Written contributions from delegations

Comments from the Belgian delegation

Written comments EMA Fees Belgium – 07.02.23

ARTICLES

Proposal for amendment article 10

Article 10

Transparency and monitoring

1. The amounts set out in the annexes shall be published on the website of the Agency.

2. The Agency shall monitor its costs and the Executive Director of the Agency shall provide, as part of the annual activity report delivered to the European Parliament, the Council, the Commission and the Court of Auditors, detailed and substantiated information on the costs to be covered by fees and charges that are within the scope of this Regulation. That information shall include the performance information set out in Annex VI and a cost breakdown related to the previous calendar year and to a forecast for the following calendar year. The Agency shall also publish an overview of that information in its annual report.

3. ~~Evidence of significant changes in the costs of services provided to the Agency, excluding any effect of inflationary adjustments and any costs for activities that do not constitute a service to the Agency, may be provided 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 to the Agency. Such information may be provided once per calendar year or less frequently, as a complement to the information provided in accordance with Annex VI. Such evidence shall be based on duly justified and specific official financial information on the nature and the extent of the financial impact on costs for services to the Agency. To that end, the Agency shall may provide a common format facilitating comparison and consolidation. The competent authorities of the Member States and the experts contracted for the procedures of the expert panels on medical devices to the Agency shall provide such information in the format provided by the Agency, together with any supporting information allowing to verify the correctness of the amounts submitted. The Agency shall review and aggregate that information and shall use it, in accordance with paragraph 6, as a source for the special report provided for in that paragraph.~~

4. Article 257 of Regulation (EU, Euratom) 2018/1046 shall apply to the information provided to the Agency in accordance with paragraph 3 of this Article and Annex VI to this Regulation.

5. The Commission shall monitor the inflation rate, measured by means of the Harmonised Index of Consumer Prices published by Eurostat pursuant to Regulation (EU) No 2016/792, in relation to the amounts of fees, charges and remuneration set out in the Annexes to this Regulation. The monitoring exercise shall **start at the date of application** ~~take place~~ ~~no earlier than~~ [*OP: please insert date one year after the date of application of this Regulation]*, and thereafter on an annual basis. Any adjustment, in line with inflation, to fees, charges and remuneration established in accordance with this regulation shall become applicable, at the earliest, on 1 January of the calendar year following the calendar year in which the monitoring exercise took place.

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

   (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.

7. The special report referred to in paragraph 6 and the recommendations it contains shall be based on the following:

   (a) continuous monitoring of the information referred to in paragraphs 2 ~~and 3~~ and of the cost of the activities necessary for the fulfilment of the statutory tasks of the Agency, aimed at identifying significant changes to the cost base of services and activities of the Agency;

   (b) objective and verifiable information and quantification that directly supports the relevance of the recommended adjustments.

7.(bis) **The competent authorities of the member states responsible for medicinal products and the experts contracted for the procedures of the expert panels on medical devices shall monitor their costs and provide evidence of significant changes in the cost of services provided to the Agency by means of a joint special report.**

8. The Commission may request any clarification or further substantiation of the report**s** and **their** ~~its~~ recommendations, if considered necessary. Following such a request, the Agency **and the competent authorities of the member states responsible for medicinal products and the experts contracted for the procedures of the expert panels on medical devices** shall without undue delay provide the Commission with ~~an~~ updated version**s** of the report**s** which address~~es~~ any comments made and questions raised by the Commission.

9. The reporting time interval **and timing of the first joint special reports and first special report** referred to in paragraph 6 **and 7(bis)** 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) **upon request of the EMA management board**

Rationale

in §5-6 the timelines are adapted to allow for more speedier adaptations, which is needed given the inflation rate that is currently used in the proposal and to ensure the possibility for timely adaptation of amounts.

In §6 the EMA management board should revise and approve the special report, ensuring a better distribution of power consisting of more weight for the management board in developing the report. Likewise for §9.

A new §7 Bis is proposed to ensure a stronger role of the member states in cost monitoring and in the mechanism (special report) to translate cost monitoring in adaptations to the fees and renumerations through delegated acts.

Proposal for amendment article 11

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 justified in view of any of the following:

   (a) a special report **by the Agency and a joint special report by the competent authorities of the member states responsible for medicinal products and the experts contracted for the procedures of the expert panels on medical devices** received by the Commission in accordance with Article 10(6 **and 7(bis)**);

   (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;

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

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 costs of the services provided to the Agency by the competent authorities of the Member States.

Rationale

Point A in §1 should be amended to be consistent with our proposal to have a separate joint special report by member states.

Point E in §1 should be deleted as it gives too much liberty to the commission to adopt delegated acts, potentially leading to unilateral adaptations that might impact NCAs without profound consultation.

ANNEXES

General comments

Belgian keeps a general reserve on the amounts of the annexes.

Comment on Annex 3

We believe that the repartition of the annual fees should take into account rapporteurship for both CHMP rapporteur and PRAC rapporteur, and include a share for the HMA/network for the financing of the HMA network activities.

Proposal to amend annex 3

4 (new). Annual fee for non-procedure related activities at EU level conducted by Competent Authorities

4.1. **For medicinal products for human use authorised in accordance with Directive 2001/83/EC, a fee of EUR XX per chargeable unit-human, shall apply once per year to cover non-procedure related activities at EU level conducted by Competent Authorities.**

4.2. **For veterinary medicinal products authorised by competent authorities of the Member States in accordance with Chapter III, Sections 2 to 5 of Regulation (EU) 2019/6, a fee of EUR XX per chargeable unit-veterinary shall apply once per year to cover non-procedure related activities at EU level conducted by Competent Authorities.**

4.3. **The total payable amount of the annual fees referred to in points 4.1 and 4.2 for each marketing authorisation holder shall be calculated by the Agency on the basis of the number of chargeable units-human and chargeable units-veterinary, respectively, which correspond to the information recorded on 1 July of each year.**

4.4. **The annual fees referred to in points 4.1 and 4.2 shall be due on 1 July of every year and shall cover the period from 1 January to 31 December of that calendar year.**

4.5. **The remuneration shall be calculated on a yearly basis based on the participation of the receiving national competent authorities in non-procedure related activities in the context of EU level activities.**

Rationale

In the current proposal, non-procedure related activities on EU level such as active participation in and member ship of committees, working parties, projects and other, are not renumerated. We therefore propose a separate annual fee to renumerate these activities, based on the chargeable units.

Proposal to amend annex 5

5. Applications relating to core dossier medicinal products to be used in a human pandemic situation

5.1 The payment of the fee for an application for a marketing authorisation of a medicinal product to be used in a human pandemic situation shall be deferred until the pandemic situation is duly recognised, either by the World Health Organisation or by the Union in accordance with **Regulation (EU) 2022/2371** ~~Decision No 1082/2013/EU~~.

Such deferral shall not exceed 5 years.

5.2 In addition to the deferral provided for in point 2.1, for regulatory activities within the framework of the submission of a core dossier for a **pandemic treatments and vaccines** ~~influenza vaccine~~ and the follow-up submission of a pandemic variation, a fee reduction of 100 % shall apply in the following cases:

(a) pre-submission activities pursuant to section 9 of Annex IV;

(b) scientific advice pursuant to section 1 of Annex I;

(c) extension of marketing authorisation pursuant to section 4 of Annex I;

(d) major type-II variation pursuant to section 5 of Annex I;

(e) annual fee pursuant to section 1 of Annex III.

Those reductions shall apply until the human pandemic situation is duly recognised.

5.3 Where reductions apply pursuant to point 2.2, no remuneration shall be paid to the national competent authorities for the annual fees referred to in point 2.2(e).

Rationale

In §1.1, the relevant legislation should be the regulation on cross-border health treats that repeals the decision that was mentioned

In §1.2, there is no reason to limit to 'influenza' or to vaccines.

Proposal for adding a point in annex 5

9 (New). **Fee reduction for products addressing unmet medical needs according to [article 73 of revised directive 2001/83/EC] and antimicrobial resistance as referred to in [article 40 of revised regulation 726/2004].**

A 50 % fee reduction shall apply to products adressing a unmet medical need according to [revised directive 2001/83/EC (article 73)] for the following services:

a) initial marketing authorisation application pursuant to section 3 of Annex I, to this Regulation;

b) pre-authorisation inspection pursuant to section 1 of Annex IV, to this Regulation;

c) extension of a marketing authorisation pursuant to section 4 of Annex I, to this Regulation, in the first year from granting of the marketing authorisation;

d) **major type-II variation pursuant to section 5 of Annex I, to this Regulation, in the first year from granting of a marketing authorisation;**

e) **annual fee pursuant to section 1 of Annex III, to this Regulation, in the first year from granting of a marketing authorisation;**

f) **post-authorisation inspection pursuant to section 1 of Annex IV, to this Regulation, in the first year from granting of a marketing authorisation.**

Rationale

We support incentives that are needs-based, rather than product based, producer based, or technology based.

Comments from the Cypriot, Latvian, Maltese and Slovenian delegations

COMMENTS BY CYPRUS, LATVIA, MALTA AND SLOVENIA

ANNEX

to the

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

{SEC(2022) 440 final} - {SWD(2022) 413 final} - {SWD(2022) 414 final} - {SWD(2022) 415 final}

ANNEX III

Annual fees and remuneration

3. Annual pharmacovigilance fee for medicinal products for human use authorised in accordance with Directive 2001/83/EC and for veterinary medicinal products authorised by competent authorities of the Member States in accordance with Regulation (EU) 2019/6

3.1. For medicinal products for human use authorised in accordance with Directive 2001/83/EC, a fee of EUR 190 per chargeable unit-human, shall apply once per year for the Agency's pharmacovigilance activities including analysis of Union-wide health data to support better decision-making with real world evidence. Such fee shall be waived in full for medicinal products authorised in EU member states with a population of about three million people or less. The Agency shall retain the fee revenue from the annual pharmacovigilance fee.

Justification:

The Pharmaceutical Strategy for Europe aims at creating a future proof regulatory framework and at supporting industry in promoting research and technologies that actually reach patients in order to fulfil their therapeutic needs while addressing market failures. the improvement of market access in particular for smaller Member States is also one of the objectives of the strategy and the upcoming legislation.

The increase in fee proposed by the commission in this legislative proposal is anticipated to introduce an additional disincentive for marketing authorization holders to market their products in small EU markets and therefore negatively 2 contributing to medicine accessibility.

Whilst a single EU fee for the EU single market is the preferred option and should become the rule with the revision of the pharmaceutical legislation, in which the 450 EU market should be treated as a whole (rather than then the current fragmented market), as a temporary measure until the legislative framework is revised is it proposed to waive the fee for small Member States.

Country size is often measured in terms of population size, and in the book Small States of the European: Economic Perspectives, small states of the EU are defined as those with a population of about three million people or less. According to this definition seven EU member states qualify for inclusion in this group, namely Cyprus, Estonia, Latvia, Lithuania, Luxembourg, Malta, and Slovenia.

It is therefore proposed that the current fee as per Regulation (EU) 658/2014 is waived for small markets since fee reductions and exemptions are already available for micro-, small- and medium-sized-enterprises (SMEs) and for certain categories of medicines such as generics, well-established use, homeopathic and herbal products. The fee for a chargeable unit for a medicinal product marketed in a small market should be waived.

Comments from the Czech delegation

Comments from the Czech delegation, following the WP on 2 February 2023

Article 10

Transparency and monitoring

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

9. 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.

Article 11

Revision

1. The Commission is empowered to adopt delegated acts in accordance with Article 13 to amend the Annexes **relative to the specific rates only** where it deems it justified 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;

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

Article 13

Exercise of the delegation

4. Before adopting **and while drafting/preparing** a delegated act, the Commission shall ~~consult~~ **dully take into account the opinion delivered by** 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.

Additional comments with respect to provisions related to veterinary medicinal products.

Additionally, we would also like to stress that we support any further safeguards concerning the delegated acts. In this regard, we can support HU proposal expressed in the email below as well as FR proposal, which was expressed during the last WP meeting, that the scope of revision done via delegated acts could be defined by the Special Report.

A: Flexibility and delegation of powers

CZ-vet requests that the following items / issues shall be exempted from the flexibility mechanism and from the empowerement of the Commision for amendments:

- **A1 - Country coefficients** in any form shall be excluded from the flexibility mechanisms and from the scope of the delegation of powers to the European Commission
    - This should be made by introducing specific recital provisions as well as by adding specific provisions to the Article 11 of draft Regulation
- **A2 – Annex II – Waivers and conditions for referral and arbitration procedures** provided in Annex II (VMPs), Section 7, if it is retained – please see comments below - shall be excluded from the flexibility mechanisms and from the scope of the delegation of powers to the European Commission
    - This should be made by introducing specific recital provisions as well as by adding specific provisions to the Article 11 of draft Regulation
- **A3 – Annex III, section 3, point 3.2 - Annual pharmacovigilance fee** for medicinal products for veterinary medicinal products authorised by competent authorities of the Member States in accordance with Regulation (EU) 2019/6, if it is retained – please see comments below, shall be excluded from the flexibility mechanisms and from the scope of the delegation of powers to the European Commission
    - This should be made by introducing specific recital provisions as well as by adding specific provisions to the Article 11 of draft Regulation

B: Deletion of specific fees which will impact negatively availability of veterinary medicinal products, in particular in smaller markets and /or other specific amendments to be made in order to reduce negatve impact of the fees on availability of VMPs

CZ request that following changes are made

B1 - Annex II, Section 7 (Referrals and arbitration procedures), point 7.4. (procedure initiated under Article 82 of Regulation (EU) 2019/6) shall be deleted due to the fact, that such fee might have an immense negative effects on availability of veterinary medicinal products in all Member States, but in particular in those Member States with smaller markets.

If the item is not deleted we request to amend the text by adding the text introducing a full waiver as follows:

Current text	Proposed amendment
7.4. A fee of EUR 209 300 shall apply to the assessment carried out in the context of a procedure initiated under Article 82 of Regulation (EU) 2019/6. The remuneration shall be EUR 29 200 for the rapporteur and EUR 12 900 for the co-rapporteur.	7.4. A fee of EUR 209 300 shall apply to the assessment carried out in the context of a procedure initiated under Article 82 of Regulation (EU) 2019/6. ***Such fee shall be waived in full.*** The remuneration shall be EUR 29 200 for the rapporteur and EUR 12 900 for the co-rapporteur.

In line with comments raised under A, the waiver shoud be excluded from the flexibility mechanism and delegation of powers to the EC.

If the waiver is not introduced, we propose to amend the text by adding the provision that the fee shall only apply if the referral procedur is initiated at the request of the Marketing Authorisation Holder as follows:

Current text	Proposed amendment
7.4. A fee of EUR 209 300 shall apply to the assessment carried out in the context of a procedure initiated under Article 82 of Regulation (EU) 2019/6. The remuneration shall be EUR 29 200 for the rapporteur and EUR 12 900 for the co-rapporteur.	7.4. A fee of EUR 209 300 shall apply to the assessment carried out in the context of a procedure initiated ***at the request of the Marketing Authorisation Holder*** under Article 82 of Regulation (EU) 2019/6. The remuneration shall be EUR 29 200 for the rapporteur and EUR 12 900 for the co-rapporteur.

In line with comments raised under A, the condition shoud be excluded from the flexibility mechanism and delegation of powers to the EC.

B2 - Annex II, Section 10 (Assessment of post-marketing surveillance studies), point 10.1. (Assessment of post-marketing surveillance studies pursuant to Article 76(3) of Regulation (EU) 2019/6) shall be deleted due to the fact, that such fee might have an immense negative effects on availability of veterinary medicinal products in all Member States, but in particular in those Member States with smaller markets.

If the item is not deleted we request to amend the text by adding the text introducing a full waiver as follows:

Current text	Proposed amendment
10.1. A fee of EUR 37 800 shall apply to the assessment of post-marketing surveillance studies pursuant to Article 76(3) of Regulation (EU) 2019/6 that are conducted in more than one Member States.	10.1. A fee of EUR 37 800 shall apply to the assessment of post-marketing surveillance studies pursuant to Article 76(3) of Regulation (EU) 2019/6 that are conducted in more than one Member States. ***Such fee shall be waived in full.***

- Subsequent amendment to point 10.2 and 10.3 shall be made.
- In line with comments raised under A, the waiver shoud be excluded from the flexibility mechanism and delegation of powers to the EC.

If the waiver is not introduced, we propose to amend the text by adding the provision that as regards the Union interest referral, the fee shall only apply when the the referral procedure has been initiated at the request of the Marketing Authorisation Holder as follows:

Current text	Proposed amendment
10.1. A fee of EUR 37 800 shall apply to the assessment of post-marketing surveillance studies pursuant to Article 76(3) of Regulation (EU) 2019/6 that are conducted in more than one Member States.	10.1. A fee of EUR 37 800 shall apply to the assessment of post-marketing surveillance studies pursuant to Article 76(3) of Regulation (EU) 2019/6 that are conducted in more than one Member States. ***When it concerns the case falling within the scope of procedure under Article 82 the fee only applies if the procedure has been initiated at the request of the Marketing Authorisation Holder***.

In line with comments raised under A, the conditions shoud be excluded from the flexibility mechanism and delegation of powers to the EC.

- **B3 - Annex III, section 3, point 3.2 - Annual pharmacovigilance fee** for medicinal products for veterinary medicinal products authorised by competent authorities of the Member States in accordance with Regulation (EU) 2019/6, shall be deleted due to the fact, that such fee might have an immense negative effects on availability of veterinary

medicinal products in all Member States, but in particular in those Member States with smaller markets.

If the item is not deleted we request that the Commisison provides detailed calculation based on which this fee has been established, including posibble impacts on the availability of VMPs in Member States with smaller markets as well as possible conflict with Article 2(8) of Regulation 2019/6 where fees VMPs authorised by the Member States are subect to national provisions.

