Written contributions from delegations

Comments from the Belgian delegation

Article 10

Transparency and monitoring

6. At the earliest on [OP: please insert date ~~3~~ **1** years~~s~~ after the date of application] and at three year intervals thereafter, the Executive Director of the Agency ~~may~~ **shall**~~,~~ ~~[where considered relevant in view of Article 11(2)], and after consultation of the Management Board of the Agency,~~ provide the Commission with a special report **adopted by the Management Board of the Agency in consultation with the national competent authorities of the member states,** outlining, in an objective, fact-based and sufficiently detailed manner, justified recommendations **to**:

   (a) to increase or decrease the amount of any fee, charge or remuneration, following a significant change in the respective costs as identified, documented and justified in the report;

   (b) ~~to~~ amend any other element of the Annexes pertaining to the levying of fees and charges, including additional fees and charges referred to in Article 4.

   (c) ~~to~~ **amend the information on practical aspects for the execution of activities for which the Agency collects fees or charges.**

In line with the Joint Statement of the European Parliament, the Council of the EU and the Commission of 19 July 2012 on decentralized agencies, for bodies for which the revenue is constituted by fees and charges in addition to the Union contribution, fees should be set at a level that avoids a deficit or a significant accumulation of surplus, and should be revised when this is not the case. Therefore, a cost monitoring system should be put in place. The purpose of such monitoring system should be to detect significant changes of costs of the Agency that, taking into account the Union contribution and other non-fee revenue, could require a change in fees, charges or remuneration established under this regulation. That monitoring system should equally be able to detect, based on objective and verifiable information, significant changes of costs of remuneration of services provided to the Agency by the competent authorities of Member States, which act as rapporteurs and, where applicable, co-rapporteurs and by experts contracted by the Agency for the procedures of the expert panels on medical devices. **The special report in which the Agency will compile this cost information shall be subject to adoption by the EMA management board, following a consultation process between the EMA management board and the Competent Authorities of the Member States. This consultation can take place between the EMA**

management board and a Competent Authority separately, or via common consultation between the EMA management board and more than one member state, represented by an existing coordination body, like HMA. Cost information relating to services remunerated by the Agency should be auditable
in accordance with Article 257 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council16

Recital 3

Comments from the Estonian delegation

Article 11:

Para 3. The remuneration paid to competent authorities of the Member States provided for in this Regulation shall be maintained **as a single remuneration amount** in any revision of the Annexes.

During the WP we suggested to add „single remuneration amount valid for all Member States“ or „single EU remuneration amount“.

Comments from the German delegation

DE comments on the proposal for a regulation on fees and charges payable to the European Medicines Agency

The comments are preliminary. We also refer to our written comments submitted on 10 and 17 February and 1 March. The wording is based on the text proposed by the Presidency in Doc 7350/23.

DE changes are marked **underlined and bold.**

I. Article 5

Article 5
Payment of remuneration to competent authorities of the Member States for the provision of services to the Agency

1. […]

2. Unless otherwise provided for in this Regulation, where fee reductions **or waivers** apply, the remuneration to competent authorities of the Member States payable in accordance with this Regulation shall not be reduced.

Rationale:
It should be clarified that Article 5(2) also applies to complete fee exemptions (i.e. waivers), not only gradual fee reductions.

II. Article 6

Article 6
Reductions of fees and charge

1. […]

3. Where the applicant or marketing authorisation holder may also benefit from another reduction provided for in Union legislation, only the reduction that is the most favourable to the applicant or marketing authorisation holder shall apply. **Article 5(2) applies**.

4. On a duly justified proposal from the Executive Director of the Agency, in particular for the protection of public or animal health or for the support of specific types of products or applicants, selected for duly justified reasons, the Management Board of the Agency may grant, following a favourable opinion from the Commission, a total or partial reduction of the applicable amount **of fees**, in accordance with Article 8.

Rationale:
Para 3: We propose clarification that competent authorities are fully compensated even if the applicable highest fee reduction follows from another Regulation.

Para 4: It should be clarified that the Management Board may exclusively grant a reduction of fees and that it does not have the authority to reduce the amount of the remuneration paid to competent authorities.

III. Article 8

Article 8
Working arrangements

The Management Board of the Agency shall, on a justified proposal from the Executive Director and following a favourable opinion from the Commission, establish working arrangements to facilitate the application of this Regulation, including payment methods of the fees and charges levied by the Agency, and the mechanism for payment of remuneration to competent authorities of the Member States under this Regulation and a common format to be used by competent authorities of the Member States when providing to the Agency the financial information in accordance with Article 10(3). **The common format shall be based on a transparent and uniform methodology to survey the financial impact on the costs of services to the Agency.**

Rationale:
We welcome the addition proposed by the Presidency. It would be useful to further define the minimum requirements the common format should conform to. In particular, it should be based on a transparent and uniform methodology to ensure that the data submitted is comparable.

