Written contributions from delegations

Comments from the French delegation

Objet : Commentaires des autorités françaises sur le compromis proposé par la présidence suédoise relatif à la proposition de règlement redevances, suite aux réunions du groupe de travail « Produits pharmaceutiques et dispositifs médicaux » des 27 et 28 mars 2023.

Ref : **ST 7350/1/23 REV 1.**

Les autorités françaises saluent le travail de la Présidence et soutiennent la proposition de compromis proposé, qui répond aux préoccupations qui ont été exprimées par la délégation française lors de l'examen du projet de règlement par le groupe de travail.

French authorities welcome the work of the Presidency and support the proposed compromise, which meets the concerns expressed by the French delegation during the examination of the regulation project by the working group.

Les autorités françaises rappellent cependant qu'elles estiment nécessaire de clarifier le positionnement des autorités nationales compétences (ANC) par rapport à l'EMA dans la conduite des travaux confiés au réseau réglementaire. Pour les autorités françaises, les ACN ne doivent pas être présentées comme des prestataires de services de l'EMA mais bien comme des contributeurs majeurs aux travaux, dont la capacité d'expertise est mise au service du réseau européen. Au sein de ce réseau, l'EMA assure pour sa part l'animation et la coordination des travaux.

Les autorités françaises proposent ainsi :

- de modifier le premier considérant pour insérer les mots : « avec les autorités compétentes des États membres chargées de la réglementation des médicaments » après les mots : « joue un rôle clé» ;
- D'insérer, après le premier considérant, un nouveau considérant rédigé ainsi qu'il suit : « l'Agence européenne du médicament est un animateur de réseau auquel les autorités compétentes nationales sont des contributeurs majeurs aux travaux du réseau européen ».

However, the French authorities reiterate that they consider it necessary to clarify the position of the national competent authorities (NCAs) in relation to the EMA in the conduct of the work entrusted to the regulatory network. For the French authorities, the NCAs must not be presented as service providers to the EMA but as major contributors to the work, whose expertise is placed at the service of the European network. Within this network, the EMA is responsible for leading and coordinating the work.

The French authorities therefore propose:

- **to amend the first recital to insert the words: "with the competent authorities of the Member States responsible for the regulation of medicinal products" after the words: "plays a key role » ;**
- **to insert after the first recital a new recital worded as follows "The European Medicines Agency is the coordinator for the centralized activities of the European medicines regulatory network where the national competent authorities are major contributors ».**

Les autorités françaises considèrent par ailleurs que la modification des annexes du présent projet de règlement, induite par une modification des tâches statutaires de l'Agence entraînant une modification significative de ses coûts, constituent des éléments essentiels qui devraient relever d'un acte de codécision. Toutefois, afin de ne pas alourdir et complexifier la procédure, les autorités françaises rejoignent la proposition de la délégation allemande de modifier l'article 10 pour permettre au rapport spécial validé par le Conseil d'administration de l'EMA de comporter des recommandations précises et étayées en vue d'adapter les droits, redevances ou rémunérations existants ou à introduire de nouveaux droits, redevances ou rémunérations à la suite d'une modification des tâches statutaires de l'Agence. La Commission serait ainsi habilitée, en application de l'article 11, d'adopter un acte délégué sur la base de ce rapport spécial élargi. Il conviendrait en parallèle de procéder à la suppression du c) de l'article 11. Les autorités françaises soutiennent également la proposition d'ajout apportée par la délégation allemande à l'article 11 qui précise : « Par actes délégués, le pourcentage de répartition des redevances entre les autorités compétentes des États membres et l'Agence ne peut être modifié au détriment des autorités compétentes nationales. ».

The French authorities also consider that the amendment of the Annexes to this draft Regulation, resulting from a change in the Agency's statutory tasks leading to a significant change in its costs, are essential elements which should be dealt with by a codecision act. However, in order not to make the procedure more cumbersome and complex, the French authorities agree with the German delegation's proposal to amend Article 10 to allow the special report drawn up by the EMA Management Board to include precise and substantiated recommendations with a view to adapting existing rights, fees or remuneration or to introducing new rights, fees or remuneration following a change in the Agency's statutory tasks. The Commission would thus be empowered under Article 11 to adopt a delegated act on the basis of this extended special report. In parallel, Article 11(c) should be deleted. The French authorities also support the German delegation's proposed addition to Article 11,

which states: "By means of delegated acts, the percentage of distribution of fees between the competent authorities of the Member States and the Agency may not be changed to the detriment of the national competent authorities ».

Enfin, s'agissant des médicaments vétérinaires, les autorités françaises relèvent que la fixation des montants des redevances n'ayant pas pu être étayée par des éléments de coûts suffisamment objectivés, il convient de prévoir leur révision dans des délais brefs. Aussi, elles proposent que l'article 10 soit complété par un paragraphe 7.a. ainsi rédigé :

« 7.a. S'agissant des médicaments vétérinaires, le rapport spécial mentionné à l'article 10 (6) est adopté au plus tard 9 mois après l'entrée en vigueur du présent règlement. ».