If the detailed calculation and the impact is not provided by the Commission, we request, that the Annex III, section 3, point 3.2 is amended as follows:

Current text	Proposed amendment
3.2. For veterinary medicinal products authorised by competent authorities of the Member States in accordance with Chapter III, Sections 2 to 5 of Regulation (EU) 2019/6, a fee of EUR 80 per chargeable unit-veterinary shall apply once per year for the Agency's pharmacovigilance activities. The Agency shall retain the fee revenue from the annual pharmacovigilance fee.	3.2. For veterinary medicinal products authorised by competent authorities of the Member States in accordance with Chapter III, Sections 2 to 5 of Regulation (EU) 2019/6, a fee of EUR **10 ~~80~~** per chargeable unit-veterinary shall apply once per year for the Agency's pharmacovigilance activities. The Agency shall retain the fee revenue from the annual pharmacovigilance fee.

In line with comments raised under A, the fee shoud be excluded from the flexibility mechanism and delegation of powers to the EC.

Comments from the French delegation

Objet :commentaires des autorités françaises suite aux groupes de travail « Santé publique » du 26 et 27 janvier et du 2 février 2023 relatifs aux redevances et aux droits dus à l'Agence européenne du médicament (EMA), modifiant le règlement 2017/745 ainsi que les règlements 297/95 et 658/2014 du Parlement et du Conseil

En préambule, les autorités françaises souhaitent remercier la Commission européenne pour ses présentations et explications fournies lors des groupes de travail du 26 et 27 janvier et du 2 février 2023. Nous souhaitons également soutenir l'objectif de la Présidence suédoise de parvenir à des orientations générales, voire à un rapport de progrès d'ici l'EPSCO de juin 2023.

Les autorités françaises souhaitent rappeler l'importance de disposer d'un système financier fiable, équitable et conforme aux activités de l'EMA et aux contributions des autorités compétentes nationales (ACN). Il s'agit de la condition première pour assurer la pérennité du réseau et sa capacité à faire face aux enjeux à venir.

En complément de nos interventions faites lors des groupes de travail, veuillez trouver ci-dessous nos commentaires.

As a preamble, the French authorities would like to thank the European Commission for its presentations and explanations shared during the working groups held on 26th, 27th of January and 2nd of February 2023. We also support the Swedish Presidency's objective of reaching general orientations or even a progress report by the EPSCO of June 2023.

The French authorities would like to reiterate the importance of having a reliable and fair financial system that is consistent with the activities of the EMA and the contributions of the national competent authorities (NCAs). This is the first condition to ensure the sustainability of the network and its ability to meet future challenges.

In addition to our interventions made during the working groups, please find below our comments.

Articles 1, 5, 10 et 11

Il convient que les ACN ne soient pas présentées comme des prestataires de service de l'EMA mais bien comme des contributeurs majeurs aux travaux du réseau européen. L'EMA est un animateur de réseau et un facilitateur pour l'harmonisation entre Etats membres.

National competent authorities (NCA) should not be presented as EMA services providers but as major contributors to the work for the European network. The EMA is a network animator and a facilitator for harmonization between Member States.

Article 10

Les montants révisés devraient être aussi publiés sur le site internet de l'EMA. Nous souhaitons modifier le point 1 dans ce sens : *«1. Les montants fixés dans les annexes et ceux révisés sont publiés sur le site internet de l'Agence. ».*

The revised fees amounts should also be published on the EMA website. We would like to amend point 1 according to this way: *« 1.The amounts set out in the annexes and the one revised shall be published on the website of the Agency ».*

Article 11

Au point 2, la révision des montants doit également prendre en compte la pérennité du réseau réglementaire et de la stratégie européenne adoptée pour le développement des produits de santé. Nous souhaitons rajouter au point 2 que toute révision des redevances et des droits, ainsi que des rémunérations des autorités compétentes des États membres, prévus par le présent règlement procède également de l'évaluation de la soutenabilité du système de régulation européen ou encore des orientations stratégiques de l'UE.

At the point 2, the revision of the fees amounts must also take into account the sustainability of the regulatory network and the European strategy adopted for the development of healthcare products. We would like to add to the point 2 that 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 also based on the evaluation of the European regulatory system sustainability or the EU's strategic orientations.

Annexe I, point 4

L'instruction des demandes d'autorisation de mise sur le marché dans le cadre de procédure accélérée justifie un niveau de rémunération supérieur du fait des contraintes imposées aux évaluateurs et du niveau d'expertise requis. Un relèvement du montant des redevances peut être introduit pour prendre en compte des procédures spécifiques mises en place pour accélérer l'accès à l'innovation au sein de l'UE (dispositif PRIME, évaluation accélérée, « rolling review » …).

The examination of market authorisation (MA) applications under the accelerated procedure justifies a higher level of remuneration due to the constraints imposed to the evaluators and to the level of expertise required. An increase of the MA fees may be introduced to take into account specific procedures set up to accelerate access to innovation within the EU (PRIME system, accelerated evaluation, rolling review, etc.).

Annexe V

Pour avoir un règlement clair, l'ensemble des réductions applicables recensées dans la note explicative publiée sur le site de l'EMA doit être reporté dans le texte. Ainsi, l'annexe V doit reprendre à travers 3 nouveaux points les réductions de redevance pour les médicaments orphelins, les vaccins autorisés sous conditions exceptionnelles et les médicaments de thérapie innovante. Pour les autorités françaises, il parait plus cohérent de pérenniser ces réductions de redevance dans le règlement puisqu'il s'agit de mesures incitatives consensuelles.

In order to have a clear regulation, all the applicable fee reductions listed in the explanatory note published on the EMA website must be included in the text. Thus, Annex V must include three new points on fee reductions for orphan drugs, vaccines authorized under exceptional conditions and advanced therapy medicinal products. For the French authorities, it seems more coherent to perpetuate these fee reductions in the regulation since they are consensual incentives.

Par ailleurs, permettre une réduction de redevance pour les médicaments luttant contre la résistance aux antimicrobiens et pour les médicaments repositionnés contribuerait à enrichir l'arsenal de mesures pouvant être mises en place pour proposer un modèle économique plus attractif, afin de soutenir l'arrivée et le maintien sur le marché de ces types de médicament. Une réduction des redevances procédurales de -50% (alignée sur celle proposée pour les médicaments pédiatriques) agirait sur l'attractivité du marché

pour l'arrivée de nouveaux médicaments, tandis qu'une réduction des redevances annuelles de -50% faciliterait le maintien de ces médicaments sur le marché.

Ces nouvelles réductions peuvent être proposées, bien que la Commission indique que faciliter le développement et la commercialisation de médicaments sûrs et efficaces est un objectif de la législation pharmaceutique globale de l'UE et non un objectif de cette révision des redevances de l'EMA.

In addition, allowing a fee reduction for antimicrobial drugs and repurposing drugs would complete the arsenal of measures that can be put in place to provide a more attractive economic model to support the arrival and the maintaining on the market of these types of drugs. A reduction in procedural fees of -50% (in line with what it proposed for paediatric medicines) would act on the attractiveness of the market for the arrival of new medicines, while annual fees reductions of -50% would facilitate the maintenance of these medicines on the market.

These further reductions may be proposed, even if the Commission indicates that facilitating the development and marketing of safe and effective medicines is an objective of the EU pharmaceutical legislation and not an objective of this EMA fees revision.

Comments from the German delegation

DE comments on the proposal for a regulation on fees and charges payable to the European Medicines Agency – following the WP on 2 February

The comments are preliminary.

Article 6

Article 6
Reductions of fees and charges
[…]

~~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, in accordance with Article 8.~~

5. In exceptional circumstances ~~and for~~ **such as** imperative reasons of public or animal health, the Executive Director of the Agency may grant, on a case-by-case basis, total or partial reductions for the fees set out in Annexes I, II, III and IV, with the exception of the fees set out in points 6, 15 and 16 of Annex I, points 7 and 10 of Annex II and point 3 of Annex III. Any decision taken pursuant to this Article shall state the reasons on which it is based.

Rationale:

Fee reductions should be specified in the regulation itself to be transparent and predictable. Fee reductions beyond those provided for in the regulation must be limited to exceptional cases to ensure stable financing.

In our view, there is no need for additional reductions as set out in paragraph 4. We propose that paragraph 4 be deleted.

As to paragraph 5, we propose a small amendment. The sentence structure in paragraph 5 suggests that "exceptional circumstances" is an additional, independent category. We assume that "imperative reasons of public or animal health" are meant as examples of exceptional circumstances.

Article 10

We will submit text proposals for Article 10, in particular with regards to the interaction with delegated acts provided for in Article 11, in due course.

Article 11

Article 11

Revision

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

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

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

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

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

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

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

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

Rationale:

Article 11(1) provides for extensive powers to be conferred on the Commission, and does so in a way that is not common for other EU Agencies. DE would prefer to limit it to an inflation adjustment.

We are aware that external and internal developments may require adjustments. However, these adjustments should be subject to well-defined limits.

Our understanding of the proposal is that fast adjustments are intended to ensure financial stability and operational capacity. Reductions, which often require structural changes, should continue to be determined through the ordinary legislative process. Therefore the power to adopt delegated acts should be limited to an increase in the amounts.

In our view, it is a more suitable approach – and is common practice - to make changes to the regulation affected within the same procedure and in the same legal act. When amending a regulation, the consequences to other legal acts must already be taken into account. This would be more efficient and less error-prone. Delegated acts are not needed for immediate adjustment. Point (c) should be deleted.

Point (e) is too vague and open to interpretation. A need for this has not been sufficiently demonstrated. Point (e) should therefore be deleted.

It is crucial for DE that the share of fees allocated to the national competent authorities is not reduced any further in relation to the share allocated to the Agency. The percentage allocation must therefore not be changed to the detriment of the national competent authorities by delegated acts. Any such adjustment requires a policy decision on the mode of operation with structural implications and is therefore reserved for the ordinary legislative procedure.

We would like to thank the Council Legal Service for offering to examine whether the options mentioned in points (a) to (c) in the proposal above could be regulated by means of implementing acts.

Article 13(2)

According to the Inter-institutional Agreement of 2016 on Better Law-Making, the COM should complete its report **9 months** (instead of 6 months) before the end of the 5-year period. We kindly ask to apply this period here as well.

Rationale:

To ensure sufficient time to review the delegation of power and on the basis of the "Common Understanding", we ask for adjustment in line with the standard clause.

Article 14

Article 14

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

~~Article 106 of Regulation (EU) No 2017/745, to paragraph 14 is replaced by the following:~~

~~'14. The fees payable to EMA in accordance with the procedure under paragraph 13 of this Article related to the advice provided by expert panels for which EMA provides the secretariat in accordance with Article 30 of Regulation (EU) 2022/123 of the European Parliament and of the Council shall be set in a transparent manner and on the basis of the costs for the services provided. The fees payable shall be reduced in the case of a clinical evaluation consultation procedure initiated in accordance with section 5.1, point (c), of Annex IX to this Regulation involving a manufacturer who is a micro, small or medium-sized enterprise within the meaning of Recommendation 2003/361/EC'.~~

1. In Article 106 of Regulation (EU) No 2017/745, the following paragraph 14a is inserted:

'14a. The EMA supports the Commission in accordance with Article 30 of Regulation (EU) 2022/123.'.

2. In Article 30 of Regulation (EU) No 2022/123, the following point (i) is added:

'(i) charge fees payable to the Commission in accordance with Article 106(14) Regulation (EU) 2017/745.'.

Recital 27

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

receive those fees, once such fees are established by the Commission in accordance with ~~**that**~~ **Article 106 (13) of** Regulation **(EU) 2017/745**.

Rationale:

The proposed amendment of Article 106(14) Regulation (EU) 2017/745 might be misleading. The impression, that the EMA was assigned additional tasks should be avoided. Therefore, it is necessary to clarify in Article 106 Regulation (EU) 2017/745 that the EMA supports the Commission, and amend Article 30 Regulation (EU) 2022/123 accordingly.

Article 16

We ask the Council Legal Service to review the wording of Article 16(2), as the current phrasing could be misleading. As the context indicates, it is intended that two annual fees should not be levied in the year of entry into force of the regulation. However, the wording suggests that Annex 3 does not apply at all to products for which an annual fee is payable under the old rules in the year of entry into force. It should be clarified that the new annual fee will apply to those products from the year after entry into force.

Further comments following the WP on 13 February

The comments are preliminary.

Annex 5:

6. Veterinary vaccines against certain major epizootic diseases

6.1. A fee reduction of 100 % shall apply to the annual fee for vaccines against ~~bluetongue~~ **infection with bluetongue virus (serotypes 1-24)**, ~~pandemic avian influenza~~ **highly pathogenic avian influenza**, foot and mouth disease and classical swine
fever, where the vaccine is authorised under normal circumstances and the product has not been marketed within the Union at any time during the totality of the period covered by the fee.

Rationale:

We propose an adjustment according to the nomenclature of Regulation (EU) 2016/429 (Art. 5(1) and Annex II).

Comments from the Hungarian delegation

HUNGARIAN AMENDMENTS TO 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

Article 11

Revision

3. Amendments to the Annexes in accordance with this Article shall not result in any differentiation of remuneration between national competent authorities providing the same services to the Agency.

Corresponding recital

(x) The remuneration of services provided to the Agency by the competent authorities is based on single european price, therefore this regulation does not differentiate between such remunerations on the basis of the country of the competent authority concerned.

Justification

Hungary welcomes that the current proposal is not based on country coefficients as this option was unanimously rejected during the consultations. Nevertheless we need guarantees that further revisions via delegated acts will not bring any change to the status quo.

Comments from the Italian delegation

COMMENTS FROM ITALY ON THE PROPOSAL FOR A REGULATION ON FEES AND CHARGES PAYABLE TO THE EUROPEAN MEDICINES AGENCY (COM(2022)721 final)

1) The "time data" sheet of Annex_COMM reports the weighted average time for all procedures ("Average NCA (hrs)"). With reference to the procedures subject to targeted revision only, we kindly request the **anonymised list containing the average times declared by the NCAs,** with an indication of the number of procedures for each NCA.

2) With reference to the procedures subject to targeted revision only, we kindly ask the COM to **remove the average UK time** from the count, as well as the average cost, and to communicate the result to the NCAs.

3) We are aware that "*the hourly cost data for each NCA have been derived directly in the coding from aggregate organisational cost data collected for the 2016 model*". We welcome the disclosure of the output of the system, not the complete coding activity. Therefore, with reference to the procedures subject to targeted revision only, we kindly ask for the **anonymised list containing the hourly cost data for each NCA,** with an indication of the number of procedures for each NCA.

4) We are aware that "the participation of MSs with a lower co-efficient in some works reduces the remuneration". For procedures where the majority participation of MSs with a lower co-efficient is evident, we kindly ask the COM to **introduce a corrective mechanism** of the final result (e.g. envisaging and including the participation of MSs with a higher co-efficient in the coding).

5) If we have understood correctly, **EMA remuneration should remain unchanged** in order to ensure that its costs are covered. Therefore, we ask for confirmation that, with fees being the same, a different allocation of remuneration between EMA and NCAs is not possible.

6) Article 10(3) establishes that NCAs provide evidence of significant changes in the costs of services provided based on "duly justified and specific official financial information on the nature and the extent of the financial impact on costs for services to the Agency". This provision is considered burdensome and unclear concerning the type of information to be

given. In that regard, it could be envisaged that EMA provides, on a regular basis, a common format that facilitates the comparison and consolidation of information and that this format is assessed and approved by the Member States in the context of this Regulation.
7) Article 10(3) does not provide for **precise parameters or material thresholds** at which the significant changes in the costs of NCAs are in any case taken into account by EMA in the special reports (Article 10(3)) and/or allow for a reduction in the reporting time interval (Article 10(9)). It would therefore be appropriate to consider whether envisaging a **definition of significant changes in costs** in Article 2 of the Proposal for a Regulation.

8) In Article 10(9), the definition of '**public health emergency**' (also referred to in Article 2 and Article 10) should be amended to include the reference to a situation identified by Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU;

9) In Article 11(1), we suggest to include, as an element allowing for the adoption of delegated acts amending the tariffs contained in the Proposal for a Regulation, the publication of the new pharmaceutical legislation in the EU official journal, including a deadline for the Commission to implement the revision of the delegated acts.

10) The amendment to Article 10(6), which establishes that the report submitted by the Agency is not only submitted but also approved by the Management Board, seems to go towards favouring the introduction of mechanisms allowing for the opinions of NCA representatives to be taken into account when approving the delegated acts. This is also in line with Regulation No 297/95, which empowers the European Commission to amend the amount of fees under the procedure laid down in Article 5 of Regulation No 182/2011. Such article specifies that, for the adoption of an implementing act by the Commission, (i) the positive opinion of a committee composed of Member State representatives needs to be obtained and that (ii) the Commission shall not adopt the implementing act in the event of a negative opinion by the committee (except for certain mechanisms provided for in that Article).

11) Finally, it should be noted that no provisions on the reimbursement of the fees paid have been found in the Proposal for a Regulation, which should in any case be envisaged.