IV. Article 10

Article 10
Transparency and monitoring

1. […]

6. At the earliest on [OP: please insert date 1 years after the date of application] and at three-year intervals thereafter, the Executive Director of the Agency shall provide the Commission with a special report adopted by the Management Board of the Agency outlining, in an objective, fact-based and sufficiently detailed manner, justified recommendations to:

(a) increase or decrease the amount of any fee, charge or remuneration, following a significant change in the respective costs as identified, documented and justified in the report;
(b) amend any other element of the Annexes pertaining to the levying of fees and charges, including additional fees and charges referred to in Article 4.
(c) **adapt the specification of activities** ~~amend the information on practical aspects for the execution of activities~~ for which the Agency collects fees or charges **to changing conditions and requirements**.

9. The time interval to the first special report as well as the reporting time interval referred to in paragraph 6 may be shortened in any of the following situations:

(a) in the case of a public health emergency;
(b) in the case of a change of the legal mandate of the Agency;
(c) in the case there is ~~clear and compelling~~ evidence of significant changes in the costs or the cost-revenue balance of the Agency~~, including costs for cost-based remuneration to competent authorities of the Member States~~;
(d) **in the case there is evidence of significant imbalances regarding the remuneration to competent authorities of the Member States for the services they provide;**
(e) upon request of the Management Board of the Agency.

Rationale:
Para 6: We propose an alternative text with the goal of increasing clarity.

Para 9: It should be emphasized that imbalances in the remuneration of competent authorities also warrant a shortening of the regular timeframe.

Comments from the Irish delegation

Please see suggestions from IE concerning Articles 8 and 11 below, for your consideration:

Linked with Article 8 - suggested addition for recitals (possibly #18) to provide context for the addition to A8

The common format referred to in Article 8 should allow the NCAs to report all relevant costs. Given that remuneration and cost levels vary across MS, the common format should be sufficiently flexible in order to capture such variation.

Article 11 – suggested re-wording of the added para 3

The remuneration paid to competent authorities of the Member States provided for in this Regulation shall be maintained as a single remuneration amount **applicable EU-wide, including** in any revision of the Annexes.

Comments from the Netherlands delegation

<u>Comments from the Netherlands</u> on 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 (COM(2022) 721 final)

The comments below are in response to the Presidency compromise text (7350/23) as discussed during the CWP of 27 March 2023.

1. Recital 10

Since both Type I variations and renewals are proposed to be included in the CAP annual fee, the recital should be revised as follows (bold-underlined text added):

"For the purpose of simplification, the costs related to minor variations of Type I ***<u>and renewals</u>*** *should equally be included in the annual fee on the basis of an average estimation."*

2. Article 1 (subject matter) and Article 2 (definitions)

In regards Article 2, para 1, the Netherlands agrees that medicines authorised under Article 126a of Dir. 2001/83/EC continue to be excluded from paying procedural and annual fees for pharmacovigilance activities. However, Article 2 of the current proposal might not be the best place to articulate this exemption. In principle, all that Article 2 states is that the definition of a chargeable unit does not apply to these type of medicines. From this, one then has to deduct that, apparently, those products are excluded from paying pharmacovigilance fees. In our view, the regulation should be more specific. We propose to instead amend Article 1 of this legal proposal in line with Article 1 of the current Pharmacovigilance Fee Regulation (658/2014), which reads *"…and medicinal products which are authorised to be placed on the market in accordance with Article 126a of Directive 2001/83/EC, shall be excluded from the scope of this Regulation".* This means that the title of Article 1 of the current legal proposal would be changed to 'Subject matter and scope', and that the article itself stipulates that Article 126a products are exempted from paying fees X, Y and Z.

3. **Article 5 (payment of remuneration to competent authorities of the Member States for the provision of services to the Agency)**

We support the comment from the German delegation made during the CWP of 27 March 2023 that para 2 should read: "*…where fee reductions **or waivers** apply*".

4. **Article 6 (reductions of fees and charges)**

Paragraph 2

Para 2 reads: *"Where an assessment, an opinion or a service of the Agency is requested either by a Member State or by a Union institution, the Agency shall waive the respective fee or charge, as applicable, in full."*

During the CWP discussions on 27 March 2023, the Danish delegation made the comment that more flexibility is needed as there may be a situation where it is justifiable to not waive the respective fee or charge. The Netherlands agrees that it should be carefully investigated whether such situations could exist, and if that is found to be the case, this should be specified in the text.

