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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	Regulation on fees and charges payable to EMA *- Preparation for the trilogue*

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 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.

II. STATE OF PLAY

6. So far, one trilogue and five technical meetings have been held with the European Parliament and the Commission. These meetings have allowed to discuss and provisionally agree on a number of provisions highlighted in green in the fourth column of the four-column table, still to be issued as an addendum to this note.

7. The discussions during the inter-institutional negotiations allowed provisionally to identify the following most relevant issues:

- The **role of the EMA Management Board**, in particular to adopt the special report (Row 97 - Article 10.6) and to shorten the time interval to the special report (Row 107b – Article 10.9.e), as included in the general approach;
- Parliament **transparency** amendments: Rows 78 and 79 (Articles 6.4 and 6.5), Row 93 (Article 10.2), Row 97 (Article 10.6), Row 99c (Article 10. (6.1) (new), Row 99d and 99e (Article 10.6.a and paragraph 6b(new), Row 103 (Article 10.8), Row 464 (Annex VI);

[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

- **Some other elements of the targeted approach** on the figures for fees for: Type II variations (Annex I, point 5.1); referrals (Annex I, point 6.7.1); periodic safety update reports (PSURs) (Annex I, point 14.1); rolling review (Annex I, points 2.1 and 2.1a(new)) ; inspection outside the EU (Annex IV, points 1.1.2, 1.1.4 and 1.1.5); and the inclusion of remuneration for the PRAC[4] rapporteur in the procedures where it has a role (Annex I point 3.1 to 3.7; Annex II points 1.1 to 1.3).
- **Veterinary sector fees**: figures in Annex II.
- **Sustainability factor** of approximately 7% applied by the Council in the recalculation of the remuneration to the national competent authorities;
- **Parliament amendment for "burden-sharing" via a 50% reduction in remuneration where there are full waivers** (Row 72);
- **Detailed information on NCAs remuneration (transparency)** Row 93a (Article 10.2a (new);
- Parliament amendment on the **inclusion of academia and non-profit research sector in the scope of the Regulation**, which is linked to "burden-sharing" because the Parliament is asking for a full waiver of fees and remunerations;
- A package of three elements on **generics** covering: the figures for fees on authorisation for generics (Annex I, 3.6); the figures for fees for Type II variations for generics (Annex I, 5.2); the increase in the reduction of the annual pharmacovigilance fee for generics from 20% to 30% as per the European Parliament mandate (Annex V, row 456);

8. The main political issues mentioned above were discussed at the meeting of the Working Party on Pharmaceuticals and Medical Devices on 15 September 2023 which gave guidance to the Presidency.

9. Based on the guidance from the Working Party on Pharmaceuticals and Medical Devices on 15 September 2023 and the inter-institutional discussions so far, provisional solutions have been put forward on the issues below, while some questions will remain open for the political trilogue.

[4] PRAC is the Agency's committee for assessing pharmacovigilance risk

10. **Provisional solutions** put forward at technical level:

a) As regards the **role of the EMA Management Board**, the Parliament accepts the Council position that the Management Board adopts the special report as set out in the general approach (Row 97 - Article 10.6) and in return the Parliament asked the Council to drop its position in the general approach that the Management Board can request to shorten the time interval for a special report (Row 107b – Article 10.9.e); the Presidency believes that this could be acceptable considering the overall compromise.

b) For **transparency**, Parliament included several amendments to increase the transparency as regards the public information available on the fee system. The Parliament agreed to drop the following amendments that caused unnecessary burden to the Agency, that were duplications or were problematic or were against the logic of the Interinstitutional agreement on Better Law Making[5]: Row 96 (Article 10.5) (Commission report on inflation); Row 99c (Article 10. (6.1) (new) (special report was to be submitted to the co-legislators); Row 99d and 99e (Article 10.6.a and paragraph 6b(new)) (stakeholders consultations to prepare the special report), and Row 103 (Article 10.8) (co-legislators could request clarifications on the special report). In return, the Presidency indicated its provisional agreement at technical level on other amendments related to transparency, except for Row 93a (see point 11.A.ii) below) where the Presidency systematically rejected this addition.

c) As regards the **targeted approach**, the Parliament accepts the Council's position on the fees as regards referrals (Annex I, point 6.7.1), periodic safety update reports (PSURs) (Annex I, point 14.1), rolling review (Annex I, points 2.1 and 2.1a(new)) and on the inclusion of remuneration for the PRAC rapporteur (Annex I point 3.1 to 3.7; Annex II points 1.1 to 1.3). At the request of the Parliament, the Presidency proposed reducing the remuneration for some Type II variations (Annex I, point 5.1) by 15% from the general approach. The Presidency also adjusted the figures for fees for inspections outside the EU (Annex IV, 1.1.2, 1.1.4 and 1.1.5) to apply the lowest percentage increase of the fees among the three abovementioned points, which is for Good Clinical Practice (GCP) in point 1.1.4, and to apply the same percentage increase to remunerations for Good Manufacturing Practice (GMP) in point 1.1.2 and for the Plasma Master File (PMF) in point 1.1.5;

[5] OJ L 123, 12.5.2016, p. 1–14

d) As regards **Veterinary sector fees**, the Parliament accepted the Council's general approach of applying only half the inflation adjustment for 2021 and 2022. In return, and following the same logic, the Council accepted the Parliament's suggestion to apply only half of the estimated inflation adjustment for 2023.