Finally, as regards veterinary medicinal products, the French authorities note that since the fixing of the amounts of the fees could not be supported by sufficiently objective cost elements, provision should be made for their revision within a short time. They therefore propose that Article 10 be completed by a point 7.a. worded as follows:
"7.a. In the case of veterinary medicinal products, the special report referred to in Article 10(6) shall be adopted no later than nine months after the entry into force of this Regulation".

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 and 27 March. The wording is based on the revised compromise text proposed by the Presidency on 27 March.

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

So far, the member states indicated below have signalled their support for our proposals. And we are grateful for any further support of other member states at a later stage.

I. Article 8 (proposal supported by NL, IT, HR, HU, MT)

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, the mechanism for payment of remuneration to competent authorities of the Member States under this Regulation, a total or partial reduction in accordance with Article 6(4) 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.**

Those arrangements shall be made publicly available on the Agency's website.

Rationale:
For adequate comparative value of the data submitted to the Agency, we propose that the common format shall be based on a shared methodology. This is to ensure that the format does not merely establish a shared layout for future data queries. We believe it is necessary to achieve a common understanding of the defining characteristics of the categories to be submitted. This will help identify the cause of discrepancies between competent authorities avoiding serious misalignments. An agreement on shared principles would not preclude the system from dealing with complexities and unique constellations.

Therefore, the proposal does not provide for specific criteria, but is merely setting the goal of a common methodology. EMA and the NCAs will then be able to determine which criteria and which level of detail are necessary to further enhance comparability. National specificities could be taken into account. To develop and maintain such a methodology we would suggest to form a group of experts of NCA and EMA professionals.

If the proposed wording does not meet the approval of the other Member States, we could also accept the proposed amendment to Article 8 of the Netherlands.

II. Article 10 and 11 (proposal supported by FR, IT, HR, HU, FI, MT, SI (SI excluding Article 11(1)subpara 2)

Article 10
Transparency and monitoring

1. […]

6. At the earliest on [OP: please insert date 1 [DE: 2] 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) **adapt any fee, charge or remuneration, or introduce a new fee, charge or remuneration following a change in the statutory tasks of the Agency leading to a significant change in the costs;**
(c) 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;
(d) adapt the specification 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~~ **in the statutory tasks** of the Agency;

(c) in the case there is evidence of significant changes in the costs or the cost-revenue balance of the Agency;
(d) in **the** case there is evidence of significant changes in the costs for cost-based remuneration to competent authorities of the Member States;
(e) upon request of the Management Board of the Agency.

Article 11
Revision

1. The Commission is empowered to adopt delegated acts in accordance with Article 13 to amend the Annexes 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;~~
(d) the budgetary reporting of the Agency.

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 of the ~~relevant~~ **full** costs of the services provided to the Agency by the competent authorities of the Member States, taking into account also the sustainability of the Union regulatory network including a fair and objective allocation of fees, charges and remuneration.

[…]

Rationale:

Moving Art. 11(1)(c) to Article 10(6) and aligning the wording of Article 10(9)(b):
While in principle, amendments to the EMA Fees Regulation should already be made in the regulation which changes the statutory tasks of the Agency, we recognize that more flexibility might be of use. Since changes to EMA tasks may also affect the NCAs, they need to be involved in the process of amending or adding new fees, at least through the Management Board.

Therefore, we propose to delete Article 11(1)(c) and moving the wording to Article 10(6), where it is inserted as a new point (b). Under the new Article 10(6)(b) the special report may contain recommendations to adapt existing fees, charges or remunerations or introduce new fees, charges or remunerations following a change in the statutory tasks of the Agency. Flexibly adapting the fee structure to new tasks would still be possible via delegated acts (Article 11(1)(a)), but would require a special report adopted by the Management Board. The involvement of the Board of Directors will ensure that all relevant information is duly accounted for.

The wording "change in the legal mandate" and "change in the statutory tasks of the Agency" seem to refer to the same situation. We therefore propose to align the wording of Article 10(9)(b) with the phrasing used in Article 10(6)(b) (NEW) and use "change in the statutory tasks of the Agency" instead.

Choice of procedure: Article 11(1) subpara 2:

The proposal does not seek to preclude fee reductions for NCAs, thereby abandoning the cost-based approach. It simply concerns the choice of procedure if the NCA's share of a fee (i.e. the percentage of a fee allocated to NCAs) is to be decreased, potentially resulting in the role of the NCAs being diminished. Such fee adjustment should be reserved for the ordinary legislative procedure, as such adjustments directly affect the legitimate interests of Member States and their competent authorities. For fee increases a quick adjustment via delegated acts is warranted because these carry the risk of adversely affecting the EMA's ability to properly execute its tasks and its financial stability. Fee reductions would not be excluded any longer in the proposal above.[1] However, in those cases that could impair the sustainability of the network by diminishing the role of the NCAs, we believe it to be fair to use the standard procedure, which assures MS an equal level of participation. The involvement of the Management Board is not sufficient on this sensitive issue, as the Commission is not strictly bound by the recommendations of the special report.