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)

1. Introductory comments

The Netherlands recognises the problems as identified by the Commission in their evaluation of the EMA fee system. In the past, the EMA fee system has generally proven to be efficient and effective in achieving its goals. But the system is now severely underperforming, particularly in providing adequate fees to National Competent Authorities (NCAs). This is partly due to the many uncompensated activities they perform for the EMA. The work of the regulatory network is also becoming increasingly complex and thus time-consuming, partly due to scientific and technological innovations in the pharmaceutical sector. Also, the new Veterinary Medicinal Products (VMP) Regulation has brought about a change in activities. Fees and remuneration amounts have not been adjusted accordingly, partly because the system lacks the necessary flexibility. In addition, the Covid-19 crisis brought additional work for the regulatory network, which was not compensated for. As a result, in recent years it has become increasingly challenging for NCAs to adequately perform all EMA-related work, and for the EMA to distribute the work among NCAs. This is an urgent problem and an unsustainable situation. The Netherlands therefore welcomes the Commission's initiative to revise the EMA fee system. We are however of the view that the proposal addresses some but not all of the identified problems. We therefore support the proposal in parts, but also highlight some important issues that needs addressing.

2. General comments

<u>2.1. Complexity of the system</u>

The current system is characterised by a large number of categories of fees. This does not improve the practicability and predictability of the system, especially for the EMA as the entity responsible for implementing the system, but also for companies and NCAs. The proposal reduces the number of fees, including by bringing a limited number of post-authorisation activities under the annual fee. **The Netherlands supports the proposed simplification under the chosen policy option 3 'light'.** The proposal delivers a more

practicable, controllable and predictable system. In addition, by including only a limited number of assessment activities into the annual fee, there is a good balance between simplicity on the one hand and a detailed cost-based approach on the other.

2.2. Flexibility and future-proofing of the system

Scientific and technological advances in innovation, research and development of medicines and the upcoming broad review of EU pharmaceutical legislation lead to changes in the work of the regulatory network and, consequently, their costs. The fee system will therefore have to be regularly adjusted to continue to provide appropriate fees for services provided. The current system allows adjustments to fees in line with inflation via a delegated act. Adjustments not related to inflation can only be made through the ordinary legislative procedure (co-decision of the European Parliament and the Council), which is very lengthy and burdensome. The Netherlands shares the Commission's view that this makes the system inflexible. This became particularly clear during the Covid-19 crisis and after the entry into force of the Pharmacovigilance and VMP legislative frameworks. The current system proved unable to respond timely and adequately to the additional and changed work for the regulatory network, with negative financial consequences for NCAs in particular. Finally, we'd like to point out that since the adoption of the fee system, no actual alignment of fees and remuneration to costs incurred by EMA and NCAs has taken place, which has led to the current situation of a strong mismatch between the two and, as such, to underfinancing of NCAs, cross-financing by EMA and NCAs, and non-cost based fees for industry.

To ensure that the system can respond flexibly to changes in the activities and/or costs of the regulatory network and any future public and/or animal health crises, the Commission proposes several measures. These include maintaining the current possibility for EMA's Management Board and EMA's Executive Director to apply additional reductions or full waivers on fees for reasons of public or animal health or for particular products or applicants. These measures further include a cost-monitoring system and the possibility to adjust fees, remuneration amounts and fee reductions included in the annexes of the regulation through delegated acts in response to, among others, a change in EMA's legal mandate, a change in inflation rate, or changed costs for the regulatory network. **The Netherlands believes that the total of these measures ensures a system that is sufficiently responsive to changing costs and circumstances.**

The Netherlands does however have some specific comments on the related articles in order to, among others, create clarity on the role of the EMA Management Board in creating the special report referred to under article 10 and the criteria applying to the delegation of powers of the Commission referred to in article 11. These are detailed further below.

2.3. Ensuring solid funding for a well-functioning regulatory network

The proposal seeks to align the fees for the EMA and the fees for NCAs with their costs for issuing and maintaining European marketing authorisations. However, the Netherlands notes that it only succeeds in doing so to a limited extent.

In the current system, there are several activities for which fees and remuneration amounts do not exist (e.g. certain paediatric and orphan medicinal product procedures). In addition, certain fee reductions and waivers currently reduce not only the fee for the EMA but also the remuneration to NCAs. While the EMA, partly due to the Union budget contribution, manages to cover this loss in revenue, this is not the case for many NCAs. They have to cover part of the costs of their EMA-related activities with income from other (national) sources (cross-financing). Such a system is financially unsustainable for NCAs. Also, a fair, cost-based system requires companies pay only for costs incurred specifically for them. **The Netherlands therefore supports the Commission's proposal to introduce fees for NCAs for assessment activities for which they previously were not financially compensated, as well as the proposal that fee reductions and waivers be borne entirely by the EMA**.

However, **the Netherlands also concludes that, with regard to medicines for human use, the proposed NCA fees for many procedures are significantly lower than the costs incurred by the Dutch Medicines Evaluation Board and Dutch Inspectorate. The same was concluded for the NCA-network as a whole by the HMA in their letter to the Commission, dated 18 January 2023.** This is problematic, as it makes it very challenging for NCAs to adequately carry out all EMA-related work. Moreover, this leads to a situation where the choice to take on certain assessment activities are and can no longer be based solely on reasons for patient safety but also on cost considerations. If costs incurred by NCAs are insufficiently covered, this compromises the proper functioning of the regulatory network, and, thereby, the assurance that only medicines that are effective, safe and of high quality are and will become available to patients. Also, it may deter currently less active, smaller NCAs from becoming more involved, whereas increased work-sharing adds to the sustainability of

the network. A well-functioning, sustainable regulatory network is also crucial to ensure that the Union remains an attractive market for medicine innovation and development. The Netherlands therefore does not support many of the proposed NCA remuneration amounts included in Annex I and Annex IV.

Finally, it is noted that the role of PRAC rapporteur is not always financially compensated where duly justified. This leads to this role being unattractive and unaffordable to NCAs, whereas strong PRAC rapporteurships are essential in regards guaranteeing patient safety.

Detailed comments on the proposed remuneration amounts and financial compensation of the PRAC rapporteur role are included further below.

3.3. Equal access for companies and innovation

The Netherlands shares the Commission's view that companies should be charged fees that are fair and proportionate to the costs incurred by the regulatory network for its assessment work. This is necessary to ensure a level playing field for companies on the one hand and to create a competitive market for innovation and development on the other. The cost of assessment activities of the regulatory network varies significantly by type of medicine (e.g. innovator or generic, medicinal product for human use or veterinary medicinal product, medicinal product with known versus unknown safety profile). The Netherlands therefore supports a fee system that is cost-based with different levels of fee and remuneration amounts for different types of products. The Netherlands also supports the retention of targeted reductions or a full fee exemption for certain categories of medicines (e.g. medicines for rare conditions or children, veterinary medicines for a limited market or less common species) and companies (micro, small and medium-sized companies), as well as the possibility for EMA's Management Board and Executive Director to apply additional fee reductions.

However, a cost-based system implies an increase in fees for SMEs, although this is partially mitigated by the proposed fee reductions and above mentioned possibility for additional fee incentives. As SMEs play an important role in the innovation and development of novel medicinal products, the Netherlands asks the Commission to monitor the impact of a cost-based fee system on SMEs.

A cost-based system also implies an increase in fee and remuneration amounts for veterinary medicinal products. Although the proposed fees, remuneration amounts and fee reductions for veterinary medicinal products have not yet been addressed in the Council Working Party (first discussion scheduled for the CWP of 13 February 2023), the Netherlands already wishes to make a general statement in regards the veterinary medicines sector. Market conditions for the veterinary pharmaceutical sector differ from those for the sector for medicines for human use. For instance, it is characterised by a general lack of public reimbursement schemes, and the incentives for investment and pricing mechanisms are different, resulting in significantly lower prices and in costs for investments being passed on directly to the animal owner. Overpriced veterinary drugs are purchased less or not at all, especially in food-producing animals. Also, the sector is relatively small and fragmented due to the different types of animal species to be taken into account. The current fee system takes these market characteristics into account by reducing all fees for veterinary medicines by 50% compared to fees for medicines for human use. However, this reduction is unsubstantiated and not cost-based and has led to underfinancing of EMA and NCAs for veterinary medicines related activities. In its legislative proposal, the Commission has attempted to strike a better balance between a system based on actual costs and the specificity of the veterinary medicines market. All fees and remuneration amounts have been recalculated on a cost basis, with the annual fee subsequently being reduced by 25%. The current fee waivers and reductions, as well as the possibility for EMA's Executive Director and Management Board to apply additional fee reductions, remain in place. At present, the precise impact of the totality of these measures on the total annual costs for the veterinary industry is difficult to determine due to insufficient experience with the VMP Regulation, which became applicable as of 28 January 2022. The Netherlands sees the need for the Commission to closely monitor the impact of a cost-based fee system on the veterinary sector to ensure that one of the main aims of the VMP Regulation, improving availability of veterinary medicines across the EU, is upheld.

3. Comments on the articles in the proposed regulation

***NOTE:** Our comments below only relate to the articles already addressed in the Council Working Party. Comments on articles 9 and 12 – 17 will follow in the upcoming Council Working Party meetings, as necessary.*

Please find below our proposals for amendment per article, where relevant. Proposals for amended wording are indicated as strike-through (to be deleted) or underlined (to be added) text.

Articles 1, 3, 4, 5, 7, 8

The Netherlands has no comments on these articles.

Article 2

Point 6 should refer to Regulation (EU) 2022/2371 on serious cross-border threats to health, which repealed Decision No. 1082/2013/EU.

Article 6

The following correction should be made to art. 6.5:

*In exceptional circumstances and for imperative reasons of public or animal health, the Executive Director of the Agency may grant, on a case-by-case basis, total or partial reductions for the fees set out in Annexes I, II, III and IV, with the exception of the fees set out in points 6, **~~15 and 16~~** **14 and 15** of Annex I, points 7 and 10 of Annex II and point 3 of Annex III. Any decision taken pursuant to this Article shall state the reasons on which it is based.*

Article 10

The Netherlands proposes the following changes to, among others, clarify and strengthen the role of the EMA Management Board in the cost monitoring system and the special report:

…[…]…

3. *Evidence of significant changes in the costs of services provided to the Agency, excluding any effect of inflationary adjustments and any costs for activities that do not constitute a service to the Agency, may be provided 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 to the Agency. Such information may be provided once per calendar year or less frequently, as a complement to the information provided in accordance with Annex VI. Such evidence shall be based on duly justified **~~and specific official~~** financial information on the nature and the extent of the financial impact on costs for services to the Agency. To that end, the Agency may provide a common format facilitating comparison and consolidation. The competent authorities of the Member States and the experts contracted for the procedures of the expert panels on medical devices to the Agency shall provide such information in the format provided by the Agency, together with any supporting information allowing to verify the correctness of the amounts submitted. The Agency shall review and aggregate that information and shall use it, in accordance with paragraph 6, as a source for the special report provided for in that paragraph.*

…[…]…

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

   (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.*

7. *The special report referred to in paragraph 6 and the recommendations it contains shall be based on the following:*

   (a) ~~***continuous***~~ *monitoring of the information referred to in paragraphs 2 and 3 and of the cost of the activities necessary for the fulfilment of the statutory tasks of the Agency, aimed at identifying significant changes to the cost base of services and activities of the Agency;*

   (b) *objective and verifiable information and quantification that directly supports the relevance of the recommended adjustments.*

8. *The Commission may request any clarification or further substantiation of the report and its recommendations, if considered necessary. Following such a request, the* ~~***Agency***~~ ***Executive Director of the Agency*** *shall without undue delay provide the Commission with an updated version of the report* ***endorsed by the Management Board of the Agency*** *which addresses any comments made and questions raised by the Commission.*

9. ***The time 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:*

   (c) *in the case of a* ~~*public health emergency*~~ *[replace by definition referred to in article 2 point 6];*

   (d) *in the case of a change of the legal mandate of the Agency;*

   (e) *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.

10. ***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.***

In addition to the above, the Netherlands is of the view that the first adjustment of the fee and remuneration amounts to the inflation rate, as referred to in paragraph 5, should take place prior to adoption of this regulation due to the unexpected high EU-wide increase of the inflation.

Article 11

The Netherlands proposes the following changes to provide clear criteria for the applicability of the delegation of powers. The reason is that the criterion under paragraph 1(e) is broad and unspecific. Alternatively, paragraph 1(e) may be deleted entirely and any such change necessary may be addressed via the provisions under article 8 (working arrangements) instead, as appropriate.

1. *The Commission is empowered to adopt delegated acts in accordance with Article 13 to amend the Annexes where it deems it justified 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;*
   (e) ***upon endorsement by the Management Board of the Agency,*** *other relevant information****, in particular*** *on practical aspects for the execution of activities for which the Agency collects fees or charges.*

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 costs of the services provided to the Agency by the competent authorities of the Member States.*

4. Comments on Annexes to the proposed regulation

<u>NOTE:</u> Our comments only relate to the annexes and the points in those annexes already addressed in the Council Working Party. Comments on points and annexes not yet addressed (such as those related to veterinary medicinal products) will follow in the upcoming Council Working Party meetings, as necessary.

<u>4.1. General comments on the need for financial compensation for the PRAC rapporteur</u>

NCAs receive a share of the CAP annual fee for products for which they are CHMP rapporteur or CHMP co-rapporteur. This means that the PRAC rapporteur, which is a different NCA for new products[1], does not receive financial compensation for additional activities they play an important or even leading role in, for instance signal detection. Similarly, the PRAC rapporteur plays a significant role in the assessment of initial applications, but also there does not receive remuneration. This makes the PRAC rapporteur role unattractive, whereas it is an important role in regards guaranteeing patient safety. The fact that the proposed remuneration amounts for several pharmacovigilance activities (pharmacovigilance referrals, PSUR, Type II safety) are insufficient to cover costs incurred adds to this.

To give an indication, the Dutch Medicines Evaluation Board has calculated that, on average, their PRAC rapporteur costs for additional activities equal to about 10 - 12.5% of the combined CHMP rapporteur and co-rapporteur remuneration amounts. For initial applications, PRAC rapporteur costs equal to about 5 - 6% of the total amount paid to both CHMP rapporteurs combined.

These calculations only relate to the PRAC rapporteur, because the PRAC co-rapporteur generally has a limited role and also, at least for non-legacy products, the CHMP rapporteur is also the PRAC co-rapporteur, meaning that the relevant NCA already receives a share of the annual and procedural fee.

[1] "New product" refers to products for which an application for marketing authorisation was made after the date of application of the pharmacovigilance legislation. For legacy products, it was decided that the CHMP rapporteur would also act as PRAC rapporteur.

4.2. Annex I

Remuneration amounts not covering costs incurred

The proposed remuneration amounts for NCAs for the following procedures are significantly lower than the costs incurred by the Dutch Medicines Evaluation Board:

- Point 1: Scientific advice (all proposed remuneration amounts)
- Point 3.1 and 3.2: Authorisation to market a medicinal product pursuant to Article 8(3).
- Point 5: Type II variations
- Point 6: Referrals
- Point 12: Orphan designation
- Point 14: PSUR

Underlying reasons for these remuneration amounts not covering related costs incurred are that they are based on time and cost data that are now outdated due to external factors such as Brexit, Covid-19, the current high inflation rate, and changes in the (complexity of the) work due to technological and scientific advances. The Commission is therefore asked to recalculate the proposed remuneration amounts based on updated cost data provided by the Member States / NCAs via a (to be agreed upon) targeted approach and to then apply a correction to the recalculated amounts in accordance with the current inflation rate. Such targeted approach may also require looking at the weighted average applied to each procedural remuneration amount, as portfolios of individual NCAs as well as the division of work between NCAs may have changed over the years.

Point 2.1(b): rolling review

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, 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 proposal 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 proposed 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).

Point 3: Initial applications

As indicated under section 4.1, the PRAC rapporteur should be financially compensated for their services provided in regards initial applications.

Point 5: Major variation of type II

The definition of 'a major Type II variation' applied here is more narrow than the definition in article 2(3) of the Variation Regulation (No. 1234/2008). As a result, all major Type II variations that are not a change in indication or the addition of a new indication will be covered by the proposed lower fee. This is different from the current system, where only those variations that only contain quality data attract a lower fee. The proposal does not adequately reflect the work involved. Variations that also include clinical and/or non-clinical data should be rewarded a higher fee than those only containing quality data, because they involve significantly more work than quality variations. The Netherlands therefore proposes to either revert back to the subdivision in levels in accordance with the current fee system or to apply three level of fees, whereby a change of indication/new indication attracts the highest fee, a quality variation attracts the lowest fee and all other major Type II variations attract the intermediate-level fee.

Further, the proposal refers to "rapporteurs" only. However, Type II safety variations require significant involvement from the PRAC rapporteur. Their efforts should be rewarded by the appropriate remuneration amount.

Point 12: Orphan designation

Point 12 should be clarified by stating that the indicated (waived) fees and remuneration amounts for orphan designation apply to both initial applications for orphan designation and the reassessment of an orphan designation before the marketing authorisation. The reason is two-fold. First, both activities have a legal base in the Orphan Regulation No. 141/2000 (see Article 5.12(b) for the provision on the reassessment of the orphan designation). Second, in the 2016 data gathering exercise of the EMA Management Board, and the subsequent NCA survey, time data for the initial application and the reassessment were combined because the work involved and, therefore, costs incurred by EMA and NCAs are similar.

4.3. Annex III – annual fee

Reference is made to the comment under section 4.1 on the need for a share of the annual fee for the PRAC rapporteur.

4.4. Annex V – fee reductions

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

Additional fee reductions for (certain) new antimicrobial products may be considered for inclusion in this Annex. Alternatively, such reductions could be considered by the EMA Management Board in accordance with Article 8 (working arrangements) of the proposed regulation.

Some delegations in the Council Working Party also suggested the inclusion of fee reductions for repurposed products. The Netherlands is critical of this suggestion because such provision is difficult to frame clearly. Chances are that “repurposed” products for which no or very minimal investments were made in regards (non-)clinical studies become eligible for such fee reductions. The same is seen with the application of the 10 year market exclusivity for orphan products where existing products that are already used off-label are then registered as an orphan product and consequently awarded with said exclusivity. Hence, a blanket fee reduction for repurposed products is not supported. At a minimum, such reduction needs careful consideration and clear framing, which is best done by the EMA Management Board in accordance with Article 8.

