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NOTE

From:	Presidency
To:	Delegations
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Subject:	Supplementary Protection Certificate (SPCs) Register and Database - Presidency steering note

Delegations will find attached a steering note from the Presidency in relation to the SPCs Register and Database to facilitate the discussion during the meeting of the Working Party on Intellectual Property on 8 May 2025.

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Presidency note on the SPC Register and Database

I. Introduction

At the meetings of the Working Party on Intellectual Property on 14 and 31 January 2025, the Polish Presidency led discussions on the structure of the SPC Register and Database. Three options A, B, and C were presented[1], accompanied by a set of guiding questions[2] to facilitate further deliberations. The objective was to clarify and address the expectations of Member States regarding the scope and accessibility of data within the Register and Database.

Drawing on the valuable feedback provided by delegations during the two Working Party meetings, as well as their written contributions (WK 601/2025, WK 2110/2025), the Presidency would like to present in section II of this note a summary outlining the principal issues raised during the discussions and, where a broad consensus has emerged, propose corresponding drafting suggestions.

This paper focuses on the Commission proposal for a Regulation on supplementary protection certificates (SPCs) for medicinal products (recast), COM(2023)231, which provides that the Register established under this proposal shall also be used to publish information on certificates for plant protection products under Regulation COM(2023)223, as well as on unitary certificates under Regulation COM(2023)222 and Regulation COM(2023)221.

II. Outcomes of the discussions on the Register and Database

During the discussion of options A, B, and C presented in WK 72/2025, the majority of delegations who expressed their views indicated a preference for Option B, which was seen as the most balanced approach in terms of operational costs and data accessibility.

Overview of option B:

- The **Register** will serve as a single access point for information on all SPC applications across the EU - centralised, unitary, and combined applications. It will provide free access to bibliographic data relating to SPC applications in all official EU languages. To minimise translation costs, documents available in the Register will be presented as annotated links. In order to prevent duplication of information, the Register will also include links to national registers maintained by Member States and other relevant sources. The Executive Director of the Office will be authorised to determine which external links may be included in the Register.

[1] WK 72/2025
[2] WK 889/2025

- The **Database** will serve as a centralised platform for collecting and storing all the particulars provided by applicants, as well as any other documents filed under the SPC Regulation(s) or implementing act(s), including, for example, third-party observations, manufacturing waivers, or examination opinions. All documents contained in the Database will be accessible via the File Inspection function. They will be made available in the language of the proceedings (to be determined in due course), with machine translations into all 27 official EU languages provided as needed.

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Key results of the discussions so far and the corresponding drafting proposals:

1. **Annotated Links**

   Most delegations agreed that, to minimise translation costs, all documents in the Register should be presented as annotated links. In light of this broad consensus, the Presidency proposes corresponding drafting suggestions in **Article 35(2) points (c), (e), (n), and (o).**

2. **Third-party Observations and Manufacturing Waivers**

   Most delegations agreed that the Register should include a simple entry indicating the submission of third-party observations or manufacturing waivers, with the full documents stored in the Database and accessible via the File Inspection function. To accommodate this view, the Presidency proposes corresponding drafting suggestions in **Article 35(2), points (t) and (u).**

3. **Appeals**

   Most delegations agreed that the Register should include only an entry indicating the submission, status, and outcome of an appeal. Related, non-confidential documents should be made available through the File Inspection function in the Database. In light of this, the Presidency proposes corresponding drafting suggestions in **Article 35(2), point (o)**.

4. **Examination Opinions**

   Several delegations supported including in the Register a short summary of the examination opinion, provided the full document is available in the Database. To incorporate this in the legislative text, the Presidency proposes corresponding drafting suggestions in **Article 35(2) points (k), (m), (n), and (o), Article 36(1) and Recital 60 (a)**.

   Furthermore, delegations broadly agreed that the summary should follow a standardised format, to be established in the implementing legislation.

