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CONTRIBUTION

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés) Working Party on Pharmaceuticals and Medical Devices (EMA fees)
Subject:	EMA fees proposal - comments from the German delegation

Delegations will find attached comments from the German delegation on EMA fees proposal.

2 March 2023

DE comments on the proposal for a regulation on fees and charges payable to the European Medicines Agency: Articles 4, 10, 11, 14, 16 and Annex IV, VI

The comments are preliminary. We also refer to our written comments submitted on 10 and 17 February 2023.

German proposals for amendments are marked as ~~strike-through~~ or **bold/underline**.

I. Article 4 and Annex IV

Article 4

Additional fees and charges

1. The Agency may levy a scientific service fee for scientific services it provides if these services are not covered by another fee or charge provided for in this Regulation. The amount of the scientific service fee shall ~~take into account~~ **correspond to** the workload involved. Its minimum and maximum amount and, where relevant, the corresponding remuneration to the rapporteurs and, where relevant, co-rapporteurs, are set out in point 5 of Annex IV. **The remuneration shall respect the percentage distribution of fees between the Agency and the competent authorities of the Member States in accordance with the distribution set in the most comparable types of procedures.**
[…]

2a. The Agency may increase a scheduled fee on a case-by-case basis if the foreseeable workload significantly exceeds the usual workload. The case-by-case increase of a fee shall also be determined at the request of a competent authority of the Member States involved. Any case-by-case increase of a scheduled fee shall be duly justified on the evidence of a corresponding exceptional workload. The maximum amount for the increase of a scheduled fee including remuneration for rapporteur and co-rapporteur is set out in Point 5a of Annex IV. The applicable amounts of the fee and the remuneration within the above range shall be determined on a duly justified proposal from the Executive Director of the Agency and after approval of the Management Board.
[…]

Annex IV

5a. Scientific services referred to in Article 4 (2a) (NEW)

The increase of a scheduled fee referred to in Article 4(2a) shall not exceed EUR 217 300.

Rationale:

Paragraph 1:
The essential criterion for the fee should be the workload. We suggest also adding a specification

Paragraph 2a and Annex IV point 5a (NEW):
In parallel to fee reductions, it should also be possible to increase fees. An exceptionally high workload may for instance be caused by accelerated processing or the special complexity involved in a scientific evaluation. Such circumstances originating from the requested service itself should be reflected by an increase of the scheduled fee. Such an increase shall be determined on a case-by-case basis if the foreseeable workload significantly exceeds the usual workload and if duly justified on the evidence of a corresponding workload. The amount applicable is determined on a duly justified proposal of the Executive Director and after approval of the Management Board. The maximum amount of the increase is set out in point 5a of Annex IV.

Annex VI point 4a (NEW): For transparency reasons and to monitor the financial impact, we propose to add the additional scientific fee in Article 4(2a) to the performance information as set out in Annex VI (see below point VI.).

II. Article 10

Comments in reference to Document 6089/23 (EPSCO Council - Presidency steering note)

DE is still very concerned by the extent to which Article 11 allows for a delegation of powers to the Commission. Although we support the deletion of Article 11(1)(e) as agreed, we are not in favour of the proposed amendment as put forward in footnote 6 of Document 6089/23 (EPSCO Council - Presidency steering note). There it is suggested: "*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).*" **Moving the wording would not be sufficient. We would like to ask that the wording be put in more concrete terms**.

The wording of Article 11(1)(e) is too vague and open to interpretation. If any "other relevant information" was admissible for a delegated act following a special report, it would possibly give the Commission the power to regulate on essential elements of the EMA Fees Regulation. According to Article 290(1) TFEU essential elements of an area shall be reserved for the legislative act.

III. Article 11

Comments in reference to Document 6089/23 (EPSCO Council - Presidency steering note)

In line with the above and referring to No. 6(b)(ii) of Document 6089/23 we welcome that the Management Board would have to approve the special report as a means to limit the powers delegated to the Commission. Equally, we support the deletion of Article 11(1)(e). However, we are worried that these are the only steps being taken to limit the delegation of powers. The ordinary legislative procedure is the regular procedure for amending regulations. Only there do the member states have an equal and effective right to participate and the power to amend. In comparison to that, the proposed approval by the Management Board is limited to the special report as a preliminary step and will only be requested once the report has taken its final form. Therefore we urge to limit the powers delegated to the Commission in Article 11.

As one of many other possible ways to be discussed, we would like to **propose that Article 11(1)(c) will be deleted**. It would have several advantages to make amendments to the EMA Fees Regulation already in the regulation which changes the statutory tasks:

- First, the consequences to other legal acts must already be taken into account in the regulation changing the statutory tasks. Therefore, it would be more efficient and less error-prone to amend the EMA Fees Regulation in the same procedure and the same legal act.
- Second, this approach would allow for a faster adjustment since the regulation changing the statutory tasks would simultaneously amend the EMA Fees Regulation, and no delegated act would be needed.
- Third, fee amounts could be estimated on the basis of the existing fees. Whether adjustments, which would be needed due to unforeseen developments, would fall within the scope of the cost monitoring system.