As a consequence of the proposal, necessary reductions on the part of NCAs could still be implemented, but will be discussed and decided in the ordinary format and procedure.

[1] Let us assume that the current fee is 100.000 Euro and both EMA and NCAs receive 50.000 each under the current proposal. The fee distribution EMA-NCA is therefore 50% (it could be any other number, of course – the current distribution of each individual fee can easily be calculated on the basis of the Annexes).
The fee in absolute terms can be reduced by delegated act to e.g. 80.000 Euro. The fee distribution could remain the same (40.000 EMA and 40.000 NCAs) or the percentage distribution could be shifted in favour of the NCAs (e.g. 35.000 EMA and 45.000 NCA) via delegated act. The standard procedure would be required only if the percentage distribution would be shifted to the detriment of the NCAs (e.g. 45.000 EMA and 35.000 NCA), because here "percentage distribution of fees between the competent authorities of the Member States and the Agency" would be "changed to the detriment of the national competent authorities."
Likewise, the fee in absolute terms can be increased by delegated act to e.g. 140.000 Euro. The fee distribution could remain the same (70.000 EMA and 70.000 NCAs) or the percentage distribution could be shifted in favour of the NCAs (e.g. 60.000 EMA and 80.000 NCAs) via delegated act. The standard procedure would be required only if the percentage distribution would be shifted to the detriment of the NCAs (e.g. 80.000 EMA and 60.000 NCAs).

Comments from the Irish delegation

Article 10 (6)

Text proposal

At the earliest on [*OP: please insert date ~~3~~ **1** years~~*~~ after the date of application*] and at three-year intervals thereafter, the Executive Director of the Agency ***may*** ~~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** outlining, in an objective, fact-based and sufficiently detailed manner, justified recommendations **to**:

Rationale

Given its onerous nature, the preparation of any special report should be informed by need rather than predetermined by a mandatory interval.

Article 16 (2)

Text propsoal

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 become due pursuant to Regulation (EC) No 297/95 or Regulation (EU) No 658/2014 in that year ***prior to the application of this Regulation***. ~~in the year *[OP: please insert calendar year of application]*~~.

Rationale

Applicable annual fees should be informed by the date of application of the Regulation.

Comments from the Italian delegation

IT COMMENTS TO THE TEXT OF THE PROPOSAL FOR A REGULATION 2022/0417(COD)

Below are some observations and proposed amendments to the text of the Proposal for a regulation on the fees and charges payable to the European Medicines Agency, sent by the Presidency to the Delegations on 28 March 2023.

In principle, we agree with the changes introduced by the Presidency, which also incorporate in some cases the Italian position already expressed, including:

- the correction of the definition of "public health emergency";
- the simplification of the text in Article 10(3) and the amendment introduced to Article 8, which provides for the adoption by the EMA's Management Board of a "common format" to be used by NCAs when submitting financial information pursuant to Article 10(3), so as to give greater concreteness to the device in Article 10(3), to ensure greater uniformity of content and transparency to the financial information submitted, and to simplify the comparison and consolidation of financial information;
- the strengthening of the role of the EMA's Management Board, through the amendment introduced in Article 10(6) and subsequently reflected in Article 10(8) as well;
- the amendment of the time limit in Article 10(6) - from three years to one year - for the production of the special report by the EMA. Should this change not be in line with the proposals of the other Member States, it is nevertheless considered appropriate to amend the text by providing for an interval of 2 years, as proposed by Germany.
- through the introduction of point (d) of Article 10(9), the possible shortening of the reporting interval in case evidence of significant cost variations is provided by the competent authorities of the Member States;
- the limitation of the powers delegated to the European Commission, through the elimination of Art. 11(1)(e) and the clarification that fee revisions must also take into account the sustainability of costs for NCAs, ensuring a fair allocation of fees (Art. 11(2)).

In the fee review and monitoring procedure, it is considered appropriate to point out that the text of the proposed regulation in question should provide, in addition to the foregoing, a greater involvement of the Member States and consequently of the NCAs, in line with the current regulatory framework. Consequently, in order to more directly protect the financial needs of the NCAs, it would be appropriate to integrate the proposed regulation with some safeguards aimed at counterbalancing the regulatory flexibility in the fee revision, which:

- guarantee maximum transparency in the fee review and modification procedure;
- limit the powers of the Commission to adopt delegated acts; and
- allow for maximum consideration of what has been expressed by the Member States/NCAs.

Therefore, below are some comments and proposed amendments, marked **in bold**, to the text proposed by the Swedish Presidency.