Comments from the Polish delegation

Comments from Poland

ANNEX I

Fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use

1. **Scientific advice provided by the Agency in accordance with Article 57(1)(n) of Regulation (EC) No 726/2004**

1.1. A fee of EUR 55 200 shall apply to any of the initial or follow up ~~following~~ requests referring to:

(a) a request on quality, non-clinical and clinical development;
(b) a request on quality and clinical development;
(c) a request on non-clinical and clinical development;
(d) a request on qualification of novel methodologies.

The remuneration shall be EUR 10 400 for each of the two scientific advice co-ordinators.

Rationale: Following the Commission explanations presented during the working party meetings we believe it should be clarified in the text that both initial and follow up requests concerning the scientific advice procedures mentioned in art 1 (1.1)(a)(b)(c)(d) are covered by the designated fee.

Comments from the Romanian delegation

Comments on 16070/22 Proposal for a Regulation of the European Parliament and Council on fees and charges payable to the EMA

RO appreciates the effort made towards harmonisation in this area, and the document produced.

With regard to the proposal submitted, please make the following amendment on:

- Annex III, point 3.2.
- Preamble (12)
- Annex V point 8

To Annex III, point 3.2, where it is proposed to introduce an annual fee for the pharmacovigilance activities carried out by the Agency (EMA) for veterinary medicinal products authorized through all procedures, not only for centralized ones.

In this sense, **we propose the elimination of point 3.2 of Annex III and the consequent modification of the preamble (12) and point 8 of Annex V** to the draft Regulation of the European Parliament and of the Council regarding the fees and commissions owed to the European Medicines Agency, respectively: *(as are in the attached st16070-ad03.en22_RO, st16070.en22_RO, st16070-ad05.en22_RO)*

Annex III point 3.2

~~In the case of veterinary medicinal products authorized by the competent authorities of the Member States in accordance with Chapter III sections 2-5 of Regulation (EU) 2019/6, a fee of EUR 80 per billing unit applies once a year - veterinary use for the pharmacovigilance activities carried out by the Agency. The Agency retains the revenue from the annual pharmacovigilance fee.~~

Preamble (12)

A specific annual fee should be levied for medicinal products authorized in accordance with Directive 2001/83/EC ~~and for veterinary medicinal products authorized by Member States in accordance with Regulation (EU) 2019/6,~~ in particular for pharmacovigilance activities carried out by the Agency for the benefit of marketing authorization holders as a whole. Those activities are related to information technology, in particular for the maintenance of the EudraVigilance database, as referred to in Article 24(1) of Regulation (EC) no. 726/2004, ~~the~~

~~Union product database as referred to in Article 55(1) of Regulation (EU) 2019/6 and the Union pharmacovigilance database as referred to in Article 74 paragraph 1 of that Regulation,~~ with the monitoring of selected publications in the medical literature and the timely access and analysis of health data at Union level to support decision-making throughout the entire product life cycle of evidence-based medicinal products valid and reliable generated under real conditions.

Annex V point 8

Annual pharmacovigilance fee for generic, homeopathic and herbal medicines and medicinal products.

In the case of the annual pharmacovigilance fee, as set out in section 3 of Annex III, a 20% discount applies to the following medicinal products and medicinal products:

(a) medicinal products for human use as referred to in Article 10(1) and Article 10a of Directive 2001/83/EC;
(b) homeopathic medicines for human use;
(c) herbal medicines for human use;
~~(d) veterinary medicinal products, as referred to in Articles 18 and 22 of Regulation (EU) 2019/6;~~
~~(e) homeopathic veterinary medicinal products;~~
~~(f) homeopathic veterinary medicinal products registered in accordance with Article 87 of Regulation (EU) 2019/6.~~

We emphasize that preamble (12) and point 3.2 of Annex III contradict the provisions of art. 2 para. (8) of Regulation (EU) 2019/6, respectively:

"This Regulation is without prejudice to the provisions of domestic law on taxes, with the exception of the centralized procedure for granting a marketing authorisation."

We also consider that the charging by the EMA of an annual fee for holders of products authorised through the procedures: national, decentralised, mutual recognition and subsequent recognition, may have a negative impact on the market/availability of veterinary medicinal products.

Annexes

- *st16070-ad03.en22_RO,*
- *st16070.en22_RO,*
- *st16070-ad05.en22_RO*

ANNEX III

ANNEX III

Annual fees and remuneration

2. Annual fee for medicinal products for human use authorised in accordance with Regulation (EC) No 726/2004

2.1. An annual fee of EUR 48 900 shall apply to each marketing authorisation of a medicinal product for human use authorised on the basis of an application submitted under Article 10(1) and (3) and Article 10c of Directive 2001/83/EC. The remuneration shall be EUR 6 400 for the rapporteur and EUR 5 600 for the co-rapporteur.

2.2. An annual fee of EUR 95 600 shall apply to each marketing authorisation of a medicinal product for human use authorised on the basis of an application submitted under Article 10(4) of Directive 2001/83/EC. The remuneration shall be EUR 12 900 for the rapporteur and EUR 11 400 for the co-rapporteur.

2.3. An annual fee of EUR 188 000 shall apply to each marketing authorisation of a medicinal product for human use not covered by point 1.1 or 1.2. The remuneration shall be EUR 25 700 for the rapporteur and EUR 22 700 for the co-rapporteur.

3. Annual fee for veterinary medicinal products authorised through the centralised procedure in accordance with Regulation (EU) 2019/6

3.1. An annual fee of EUR 21 500 for shall apply for each marketing authorisation of a veterinary medicinal product authorised pursuant to Article 18, 19 or 21 of Regulation (EU) 2019/6. The remuneration shall be EUR 5 000 for the rapporteur and EUR 4 600 for the co-rapporteur.

3.2. An annual fee of EUR 87 500 shall apply to each marketing authorisation not covered by point 2.1. The remuneration shall be EUR 20 400 for the rapporteur and EUR 18 800 for the co-rapporteur.

4. Annual pharmacovigilance fee for medicinal products for human use authorised in accordance with Directive 2001/83/EC and for veterinary medicinal products authorised by competent authorities of the Member States in accordance with Regulation (EU) 2019/6

4.1. For medicinal products for human use authorised in accordance with Directive 2001/83/EC, a fee of EUR 190 per chargeable unit-human, shall apply once per year for the Agency's pharmacovigilance activities including analysis of

Union-wide health data to support better decision-making with real world evidence. The Agency shall retain the fee revenue from the annual pharmacovigilance fee.

4.2. For veterinary medicinal products authorised by competent authorities of the Member States in accordance with Chapter III, Sections 2 to 5 of Regulation (EU) 2019/6, a fee of EUR 80 per chargeable unit-veterinary shall apply once per year for the Agency's pharmacovigilance activities. The Agency shall retain the fee revenue from the annual pharmacovigilance fee.

4.3. The total payable amount of the annual fees referred to in points 3.1 and 3.2 for each marketing authorisation holder shall be calculated by the Agency on the basis of the number of chargeable units-human and chargeable units-veterinary, respectively, which correspond to the information recorded on 1 July of each year.

4.4. The annual fees referred to in points 3.1 and 3.2 shall be due on 1 July of every year and shall cover the period from 1 January to 31 December of that calendar year.

16070/22

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**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4), points (b) and (c), thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[2],

Having regard to the opinion of the Committee of the Regions[3],

Acting in accordance with the ordinary legislative procedure,

Whereas:

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2 OJ C , , p. .

3 OJ C , , p. .

(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.

ANNEX V

ANNEX V

Fee reductions

5. Annual pharmacovigilance fee for generic, homeopathic and herbal medicinal products

A fee reduction of 20 % shall apply to the annual pharmacovigilance fee set out in section 3 of Annex III for the following medicinal products:

(a) medicinal products for human use as referred to in Article 10(1) and Article 10a of Directive 2001/83/EC;

(b) homeopathic medicinal products for human use;

(c) herbal medicinal products for human use;

~~(d) veterinary medicinal products as referred to in Articles 18 and 22 of Regulation (EU) 2019/6;~~

~~(e) homeopathic veterinary medicinal products;~~

~~(f) homeopathic veterinary medicinal products registered in accordance with Article 87 of Regulation (EU) 2019/6.~~

Comments from the Slovakian delegation

Position of the Slovak Republic to EMA fees regulation and respective SE PRES working document

- We agree with SE PRES proposal that for selected fees (scientific advice, generics, type II variations, PSURs, PRAC rapporteurship, Type II variation) the amounts for Rapp/CoRapp should be reconsidered (increased). In addition to the fees already proposed by the SE PRES, we would also propose to **increase the amounts for Rapp/CoRapp for referrals** (pharmacovigilance and non-pharmacovigilance, Annex I, point 6), as these amounts are lower in the proposed Regulation compared to the current one, as the **amount for scientific evaluation for NCAs** is disproportionately lower than the one for the EMA.

- We also **support SE PRES proposal in Article 10**, as regards **articles 9,12, 14-17 and Annex IV and VI** we **do not have any specific comments.**

- Regarding **article 11 we also would like to limit the powers delegated to the Commission**, therefore SE PRES suggestion 11.1e) seems reasonable for us.

Comments from the Slovenian delegation

Opinion of Slovenia 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

The Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (hereinafter: the JAZMP) supports the endeavours of the European Commission (hereinafter: the EC or the Commission) for the setting up of a revised and uniform legislative act on fees and charges payable to the European Medicines Agency (hereinafter: the Agency or the EMA).

Article 67(3) of Regulation (EC) No 726/20044 stipulates that fees and charges are part of the revenues of the Agency. Furthermore, Article 86a of that regulation, as amended by Regulation (EU) 2019/52, provides that the Commission is to put forward, as appropriate, legislative proposals with a view to update the regulatory framework for fees payable to the Agency in relation to medicinal products for human use and veterinary medicinal products.

The EMA is a decentralised agency of the EU. The services for which the EMA charges fees include scientific advice, assessment of applications for a marketing authorisation, changes to existing marketing authorisations (variations and extensions), and other pre- and post-authorisation procedures, and annual fees for the maintenance of already authorised medicines. Pharmacovigilance activities conducted at EU level for nationally authorised medicines for human use are also financed by fees paid by marketing authorisation holders to the EMA.

The legal framework governing EMA fees is laid down in the following regulations:

- Council Regulation (EC) No 297/95[5] and
- Regulation (EU) No 658/2014[6].

Both regulations stipulate that the fees levied by the EMA should be based on an evaluation of the costs of the EMA and the costs of the tasks carried out by national competent authorities (hereinafter: the NCAs) in Member States.

The JAZMP has significant concerns about the proposed amendments and finds it difficult to support the Proposal for a Regulation in its proposed form, despite the positive objectives that it pursues. We have concerns both with regard to the value of the individual fees and with regard to the inappropriate division of payment between the EMA and the NCAs for the individual provided services.

The proposal to amend the fees payable to the EMA is drafted in a way that reflects an increase in the EMA's revenue in line with its projected costs and the development of digitalisation and the development of the pharmaceutical industry. On the other hand, it puts Member States in an unequal position, as the network of NCAs experts is the cornerstone for the evaluation of documents in the EMA's procedures. Furthermore, the fees paid to the NCAs for certain services are being significantly reduced and do not cover the costs incurred for the work carried out by the NCAs.

We also have concerns in view of the fact that the proposal is based on data collected 6 years ago, i.e. before Brexit and the SARS-CoV-2 pandemic, two important milestones which have a significant effect on the content of the drafted proposal. The post-data collection period is also characterised by the increased complexity of medicinal products and the functioning of the EU network, as has been particularly demonstrated during COVID-19.

Negotiations should support solutions that would lead to a concrete and transparent area of fees. Furthermore, we support the Proposal for a Regulation which provides that the EMA fee system should be based on the necessary agility to respond to future developments in science and possible changes in the complexity of scientific assessments that are required by existing regulatory procedures and consequently also amendments to the legislative framework. For reasons that will be explained below, we consider that the impact of the NCAs has not been sufficiently taken into account in this respect.

Certain improvements to the text should be advocated in the negotiation process, especially in parts where the proposed articles are unclear or may lead to different interpretations. Particular attention should be paid to the provisions in Annexes I through VII, which, inter alia, set out a specific fee for the services of the EMA and the NCAs, but – as will be explained below – the methodology for the division of the total fee between these two bodies is not clear from the currently proposed version.

We also propose that the Republic of Slovenia advocates for improvements to the text that will consider the contribution of the scientific evaluation of the EU network of competent authorities, which is a prerequisite for ensuring the protection of human and animal health, but also for managing potential emergencies through a fast, effective and coordinated response, as was the case during the COVID-19 pandemic.

The text of the Proposal for a Regulation was presented to the Member States for consideration ahead of the revision of the EU basic pharmaceutical legislation. In order to allow for a more agile EMA fee system, the EC proposal enables the setting of the amount of the fees **through Commission delegated acts**. While this would indeed bring about a quicker adaptation to any changes resulting from the above-mentioned revision of the pharmaceutical legislation, it would also significantly reduce the influence of individual Member States on the setting of fees, which could lead to an under-recovery of the incurred costs.

We also point out at this point that the current legislative revision process is not concerned with deciding on fees for activities and procedures carried out at national level by the competent authorities of the Member States, but only regulates the fees and charges levied by the EMA for its statutory tasks.

In view of the concerns expressed above, and with the assumption that the open issues will be adequately addressed in the course of the negotiations in the Council of the EU and with the assumption that the Republic of Slovenia is unlikely to oppose the adoption of the Regulation in question, the JAZMP gives below its substantive opinion on the proposed amendments.

THE MAIN SOLUTIONS AND OBJECTIVES OF A PROPOSAL FOR A REGULATION:

I. Summary of objectives of the proposed amendments

On 13 December 2022, the Commission submitted the *Proposal for a Regulation of the European Parliament and of the Council on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014 of the European Parliament and of the Council* (hereinafter: the Proposal for a Regulation) to the co-decision procedure.

The general objective is to provide a sound financial basis for the Agency to properly implement the applicable legislation, while the conditions for its funding, including fees as a source of revenue, are laid down exclusively in EU legislation. The drafting of the new Regulation of the Council and of the European Parliament will be subject to the ordinary legislative procedure (Article 294 of the TFEU).

The objective of the proposed amendments is to particularly address the following issues specified in the EC Impact Assessment Report[7]:

- The fee system is too complex due to many different categories and types of fees that it currently stipulates;
- There is a misalignment of some fees with the underlying costs;
- No fee or payments exist for NCAs for some procedures;
- There is a misalignment of some NCAs remuneration with the underlying costs, and
- The main Fee Regulation (Council Regulation (EC) No 297/95) and the Pharmacovigilance Fee Regulation (Regulation (EU) No 658/2014) differ in their approach to determining the amount of payment of fees to NACs and NACs' payment in the event of fee reductions.

The current legislation does not envisage fees in support of new or changed activities introduced by Regulation (EU) 2019/6 (new Veterinary Medicinal Products Regulation), which became applicable in January 2022. In addition, Regulation (EU) 2022/123 introduced new activities for the Agency that require further adjustments of the costs that the EMA fees should take into account.

In view of the above, the general objective of the proposal is to contribute to providing a sound financial basis to support the Agency's operations, including remuneration for services to the Agency rendered by the NACs, in line with the applicable legislation. In addition, the proposal aims to streamline the system by simplifying the fee structure and by addressing the unnecessary complexity of the corresponding legal framework through bringing together in a single legal instrument fee rules that are currently governed by two regulations. A key objective pursued by this proposal is to make the fee system future-proof by introducing regulatory flexibility in the way it is adjusted, on an objective basis. This initiative is part of the Regulatory Fitness Programme (REFIT).

The impact assessment analysed several policy options together with a number of horizontal measures and compared them with a **'do-the-minimum'** scenario describing what would likely happen in the absence of legal action to update the Agency fee legislation:

[7] Brussels, 13.12.2022 SWD(2022) 414 final COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT, Draft SWD IA EMAFees legiswrite final (1) (europa.eu).

- **Option 1** – align the fee system with the new Veterinary Medicinal Products Regulation only. Unchanged fees for human medicines.
- **Option 2** – revise the entire Agency fee system with a cost-based principle being used to set all fees and all NCAs remuneration rates for both veterinary and human medicine activities.
- **Option 3** – same as Option 2, except that the fee system is simplified by including the cost of the majority of post-authorisation procedures under the annual fees (as opposed to charging a fee as the procedure occurs, as in Option 2).
- **Option 3 Light** – same as Option 3, however, with only partial simplification of the fee system structure by including in the annual fee the cost of only minor post-authorisation procedures (other procedures continue to attract a per-procedure fee).

All four options are cost-reflective, based on the estimated average costs of procedures reported by the NCAs and the EMA as part of the data collection process that took place before Brexit and the SARS-CoV-2 pandemic (the sample covered ongoing procedures starting in 2015 and ending in the first quarter of 2017).

The 'do-the-minimum' scenario and Option 1 were dismissed by the EC, as they would result in a deficit for the EMA budget, given the cost estimations made for the impact assessment, and taking into account the EU budget contribution to the EMA budget under the current multiannual financial framework.

The EC considers that Options 2 and 3 and Option 3 Light allow the Agency to cover its total costs, including the payment for the services provided by the competent Member States, with **Option 3 Light** being assessed as the most efficient overall and is reflected in the present Proposal for a Regulation.

