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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	Regulation on fees and charges payable to EMA - Analysis of the final compromise text with a view to agreement

I. INTRODUCTION

1. On 13 December 2022, the Commission submitted the proposal for a Regulation of the European Parliament and of the Council on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014 of the European Parliament and of the Council.

2. The proposal is based on Article 114 and Article 168(4), points (b) and (c) of the Treaty on the Functioning of the European Union. The ordinary legislative procedure is applicable.

3. The proposal has three objectives:

   (i) to move from a flat-rate system to a cost-based system for EMA fees as foreseen in existing legislation[1];

[1] Article 12 of Council Regulation (EC) No 297/95 and recital 7 of Regulation (EU) 658/2014 of the European Parliament and of the Council

(ii) to ensure the sustainability of the European regulatory network formed by the EMA and National Competent Authorities (NCAs);

(iii) to simplify exiting legislation by merging the content of the two current EMA Fee Regulations[2] for pharmacovigilance and non-pharmacovigilance fees into one single legal instrument.

4. On 13 June 2023, the EPSCO Council (Health) reached a general approach[3] and gave a mandate to the Presidency to enter into negotiations with the European Parliament.

5. At the European Parliament, the Committee on the Environment, Public Health and Food Safety (ENVI) is responsible for the file and MEP Cristian-Silviu BUSOI (RO, EPP) was appointed as Rapporteur. The report was adopted by the Plenary on 12 July 2023.

6. After the start of the negotiations, it became clear that additional flexibility would be necessary for the Presidency to successfully move forward the discussion with the European Parliament. At its meeting on 22 September 2023, the Permanent Representatives Committee approved a revised mandate[4].

7. Two trilogues took place on 5 and 25 September 2023. In addition, seven technical meetings were held on 6, 8, 12, 14, 18, 21 September and on 3 October 2023.

8. At the last trilogue, on which the Presidency debriefed Coreper at its meeting of 29 September 2023, the co-legislators provisionally agreed on an overall compromise text, as set out in document 13721/23.

The main elements of this compromise text are outlined in Section II below. The Presidency considers that the overall compromise package reached with the European Parliament is balanced and that it respects the mandate the Presidency received.

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[2] Council Regulation (EC) No 297/95 and Regulation (EU) No 658/2014 of the European Parliament and of the Council

[3] 9674/1/23

[4] 12919/23

II. COMPROMISE PACKAGE

i) The sustainability factor

9. The negotiating teams agreed that the sustainability factor, added to some of the remunerations paid to NCAs (the ones changed in the General approach with the horizontal adjustment), be set at 5,5%. Fees and remunerations across the text have been adjusted accordingly.

ii) "Burden-sharing" (fee waivers and reductions to NCAs remunerations)

10. The European Parliament negotiating team accepted to withdraw its amendments to reduce remunerations to NCAs by 50% in case of full waivers (recital 19, Article 5.2 and related changes in Annexes I and II).

iii) Detailed information on NCAs remuneration (transparency)

11. The Presidency agreed that a "detailed breakdown of remunerated amounts paid" to NCAs for their work (recital 17a and Article 10.2a) be listed in EMA's annual activity report.

iv) "Academia and non-profit research sector"

12. The Presidency agreed that "entities not engaged in an economic activity" would also receive fee waivers for protocol assistance and scientific advice requests in medicinal products (recital 15 and Annex V – point 1a).

    In return, the Parliament negotiating team accepted that the granting of fee waivers to applicants should not affect the payment of full remunerations to NCAs. It also agreed to withdraw its amendments with new definitions (on Academia, non – profit legal entity, International European interest organisation) from Article 2. These terms will remain undefined in this Regulation, but Recital 15 offers guidance on how they should be interpreted.

v) Generics package: (Annex I points 3.6 and 5.2 and reduction of pharmacovigilance annual fee for generics)

13. The European Parliament negotiating team accepted the principle of targeted adjustments of fees and remunerations for generic authorisations and for type II variations (Annex I points 3.6 and 5.2, respectively), but requested a reduction of these fees and remunerations. The negotiating teams showed flexibility and agreed to adjust those fees and remunerations, while still reaching a level that ensures the sustainability of the European medicines regulatory network.

    The negotiating teams reached a compromise on a reduction by 25% of the pharmacovigilance annual fee.

14. The negotiating teams agreed that all fees, remunerations and charges in the text be adjusted for the 2023 inflation forecast. In the case of figures in Annex II, for veterinary medicines, this adjustment will be done with only 50% of the 2023 inflation forecast, as previously done in the General Approach for 2021 and 2022 due to the particularities of the sector.

III. CONCLUSION

15. In light of the above, the Permanent Representatives Committee is invited to:

    - confirm its agreement on the compromise text set out in document 13721/23,

      and

    - mandate the Presidency to send a letter to the Chair of the ENVI Committee of the European Parliament confirming that, should the Parliament adopt its position at first reading in accordance with Article 294 (3) TFEU and in the exact form set out in document 13721/23 – subject to legal-linguistic revision – the Council would, in accordance with article 294 (4) TFEU, approve the European Parliament's position and the act would be adopted in the wording which corresponds to the European Parliament's position.