Article 5

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

[…]

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

[…]

Comment

It is suggested to broaden the case in Article 5, paragraph 2, by extending it also to "charges", as the reductions also apply to charges (see Article 6) and it is therefore more correct to state that the remuneration to the NCAs is recognised regardless of the reduction of the charges themselves.

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, a total or partial reduction in accordance with Article 6(4) 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 and is adopted by the Management Board after consulting the competent authorities of the Member States.**

Those arrangements shall be made publicly available on the Agency's website.

Comment

Greater transparency in the fee change procedure should be ensured. It is therefore proposed to amend the text of this article in order to provide for the consultation of the Member States/NCAs by the EMA Management Board, before the adoption of the common format. It is hoped that the common format will indicate:

- the nature of the financial information that must be provided and the criteria for determining the extent of the financial impact on the costs of the services provided to the Agency, to ensure maximum uniformity of the financial information provided and the related impacts;
- the parameters or relevance thresholds, upon reaching which, the significant changes in the costs of the NCAs are in any case taken into consideration by EMA in the special reports (art. 10(3) and (6)) and/or allow for a reduction of time interval for special reports (art. 10(9)).

The proposed change regarding the need to carry out a consultation procedure for NCAs protects their financial needs more directly and amplifies discussion and transparency on the proposal. However, should this change not be in line with the proposals of the other Member States, the approval by the EMA Management Board is still deemed sufficient.

Article 10

Transparency and monitoring

[….]

6. At the earliest on [OP: please insert date 1 year 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**, after having carry out appropriate consultations with the competent authorities of the Member States,** 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 **of the Agency or of the competent authorities of the Member States** as identified, documented and justified in the report;
   b) adapt any fee, charge or remuneration, or introduce a new fee, charge or remuneration following a change in the statutory tasks of the Agency leading to a significant change in its costs;
   c) 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;
   d) adapt the specification 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~~ **in the statutory tasks** of the Agency;
   c) in the case there is evidence of significant changes in the costs or the cost-revenue balance of the Agency;
   d) in **the** case there is evidence of significant changes in the costs for cost-based remuneration to competent authorities of the Member States;
   e) upon request of the Management Board of the Agency.

Comment

The current text of the article, together with art. 11, gives the European Commission discretion in the fee review process, including the possibility of modifying the structure of the same as well as the amount.

Therefore, in order to counterbalance the regulatory flexibility in the fee review and to more directly protect the financial stability needs of the NCAs, it is proposed to amend the text by providing that:

- EMA Management Board consults with the NCAs on the text of the special report, before its approval;
- in the presence of a change in the tasks of the EMA, the revision of the fees takes place only if foreseen in the special report of the Management Board of the EMA (see amendment to article 11 below), in line with what was proposed by the German Delegation , in order to ensure adequate involvement in this process of modification of the EMA and the NCAs.

To evaluate whether to leave the letter d) of paragraph 6, considering that the letter c) already allows any changes to the Annexes.

The proposed change regarding the need to carry out a consultation procedure for NCAs protects their financial needs more directly and amplifies discussion and transparency on the proposal. However, should this change not be in line with the proposals of the other Member States, the approval by the EMA Management Board is still deemed sufficient.

Article 11

Revision

1. **Except for the repeal of fees or charges referred to in the Annexes, ~~T~~t**he Commission is empowered to adopt delegated acts in accordance with Article 13 to amend the Annexes where it **is** ~~**deems it**~~ 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;**~~

   (d) the budgetary reporting of the Agency.

   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 of the ~~**relevant**~~ **full** costs of the services provided to the Agency by the competent authorities of the Member States, taking into account also the sustainability of the Union regulatory network including a fair and objective allocation of fees, charges and remuneration.

[…]

Comment

Pursuant to art. 11 of this proposal, the procedure for the adoption of delegated acts provides for:

- consultation by the Commission of the experts designated by each Member State, in accordance with the principles set out in the Interinstitutional Agreement of 13 April 2016 on better law-making, and
- the entry into force of the delegated act only if neither the European Parliament nor the Council has objected within a period of two months from the date on which it was notified to them or if, before the expiry of this period, the European Parliament and the Council have both informed the Commission that they will not object.

In order to limit the power of the European Commission to adopt these acts, it is suggested to clarify that the amendments of the European Commission cannot:

i. eliminate fee cases or charges provided for in the attachments;
ii. change the percentage of the distribution of fees to the detriment of NCAs, as also indicated by other Member States.

The amendments referred to in points i) and ii) may possibly be made through the adoption of an amending regulation of the European Parliament and of the Council.

Article 13

Exercise of the delegation

[…]

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making. **The Commission shall in a transparent manner take the utmost account of opinions, recommendations or reports provided by the experts designated by each Member State.**

[…]

Comment

To ensure greater involvement of the Member States, it is suggested to integrate the article relating to the exercise of delegated powers as indicated.

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 revised Presidency compromise text (7350/1/23 REV 1) as discussed during the CWP of 28 March 2023. Changes proposed by the Presidency that are not mentioned in this document are endorsed.