Paragraph 4

As indicated by the German delegation, in para 4 it should be specified that the "applicable amount" refers to the total fee charged by EMA to applicants.

5. **Article 8 (working arrangements) (in relation to Article 10)**

In principle, the Netherlands agrees with the amendment proposed by the Presidency. However, we believe further amendment is needed, as follows:

"*the mechanism for payment of remuneration to competent authorities of the Member States under this Regulation, **details on the financial information on the nature and the extent of the financial impact on costs for services to the Agency as well as** a common format to be used by…"*

Alternatively, it could be added as an additional paragraph under Article 10, as follows:

"***Details on the financial information on the nature and the extent of the financial impact on costs for services to the Agency as well as the common format referred to in paragraph 3 shall be determined in accordance with Article 8.**"*

The reason for this addition is that Article 10.3 refers to 'duly justified financial information on the nature and the extent of the financial impact on costs for services to the Agency', to be provided for by competent authorities of the Member States responsible for medicinal products or by experts contracted for the procedures of the expert panels on medical devices. We believe that the details on what this 'duly justified financial information' should encompass is to be established by the EMA Management Board via the working arrangements.

6. Article 10 (transparency and monitoring)

Paragraph 6 - Submission of the special report

The Netherlands agrees with the Presidency proposal to delete the reference to Article 11.2 as that article only relates to amending fees on the basis of a change in EMA's or NCAs' costs, whereas the special report can also recommend the amendment of fees for reasons referred to under Article 10.6.b and c. However, due to the deletion of the text 'where considered relevant…' the submission of the special report every three years now becomes a legal obligation. This, regardless of whether there is cause for such a report. If there is no cause, this means a lot of additional work for the Agency, the Management Board and NCAs with no added value or specific purpose. We therefore propose to amend the text as follows:

"*…the Executive Director of the Agency shall**, where considered relevant following the findings of the cost monitoring in accordance with Articles 10.2 or 10.3, following a change in the practical aspects related to the execution of activities or any other aspect pertaining to the levying of fees and charges, or upon request by the Management Board of the Agency,** provide the Commission with a special report…*".

The Netherlands further agrees with the comment made by the German delegation that a one year interval for the first report may be too short of a period to collect sufficient data on veterinary procedures considering the limited frequency with which (some) procedures occur. This also relates to our comment above that a legal obligation to submit a special report at a certain interval may be problematic.

Paragraph 6 - Mechanism for monitoring the functioning and impact of the revised fee system

In its Staff Working Document on the impact assessment (SWD(2022)414), the Commission indicates that it envisions a periodic evaluation of the fee system, with the first evaluation no earlier than five years after the regulation comes into force. Such a provision is however missing from the legislative proposal. In our view, the possibility for cost monitoring under Article 10 provides sufficient safeguarding to keep fees in line with costs. However, this does not review the functioning of the EMA fee system as a whole, including the cost monitoring system itself, or impacts of the revised fee system on different sectors or applicants such as generic companies, SMEs and the veterinary medicine sector. We consider it therefore desirable that the Regulation be supplemented with a mechanism for evaluation. However, since a separate provision for evaluation or a "standard" periodic evaluation may be too burdensome of a procedure to monitor these aspects, such a mechanism could be made part of the cost monitoring system and special reporting under Article 10 in order to ensure an efficient approach.

For instance, EMA's Executive Director, upon endorsement by the EMA Management Board, may include in the special report **experience gained by NCAs and EMA on the functioning of the cost monitoring system**. In case it is concluded that the system needs optimizing, it should first be looked at whether the required changes can be introduced via the working arrangements under Article 8. Only if such changes are insufficient, the Commission should initiate an evaluation of (the relevant parts of) the legislation and, if warranted by the outcomes of this evaluation, propose the necessary legislative changes.

Similarly, the special report referred to in Article 10 may include **information on trends in regards the number and type of applications made by specific sectors or applicants**, with a request to the Commission to look at possible links between any negative trends and fees charged, if such link is suspected, and the need for amendment of fees and/or fee reductions, as necessary. Such changes could then be made through the adoption of delegated acts, in accordance with Article 11.