5. **Access and Fees**

Delegations agreed that the information in the Register should be publicly available and free of charge**.** To reflect this in the text, the Presidency proposes corresponding drafting suggestions in **Article 35(7)** and **Recital 60**.
Moreover, most delegations agreed that all documents in the database, except confidential information, should be accessible for public file inspection and be made available in the language of the proceedings, with machine translations provided in all 27 official EU languages as necessary. A corresponding amendment is proposed in **Article 36(6)** and **36(7).**

6. **Data Contribution by National Offices**

Most delegations agreed that, to ensure a **single point of access to data on all SPCs in the EU**, the information set out in **Articles 35(5) and 34(4)** of the proposals for the two SPC recast proposals should be made mandatorily available by national offices and included in the central Register. The Presidency proposes to retain these provisions unchanged.
It was also agreed that the procedure for making these data and information available should be laid down in implementing acts.

7. **Links to National Registers and External Databases**

Delegations expressed divergent views on the inclusion of links to national registers and external databases. While some delegations considered such links to be valuable, others saw limited added value. As a possible compromise, the Presidency proposes empowering the Executive Director of the Office to determine which external links are to be included in the Register. A corresponding amendment is proposed to **Article 35(6)**.

8. **Information on the Basic Patent**

Delegations expressed differing views regarding the scope of the basic patent information to be included in the Register. While some supported limiting this to bibliographic data (e.g. patent number, title, filing date, expiry date, legal status), others favoured a broader scope, including full texts or claims. Several delegations considered a link to the EPO Register sufficient, with some of them suggesting that the patent number alone would enable full access. In light of these divergent positions, the Presidency proposes a compromise in line with the Commission's original proposal: inclusion of the basic patent number only, as set out in **Article 35(2)(g).** This ensures comprehensive access via the EPO Register, avoids duplication, and allows for potential future expansion based on user needs and technical capacity.

III. Drafting suggestions

Below, delegations will find a revised version of **Article 35 (Register) and Article 36 (Database)** of the Commission's proposal for a Regulation on supplementary protection certificates (SPCs) for medicinal products (recast), COM(2023)231. Should these suggestions be agreed upon, they will be adapted accordingly to the three related proposals.

Changes compared to the text of the Commission proposal are indicated in **bold underlined**/strikethrough.

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Article 35

Register

1. The Office shall develop, keep and maintain an electronic Register, providing up-to-date information regarding the status of all published centralised applications, and of all centralised applications for an extension of the duration of certificates.

2. The Register shall include, for each centralised application or certificate, all of the following information:

   (a) the name and address of the applicant or certificate holder;

   (b) the name and business address of the representative, other than a representative as referred to in Article 37(3);

   (c) ~~as well as its~~ date of lodging and date of publication of the application;

   (d) whether the application relates to a medicinal product or to a plant protection product;

   (e) where applicable, ~~an indication that the application includes~~ **a date of** an application for an extension of the duration;

   (f) the designated Member States;

   (g) the number of the basic patent;

   (h) an identification of the product for which certificates are requested;

   (i) the number and date of the authorisation to place the product on the market referred to in Article 3(1), point (b), and an identification of the product identified therein;

   (j) the number and date of the first authorisation to place the product on the market in the Union;

   (k) the date and a **short** summary of the examination opinion in respect of each of the designated Member States;

   (l) where applicable, the duration of the certificates to be granted;

(m) where applicable, the date and a **short** summary of the examination opinion relating to an application for an extension of the duration of a certificate;

(n) where applicable, the filing **date** of an opposition, and its outcome, including where applicable a **short** summary of the revised examination opinion;

(o) where applicable, the filing **date** of an appeal, and the outcome of the appeal proceedings, including where applicable a **short** summary of the revised examination opinion;

(p) where applicable and available, the particulars of the certificates granted in each of the designated Member States;

(q) where applicable, a mention that the centralised application was rejected in one or more of the designated Member States;

(r) where applicable, a mention that a certificate has lapsed or was declared invalid;

(s) information on the payment of annual fees, as provided by the relevant competent national authorities.

(t) **where applicable, the filing date of third party observations**;

(u) **where applicable, the filing date of notification(s) referred to in Article 5(6)**.

3. The Register shall contain changes to the information in paragraph 2, including transfers, each accompanied by the date of recording of such entry.

