## USPC: Article 32 – Combined applications

**Minor linguistic changes** have been made to the **USPC proposal** to clarify that an USPC may be applied for as part of a centralised application.

In the **recast proposal**, similar **minor linguistic amendments** have been introduced.

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