

Brussels, 13 December 2024  
(OR. en)

16732/24

LIMITE

PI 204  
PHARM 168  
PESTICIDE 59  
COMPET 1204

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**Interinstitutional Files:**

2023/0127(COD)  
2023/0128(COD)  
2023/0130(COD)  
2023/0126(COD)

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**NOTE**

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From: Presidency

To: Permanent Representatives Committee

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Subject: **Supplementary protection certificate proposals (SPCs):**  
Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the supplementary protection certificate for plant protection products (recast);  
Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the supplementary protection certificate for medicinal products (recast);  
Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the unitary supplementary protection certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013; and  
Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the unitary supplementary protection certificate for plant protection products  
**- State of play**

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**DOCUMENT PARTIALLY ACCESSIBLE TO THE PUBLIC (18.02.2025)**

**I. BACKGROUND**

1. On 27 April 2023, the European Commission submitted four proposals concerning supplementary protection certificates (SPCs) for medicinal products and plant protection

products. The proposals introduce the possibility of obtaining a unitary SPC<sup>1</sup>, as well as a new centralised procedure for the grant of national SPCs<sup>2</sup>.

2. The legislative reform aims to reduce the fragmentation of the SPC landscape within the Union resulting from divergent national practices regarding the granting of SPCs, to simplify the granting of SPCs, to create a unitary SPC title complementing the Unitary Patent, to increase the transparency, predictability and enhance the legal certainty of the SPC system, and to lower the costs and reduce the administrative burden for applicants.
3. On 28 February 2024 the European Parliament adopted its first reading position on the four SPC proposals.
4. The examination of the proposals was launched during the Swedish Presidency with the presentation by the Commission of the proposals and of the accompanying impact assessment. Furthermore, delegations had a first exchange of views on the key elements of the proposals.
5. Under the Spanish Presidency the article-by-article examination of the two recast SPC proposals was completed.
6. The Belgian Presidency carried out the article-by-article examination of the two unitary SPC proposals and organised a focused discussion at the Working Party in thematic blocks, on the basis of a questionnaire<sup>3</sup>. Based on the inputs received, a stocktaking paper<sup>4</sup> was tabled. As part of the discussions, **DELETED** Member States, **DELETED**, expressed a strong plea, **DELETED**<sup>5</sup>, that the Unified Patent Court (UPC), instead of the European Union Intellectual Property Office (EUIPO) should be competent to rule on the validity of unitary SPCs. In response to this call, the Belgian Presidency sought political guidance from Coreper on how

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<sup>1</sup> Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013 (**doc. 8869/23 + ADD 1-6**); and proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products (**doc. 8851/23 + ADD 1-4**).

<sup>2</sup> Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast) (**doc. 8894/23 + ADD 1-7**); and proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for plant protection products (recast) (**doc. 8887/23 + ADD 1-5**).

<sup>3</sup> WK 3025/2024

<sup>4</sup> Doc. 9519/24

<sup>5</sup> **DELETED**

to define a possible way forward regarding the design of the system of remedies in the unitary SPC proposals, in particular in relation to the invalidity procedure.

7. At the Coreper meeting on 29 May 2024, **DELETED** delegations expressed preference for a solution, whereby direct invalidity actions regarding unitary SPCs would fall within the jurisdiction of the UPC. In addition, in order to guarantee a simple and user-friendly framework for SPCs, **DELETED** delegations expressed the wish to avoid a cascade of procedures. **DELETED** Member States also expressed support for a role of the EUIPO as the central authority for filing and examining the application for an SPC. In conclusion of the debate, Coreper asked the Commission to explore, in cooperation with the Presidency, solutions to achieve the objective of ensuring that direct invalidity actions regarding unitary SPCs would fall within the jurisdiction of the UPC.