I. General opinion of the JAZMP

The fee system is partially simplified in the Proposal for a Regulation. The annual fees include only costs related to minor post-authorisation procedures (e.g. notifications, variations of Type I, renewals), while all other post-authorisation procedures still attract a fee per procedure (variations of Type II). The simplification of the fee system also includes the abolition of the fee at the time of marketing authorisation for an additional pharmaceutical form or strength, and the abolition of the fee for any additional presentations.

In view of the above, the administrative burden for both the applicants and the EMA has been reduced, and the JAZMP does not oppose the proposed amendments in this respect.

However, the Proposal for a Regulation significantly reduces fees for certain procedures (e.g. applications for generic medicinal products, variations of Type II). Furthermore, the proposal to divide the fee between the EMA and the NCAs represents a disproportionate division of the fees in relation to the work carried out. The fee has been divided in favour of the EMA. From the current 50% for the EMA and 50% for the NCAs, this division has now been increased to the benefit of the EMA, even though the cost analysis shows that it is the NCAs that contribute the majority of the expert work. The proposal of the new fee level and its division between the EMA and the NCAs has a significant impact on the reduction of the NCAs' revenue and thus on the under-recovery of the NCAs' costs.

The cost analysis for the NCAs only considers the costs of the expert work of the NCAs and excludes practically all other costs. We point out that the cost analysis for the EMA shows that, in addition to the costs of expert staff, costs for administrative staff and indirect costs *(overheads)* are also considered, which are certainly not sufficiently taken into account in the case of the NCAs. The cost analysis further shows that minimum costs of administrative staff are taken into account for the NCAs (on average 2–6%), which does not reflect the actual costs. Furthermore, the analyses for the NCAs do not take into account the costs of other activities related to the EMA, which they have similarly as the EMA and which the EMA includes in the annual fees (costs related to databases, preparation of guidelines, safety monitoring of medicinal products, work in committees).

The new proposal of the fees also assumes an inflation rate which justifies the increase in fees and which is already reflected in the increase in all fees compared to the 2021 proposal. The increase in all fees is thus higher by approximately 14% compared to the 2021 proposal; however, this fee increase is only for the benefit of the EMA's revenue and not for the NCAs', which in turn further reduces the payments for the provided services. As the inflation rate concerns all Member States and not only the EMA, the JAZMP proposes the same to be taken into account for the NCAs.

The opinion of the JAZMP includes the preparation of position papers on:
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
- Annex I: Fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use

- Annex II: Fees, charges and remuneration for assessment procedures and services relating to veterinary medicinal products
- Annex III: Annual fees and remuneration
- Annex IV: Other fees and charges for medicinal products for human use, veterinary medicinal products and consultations on medical devices
- Annex V: Fee reductions
- Annex VI: Performance information
- Annex VII: Correlation table

II. The opinion of the JAZMP according to individual articles

Article 1 Subject matter

The legal framework of the Proposal for a Regulation is defined by the basic legislative acts for medicinal products for human use and veterinary medicinal products[8], while it is clear from the Explanatory Memorandum and the further text of the Proposal for a Regulation and its annexes that the proposal takes into account and defines the coverage of the costs of the EU legislation governing the Agency's activities and fees, i.e. also for services provided by the Member States, for which costs have not been reimbursed up to now and have been borne by each national competent authority from its own budget. As an example, we refer to the setting of the amounts of the fees and, furthermore, the amounts of payments to the competent authorities of the Member States for assessment activities related to the Paediatric Regulation (EC) 1901/2006[9] (more precisely point 11 of Annex I to the Proposal for a Regulation) and the Orphan Medicinal Products Regulation (EC) 141/2000[10] (more precisely point 12 of Annex I to the Proposal for a Regulation), according to which the NCAs have not been paid for the provided services.

The JAZMP considers that this is a necessary amendment to the legislation on the Agency's fees and fully supports it from this point of view.

[8] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1) and Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

[9] Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 4, 7.1.2019, p. 24).

[10] Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products.

Article 2 Definitions

The provision of the article defines a *'chargeable unit in relation to medicinal products for human use',* on the basis of which pharmacovigilance-related fees would be charged for nationally authorised medicinal products.

We suggest that rules be developed during the negotiations on how the differences between the two current approaches to data collection for medicinal products for human use and medicinal products for veterinary use will be considered in practice.

Article 3 Types of fees and charges

Article 3 describes the types of fees and charges levied by the EMA under the legislation and refers to the relevant Annexes. The Annexes set out the amounts of the fees, together with the amounts paid to the NCAs for the provided services.

In this respect, the JAZMP reiterates at this point its concerns regarding both the amount and the division of the fees between the EMA and the NCAs, as previously stated in the General opinion of the JAZMP section.

Article 4 Additional fees and charges

This Article establishes the legal basis for the EMA to levy a scientific service fee and a charge for administrative services on top of the existing fees, with the applicable amounts having to be published on the EMA's website after prior determination by the EMA Management Board and following a favourable opinion by the Commission.

The content of this Article is deficient in terms of tasks. Two items in the accompanying Annex IV are not defined in terms of content, as they only include a (large) range for fees for the provided services. Furthermore, it is not clear from the provision of the Article how the workload data will be monitored and validated, and there is no indication of what (if any) will be the division of the fee and the reimbursement of the payment to the Member States for the provided services. In this context, Member States will not be able to influence the setting of these fees, irrespective of their share of involvement in the provision of the services. The content of the Article is too general and vague and consequently shows the potential for different interpretations in the EU network; therefore, the JAZMP proposes this Article to be revised.

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

This Article deals with the conditions of remuneration paid to the NACs in relation to fees levied by the EMA. According to the proposal, the competent authorities of the Member States will thus receive full reimbursement of the costs of their services, including in those cases where a reduced fee is paid to the EMA in accordance with the legislation (i.e. e.g. reductions for micro, small and medium-sized enterprises) or the fee is waived in full, as, from a technical point of view, the entire process of document assessment has been carried out, irrespective of the status of the applicant/market authorisation holder or of the legal basis for the waiver of the fee. The JAZMP supports the adoption of the provision of this Article.

Article 6 Reductions of fees and charges

Article 6 sets out applicable fee reductions and related rules and refers to the relevant annex where the reductions are set out (i.e. Annex VI).

The JAZMP supports and agrees with the solution provided by Article 6 (4) of the Proposal for a Regulation, but proposes that the provision specifies more precisely the circumstances or reasons for the EMA to issue a decision.

Article 7 Payment of fees and charges

Articles 7 deals with conditions and rules pertaining to payment of fees and charges. The content of the provision is intended to specify in more detail the formal rules for payments between the payer and the EMA, and the JAZMP therefore supports its adoption in the proposed form.

Article 8 Working arrangements

Article 8 mandates the Management Board of the EMA to specify detailed technical arrangements to facilitate the application of the proposed regulation, such as payment methods of fees and charges and the precise mechanism under which the remuneration provided for by the proposed regulation is paid to NACs. A positive opinion by the Commission is required to ensure consistency with EU legislation, in line with the Joint Statement and Common Approach on decentralised agencies. The provision of this Article does not specify deadlines for the implementation of the activities referred to in this Article.

The JAZMP considers the proposed arrangement to be lacking and proposes that the provision of the Article be amended in this respect.

Article 9 Due date and measures in case of non-payment

Article 9 deals with due dates and provides for the possibility for the EMA Executive Director to suspend services in the case of non-payment. The content of the provision is intended to specify in more detail the rules for payments between the payer and the EMA; the JAZMP has no objections to the adoption of the Article in the proposed form.

Article 10 Transparency and monitoring

Article 10 sets out requirements for transparency of the amounts provided for by the proposed regulation and provides for monitoring of costs and inflation and reporting. It provides for the possibility for the EMA Executive Director to present to the Commission a factual and quantified *ad hoc* special report based on the above monitoring and to recommend amendment of the fees, charges and remuneration laid down in the annexes.

The JAZMP considers that point (3) of this Article of the Proposal for a Regulation is substantively deficient and should be supplemented with criteria regarding 'significant changes in the costs of services'. This deficiency of the provision is evident in the context of the whole material to the Proposal for a Regulation, as comparable data which are used by a Member State to express the 'significant changes in the costs of services' are not evident nor is the methodology for the division of the fees received by the Member States from the EMA for the individual activities.

Furthermore, the JAZMP is of the opinion that the development of a common format for reporting on the implementation of the Regulation by the EMA should be mandatory and not only an option, as stipulated in the current Proposal for a Regulation. This is the only way to ensure reporting with well-defined, demonstrable parameters that are common to all reports by all Member States in order to ensure equivalent treatment and evaluation of the data submitted to the EMA. In our view, the provision should also include a specific cut-off date for reporting common to all Member States; in fact, this is only defined as an option in the proposal (or a defined time for reporting after the point of significant changes in the costs of services).

In order to allow for a more agile EMA fee system, Article 10 (6) of the EC proposal enables the setting of the amount of the fees through Commission delegated acts. While this would bring about a quicker adaptation to potential amendments in pharmaceutical legislation, the JAZMP considers that, despite the participation of Member States through the Agency's Management Board, their impact would be significantly reduced.

Article 11 Revision

Article 11 sets out the conditions for a review of the amounts laid down in the Regulation and its Annexes, following a cost-based approach. It enables the Commission to adopt delegated acts to amend the annexes, based on the above-mentioned *ad hoc* report or the budgetary reporting of the EMA, a monitoring of the inflation rate, a change in EU legislation with respect to tasks of the EMA or new information on practical aspects of implementation of activities that attract a fee or a charge.

The JAZMP proposes that the above provision be supplemented, taking into account the principle of transparency, with a description of how the fees are to be evaluated and a description of the process for the revision of the above acts. Furthermore, the JAZMP reiterates the need to regulate the fee-sharing relationships between the EMA and the NCAs.

Article 12 Estimate of the Agency's budget

Article 12 sets out how the EMA will provide budgetary estimates, including detailed information on income from various types of fees and charges.

For reasons of transparency, the JAZMP proposes to amend this provision in such a way that the budgetary estimate for the following financial year should also include the additional fees and charges referred to in Article 4 of the Proposal for a Regulation.

Article 13 Exercise of the delegation

Article 13 sets out the conditions for the delegation of powers to adopt delegated acts and the procedural steps to be followed by the Commission for their adoption, in consideration of the criteria stipulated in Article 11 of the Proposal for a Regulation.

In principle, the JAZMP does not object to the proposed conditions; however, it has reservations concerning the provision under item (4) that before adopting a delegated act, the Commission shall consult experts designated by each Member State. In light of the previously expressed concerns, the JAZMP considers that in order to avoid the Commission's arbitrary decisions, the possibility for NCAs to have a real influence on the level of fees should be formally regulated (e.g. in a way that the Commission has to justify its deviation from the experts' recommendations).

Article 14 Amendment to Regulation (EU) No 2017/745

Article 14 provides for a new legal basis for fees and advice provided by expert panels payable to the EMA in accordance with the procedure under Article 106(14) of Regulation (EU) No 2017/745.

The JAZMP has no objection to the adoption of this provision in its proposed form.

Article 15 Repeal

Article 15 repeals the two current EMA Fee Regulations, i.e. Regulation (EC)

No 297/95 and Regulation (EU) No 658/2014. The proposed fees and charges are levied by the Proposal for a Regulation for the activities of the EMA as laid down in Regulation (EC) No 726/2004 and Regulation (EU) No 2019/6 and the consistency of the fee reductions and exemptions is based in accordance with Regulations (EC) No 2049/2005, 1901/2006, 141/2000 and 1394/2007 and is ensured by the correlation table in Annex VII.

The JAZMP supports the repeal of the existing EMA Fees Regulations, as it removes a complex dual legal basis and introduces a single legal instrument for this area.

Article 16 Transitional provisions

Article 16 specifies the conditions for applicability of the proposed regulation in relation to its date of entry application. The JAZMP has no comments on the proposed text.

Article 17 Entry into force and date of application

Article 17 provides the date of entry into force and application. The Proposal for a Regulation stipulates that the regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union and shall apply following the expiration of 6 months after entry into force. The JAZMP has no comments on the proposed text.

I. The opinion of the JAZMP on individual Annexes to the Proposal for a Regulation

ANNEX I Fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use

ANNEX I sets out fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use.

The JAZMP emphasises that NCAs must meet the conditions for investing in building and maintaining knowledge and expertise. This is the only way for them to expertly and effectively respond to current challenges and to maintain a sustainable role in the EU network of competent authorities. Unfortunately, it has recently become apparent on several occasions that there are already problems with the timely provision of experts according to the needs of the EMA, in particular due to the increase in the volume of procedures, the increased use of accelerated timelines, and the increased complexity of the assessment of documents in the context of procedures.

The contribution of the NCAs should therefore be properly assessed and financially compensated. In this respect, both the level of the full fee and the proportion of the fee that is allocated to the NCAs as remuneration for the provided services should be appropriately determined. The proposed fees in the Proposal for a Regulation, in the part dedicated to the NCAs, are in some cases heavily reduced, which reduces the level of their revenue for the services provided on an annual basis and may jeopardise both the functioning of the EU network and public health. While the Proposal for a Regulation includes some welcome fee increases, including new applications for marketing authorisations and extensions of marketing authorisations and additional fees under the Paediatric Regulation (PIPs/waivers), there are also significant fee reductions, e.g. for generic medicines, scientific advice, and variations of Type II.

In the context of marketing authorisation procedures, the fees for applications for a medicinal product with new active constituents under Article 8(3) of Directive 2001/83/EC, for a fixed combination medicinal product under Article 10(b) of Directive 2001/83/EC have been increased, which is reasonable in view of the increasing complexity of the applications and in the light of the analysed costs.

However, the new fee calculations particularly stand out in the case of a marketing authorisation for a generic medicinal product under Article 10(1) of Directive 2001/83/EC, where, in our view, the level of the fee itself does not reflect the complexity of the procedure, and the split ratio underestimates the input/contribution of the NCAs. For these procedures, the new fee has actually been reduced by an indicative amount of more than 20% compared to the current fee. As evident from the analysis of the working hours (780 h), the ratio of the hours spent by the EMA (272 h or 35%) compared to those spent by the NCAs (507 h or 65%), and from the proposed division of the fee of €141,200, the ratio is in favour of the EMA (i.e. €101,000 or 72% for the EMA compared to €40,200 or 28% for the NCAs).

Table 1: Medicinal products for human use

Fee	Opinion
Scientific advice	Scientific advice is one of the procedures that contribute to the development of new medicines and improves the accessibility of innovative medicines. Its scope and technical complexity are increasing compared to previous years, while in justified cases (e.g. vaccines and therapeutics for COVID-19) the procedural timeline has been significantly reduced in terms of regulatory flexibility. Consequently, difficulties have already arisen in the EU network in ensuring that the NCAs can provide expertise on a timely basis. The envisaged reduction in payments for the services provided by the NCAs has been reduced by 67%, which is certainly not something we can support.
Generic applications	It should be noted upfront that the proposal has a disproportionate impact on the revenue of the NCAs that provide the assessment for generic medicinal products. The fee for applications for generic medicinal products has been significantly reduced, but the reduction cannot be accurately assessed, as the model of levying the fees has also been changed. We support the new model of levying the fees only from the view point of removing the complexity of the current system (the proposal does not include additional fees for pharmaceutical form/strength or presentations). We estimate that the envisaged fee reduction would result in a reduction of revenue for the NCAs by approximately 40%. The handling of generic medicinal products under the centralised procedure is mainly carried out by smaller Member States, as the handling of applications under legal basis 10(1) of Directive 2001/83/EC is used by a number of smaller agencies as an entry point to carry out other EMA activities (handling of applications under other legal bases of Directive 2001/83/EC). Furthermore, the division of the fee between the EMA and the NCAs is also unfavourable and disproportionate for the NCAs, as their share has been substantially decreased (from 50% to 28%, while the share according to the calculation of the hours spent on the processing of an application for generic medicinal products is 65% in favour of the NCAs). In view of the above, the NCAs foresee potential revenue losses which may have a negative

	impact on their financial stability. Due to the reduction of the fee for applications for generic medicinal products under the centralised procedure, the possibility that manufacturers of generic medicinal products will more frequently opt for the centralised procedure must not be overlooked, which will in turn further reduce NCAs' revenue. The proposed fee is set very low compared to the fee for applications for generic medicinal products under the decentralised procedure. It is expected that manufacturers of generic medicinal products could more often opt for the centralised procedure which would represent a more financially viable fee (including from variations and annual fees).
Generic applications	It should be noted upfront that the proposal has a disproportionate impact on the revenue of the NCAs that provide the assessment for generic medicinal products. The fee for applications for generic medicinal products has been significantly reduced, but the reduction cannot be accurately assessed, as the model of levying the fees has also been changed. We support the new model of levying the fees only from the view point of removing the complexity of the current system (the proposal does not include additional fees for pharmaceutical form/strength or presentations). We estimate that the envisaged fee reduction would result in a reduction of revenue for the NCAs by approximately 40%. The handling of generic medicinal products under the centralised procedure is mainly carried out by smaller Member States, as the handling of applications under legal basis 10(1) of Directive 2001/83/EC is used by a number of smaller agencies as an entry point to carry out other EMA activities (handling of applications under other legal bases of Directive 2001/83/EC). Furthermore, the division of the fee between the EMA and the NCAs is also unfavourable and disproportionate for the NCAs, as their share has been substantially decreased (from 50% to 28%, while the share according to the calculation of the hours spent on the processing of an application for generic medicinal products is 65% in favour of the NCAs). In view of the above, the NCAs foresee potential revenue losses which may have a negative impact on their financial stability. Due to the reduction of the fee for applications for generic medicinal products under the centralised procedure, the

	possibility that manufacturers of generic medicinal products will more frequently opt for the centralised procedure must not be overlooked, which will in turn further reduce NCAs' revenue. The proposed fee is set very low compared to the fee for applications for generic medicinal products under the decentralised procedure. It is expected that manufacturers of generic medicinal products could more often opt for the centralised procedure which would represent a more financially viable fee (including from variations and annual fees).
Inspections	While the increase in fees for inspections is welcome, these fees remain low in absolute terms, especially for inspections in third countries where several inspectors may be absent for several weeks and the proposed fee consequently does not cover the overall costs. Based on the collected calculations, 90% of the workload for inspections for GMP is performed by the NCAs, while their reimbursement for the services is valued at only 66% in the proposal. The currently proposed level of fees for inspections for GMP does not reflect the actual costs incurred by the NCAs compared to the EMA and furthermore the division is not adequately defined.
MA variations of Type II	Currently, a higher fee applies for variations of Type II with clinical and non-clinical data. The proposal foresees a higher fee only for an addition of a new therapeutic indication or modification of an approved indication. However, for all other variations of Type II, a single fee is foreseen, which is not adequately fixed given the potential complexity of the variation (e.g. change of dosage). Similarly, a very low fee is foreseen for qualitative variations of Type II, which include some very complex ones, e.g. the evaluation of BE studies. Both the level and the division of the fee for the provided services are again inadequate or insufficient for the work carried out by the NCAs.

