



(32/2023)

10.10.2023

## NOTICE TO MEMBERS

**Subject: Proposal for a regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast) (COM(2023)0231 – C9-0146/2023 – 2023/0130(COD))**

The Inter-institutional agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts<sup>1</sup> requires a consultative working party of the legal services of Parliament, the Council and the Commission to consider any Commission proposal for recasting.

Please find attached the Consultative Working Party's opinions on the above proposal.

The Committee on Legal Affairs intends to state its views on the opinion at its meeting on 6-7 November 2023.

Annex

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<sup>1</sup> OJ C 77, 28.3.2002, p. 1.



CONSULTATIVE WORKING PARTY  
OF THE LEGAL SERVICES

Brussels, 26 September 2023

## OPINION

### FOR THE ATTENTION OF THE EUROPEAN PARLIAMENT THE COUNCIL THE COMMISSION

#### **Proposal for a regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products COM(2023)0231 of 27.4.2023 – 2023/0130(COD)**

Having regard to the Inter-institutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts, and in particular to point 9 thereof, the Consultative Working Party consisting of the respective legal services of the European Parliament, the Council and the Commission met on 13 July 2023 for the purpose of examining the aforementioned proposal submitted by the Commission.

At that meeting<sup>1</sup>, an examination of the proposal for a Regulation of the European Parliament and of the Council recasting Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products resulted in the Consultative Working Party's establishing, by common accord, as follows.

1. The following should have been marked with the grey-shaded type generally used for identifying substantive amendments:

- in recital 43, the deletion of the first sentence of recital 5 of Regulation (EU) 2019/933;
- in recital 59, the deletion of the first and second sentences of recital 27 of Regulation (EU) 2019/933;
- in Article 11(1), introductory wording, and in Article 11(2), the adding of the words '*as soon as possible*'.

2. The following should have been identified as formal adaptations:

- in the title of the act, the replacement of the word '*concerning*' with the word '*on*';
- in Article 8(1), point (d), the adding of the words '*for a medicinal product*';
- in Article 8(2), the replacement of the words '*extended duration*' with the words '*extension of the duration*'.

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<sup>1</sup> The Consultative Working Party worked on the basis of the English language version of the proposal, being the master-copy language version of the text under discussion.

In consequence, examination of the proposal has enabled the Consultative Working Party to conclude, without dissent, that the proposal does not comprise any substantive amendments other than those identified as such. The Working Party also concluded, as regards the codification of the unchanged provisions of the earlier act with those substantive amendments, that the proposal contains a straightforward codification of the existing legal text, without any change in its substance.

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