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| From: | General Secretariat of the Council |
| To: | Permanent Representatives Committee/Council |
| Subject: | Regulation on fees and charges payable to EMA<br>*- Policy debate* |

Delegations will find attached a Presidency steering note for the policy debate on the proposal for a Regulation on fees and charges payable to EMA at the EPSCO Council (Health) on 14 March 2023.

**ANNEX**

# Proposal for a Regulation on fees and charges payable to EMA

## I. INTRODUCTION

1. The EMA fees system plays a key part in funding the collective regulatory system at EU and national level and in ensuring coverage of the relevant costs. In place since 1995, EMA fees are charged to marketing authorisation holders and applicants for obtaining and maintaining Union-wide marketing authorisations for medicinal products for human and veterinary use.

   The fees should ensure adequate funding to guarantee the future sustainability of operations of the EMA while also providing sufficient support to the National Competent Authorities (NCAs) in the Member States.

   In 2021, the EMA got 90% of its funding[1] from these fees (roughly €342m out of €380m). Of this €342m, roughly €140m was paid to the NCAs to compensate them for their work in such things as the scientific evaluation of applications (which the EMA coordinates) and other services provided to EMA. Remuneration to the NCAs from EMA is, therefore, an important factor for many NCAs, including in deciding how to contribute with services to provide to EMA.

2. On 13 December 2022, the Council received the Commission 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].

[1] The other 10% came from the EU budget
[2] 16070/22 + ADDS 1-7

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[3];

(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[4] for pharmacovigilance and non-pharmacovigilance fees into one single legal instrument.

The legal bases of the proposal are Article 114 TFEU and Article 168(4), points (b) and (c) TFEU.

A key part of the proposal are the provisions on flexibility to future-proof the Regulation to changes in costs and structures. These include provisions for transparency and monitoring in Article 10 and for revision via delegated act in Article 11.

The provisions in Article 10, include:

- That EMA, in its annual activity report, provide detailed and substantial information on the costs to be covered by fees and charges within the scope of this Regulation;
- That NCAs may provide every year, or less frequently, evidence of significant changes in the costs of services provided to EMA;
- That every three years, the EMA Executive Director, after consulation of the EMA Management Board, may provide the Commission with a special report with recommendations to amend the annexes, which can be done by the delegated act in Article 11;

[3] 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

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

The annexes may also be amended through delegated acts when justified in view of:

- The findings from the monitoring of the inflation rate;
- A change in the statutory tasks of EMA leading to a significant change in its costs;
- The budgetary reporting of EMA;
- Information on practical aspects for the execution of actvities for which EMA collects fees or charges.

3. The ENVI Committee of the European Parliament has appointed Cristian-Silviu BUSOI (RO, EPP) as rapporteur.

4. The Working Party on Pharmaceuticals and Medical Devices examined the proposal and the impact assessment at its meeting of 26 January 2023. It continued its examination of the proposal at its meetings of 27 January and 2, 13 and 20 February 2023.

## II. ISSUES IDENTIFIED

5. Two issues emerged from the examination:

   i) First, it became clear that there was broad support for a cost-based approach but that the proposed fees and remuneration to the NCAs were not considered by delegations to be enough to cover the NCAs' costs in several procedures. Many delegations expressed a preference for a targeted approach for adjusting the fees and remuneration for those procedures that were of greatest concern, that could also be complemented by a horizontal adjustment, for example, for inflation.

   ii) Second, there was broad support for the concept of flexibility, but there were two main concerns in this regard: the first was the wish to see a greater role for Member States / the EMA Management Board in the approval of the special report in Article 10(6); the second was the request to set limits on the powers delegated to the Commission in Article 11, as concerns were expressed by a large number of delegations, especially on Article 11(1)(e).

6. At its meeting of 13 February 2023, the Working Party on Pharmaceuticals and Medical Devices examined a Presidency working document[5] setting out a suggested way forward on these two issues.

a) There was broad support for using a targeted approach for adjusting the fees and remuneration for the procedures of most concern.

There was also broad support for the five procedures identified. Two further procedures (inspections and referrals) were identified in the discussion.

The seven procedures identified for the targeted approach (and confirmed at the meeting of the Working Party on 20 February 2023) are as follows:

- Scientific Advice (Annex I, point 1)
- Generics (Annex I, point 3.6 & 3.8)
- Type II variations (Annex I, point 5)
- Referrals (Annex I, point 6)
- Periodic safety update reports (PSURS) (Annex I, point 14)
- Inspections (Annex IV, point 1)
- Pharmacovigilance Risk Assessment Committee (PRAC) rapporteurship (new fee and remuneration required)

b) There was also broad support for the suggested way forward as regards flexibility. This concerned two points.

i) *Article 10 on transparency and monitoring*, where it was agreed that the EMA Management Board would approve the special report and that the Agency be obliged to prepare a special report if asked by the Management Board;

ii) *Article 11 on revision* (by delegated acts), where it was agreed to limit the powers delegated to the Commission. This would be done by giving the Board power to approve changes to the description of activities that qualify for the operational work of the Agency[6] as currently stated in the Annexes of the Commission proposal. In the light of this, it was agreed that Article 11(1)(e) would be deleted.

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6 To achieve such a change, it is necessary to move to Article 10(6)(b) the wording used in Article 11(1)(e). This will give power to the EMA Management Board to approve the change before it is adopted via a delegated act by the Commission under Article 11(1)(a).

7. At its meeting of 13 February 2023, the Working Party on Pharmaceuticals and Medical Devices also examined the veterinary parts of the proposal. This examination revealed the need for a balance between the sustainability of the network and the viability of industry when setting the fees and remuneration. Given that the veterinary framework was recently updated, this would merit a particularly close follow up.

At the meeting of 20 February 2023 of the Working Party on Pharmaceuticals and Medical Devices, following a request by four delegations, the Presidency suggested it would look at making relevant technical adjustments to the proposal to maintain the 'status quo' as regards the pharmacovigilance fee in small markets.

## III. CONCLUSION

8. In the light of the issues identified above, the Presidency concluded that it would invite the EPSCO Council (Health), at its meeting on 14 March 2023, to hold a policy debate on fees and charges payable to EMA. Ministers are encouraged to address the following questions, prepared by the Presidency, during the debate:

**Question 1: Targeted approach**

**Would Ministers agree on the targeted approach to adjusting fees and remuneration outlined in point 6a) above including a general adjustment taking into consideration developments in recent years?**

**Question 2: Flexibility**

**Within the context of the broad support for flexibility set out in point 5 ii) above, would Ministers agree on the need for a larger role for the EMA Management Board and the Member States in the future-proofing of fees and remuneration as well as on setting limits on the powers delegated to the European Commission as outlined in point 6b) above?**