III. PROPOSAL FOR A REVISED MANDATE

11. Regarding the main political issues mentioned in point 7, five issues would seem to remain for the political trilogue.

It is clear that the current mandate does not provide the Presidency with a sufficient margin to negotiate with the European Parliament. To be able to progress efficiently during the negotiations, the Presidency believes that this mandate needs to be updated.

The Presidency considers that for this discussion, the following approach could be used:

i) Sustainability factor

The Parliament finally, reluctantly and provisionally agreed on the concept of a sustainability factor, but requested a substantially lower percentage for it. This appeared to be a hard red line for the Parliament.

In order to close the deal, the Presidency would need some flexibility for the sustainability factor applicable to remunerations, to a level that would still ensure the sustainability of the network. This should be considered together with the Parliament's request for transparency and with the line proposed for the "burden-sharing" below.

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

The Parliament amended the Commission proposal to reduce remuneration to NCAs by 50% in case of full waivers (Article 5.2 (row 72) and related changes in Annexes I and II). As regards the introduction of fee waivers for the academia and non-profit research sector, the Parliament proposes to entirely waive the NCAs remunerations (Annex V, see point D of this note).

The Parliament argued that this was to ensure that Member States shared the burden of these waivers with the EMA, as they are often in products of public interest, or for applicants needing specific support (such as academia).

The Commission proposal had as a principle that remuneration to NCAs remained payable despite fees being fully waived. The Presidency proposes to insist on the general approach and to maintain the remunerations in those cases untouched.

iii) Detailed information on NCAs remuneration (transparency)

In order to be able to assess, first, the sustainability of the Union regulatory network and how the sustainability factor contributes to it, and, second, to adopt the delegated acts, the Parliament feels it needs information on the remuneration of the NCAs per country and per procedure. To that end, it insists on its amendment to publish a "list [with] a detailed breakdown of all remunerated amounts paid to the national authorities for their work" (row 93a). The Presidency would request flexibility to accept the Parliament's request if that is required to seal the deal.

iv) "Academia and non-profit research sector"

The Parliament introduced new fee waivers for academia and the non-profit research sector for protocol assistance and scientific advice requests in medicinal products (Annex V – point 1 a (new)) (row 408a) linked to new definitions in Article 2 (Academia, non – profit legal entity, International European interest organisation), (rows 57a – 57c) and the related recital 15. In such cases, the remuneration would also be waived .

It proved difficult for the Council to accept the definitions, despite being the ones used in the Decision of the Executive Director on fee reductions for scientific advice requests on PRIME products for SMEs and applicants from the academic sector, as these definitions do not yet exist in European law. The institutions preliminarily agreed, on the basis of a Commission compromise, on referring to "entities not engaged in an economic activity" in the Annexes.

Subject to the Parliament not insisting on its request for "burden-sharing", the Presidency would propose to accept the full waivers for the "entities not engaged in an economic activity", while maintaining full remuneration for the NCAs.

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

The level of fees and remuneration for generics are essential for both the Parliament and the Council and it will be necessary for both institutions to show a certain level of flexibility to find an agreement.

The Parliament at technical level has proposed that the fees and remuneration for Annex I points 3.6 and 5.2 be increased only by the horizontal adjustment which would imply a significant reduction from the figures in the general approach as there was also a targeted adjustment for generics in the Council's position.

The Presidency considers this proposal as unacceptable, as it would not reflect the cost-based calculations in the targeted approach and would entail the risk that national agencies would not volunteer for these procedures, having as a consequence a negative impact on the EU market.

Nonetheless, the Parliament did say that an increase in the reduction of the pharmacovigilance fee for generics to 30% would allow the Parliament some flexibility to accept an increase beyond the horizontal adjustment for Annex I point 3.6.

In this context and in order to reach an agreement, the Presidency would, therefore, propose to agree on the 30% reduction of pharmacovigilance annual fee for generics (row 456) which has no impact on the national agencies. In addition, the Presidency proposes to accept a reduction compared to the general approach, while ensuring the sustainability of the European medicines regulatory network.

12. The Presidency considers that the proposal for a revised mandate is balanced and provides a sufficient margin to negotiate with the European Parliament.

IV. CONCLUSION

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

- take note of the four-column table in addendum[6] as some of the text still needs to be aligned with the issues that remain open;

- discuss the issues referred to in point 7 above and:

  I) endorse the provisional solutions found on the issues referred to in point 10 above;

  II) agree on the proposed approach as outlined in point 11.

[6] ADD1 to this note, to be issued