The above proposal could for instance be realised by the following changes to Article 10.6:

6. At the earliest on …[…]… in an objective, fact-based and sufficiently detailed manner, justified recommendations to:

(a) *increase or decrease the amount of any fee, charge or remuneration, following a significant change in the respective costs as identified, documented and justified in the report;*

(b) *amend any other element of the Annexes pertaining to the levying of fees and charges, including additional fees and charges referred to in Article 4.*

(c) *amend the information on practical aspects for the execution of activities for which the Agency collects fees or charges.*

The special report may further contain:

(d) ***Information on experience gained on the cost monitoring system by the Agency and the competent authorities of the Member States responsible for medicinal products or by experts contracted for the procedures of the expert panels on medical devices;***

(e) ***Information on trends in regards the number and / or type of applications made per type of applicant with a recommendation to look at a possible relationship between such trends and fees charged.***

Please also refer to our written comments from 24 February 2023 where we made the proposal.

Paragraph 7, point b

With the addition of para 6.c to Article 10, the wording '**AND** quantification' needs amendment. The reason being that "practical aspects for the execution of activities" cannot be quantified. We therefore propose to amend para 7.b as follows:

*"objective and verifiable information ~~and quantification~~**, including quantification where the information relates to a significant change in the relevant costs,** that directly supports the relevance of the recommended adjustments"*

Paragraph 8

It should be clarified that the updated version of the special report is also to be adopted by the EMA Management Board. This can either be done by referring to the procedure in para 6 of Article 10, or by amending para 8 as follows:

*"...as referred to in paragraph 6 **and adopted by the Management Board of the Agency**".*

7. Article 11 (revision)

Paragraph 1

During the CWP of 27 March 2023, some delegation proposed to delete para 1.c, which reads *"a change in the statutory tasks of the Agency leading to a significant change in its costs"*, stating that the required change in fees and remuneration amounts could be achieved via the special report. The Netherlands in principle has no issue with para 1.c, as in our view any amendment of fees and remuneration amounts due to a change in costs following a change in EMA's legal mandate should not have to go through a burdensome co-decision procedure. In fact, in the past exactly this led to a situation where, following the adoption of the pharmacovigilance legal framework, EMA and NCAs had to work for free for two years in regards certain pharmacovigilance activities, as this is how long it took to adopt fees via the Pharmacovigilance Fee Regulation. However, changes in fees and remuneration amounts following a change in EMA's legal mandate can only be proposed based on costs. Such a change is best provided via the special report. Indeed, Article 10 para 9.2 provides that the interval of the special report can be shortened in case of a change in EMA's legal mandate, thereby indicating the role of the special report in amending fees and remuneration amounts in such a situation. The Netherlands would therefore not oppose to a further clarification in the wording, if deemed necessary. In any case, any change proposed to para 1.c of Article 11 should not lead to a situation where a very necessary, shift amendment of fee and remuneration amounts is merely obstructed because of burdensome co-decision procedures, leading to a detrimental situation of underfinancing of EMA and NCAs.

Paragraph 2

The Presidency proposes to add '*taking into account also the sustainability of the Union regulatory network*'. Although the Netherlands agrees that a well-functioning, cost-based fee system is essential to ensure sustainability of the network, in our view the added text is of such a nature that it is better moved to the recitals. The articles should be clear on what type of information forms the basis for a revision of the fee and remuneration amounts, and this information should be evidence-based, objective, verifiable and quantifiable, as is also clarified in para 7 of Article 10. Data on costs and revenues are evidence-based, verifiable and quantifiable information. 'Sustainability of the network' however is not. Also, if the fees for EMA and remuneration amounts for NCAs are and remain cost-based in future, which is the objective of the fee system and to be achieved through the cost monitoring system, then the fee system automatically provides a solid financial basis for the network, which is one of the overarching goals of this regulation. In addition, 'sustainability of the network' does not only depend on sufficient funds, but also on whether investments can be/will be made in knowledge sharing and training, on whether procedures are not overly burdensome, on

whether sufficient capacity can be generated in the network with an (unexpected) change of the workload (e.g. Covid)...etc.

Paragraph 3

The Presidency proposes to add a new paragraph 3, which reads: "*The remuneration paid to competent authorities of the Member States provided for in this Regulation shall be maintained as a single remuneration amount in any revision of the Annexes*."

It is understood that the purpose of this addition is to avoid that, in future, the country coefficient may be included as a mechanism to determine fees and remuneration amounts depending on the Member State that acts as (co-)rapporteur. In principle, the Netherlands supports the view that country coefficients should not be the basis for calculating remuneration amounts; instead, a single amount per type of fee should be applicable to the (co-)rapporteur regardless of the country of origin. However, we doubt whether it is legally sound to include in legislation what can or cannot be amended through future revisions. We believe it would be more clear and legally sound to remove this text here and instead add a clarification under Article 5, for instance as follows:

"1. The Agency shall pay the remuneration referred to in Article 1(b) in accordance with the amounts of remuneration provided for in this Regulation.