ANNEX II Fees, charges and remuneration for assessment procedures and services relating to veterinary medicinal products

ANNEX II sets out fees, charges and remuneration for assessment procedures and services relating to veterinary medicinal products.

The objective of the new fees regulation should be to regulate fees in a way that these ensure a sustainable and forward-looking network of NCAs. The reimbursement of costs for the provided services should suffice not only to cover direct costs but also to ensure the development and maintenance of the assessment procedures.

Furthermore, it is necessary to ensure that smaller NCAs have the opportunity to develop expertise and contribute to the work of the network. Since the data collection in 2016, the entry into force of the new Veterinary Regulation 2019/6 has broadened the scope of the centralised procedure and given additional emphasis to the monitoring and assessment of antimicrobial resistance and environmental risks. In principle, an increase of certain fees is welcome for veterinary medicinal products, as is a reduction of certain other fees (e.g. for immunological medicinal products and in the case of limited markets). However, as the Regulation has only been applicable for one year, it cannot yet be fully seen how the new fees will affect the revenue of the NCAs and whether the envisaged fee reductions will be a sufficient incentive for the development of new veterinary medicinal products and improvement of their availability in the EU.

When designing the fees policy, not only the payment for the necessary contribution of the NCAs for the work carried out needs to be considered, but also the fragmentation of the market for veterinary medicinal products and the resulting cost sensitivity of the market.

ANNEX III Annual fees and remuneration

ANNEX III sets out annual fees and remuneration for medicinal products for human use and veterinary medicinal products.

Annex III foresees a general increase of the annual fees, which the JAZMP supports in view of the increasing costs, including the upgrade of digitalisation. The new annual fees increase the cumulative revenue of the EMA; unfortunately, the relevant proposal of Annex III continues to foresee only the payment of annual fees for medicinal products to NCAs where the NCAs participate as a rapporteur/co-rapporteur. For all other medicinal products authorised under the centralised procedure, no annual fee is foreseen for the NCAs. The JAZMP therefore proposes to consider paying part of the fee for all medicinal products authorised under the centralised procedure that are available in the market in a Member State for the monitoring of the medicinal product. The need for the latter became particularly

apparent during the COVID-19 epidemic, when there was also an increase in pharmacovigilance activities on the part of the NCAs, in particular due to the increased monitoring of adverse reactions following vaccination. Similarly, the EMA charges an annual fee for pharmacovigilance activities for medicinal products authorised under the national procedure (NP) or international mutual recognition procedure (MRP/DCP).

The introduction of a new fee for veterinary medicinal products for the EMA's pharmacovigilance tasks means that companies would have to pay a double fee (at national and EMA level). However, there is no provision for a payment for pharmacovigilance activities to Member States, linked to the performance of pharmacovigilance activities for the monitoring of medicinal products authorised under the centralised procedure at national level.

ANNEX IV Other fees and charges for medicinal products for human use, veterinary medicinal products and consultations on medical devices

Annex IV sets out various other fees and charges for both medicinal products for human use and veterinary medicinal products, as well as consultations on medical devices – for inspections, transfer of authorisations, pre-submission services, re-examination of opinions and other scientific and administrative services. Comment included under Annex I.

ANNEX V Fee reductions

Annex V sets out fee reductions for specific applicants and products in accordance with Articles 5 and 6 of the Proposal for a Regulation. The JAZMP has no comments on the proposed text.

ANNEX VI Performance information

Annex VI sets out the performance information, including information collected from NCAs in Member States. The JAZMP has no comments on the proposed text.

ANNEX VII Correlation table

One of the objectives of the proposal is to rationalise the system by simplifying the structure for setting fee levels and removing unnecessary complexity from the relevant legal framework by bringing together, in a single legal instrument, rules on fees that are currently governed by two regulations on the Agency's fees. The proposal removes the complexity of the dual legal basis and introduces a single legal instrument, which is duly reflected in the prepared correlation table. The JAZMP therefore has no comments on the proposed text.

III. CONCLUSIONS

The NCAs and the EMA have a constructive and long-lasting synergistic partnership for the benefit of public and animal health. Ensuring the stability of this network of competent authorities is consequently essential, as it is the only way to respond effectively and professionally at EU level to the challenges of current developments when this is most needed. The contribution of the NCAs in this network must be adequately financially valued and reimbursed so that their operations are financially sustainable. A fair distribution of the fees received by the EMA for its activities is therefore essential. We therefore emphasise that the discussions and negotiations within the Working Party on Pharmaceuticals and Medical Devices should reflect principles that create a level playing field for all partners in the EU regulatory network, while at the same time allowing for their existence and development. We further emphasise that in some areas of regulation – as we have already pointed out – clarifications are needed to allow an understanding of the amendments and to anticipate their potential implications for the functioning of the EU regulatory network.

The NCAs support the Commission's proposal that fees should be cost-based; however, they should reflect the full cost of the NCAs' providing a range of services. The sustainability of the system and its future depends, as mentioned before, on a model of fees that adequately reimburses the NCAs for all the work that keeps the Agency's activities running and that supports the authorisation and supervision of medicinal products.

Furthermore, the JAZMP considers that there should also be a statutory obligation to adjust the fee levels based on costs in the light of foreseeable negative impacts in terms of the stability of the EU network of NCAs.

ANNEX I
Fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use

SI NOTE:

The contribution of NCAs must be appropriately financially evaluated and reimbursed. It is necessary to properly determine both the total amount of the fee and the share that goes to the NCAs as payment for their services.

In the draft regulation the part of the proposed fees that is intended for NCAs is greatly reduced, which lowers the overall income / revenue of NCAs and can thus threaten the

sustainability of the EU network and public health as such.

1. Scientific advice provided by the Agency in accordance with Article 57(1)(n) of Regulation (EC) No 726/2004

1.1 A fee of EUR 78 900 shall apply to any of the following requests:

(a) a request on quality, non-clinical and clinical development;
(b) a request on quality and clinical development;
(c) a request on non-clinical and clinical development;
(d) a request on qualification of novel methodologies.

The remuneration shall be EUR 22 250 for each of the two scientific advice co-ordinators.

1.2 A fee of EUR 67 000 shall apply to any of the following requests:

(a) a request on clinical development;
(b) a request on quality and non-clinical development;
(c) a request on quality and bioequivalence studies for generic medicinal products as defined in Article 10(2), point (b) of Directive 2001/83/EC.

The remuneration shall be EUR 17 650 for each of the two scientific advice co-ordinators.

1.3 A fee of EUR 50 050 shall apply to any of the following requests:

a) a request on quality development;
b) a request on non-clinical development;
c) a request on bioequivalence studies for generic medicinal products as defined in Article 10(2), point (b), of Directive 2001/83/EC.

The remuneration shall be EUR 11 725 for each of the two scientific advice co-ordinators.

Justification

The methodology used by the EC to calculate these fees is flawed and does not even consider the hours appropriately that each NCAs contribute to such high level expertise being delivered. As per the ECs own document: **evaluation_ema_fee_frep_en.pdf (europa.eu) https://ec.europa.eu/health/sites/default/files/files/fees/evaluation_ema_fee_frep_en.pdf**.

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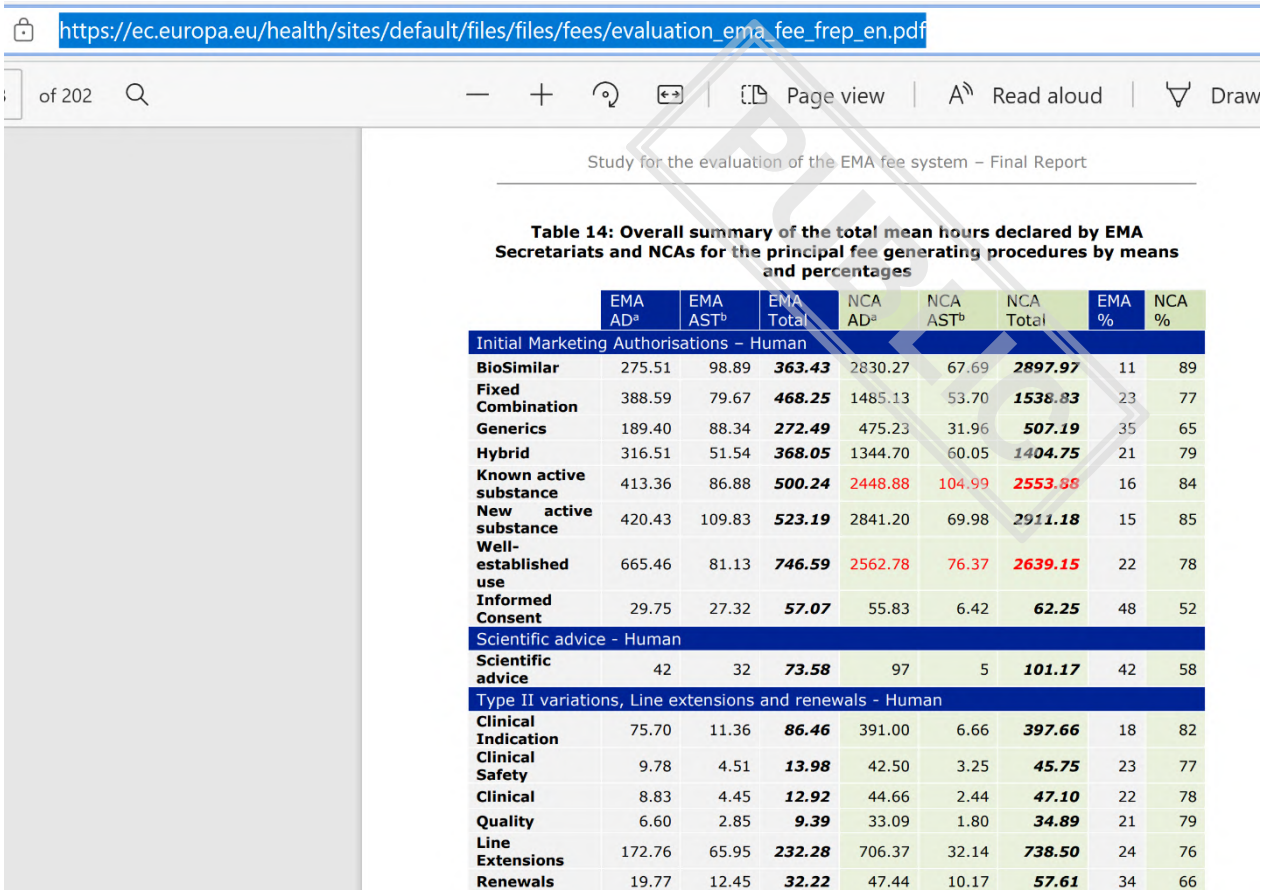

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Table 14: Overall summary of the total mean hours declared by EMA Secretariats and NCAs for the principal fee generating procedures by means and percentages

	EMA AD[a]	EMA AST[b]	EMA Total	NCA AD[a]	NCA AST[b]	NCA Total	EMA %	NCA %
Initial Marketing Authorisations – Human								
BioSimilar	275.51	98.89	***363.43***	2830.27	67.69	***2897.97***	11	89
Fixed Combination	388.59	79.67	***468.25***	1485.13	53.70	***1538.83***	23	77
Generics	189.40	88.34	***272.49***	475.23	31.96	***507.19***	35	65
Hybrid	316.51	51.54	***368.05***	1344.70	60.05	***1404.75***	21	79
Known active substance	413.36	86.88	***500.24***	2448.88	104.99	***2553.88***	16	84
New active substance	420.43	109.83	***523.19***	2841.20	69.98	***2911.18***	15	85
Well-established use	665.46	81.13	***746.59***	2562.78	76.37	***2639.15***	22	78
Informed Consent	29.75	27.32	***57.07***	55.83	6.42	***62.25***	48	52
Scientific advice - Human								
Scientific advice	42	32	***73.58***	97	5	***101.17***	42	58
Type II variations, Line extensions and renewals - Human								
Clinical Indication	75.70	11.36	***86.46***	391.00	6.66	***397.66***	18	82
Clinical Safety	9.78	4.51	***13.98***	42.50	3.25	***45.75***	23	77
Clinical	8.83	4.45	***12.92***	44.66	2.44	***47.10***	22	78
Quality	6.60	2.85	***9.39***	33.09	1.80	***34.89***	21	79
Line Extensions	172.76	65.95	***232.28***	706.37	32.14	***738.50***	24	76
Renewals	19.77	12.45	***32.22***	47.44	10.17	***57.61***	34	66

The EMA mean hours for a Scientific advice is recorded at: 73.58 hours while EACH NCA mean average is 101.17 hours the % is therefore 42% vs 58%. The fees therefore have to be amended appropriately and the appropriate percentage distribution is proposed . For this procedure 2 NCAs carryout the service and therefore the mean hours are 202.14 when all types of advices are grouped together.

The commission proposal as it stands severely undermines the sustainability of the EU medicines regulatory network reimbursing a pittance to the NCAs to deliver this service. Experts are engaged by NCAs and the costs should be appropriately reimbursed.

2. Scientific opinions and assessments prior to potential submission of an application for a marketing authorisation

2.1 A fee of EUR 549 800 shall apply to any of the following:

(a) an opinion on a medicinal product for compassionate use pursuant to Article 83 of Regulation (EC) No 726/2004;

(b) an assessment on an on-going basis of data packages of particulars and documents submitted to the Agency by a prospective applicant prior to a formal submission of an application for a marketing authorisation falling within the scope of Regulation (EC) No 726/2004.

That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 153 000 for the rapporteur and EUR 143 300 for the co-rapporteur.

2.2 In the event of multiple submissions of data packages submitted by the same prospective applicant for the same product, the fee set out in point 2.1 (b) shall only be charged once.

2.3 The amounts set out in point 2.1 shall be deducted from the respective fee and from the remuneration to competent authorities of the Member States payable for a marketing authorisation application for the same product, where such application is submitted by the same applicant.

3. Authorisation to market a medicinal product falling within the scope of Regulation (EC) No 726/2004

3.1 A fee of EUR 684 900 shall apply to an application for a marketing authorisation for a medicinal product pursuant to Article 8(3) of Directive 2001/83/EC when the applicant claims a new active substance. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 217 300 for the rapporteur and EUR 189 300 for the co-rapporteur.

3.2 A fee of EUR 549 800 shall apply to an application for a marketing authorisation for a medicinal product pursuant to Article 8(3) of Directive 2001/83/EC when the applicant claims a known active substance. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 153 000 for the rapporteur and EUR 143 300 for the co-rapporteur.

3.3 A fee of EUR 456 800 shall apply to an application for a fixed combination medicinal product pursuant to Article 10b of Directive 2001/83/EC. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 141 500 for the rapporteur and EUR 83 000 for the co-rapporteur.

3.4 A fee of EUR 575 000 shall apply to an application for a biological medicinal product which is similar to a reference biological product pursuant to Article 10(4) of Directive 2001/83/EC. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 236 500 for the rapporteur and EUR 151 700 for the co-rapporteur.

3.5 A fee of EUR 624 300 shall apply to an application for a marketing authorisation for a medicinal product pursuant to Article 10a of Directive 2001/83/EC. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 160 600 for the rapporteur and EUR 149 400 for the co-rapporteur.

3.6 A fee of EUR 241 200 shall apply to any of the following:

(a) an application for a marketing authorisation for a generic medicinal product pursuant to Article 10(1) of Directive 2001/83/EC,

That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 142 000 for the rapporteur.

SI NOTE:
We propose to split point 3.7 to two points, as explained in the following comment.

General comment in relation to generic MAAs:
In our opinion the amount of proposed fee for the obtaining the MA for a generic medicinal product does not adequately reflect the complexity of the procedure and has been reduced significantly.

The NCAs provide assessment of generic medicines, but are paid much less than EMA. JAZMP estimates that the proposed fee reduction results in a revenue reduction for NCAs of approximately more than 40%.
In these procedures, the new fee has been reduced by app 20 % compared to the current fee calculating all strengths and presentations.

Also the distribution of the fee between EMA and NCAs underestimates the input/contribution of NCAs. The share of NCAs fee has decreased significantly (from 50% to 28%).

Allocation of costs for working hours (780h) shows that EMA spent apx 272h per procedure (35 %), while NCAs contribute apx 507h per procedure (65%) for which EMA received 101k EUR (72 %) and NCAs only 28 %.

Furthermore the manufacturers/applicants of generic MPs may therefore more often obtain MA via centralized procedure, which will even further reduce the income of NCAs since the fee for obtaining MA via decentralised procedure calculating all MS might be disproportionately higher.