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 scope)

The Netherlands agrees that information on which products are exempted from paying (certain fees) is best placed in Article 1. However, the proposed text means that medicines authorised under Article 126a of Directive 2001/83/EC are exempted from paying **<u>all</u>** fees, whereas under the current fee system such products are only exempted from paying pharmacovigilance fees. More specifically, they are currently exempted from paying fees for:

- PSUR / PSUSA
- PASS
- Referrals initiated as a result of the evaluation of pharmacovigilance data under the second subparagraph of Article 31(1), Article 31(2) and Articles 107i to 107k of Directive 2001/83/EC or under Article 20(8) of Regulation (EC) No 726/2004.
- Pharmacovigilance annual fee (annual fee for information technology systems and literature monitoring)

We assume this proposed change in scope is unintended and we are of the opinion that the current scope should indeed be maintained. We therefore propose the following change in wording in the newly added para 2 (added text as bold-underlined):

"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~~ ***paying fees set out in points 6.7, 14 and 15 of Annex I and point 3.1 of Annex III****."*

3. Article 6 (reductions of fees and charges)

Initially, para 2 stated that where an assessment, opinion or service of the Agency is requested by a Member State or Union institution, the Agency shall wiave 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, because 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 there are situations where the fee payable by the marketing authorisation holder should not be waived (in full) and whether it is therefore advisable to include in para 2 some flexibility in regards the waiving of the fee. In response to the Danish comments, the Presidency made the following amendment:

"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 ***not levy the respective fee or charge to that Member State or Union institution*** *~~waive the respective fee or charge, as applicable, in full~~."*

Although the Netherlands agrees with the fact that Member States or Union institutions should not be charged the relevant fee, the proposed wording does not provide the flexibility to levy a fee or charge to the marketing authorisation holder in certain instances. We therefore propose to change the text as follows:

"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 ***may on a case-by-case basis*** *waive the respective fee or charge, as applicable, in full.* ***The Agency shall not levy the respective fee or charge to that Member State or Union institution****."*

We do realise, however, that this proposed wording leads to uncertainty for marketing authorisation holders when they are expected to pay a fee or charge. It may therefore be better to specify in which particular situation the fee or charge is not waived in full. The Netherlands has no proposal at this point. This point could potentially be scheduled for discussion for the next CWP.

4. Article 8 (working arrangements)

During the CWP of 27 March the German delegation made the comment that the common format for the cost monitoring system is to be based on a shared, transparent and uniform methodology. They propose the following wording:

"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, the mechanism for payment of remuneration to competent authorities of the Member States under this Regulation, a total or partial reduction in accordance with Article 6(4) 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.***

Those arrangements shall be made publicly available on the Agency's website."

The Netherlands supports the changes proposed by Germany and their underlying reasoning for this change.

5. 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 actual cause for such a report. If there is no cause, this means a lot of additional work for the Agency, the Agency's Management Board and NCAs, with no added value or specific purpose. The Netherlands therefore believes that the submission of the report should not be a legal obligation. The fact that EMA's Management Board has an influence on the contents of the special

report, due to the fact the special report is to be adopted by them, does not solve this issue, because even the drafting of a very short report takes time. We therefore reiterate our proposal 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 during the CWP of 27 March that a one year interval for the first special 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 deemed 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.***

We repeated this comment in the CWP of 28 March, to which the Presidency replied that a reference to monitoring of the impact on the veterinary medicine sector would be included in the recitals. In our view, this is insufficient. First, recitals are not enforceable. Their goal is to provide context and clarification for implementation. All key elements relevant to the fee system should therefore be placed in the articles, not the recitals. Also, the objective of our proposal is not merely the monitoring of the impact on the veterinary medicine sector, but also to provide efficient means for the monitoring of the fee system as a whole. We so far have not received any substantiated response as to why the above proposal would be unfeasible or unnecessary.

Paragraph 9

The following amendment is proposed:

"(a) in the case of a change ~~of the legal mandate~~ ***in the statutory tasks*** *of the Agency;*

6. Article 11 (revision)

General comment

During the CWPs of 27 and 28 March, several 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 fee 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 for non-pharmacovigilance fees (and which was proposed by several delegations to be included in the new fee system), 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 payable by industry would still have to be cost-based and include all increases in EMA and NCAs' costs, but a fixed distribution means the actual increase in costs is not necessarily fully reflected in EMA's share of the fee and the remuneration amounts for NCAs. In other words, due to the fixed ratio, the allocation of the fee to EMA and NCAs would not be based on costs incurred, and NCAs may have to operate at a loss whereas EMA receives a surplus. The opposite is of course also true in a situation where EMA's costs increase significantly

more than NCAs' costs, leading to an underpayment of EMA and an overpayment of NCAs in case of a fixed allocation ratio. Therefore, in our view, a fixed ratio may be detrimental to the ability of EMA and/or NCAs to recover their costs and, as a result, the sustainability of the network as a whole. 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.