In summary, we propose to *at least* limit the scope of the delegation of powers as follows:

1. **Delegated acts may only provide for a fee increase.**
2. **The percentage of the fee that is allocated to the national competent authorities must not be reduced any further by delegated acts.**
3. **Delete Art. 11(1)(c). Rationale: Amendments to the Fees Regulation resulting from a change in the statutory tasks should be regulated in the ordinary legislative procedure. They must therefore already be made in the same regulation changing the statutory tasks.**

For further illustration we are including our **proposal of 10 February 2023**:

Article 11
Revision

1. The Commission is empowered to adopt delegated acts in accordance with Article 13 to amend the Annexes **with regard to an increase in the amounts** where it ~~deems it~~**is** justified **on the basis of**~~in view of any of the following~~:

(a) a special report received by the Commission in accordance with Article 10(6);

(b) the findings from the monitoring of the inflation rate referred to in Article 10(5);

~~(c) a change in the statutory tasks of the Agency leading to a significant change in its costs;~~

(c)~~(d)~~ the budgetary reporting of the Agency**.**~~;~~

~~(e) other relevant information, in particular on practical aspects for the execution of activities for which the Agency collects fees or charges.~~

By means of delegated acts, the percentage distribution of fees between the competent authorities of the Member States and the Agency cannot be changed to the detriment of the national competent authorities.

2. Any revision of the fees and charges and of the remuneration paid to competent authorities of the Member States provided for in this Regulation shall be based on the Commission's evaluation of the Agency's costs and revenues and **on the full** costs of the services provided to the Agency by the competent authorities of the Member States.

IV. Article 14

** changes made to the version submitted on 10 February 2023 are indicated in red

Article 14

Amendment to Regulation (EU) No 2017/745 ***and Regulation (EU) 2022/123***

~~Article 106 of Regulation (EU) No 2017/745, to paragraph 14 is replaced by the following: '14. The fees payable to EMA in accordance with the procedure under paragraph 13 of this Article related to the advice provided by expert panels for which EMA provides the secretariat in accordance with Article 30 of Regulation (EU) 2022/123 of the European Parliament and of the Council shall be set in a transparent manner and on the basis of the costs for the services provided. The fees payable shall be reduced in the case of a clinical evaluation consultation procedure initiated in accordance with section 5.1, point (c), of Annex IX to this Regulation involving a manufacturer who is a micro, small or medium-sized enterprise within the meaning of Recommendation 2003/361/EC'.~~

1. In Article 106 of Regulation (EU) ~~No~~ 2017/745, the following paragraph 14a is inserted:
'14a. The EMA supports the Commission in accordance with Article 30 of Regulation (EU) 2022/123.'.

2. In Article 30 of Regulation (EU) ~~No~~ 2022/123, the following point (i) is added:
'(i) charge fees ~~payable to the Commission~~ in accordance with Article 106(14) Regulation (EU) 2017/745.'.

Recital 27

In accordance with Article 30 of Regulation (EU) 2022/123, the Agency provides, on behalf of the Commission, the secretariat for the expert panels designated in accordance with Regulation (EU) 2017/745. The provision in Article 106 of Regulation (EU) 2017/745 concerning the payment of fees for advice provided by expert panels **and Article 30 of Regulation (EU) 2022/123** should therefore be amended in order to allow the Agency to receive those fees, once such fees are established by the Commission in accordance with ~~that~~ **Article 106 (13) of** Regulation **(EU) 2017/745**.

Rationale**:**

The wording of Article 106 (14) Regulation (EU) 2017/745 (Medical Devices Regulation, MDR) as proposed by the Commission might be misleading. The impression, that the EMA was assigned additional tasks should be avoided.

Regulation (EU) 2022/123 provides for an assignment of tasks - the provision of a secretariat for expert panels designated in accordance with Article 106 (1) MDR - to the EMA. However, there is still no indication in the MDR that the EMA supports the Commission in this task. Therefore, we would like to propose a clarification in Article 106 Regulation (EU) 2017/745 (new paragraph 14a).

Currently, fees for the advice of the expert panels have to be paid to the Commission according to Article 106 (14) MDR. Pursuant to Art. 30 lit. f Regulation (EU) 2022/123 the EMA has to remunerate the experts and reimburse expenses. Our proposal clarifies that the fees payable to the Commission under Art. 106 (14) MDR can be charged by the EMA.

V. Article 16

Article 16
Transitional provisions

[…]
2. With regard to annual fees set out in Annex III, this Regulation shall not apply **in the year [OP: please insert calendar year of application]** to products for which an annual fee has **already been paid** ~~**become due**~~ pursuant to Regulation (EC) No 297/95 or Regulation (EU) No 658/2014 ~~**in the year [OP: please insert calendar year of application]**~~.

Rationale:
As the context indicates, it is intended that two annual fees should not be levied in the year of entry into force of the regulation. However, the wording suggests that Annex 3 does not apply at all to products for which an annual fee is payable under the previous law.

VI. Annex VI

ANNEX VI

Performance information

[…]

(4) number **and amount** of fee reductions **or waiver** granted per type of reduction **or waiver under this regulation** ~~**as set out in Annex V**~~ **and number of application holders concerned**;

(4a) number and amount of scientific service fees levied pursuant to Article 4 paragraph 1 and increases of fees levied pursuant to Article 4 paragraph 2a;

Rationale:

Point 4:

We propose an amendment to list all reductions and waivers granted under the regulation, not just in Annex 5. The resulting financial impact should be transparent and easy to monitor. The number, the amount as well as the number of affected marketing authorization holders should be gathered.

Point 4a:

For transparency reasons and to monitor the financial impact, we propose to add the scientific service fee of Article 4(1) as well as the increase of scheduled fees of Article 4(2a) to the performance information as set out in Annex VI.