2. Such remuneration is provided through a single remuneration amount per rapporteur and co-rapporteur per relevant type of fee, regardless of the Member State of origin of the competent authority that acts as rapporteur or co-rapporteur.

~~*2.*~~ ***3.*** *Unless otherwise provided for in this Regulation, where fee reductions apply, the remuneration to competent authorities of the Member States payable in accordance with this Regulation shall not be reduced. …."*

Please also note that this way, the future inclusion of the country coefficient via amendment of the annexes is equally obstructed. Indeed, both with the Presidency proposal and our proposal above, the addition of a country coefficient can only be achieved through the ordinary legislative procedure (i.e. co-decision).

General comment

During the CWP of 27 March 2023, many delegations stipulated that any change to the fees should not be at the detriment of NCAs. The Netherlands agrees this is the basic principle of a well-functioning fee system; such a system should ensure at all times a solid financial basis for both EMA ánd NCAs. Any fees and remuneration amounts should therefore be strictly cost-based, as is also stipulated in this regulation, and any changes to the fees via delegated acts should not lead to a deviation from this principle, in order to ensure both EMA ánd NCAs are and remain able to cover their relevant costs. This is where the cost monitoring system plays an important role, and the proposed enforced role of the EMA Management Board in the adoption of the special report should serve as a safeguard. A fixed distribution of the fees across EMA and rapporteurs, as is currently the case, would in our view in fact be contrary to the principles of a cost-based system and could even be detrimental to NCAs. Take for instance a situation where the costs of both EMA and NCAs increase, but not at the same rate (e.g., NCAs' costs increase significantly more than EMA's costs). The total fee would still have to be cost-based including all increases in EMA and NCAs' costs, but a fixed distribution means the actual increase in costs is not necessarily fully reflected in the remuneration amounts for NCAs. We therefore like to underline that if any wording is added to Article 11 clarifying that any amendment of fees should not be at the detriment of NCAs, or EMA for that matter, it should be carefully considered that this wording is not contrary to the principles of a cost-based system.

8. Article 16

To address previous concerns of several delegations that the wording of Article 16.2 may lead to a gap between the current and new fee system in regards the charging of (updated) annual fees, the Presidency proposed some changes to the wording. The Netherlands agrees that the text needs to be clarified to avoid such unintended situation, but believes more changes are necessary, for instance:

*"2. With regard to annual fees set out in Annex III**, for the year [OP: please insert calendar year of application]** this Regulation shall not apply to products for which an annual fee has become due pursuant to Regulation (EC) No 297/95 of Regulation (EU) No 658/2014 **in that same year. Thereafter, annual fees shall be charged in accordance with this Regulation.**"*

However, we suggest a legal check is done to verify whether our suggested wording is indeed sufficient or whether different amendments are needed to avoid described situation.

Comments from the Spanish delegation

The Spanish comments are on recital 12 which is related to Annex III.3. (the annual pharmacovigilance fee). It should be noted that at national level there is a fee covering different activities (including pharmacovigilance) for medicinal products authorised by NCAs. We request clarification as to whether the existence of the annual fee in Annex III, point 3, would not allow NCAs from charging their national fees. In case the two fees are compatible, **we propose clarification in recital 12 as follows:**

Recital l2:

(12) A specific annual fee should be charged for medicinal products authorised in accordance with Directive 2001/83/EC and for veterinary medicinal products authorised by the Member States in accordance with Regulation (EU) 2019/6 specifically for the pharmacovigilance activities carried out by the Agency that benefit marketing authorisation holders overall. Those activities relate to information technology, in particular maintenance of the EudraVigilance database referred to in Article 24(1) of Regulation (EC) No 726/2004, the Union product database referred to in Article 55(1) of Regulation (EU) 2019/6 and the Union pharmacovigilance database referred to in Article 74(1) of that Regulation, the monitoring of selected medical literature and the timely access to and analysis of Union-wide health data to support decision-making throughout the product lifecycle on medicines with valid and reliable real-world evidence. **Without prejudice to the ability of national competent authorities to levy the correspondent annual fees for medicinal products for human use authorised in accordance with Directive 2001/83/EC and veterinary medicinal products authorised by the national competent authorities in accordance with the Regulation (UE) 2019/6.**

Council of the European Union
General Secretariat

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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 delegations

Delegations will find attached comments from delegations on EMA fees proposal after Working Party on Pharmaceuticals and Medical Devices on 27 March 2023 on the Presidency compromise text 7350/23.

A separate document with comments from the delegations on the revised Presidency compromise 7350/23 REV 1 will be issued after the deadline for written comments on 4 April 2023.