Paragraph 1

During the CWPs of 27 and 28 March, 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"*. Their reasoning for this proposal is that the required change in fees and remuneration amounts could be achieved via the special report. In addition, this wording created some confusion among some delegations as to what can be changed through the delegated acts. A further suggestion was made by one of the delegations to allow that fees and remuneration amounts can be changed as part of the co-decision procedure through which the legal mandate of the EMA is changed (i.e., instead of having to change them through delegated acts following the adoption of the change of legal mandate).

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 separate burdensome co-decision procedure. In fact, in the past exactly this led to a situation where, following the adoption of the pharmacovigilance legal framework in 2012, 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 (2014). However, we could agree to some changes in the wording of para 1.c. First, the order of wording could be changed to avoid any potential confusion as to what can be changed through delegated acts (the annexes and NOT EMA's statutory tasks), i.e.:

"a significant change in the Agency's costs following a change in its statutory tasks"

Second, changes in fees and remuneration amounts following a change in EMA's legal mandate can only be proposed based on (forecasted) costs. Such a change is in our view best provided via the special report, since it ensures the involvement of NCAs/Member States from the get-go. 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. For instance:

"a significant change in the Agency's costs following a change in its statutory tasks; ***such change in costs is to be supported by a special report in accordance with Article 10(6)****"*

This could be further clarified by adding the following information to para 6 of Article 10 as suggested by the German delegation, i.e.:
*"****(b) adapt any fee, charge or remuneration, or introduce a new fee, charge or remuneration following a change in the statutory tasks of the Agency leading to a significant change in its costs;****"*

Further, we would not oppose to examining the feasability of the option where the annexes are changed as part of the same legislative procedure through which EMA's legal mandate is changed, as this could help avoiding a delay in updating the fees like unfortunately has happened with the current fee system. Because although the procedure of delegated acts generally is faster than the ordinary legislative procedure, their adoption still takes several months.

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/or NCAs.

Paragraph 2

The Presidency proposes to add '*taking into account also the sustainability of the Union regulatory network including a fair and objective allocation of fees, charges and remuneration*'. Although the Netherlands agrees that a well-functioning, cost-based fee system is essential to ensure sustainability of the EU medicines regulatory network, we reiterate that 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 which is 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 from fees and remuneration, but also on whether investments can or will be made in knowledge sharing and training, on whether procedures are not overly burdensome (e.g. rolling review used too often), on whether sufficient capacity can be generated in the network following an (unexpected) change of the workload (e.g. Covid)...etc. Further, in accordance with the proposed regulation, the allocation of industry fees to EMA and NCAs should be based on their respective costs. Assuming this objective is achieved, now and in future, this automatically leads to a fair and objective allocation of fees and remuneration to EMA and NCAs. The added text "*a fair and objective allocation of fees, charges and remuneration*" is therefore unnecessary. It also provides unclarity, as this wording may open the door to an allocation not based on actual costs incurred but on non-quantifiable and non-objective information or reasoning, which is contrary to the objective of this regulation and potentially even detrimental to the sustainability of the network. Indeed, sustainability of the network cannot be achieved if either EMA or NCAs (or both) are not able to cover their actual costs. In this regard, we also refer to our general comment above.

In conclusion, the Netherlands does not agree with the added wording in para 2. The Netherlands however would not oppose to a reference to sustainability of the EU regulatory network in the recitals.

Paragraph 3

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

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, now or in future. Instead, a single amount per type of fee should be applicable to the (co-)rapporteur regardless of the country of origin. However, we reiterate our position that 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 on the provision of remuneration, 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 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 a mere 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).

7. Article 16 (transitional provisions)

Concerns were raised by several delegations that the wording in 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 new wording to solve this issue. The Netherlands agrees that the wording in Article 16.2 may lead to an unintended gap of payment of updated annual fees. At the same time, any solution sought should not lead to double charging of industry or an otherwise unfair system for industry. In our view, solutions can be found in both Article 16.2 and the working arrangements, but these require further discussion due to conflicting implications. In detail:

First, we propose to amend Article 16.2 as follows:

"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 become due pursuant to Regulation (EC) No 297/95 of Regulation (EU) No 658/2014 ~~in that year~~ ***before [OP: please insert date of application]."***

If for instance the date of application is 1 August 2024, the text will read: "*With regard to annual fees set out in Annex III, this Regulation shall not apply in the year* ***2024*** *to products for which an annual fee has become due pursuant to Regulation (EC) No 297/95 or Regulation (EU) No 658/2014 before* ***1 August 2024***". This means that if a marketing authorisation holder has already been charged an annual fee in the year 2024 in accordance with Regulations 297/95 or 658/2014 prior to the date of application of the new regulation, they are not charged twice in the year 2024.

However, this does not address the issue of a potential gap in the payment of updated annual fees. For a solution, we should also look at the working arrangements.