3.7 A fee of EUR 141 200 shall apply to any of the following:

(b) an application based on informed consent for a marketing authorisation for a medicinal product pursuant to Article 10c of Directive 2001/83/EC.

That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 40 200 for the rapporteur.

SI NOTE:

We propose to split point 3.7 to two points:

1) one point for legal basis 10(1) - with fees and justificiation as proposed by MT.

2) New point dedicated only for legal basis 10c (= informed consent application) is proposed.

Explanation:

Despite the fact that the provision contains some criteria that are common to the definition of a generic medicinal product in Article 10, Article 10c does not concern generic medicinal products.

According to Article 10c: "Following the granting of a marketing authorisation, the authorisation holder may allow use to be made of the pharmaceutical, preclinical and clinical documentation contained in the file on the medicinal product, with a view to examining subsequent applications relating to other medicinal products possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form."

It is a prerequisite for the use of article 10c that consent has been obtained for all three modules containing the pharmaceutical, preclinical and clinical data.

Justification

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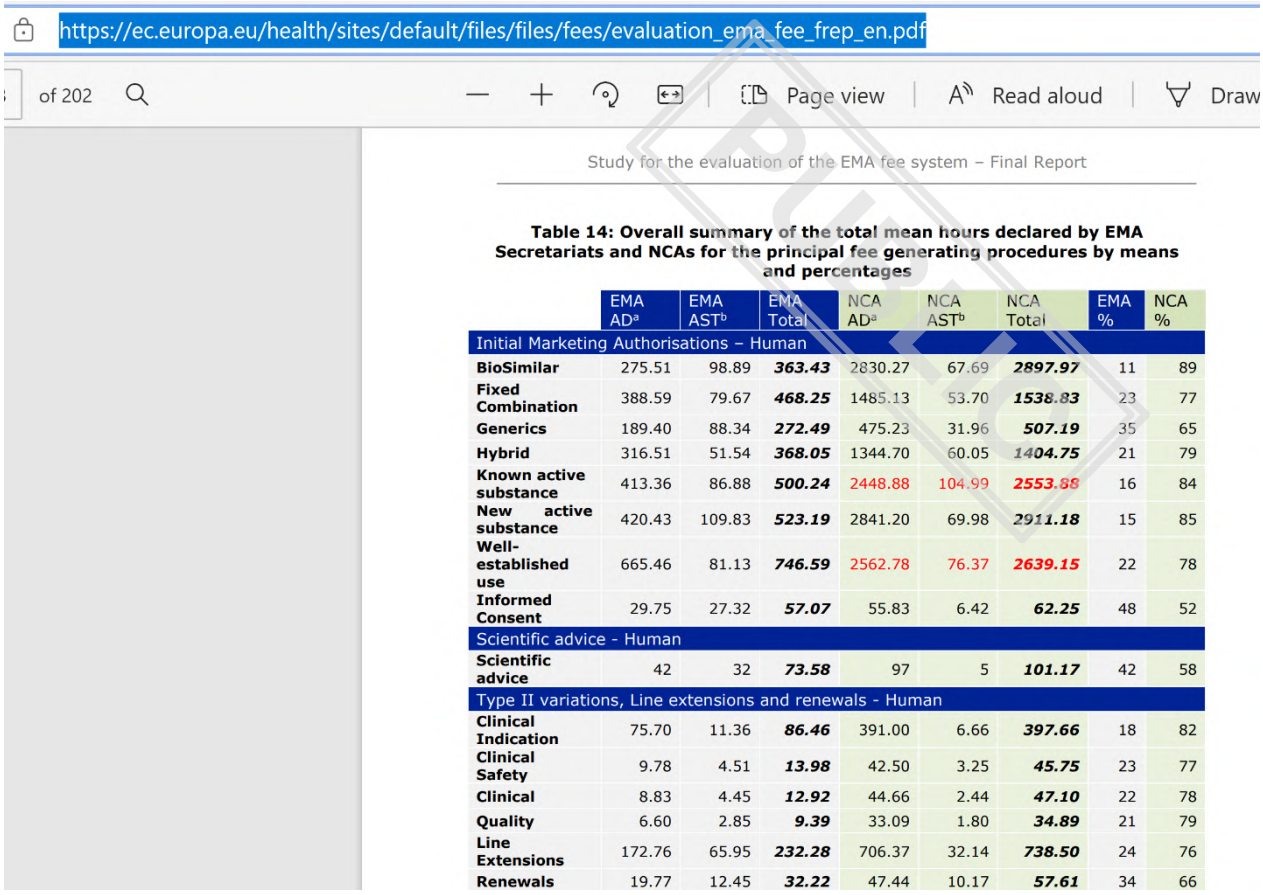

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Fixed Combination	388.59	79.67	***468.25***	1485.13	53.70	***1538.83***	23	77
Generics	189.40	88.34	***272.49***	475.23	31.96	***507.19***	35	65
Hybrid	316.51	51.54	***368.05***	1344.70	60.05	***1404.75***	21	79
Known active substance	413.36	86.88	***500.24***	2448.88	104.99	***2553.88***	16	84
New active substance	420.43	109.83	***523.19***	2841.20	69.98	***2911.18***	15	85
Well-established use	665.46	81.13	***746.59***	2562.78	76.37	***2639.15***	22	78
Informed Consent	29.75	27.32	***57.07***	55.83	6.42	***62.25***	48	52
Scientific advice - Human								
Scientific advice	42	32	***73.58***	97	5	***101.17***	42	58
Type II variations, Line extensions and renewals - Human								
Clinical Indication	75.70	11.36	***86.46***	391.00	6.66	***397.66***	18	82
Clinical Safety	9.78	4.51	***13.98***	42.50	3.25	***45.75***	23	77
Clinical	8.83	4.45	***12.92***	44.66	2.44	***47.10***	22	78
Quality	6.60	2.85	***9.39***	33.09	1.80	***34.89***	21	79
Line Extensions	172.76	65.95	***232.28***	706.37	32.14	***738.50***	24	76
Renewals	19.77	12.45	***32.22***	47.44	10.17	***57.61***	34	66

The EMA mean hours for a Generic is recorded at: 272.49 hours while the NCA mean average is 507.19 hours the % is therefore 35% vs 65%. The fees therefore have to be amended appropriately and the appropriate percentage distribution is proposed . For this procedure 1 NCA carries out the service.

Furthermore the fee for a generic medicie should be aligned internationally to similar market size as the EU. The US FDA charges approximtely $240,000 for an abbreviated new drug application for access to a 380 million market. Fees for a generic to be licensed via the Decentralised procedure in all member states costs > 300 000 EUR. This fee undermines the whole Network fees as well as is devaluing the Marketing authorisation. The EU fee should be approach the US FDA fee and be split with the above percentages.

The commission proposal as it stands severely undermines the sustainability of the EU medicines regulatory network reimbursing a pittance to the NCAs to deliver this service. Experts are engaged by NCAs and the costs should be appropriately reimbursed.

3.8 A fee of EUR 339 700 shall apply to an application for a marketing authorisation for a medicinal product pursuant to Article 10(3) of Directive 2001/83/EC. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 89 100 for the rapporteur and EUR 89 100 for the co-rapporteur.

3.9 A fee of EUR 46 600 shall apply to the second and to each subsequent application for a marketing authorisation submitted pursuant to Article 10(1), (3) or (4) of Directive 2001/83/EC on usage patent grounds where the reference medicinal product is subject to a usage patent. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 16 800 for the rapporteur and EUR 10 000 for the co-rapporteur.

Justification

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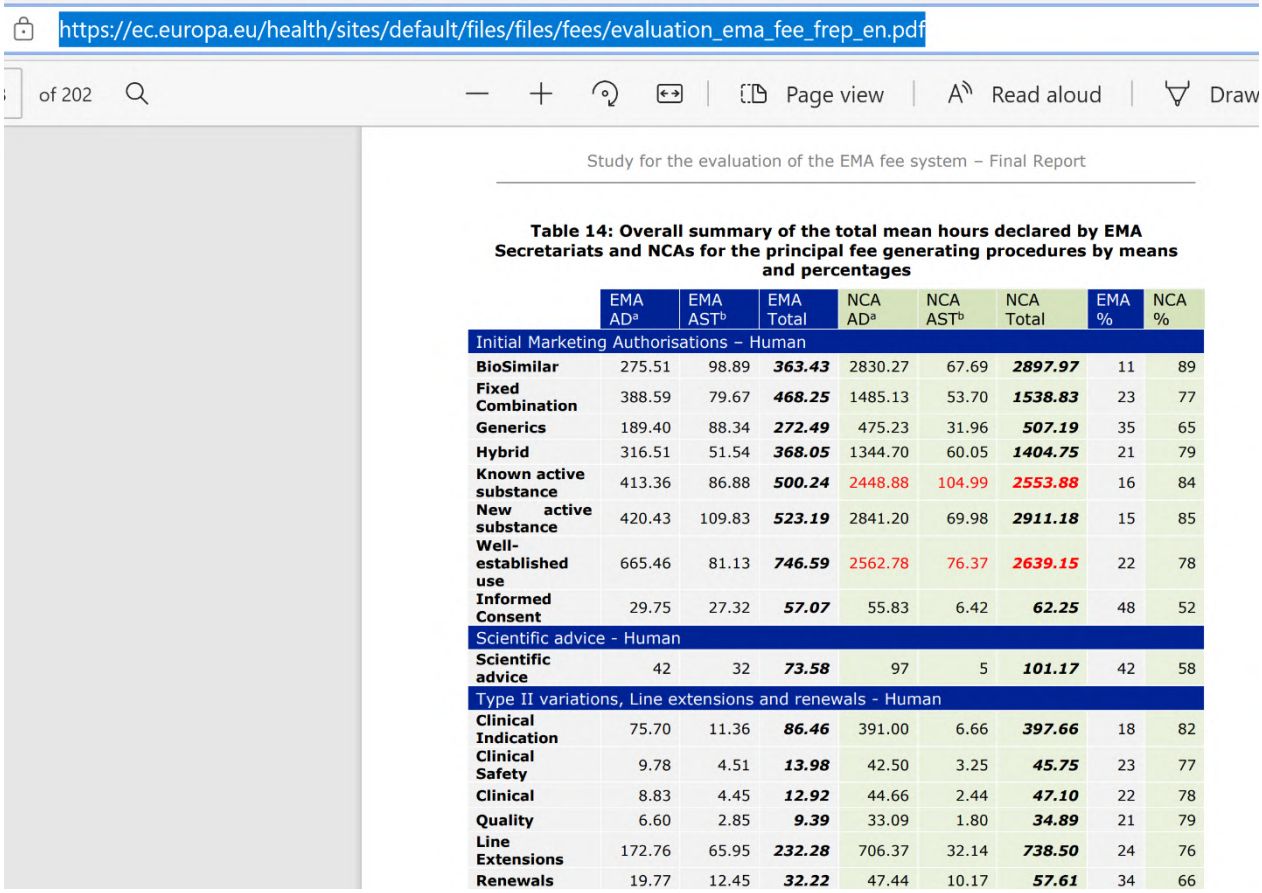

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The commission proposal as it stands severely undermines the sustainability of the EU medicines regulatory network reimbursing a pittance to the NCAs to deliver this service. Experts are engaged by NCAs and the costs should be appropriately reimbursed.

4. Extension of a marketing authorisation within the meaning of Annex I to Commission Regulation (EC) No 1234/2008[11]

4.1 A fee of EUR 138 000 shall apply to an application for an extension of a marketing authorisation requiring only chemical, pharmaceutical or biological documentation and for which no clinical or non-clinical data are submitted. That fee shall cover a single pharmaceutical form and a single associated strength. The remuneration shall be EUR 45 300 for the rapporteur and EUR 26 600 for the co-rapporteur.

4.2 A fee of EUR 161 000 shall apply to an application for an extension of a marketing authorisation not covered by point 4.1. That fee shall cover a single pharmaceutical form and a single associated strength. The remuneration shall be EUR 55 300 for the rapporteur and EUR 31 200 for the co-rapporteur.

4.3 Without prejudice to points 4.1 and 4.2, a fee of EUR 46 600 shall apply to each application for extension of a marketing authorisation on the basis of an application submitted under Article 10(1), (3) or (4) of Directive 2001/83/EC on usage patent grounds as referred to in point 3.8 of this Annex. The remuneration shall be EUR 16 800 for the rapporteur and EUR 10 000 for the co-rapporteur.

Justification

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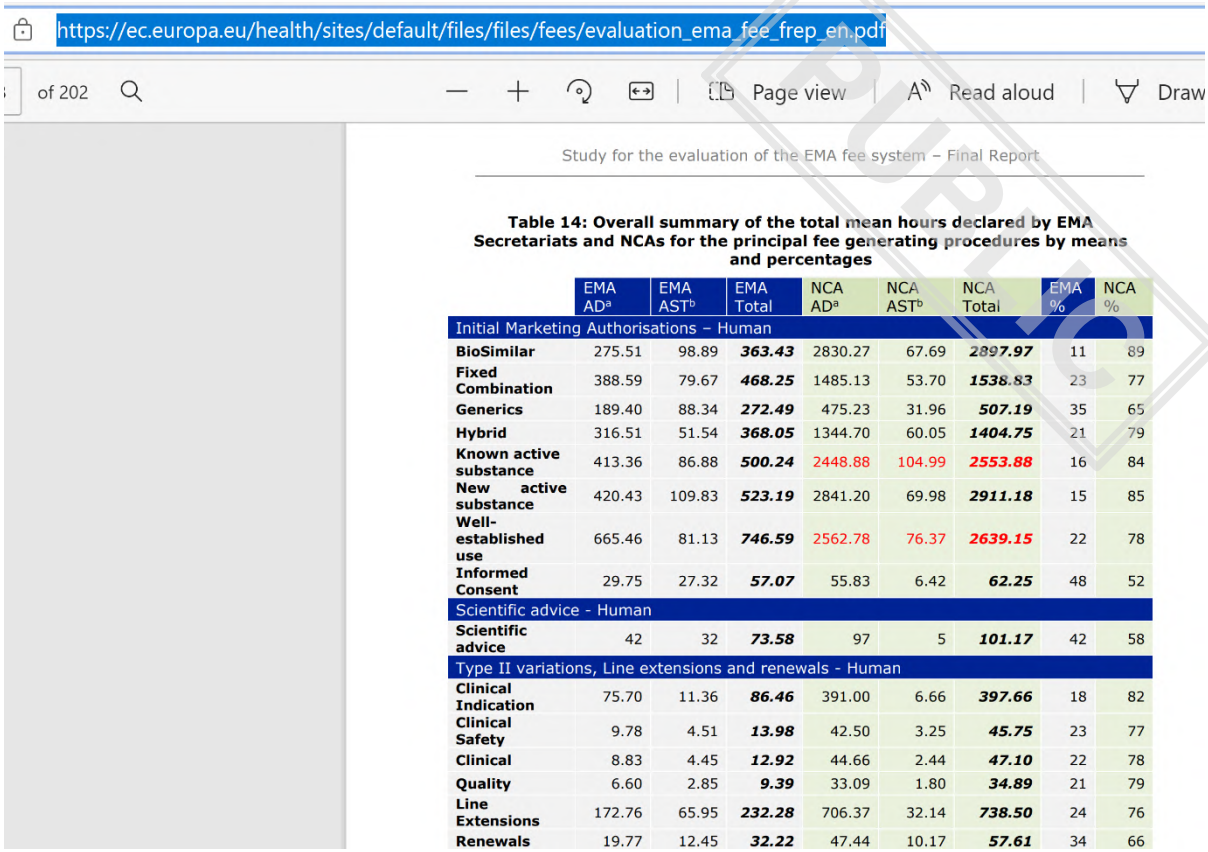

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The commission proposal as it stands severely undermines the sustainability of the EU medicines regulatory network reimbursing a pittance to the NCAs to deliver this service. Experts are engaged by NCAs and the costs should be appropriately reimbursed.

5. Major variation of type II to the terms of a marketing authorisation in accordance with Commission Regulation (EC) No 1234/2008

5.1 A fee of EUR 139 800 shall apply to an application for a major variation of type II as defined in Article 2(3) of Regulation (EC) No 1234/2008 ('major variation of type II') for an addition of a new therapeutic indication or modification of an approved indication. The remuneration shall be EUR 49 400 for the rapporteur and EUR 49 400 for the co-rapporteur.

5.2 A fee of EUR 80 500 shall apply to an application for a major variation of type II, complex clinical/non-clinical/quality variation of type II, not covered by point 5.1. The remuneration shall be EUR 56 350 for the rapporteur.

SI NOTE:

Currently there is a higher fee for type II changes with clinical and non-clinical data. The proposal envisages a higher fee only for new therapeutic indications or changes to an approved indication.

A single fee is provided for all other type II changes, which does not adequately reflect to the possible complexity of some variations (e.g. change in posology).

Similarly, a very low fee is provided for quality changes of type II, which may also include some very complex ones, e.g. assessment of BE studies (in relation to changed formulation of MP). Even in this case, both the amount and the distribution of the fee for the services provided are not appropriate and are insufficient for the work done by the NCAs.

In this respect new level of variation is proposed and aleready introduced in the text (see above).

Justification

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Study for the evaluation of the EMA fee system – Final Report

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The commission proposal as it stands severely undermines the sustainability of the EU medicines regulatory network reimbursing a pittance to the NCAs to deliver this service.

Experts are engaged by NCAs and the costs should be appropriately reimbursed. As per above document the fees should be split 82% vs 18 % (EMA). The above is therefore a compromise wher fees are split approxametly 60/40.

5.3 A fee of EUR 23 000 shall apply to an application for a variation of type II not covered by points 5.1 and 5.2. The remuneration shall be EUR 16 800 for the rapporteur.