4. The Register and information referred to in paragraphs 2 and 3 shall be available in all official languages of the Union. The Office may use verified machine translation for the information to be published in the Register.

5. Competent national authorities shall promptly share with the Office information relating to the grant, lapse, invalidity or transfers of certificates and to the rejection of applications under Chapters II and III, and to the payment of related annual fees.

6. The Executive Director of the Office may determine that information other than those referred to in paragraphs 2 and 3 shall be entered in the Register, **including links to the registers of Member States and external databases.**

7. The Office shall collect, organise, make public and store the information referred to in paragraphs 2 and 3, including any personal data, for the purposes laid down in paragraph 10. The Office shall keep the Register easily accessible ~~for public inspection~~ **to the public for free of charge inspection.**

8. The Office shall provide certified or uncertified extracts from the Register on request and on payment of a fee.

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9. The processing of the data concerning the entries set out in paragraphs 2 and 3, including any personal data, shall take place for the purposes of the following:

(a) administering the applications in accordance with this Chapter and the acts adopted pursuant to it;

(b) maintaining the Register and making it available for inspection by public authorities and economic operators;

(c) producing reports and statistics enabling the Office to optimise its operations and improve the functioning of the system.

10. All the data, including personal data, concerning the entries in paragraphs 2 and 3 shall be considered to be of public interest and may be accessed by any third party free of charge. For reasons of legal certainty, the entries in the Register shall be kept for an indefinite period of time.

11. The Register set up under this Article shall also be used to publish information relating to certificates for plant protection products under Regulation [COM(2023) 223], and relating to unitary certificates under Regulation [COM(2023) 222] and Regulation [COM(2023) 221].

Article 36

Database

1. In addition to the obligation to keep a Register, the Office shall collect and store in an electronic database all the particulars provided by applicants or any other ~~third party observations~~ **documents** pursuant to this Regulation or acts adopted pursuant to it**, including:**

(a) third party observations;

(b) full examination opinions and, where applicable, full appeal decisions and revised examination opinions;

(c) notification(s) referred to in Article 5(6).

2. The electronic database may include personal data, beyond those included in the Register, to the extent that such particulars are required by this Regulation or by acts adopted pursuant to it. The collection, storage and processing of such data shall serve the purposes of:

(a) administering the applications and/or certificate registrations as described in this Regulation and in acts adopted pursuant to it;

(b) accessing the information necessary for conducting the relevant proceedings more easily and efficiently;

(c) communicating with the applicants and other third parties;

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(d) producing reports and statistics enabling the Office to optimise its operations and improve the functioning of the system.

3. The Executive Director shall determine the conditions of access to the electronic database and the manner in which its contents, other than the personal data referred to in paragraph 2 of this Article but including those listed in Article 35(3), may be made available in machine-readable form, including the charge for such access.

4. Access to the personal data referred to in paragraph 2 shall be restricted and such data shall not be made publicly available unless the party concerned has given his express consent.

5. All data shall be kept indefinitely. However, the party concerned may request the removal of any personal data from the database after 18 months from the expiry of the certificate or, the case being, the closure of the relevant *inter partes* procedure. The party concerned shall have the right to obtain the correction of inaccurate or erroneous data at any time.

6. Except for the personal data referred to in paragraph 4, all documents contained in the database shall be made publicly available free of charge for the purposes of file inspection.

7. The documents referred to in paragraph 6 shall be made available in the language of the proceedings. Where necessary, automatic translations of these documents into all official languages of the European Union shall be provided. These translations shall be for information purposes only and shall not constitute official language versions.

Recital 60

To ensure transparency, a register should be set up that can serve as a single access point providing **free of charge** information on applications for certificates under the centralised procedure, including on certificates granted on that basis by competent national authorities, which should share with the Office any related information. The register should be available in all official languages of the Union.

Recital 60 (a)

In the interest of legal certainty and administrative efficiency, the summaries of examination opinions recorded in the Register should follow a harmonised structure, be concise in length, and sufficiently comprehensive to reflect the essential outcome of the proceedings. This should also apply, where applicable, to revised opinions issued following opposition or appeal procedures.