For the centrally authorised products (CAP) annual fee, the current fee system provides that the fee shall be due on the first and each subsequent anniversary of the notification of the marketing authorisation decision, and it shall relate to the preceding year (Article 10.1 of Regulation (EC) No 297/95). To avoid a payment gap, the exact same rule could be adopted in the new working arrangements for the annual fees in point 1 and 2 of Annex III. That way, for each medicinal product there is always exactly one year between payment of the "old" annual fee and the "new" annual fee, regardless of the date of application of the new regulation. And from the date of application onwards the new fee is the only applicable fee. The last medicinal products to be levied an updated fee is the one with a date of authorisation shortly before the date of application of the new fee regulation (i.e., if the date of application is 1 August 2024, a product authorised on 31 July of any given year will be levied the old fee on 31 July 2024 and the new fee on 31 July 2025). However, since the fee applies to the preceding year, there is no delay in payment of updated CAP fees, because any services provided after the date of application of the regulation are covered by the new fee.

There is one note that needs to be made:

This solution will create in the first year after application an unfair system for industry in regards the level of the CAP annual fee. Let's give the most simple example with again 1 August 2024 as the hypothetical date of application: medicinal products who got granted a marketing authorisation on 31 July of 2024 pay the "old" CAP annual fee for the preceding year (31 July 2023 – 30 July 2024), whereas medicinal products who got granted a marketing authorisation on 1 August 2024 pay the higher "new" CAP annual fee for the preceding year (1 August 2023 – 31 July 2024), for the exact same services provided over the same period minus one day. There are more complicated examples, for instance a medicinal product authorised on 1 March of any given year versus a medicinal product authorised on 1 July of any given year: for the period between 1 March 2024 and 1 July 2024, the first product will be charged the higher new fee whereas the second product will be charged the current lower fee for the same services provided during those same four months. This is because the first product will be charged the higher fee for the first time on 1 March 2025 covering the period 1 March 2024 – 1 March 2025, whereas the second product will be charged the higher fee for the first time on 1 July 2025 covering the period 1 July 2024 – 1 July 2025.

The issue of an unfair system only occurs in the first year after application of the new regulation, because, thereafter, the new CAP annual fee applies equally to all products. There are two ways forward: either we accept that the system is unfair in regards the CAP annual fee in the first year of application (which is contrary to the overall objective of the fee system, but keeps things simple) or we look for a solution (which would complicate the fee system temporarily, which is contrary to the objective of simplification). In case of the latter, a solution could be if the system would provide that the new updated CAP annual fee is only applicable to the period after the date of application and the old CAP annual fee applies to any period before the date of application. However, this means the first year after the date of application of the new regulation, the calculation of the total CAP annual fee becomes a complex exercise for EMA, because two different fees apply. And to make matters worse, the calculation of the total CAP annual fee differs per product, since the date of granting the marketing authorisation differs for each product and, with that, the ratio [old fee : new fee]. A simple excel sheet with fixed calculation formulas may provide a solution here. However, it should be discussed, especially also with EMA as the entity responsible for implementing the system, whether this solution is desirable and feasible or whether other options should be explored. As said, the alternative would be to accept a certain level of unfairness during the first year of application in order to keep things simple.

For the pharmacovigilance (PhV) annual fee, the current fee system provides that "*the annual fee shall be due on 1 July of every year in respect of that calendar year*" (Article 7.6 of Regulation (EU) No 658/20147). Here again, the same due date should be established via the working arrangements under the new fee system, so that for each medicinal product there is exactly one year between payment of the old and the new fee. Here, however, there may be a gap in payment of the updated annual fee to EMA, depending on the date of application of the new regulation. For example, if the date of application is 1 August 2024, the due date of the PhV annual fee precedes the date of application and the old annual fee applies to calendar year of 2024. This means that between 1 August 2024 and 31 December 2024 services provided by EMA are covered by the old fee, since the fee paid is in respect of that calendar year. If however the date of application of the regulation falls prior to 1 July, e.g. 1 May 2024, companies pay the new fee for the year 2024, even for services provided prior to the date of application. As with the CAP annual fee, either these situations are accepted or a solution is sought similar to the one explained above. Again, this is to be discussed also with EMA, as the entity responsible for implementing the system.

In any case, for both the CAP annual fee and the PhV annual fee, the solution cannot be fully captured in the legislative text. It is therefore of importance that the EMA Management Board, when establishing the working arrangements, is (made) duly aware of the importance of choosing a particular due date for the annual fees, and EMA is consulted in discussing feasibility of solutions.

8. Article 17 (entry into force and date of application)

The Netherlands agrees with the comment from the Croatian delegation that the date of application of this regulation is to be carefully considered in reference to the budgetary forecasting of the NCAs. The date of application is therefore to be decided on when the adoption date is known.