## **II. PROGRESS DURING THE HUNGARIAN PRESIDENCY**

8. With a view to achieving the greatest possible progress on the four SPC proposals, the Hungarian Presidency prioritised the discussions related to SPCs and included the topic on the agenda of nine IP Working Party meetings.
9. The discussions at the IP Working Party focused on the following topics: **DELETED** options presented by the Presidency **DELETED**; (c) drafting proposals; **DELETED**

### *****DELETED** options presented by the Presidency **DELETED*****

10. Based on the guidance provided by Coreper on 29 May 2024, the Presidency put forward in a Presidency discussion paper<sup>6</sup>, prepared in exchange with the Commission, **DELETED** options **DELETED** that would in a legally sound way confer jurisdiction to the UPC to rule on the validity of unitary SPCs. These **DELETED** options addressed the following aspects:
- the granting of the unitary SPC,
  - the rejection of the unitary SPC application,
  - the appeal against the examination opinion,
  - the appeal against the decision of the national patent offices (NPO), and
  - the invalidity proceedings.

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<sup>6</sup> Doc. 12277/24

11. **DELETED**. This solution would allow for direct actions for the declaration of invalidity of unitary SPCs to be brought before the UPC, subject to a minor amendment of the SPC definition set out in Article 2(h) of the UPCA. **DELETED**.
12. **DELETED**
13. **DELETED**
14. **DELETED**
15. **DELETED**

16. **DELETED**



aimed at ascertaining that the UPC has full competence to review the validity of the unitary SPC, subject to a minor amendment of the UPCA.

17. **DELETED**

18. Based on the guidance received from delegations, the Presidency prepared textual drafting suggestions mentioned in point c) of this document.

**DELETED**

19. **DELETED**



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21. **DELETED**

22. The Presidency finds that the details of the mechanisms **DELETED**, warrant further elaboration.

*c) Drafting proposals*

23. With a view to making progress on the substantive parts of the proposals and to illustrate how the conceptual suggestions put forward in the different options could be implemented in the legislative text, the textual drafting on the unitary SPC proposals started and two sets of drafting proposals were tabled for discussion during the Hungarian Presidency:
- one on the effects of the unitary SPCs<sup>7</sup>; and
  - one on the examination procedure<sup>8</sup>.
24. Prior to the IP Working Party on 9 October 2024 the Presidency presented new recital language in recitals (6a), (7), (7a) and (14) accompanying Article 5 of the unitary SPC proposal for medicinal products, **DELETED**.
25. At its meetings on 5 and 18 November, the Working Party examined the Presidency's drafting proposals on the examination procedure (Articles 13, 14, 16, 17, 17a, 18), which is considered as a central element of the proposals by the vast majority of delegations, who emphasised repeatedly that a high-quality examination procedure, to be built on the expertise of national SPC examiners, is key to ensure the trust of users in the system. **DELETED**
26. Discussions on these drafting proposals remained inconclusive, yet the Presidency hopes that, together with the inputs received from delegations, they will provide a good basis for further discussions.

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<sup>7</sup> **DELETED**

<sup>8</sup> **DELETED**

**DELETED**

27. **DELETED**

28. **DELETED**<sup>9</sup> **DELETED**

29. In light of the above, it is evident that the deliberations on these legal questions have to continue. However, it also emerged from the discussions that in order to tackle these issues efficiently and to make progress on the SPC proposals, it is vital that their substantive examination continues in parallel.

### **III. CONCLUSIONS**

30. The Hungarian Presidency considers that important progress and clarifications have been achieved in the negotiations of the SPC proposals during its Presidency term and that substantive discussions at the level of the IP Working Party should continue on all the four SPC proposals in order to establish the building blocks of the SPC reform. **DELETED**. All things considered, in the further work particular attention should be given to the importance of ensuring coherence between the national and the unitary SPC schemes, the importance of building on the expertise of NPOs and the guidance provided by Coreper in May 2024 to ensure an appropriate involvement of the UPC in the remedy proceedings.

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<sup>9</sup> **DELETED**

31. Coreper is invited to take note of the state of play of the discussions regarding the SPC proposals as set out in this note.

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