9. Annexes

During the CWP of 28 March the Presidency confirmed that comments on the annexes that are not related to the targeted approach could also be included in the written comments. The comments included below were already made during previous CWPs as well as sent in writing. Since so far no updated versions of the Annexes have been tabled for discussion and no response or clarification in regards comments on the annexes has been given, we reiterate our comments and kindly ask the Presidency to provide a response.

Annex I – fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use

Point 2.1(b) of Annex I refers to the so-called "rolling review". No cost and time data have been collected for this activity. The Netherlands asks the Commission to clarify the proposed fee and remuneration amounts. The Dutch Medicines Evaluation Board has calculated that their costs for a rolling review are substantially higher than for a regular application for a marketing authorisation. There are several reasons for that, one being that the underlying data are often of lower quality which takes more time to assess. Another being that the assessment reports have to be updated more often.

The Netherlands further comments that the fee under point 2.1(b) is equal to the fee for a marketing authorisation application pursuant to Art. 8(3) - known active substance as proposed under point 3.2 of this annex. This implies that if companies who choose NOT to submit a marketing authorisation application for an innovator product with a **new** active substance that has been assessed via the rolling review pay a lower fee than companies whose product were only assessed (and subsequently approved or not) via the regular marketing authorisation application procedure (difference of €135k). This, whereas the work involved for NCAs and EMA is the same or actually, as we pointed out before, significantly more. The reason for this discrepancy is the fact that: **(1)** the fee for a rolling review under point 2.1(b) equals the fee under point 3.2 of this annex for an Article 8(3) - known active substance application fee and **(2)** the amount in point 2.1(b) is to be deducted from the fee under point 3 where such application is submitted by the same application. Hence, the proposals under points 2.1(b) and 2.3 combined lead to an unfair and non-cost-based fee system.

Further, although the rules for the eligibility for the rolling review are not within the scope of the proposed EMA fee regulation, the Netherlands wishes to point out that these provisions lead to a perverse incentive for companies to choose the rolling review instead of a regular marketing authorisation application.

The Netherlands therefore proposes that, at a minimum, the fee and remuneration amounts under point 2.1(b) be equal to those under point 3 referring to the same type of dossier (i.e. 8(3) new vs. known active substance), regardless whether the same applicant subsequently submits an application for a marketing authorisation.

The Netherlands further sees the need to reassess the fee and remuneration amounts under point 2.1(b) via the cost-monitoring system and special report under Article 10 of the proposed regulation once more experience has been gained with the rolling review (i.e., once more time and cost data are available relevant to the rolling review).

Annex III – annual fees

Cyprus, Latvia, Malta and Slovenia requested in their written comments from 10 February the pharmacovigilance annual fee to be waived in full for medicinal products authorised in EU Member States with a population of around 3 million or less. In the Council Working Party of 20 February, the Presidency explained that they, together with the Commission, are looking for a technical solution maintaining the status quo. The Netherlands sympathises with the reasons underlying this proposal. However, more in-depth analysis on budgetary consequences and the number of products impacted are needed before we can take a position on this matter. We therefore kindly await the Presidency/Commission proposal for this technical solution.

Annex V – fee reductions

Point 1.1.1.(g) and (h) should refer to points 14 and 15 of Annex I, respectively.

4.3. Annex VI – performance information

- Point 1:

The Netherlands suggests that the text is slightly amended to *"…[…]…**Agency** staff and non-staff costs…[…]…"* to clarify this point, especially because this annex also refers to information to be provided by the NCAs.

- Point 6:

Point 6 requires that NCAs provide annually the number of working hours spent as (co-)rapporteur per procedure. This seems very resource intensive and the exact purpose is not clear. We do believe, however, that the provision of time data can be useful in support of the cost-monitoring system to justify proposals for adjustment of certain fee and/or remuneration amounts, especially in case the need for adjustment is based on a change in time spent (e.g. more time due to technological or scientific advances or less time due to regulatory optimisation). We therefore propose to amend point 6 in such a way that its purpose is more clearly linked to the cost monitoring and special reporting under Article 10 by specifying that the details for data collection (procedures for which time data are to be collected, period of collection, frequency of collection, etc.) are to be adopted by the EMA Management Board via the working arrangements under Article 8. This could be clarified by changing the wording as follows:

The following information shall relate to each calendar year:

(1) the overall cost and breakdown of staff and non-staff costs relating to the fees and charges referred to in Article 3;

…[…]…

This information could be supplemented by the following information:

(6) number of working hours spent by the rapporteur and the co-rapporteurs and experts contracted for the procedures of the expert panels on medical devices per procedures on the basis of the information provided to the Agency by the national competent authorities concerned. The procedures to be included shall be decided by the Management Board ***of the Agency*** ~~*based on a proposal by the Agency*~~ ***pursuant to Article 8 of this Regulation. Such information may be provided each calendar year or less frequently, as a complement to the information under points 1 to 5.***

As a final question, it is not fully clear which authority or entity shall provide the data related to the expert panels. The text reads "…by the national competent authorities". This should be clarified.

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 the revised Presidency compromise 7350/23 REV 1.