5.4 For each application for a major variation of type II that is grouped in a single application pursuant to Article 7 of Regulation (EC) No 1234/2008, the corresponding fee shall be charged as set out in points 5.1 and 5.2. Remuneration shall be paid in accordance with those points.

5.5 Where a work-sharing application pursuant to Article 20 of Regulation (EC) No 1234/2008 includes more than one centrally authorised product, the fees and remuneration specified in points 5.1 and 5.2 of this Annex shall apply to each variation of the first centrally authorised product, whereas a charge of EUR 800 shall apply to each variation of the second and subsequent centrally authorised product included in the application.

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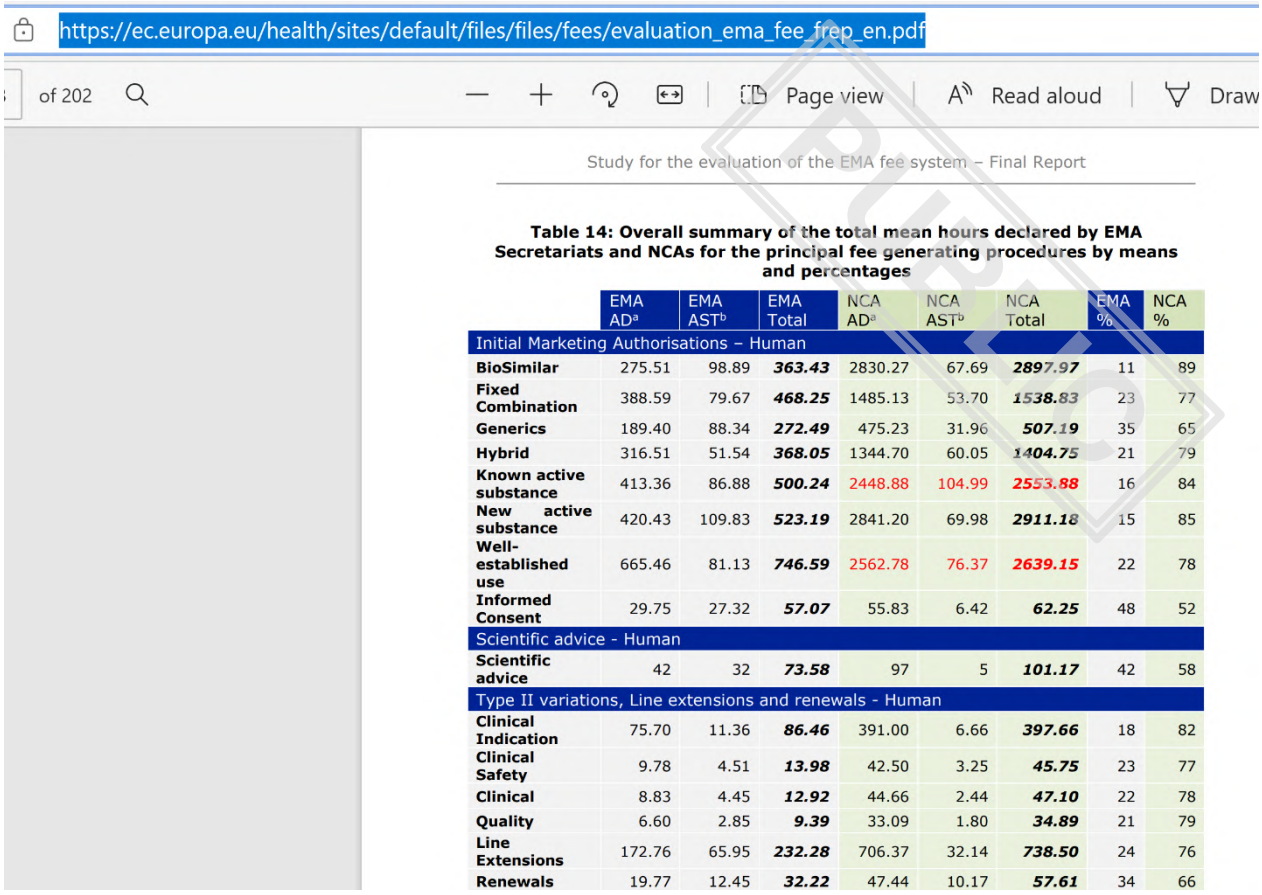

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6. Referrals and scientific opinions pursuant to Article 5(3) of Regulation (EC) No 726/2004

6.1 A fee of EUR 136 700 shall apply to the assessment carried out in the context of a procedure initiated under Article 5(3) of Regulation (EC) No 726/2004. Such fee shall be waived in full. The remuneration shall be EUR 42 400 for the rapporteur and EUR 42 400 for the co-rapporteur.

6.2 A fee of EUR 262 400 shall apply to the assessment carried out in the context of a procedure initiated under Article 13 of Regulation (EC) No 1234/2008. Such fee shall be waived in full. The remuneration shall be EUR 45 300 for the rapporteur and EUR 45 300 for the co-rapporteur.

6.3 A fee of EUR 83 000 shall apply to the assessment carried out in the context of a procedure initiated under Article 29(4) of Directive 2001/83/EC. Such fee shall be waived in full. The remuneration shall be EUR 22 800 for the rapporteur and EUR 22 800 for the co-rapporteur.

6.4 A fee of EUR 128 200 shall apply to the assessment carried out in the context of a procedure initiated under Article 30 of Directive 2001/83/EC. The remuneration

shall be EUR 36 800 for the rapporteur and EUR 36 800 for the co-rapporteur.

6.5 A fee of EUR 180 700 shall apply to the assessment carried out in the context of a procedure initiated under Article 31 of Directive 2001/83/EC where the procedure is initiated as a result of the evaluation of data other than data relating to pharmacovigilance. The remuneration shall be EUR 32 400 for the rapporteur and EUR 32 400 for the co-rapporteur.

6.6 A fee of EUR 172 100 shall apply to the assessment carried out in accordance with a procedure initiated under Article 20 of Regulation (EC) No 726/2004 where that procedure is initiated as a result of the evaluation of data other than data relating to pharmacovigilance. The remuneration shall be EUR 37 500 for the rapporteur and EUR 37 500 for the co-rapporteur

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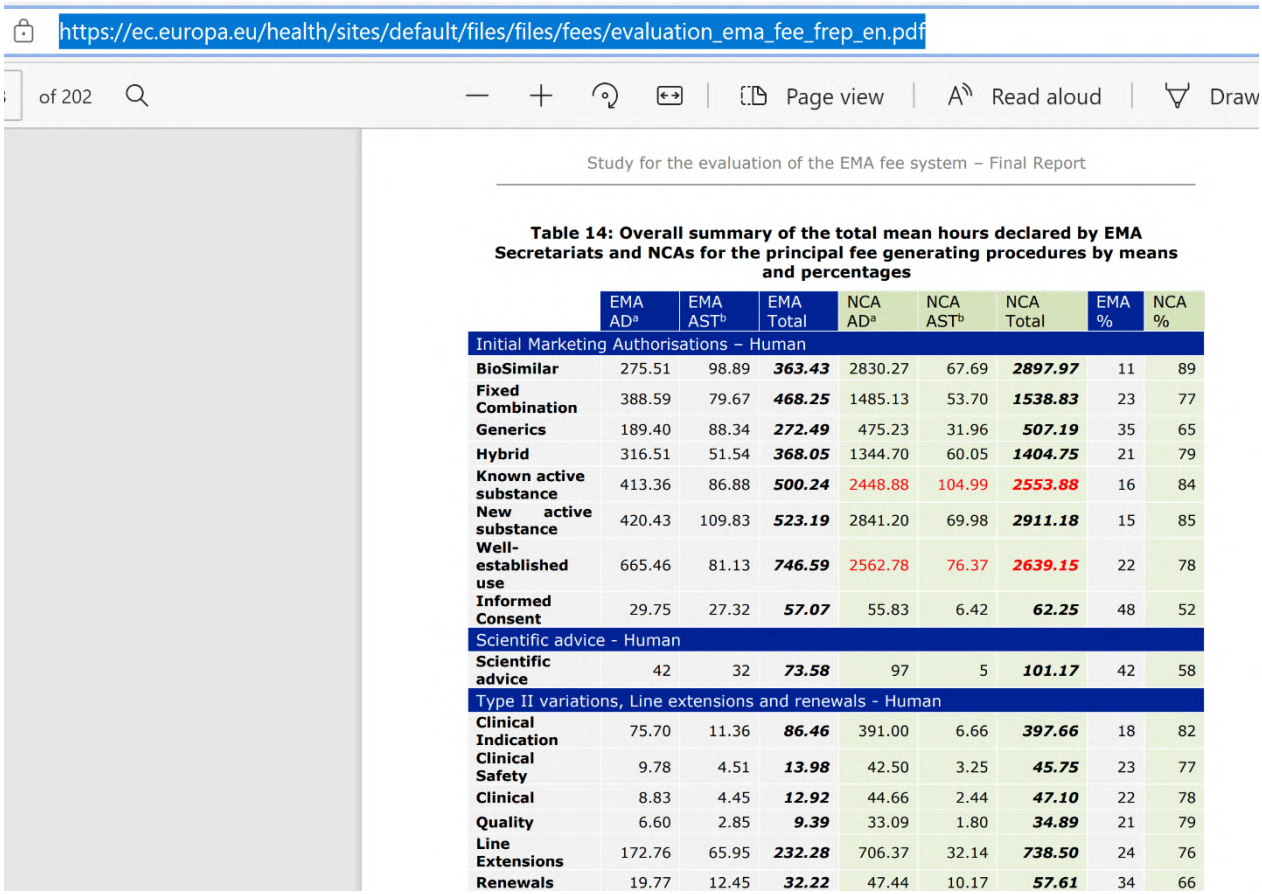

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The commission proposal as it stands severely undermines the sustainability of the EU medicines regulatory network reimbursing a pittance to the NCAs to deliver this service. Experts are engaged by NCAs and the costs should be appropriately reimbursed.

7.1. For an assessment carried out in the context of a procedure initiated as a result of the evaluation of pharmacovigilance data under Article 31(1), second subparagraph, Article 31(2) and Articles 107i, 107j and107k of Directive 2001/83/EC or under Article 20(8) of Regulation (EC) No 726/2004, the following fees shall apply:

7.1.1 a fee of EUR 172 100 where one active substance or combination of active substances and one marketing authorisation holder are included in the assessment. The remuneration shall be EUR 17 500 for the rapporteur and EUR 17 500 for the co-rapporteur;

7.1.2. a fee of EUR 258 200 where two or more active substances or combinations of active substances and one marketing authorisation holder are included in the assessment. The remuneration shall be EUR 26 300 for the rapporteur and EUR 26 300 for the co-rapporteur;

7.1.3. a fee of EUR 314 100 where one or two active substances or combinations of active substances and two or more marketing authorisation holders are included in the assessment. The remuneration shall be EUR 32 000 for the rapporteur and EUR 32 000 for the co-rapporteur;

7.1.4. a fee of EUR 426 100 where more than two active substances or combinations of active substances and two or more marketing authorisation holders are included in the assessment. The remuneration shall be EUR 43 400 for the rapporteur and EUR 43 400 for the co-rapporteur.

7.2. Where two or more marketing authorisation holders are involved in the procedures referred to in points 6.4, 6.5, 6.6 and 6.7, the amount payable by each marketing authorisation holder shall be calculated by the Agency in two steps, as follows:

(a) by dividing the total amount of the fee among the marketing authorisation holders proportionally to the number of chargeable units-human corresponding to products included in the procedure which are held by each of those marketing authorisation holders;

(b) by subsequently applying, where relevant, the fee reduction laid down in Annex V.

8. Evaluation of traditional herbal medicinal products in accordance with Article 57(1)(n) of Regulation (EC) No 726/2004

A fee of EUR 29 700 shall apply to a request for scientific advice from the Committee on Herbal Medicinal Products related to traditional herbal medicinal products. The remuneration shall be EUR 4 100 for the rapporteur.

9. Certification of compliance with Union legislation for a plasma master file (PMF) in accordance with Part III of Annex I of Directive 2001/83/EC

9.1 A fee of EUR 57 200 shall apply to an application for review of a PMF and its initial certification pursuant to Part III, point 1.1 of Annex I to Directive 2001/83/EC. The remuneration shall be EUR 8 600 for the rapporteur and EUR 8 600 for the co-rapporteur.

9.2 A charge of EUR 5 800 shall apply to the issuing of an initial PMF certification where it is submitted simultaneously with an application for a marketing authorisation for a medicinal product under the centralised procedure. The PMF

documentation shall be evaluated within the centralised marketing authorisation application.

9.3 A fee of EUR 10 600 shall apply to an application for review and certification of a major variation of type II to the PMF pursuant to Regulation (EC) No 1234/2008. The remuneration shall be EUR 1 600 for the rapporteur and EUR 1 600 for the co-rapporteur.

For two or more major variations of type II grouped in a single application pursuant to Regulation (EC) No 1234/2008, the fee and remuneration laid down in point 9.4 of this Annex shall apply.

9.4 A fee of EUR 17 000 shall apply for an application for review and annual re-certification of a PMF which may include any variation pursuant to Regulation (EC) No 1234/2008 submitted simultaneously with the application for a PMF annual re-certification. The remuneration shall be EUR 1 900 for the rapporteur and EUR 1 900 for the co-rapporteur.

10. Certification of compliance with Union legislation for a vaccine antigen master file (VAMF) in accordance with Part III of Annex I of Directive 2001/83/EC

10.1 A fee of EUR 57 200 shall apply for an application for review of a VAMF and its initial certification not submitted simultaneously with a new application for marketing authorisation under the centralised procedure pursuant to Part III, point 1.2 of Annex I to Directive 2001/83/EC. The remuneration shall be EUR 8 600 for the rapporteur and EUR 8 600 for the co-rapporteur.

10.2 In the case of a group of antigens aimed at preventing a single infectious disease, a fee shall be charged for the VAMF application for one antigen and remuneration shall be paid pursuant to point 10.1. The second and subsequent VAMF applications submitted simultaneously for antigens as part of the same group shall be charged a fee of EUR 7 800 per VAMF. The maximum total amount charged by the Agency for VAMF applications submitted simultaneously for antigens as part of the same group shall not exceed EUR 68 600. In that case, the remuneration per each second and subsequent VAMF shall be EUR 1 900 for the rapporteur and EUR 1 900 for the co-rapporteur.

10.3 A charge of EUR 5 800 shall apply to an application for issuing each VAMF certification where it is submitted simultaneously with a new application for marketing authorisation under the centralised procedure.

10.4 A fee of EUR 10 600 shall apply to an application for review and certification of a major variation of type II to the VAMF pursuant to Regulation (EC) No 1234/2008. The remuneration shall be EUR 1 500 for the rapporteur and EUR 1 500 for the co-rapporteur.

For each major variation of type II that is grouped in a single application made pursuant to Regulation (EC) No 1234/2008 a fee shall be charged as set out in the first subparagraph of this point.

11. Certification of quality and non-clinical data relating to advanced therapy medicinal products (ATMPs) developed by small and medium-sized enterprises (SMEs) in accordance with Regulation (EC) No 1394/2007 of the European Parliament and of the Council

11.1 A fee of EUR 143 200 shall apply to an application for evaluating and certifying the quality and non-clinical data pursuant to Article 18 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council[12]. Such fee shall be waived in full. The remuneration shall be EUR 47 400 for the rapporteur.

11.2 A fee of EUR 95 200 shall apply to an application for evaluating and certifying only the quality data pursuant to Article 18 of Regulation (EC) No 1394/2007. Such fee shall be waived in full. The remuneration shall be EUR 31 500 for the rapporteur.

12. Paediatric applications in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council[13]

12.1 A fee of EUR 31 700 shall apply to an application for agreement of a paediatric investigation plan requested pursuant to Article 15 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR 6 700 for the rapporteur.

12.2 A fee of EUR 17 600 shall apply to an application for a modification of an agreed paediatric investigation plan pursuant to Article 22 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR 6 400 for the rapporteur.

12.3 A fee of EUR 12 000 shall apply to an application for a product-specific waiver pursuant to Article 13 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR 1 800 for the rapporteur.

12.4 A fee of EUR 8 000 shall apply to a request for compliance check with the paediatric investigation plan pursuant to Article 23 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR 1 000 for the rapporteur.

13. Orphan designation in accordance with Regulation (EC) No 141/2000 of the European Parliament and of the Council[14]

A fee of EUR 16 800 shall apply to an application for the designation of an orphan medicinal product pursuant to Regulation (EC) No 141/2000. Such fee shall be waived in full. The remuneration shall be EUR 1 500 for the rapporteur.

14. Scientific opinion on the evaluation of medicinal product intended exclusively for markets outside the Union

A fee and corresponding remuneration as specified in points 1 to 5 of this Annex and sections 1, 3, 4 and 5 of Annex IV and points 6.1, 6.2 and 6.4 thereof shall apply for an

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12 Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced

13 Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).

14 Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1).

application for a scientific opinion following the evaluation of a medicinal product intended exclusively for markets outside the Union pursuant to Article 58 of Regulation (EC) No 726/2004.

15. Periodic safety update reports

15.1. A fee of EUR 27 000 shall apply per procedure for the assessment of periodic safety update reports referred to in Articles 107e and 107g of Directive 2001/83/EC and in Article 28 of Regulation (EC) No 726/2004. The remuneration shall be EUR 12 900 for the rapporteur.

15.2. Where two or more marketing authorisation holders are subject to the obligation to submit periodic safety update reports in the context of the procedures referred to in point 14.1, the amount payable by each marketing authorisation holder shall be calculated by the Agency in two steps, as follows:

(a) by dividing the total amount of the fee among the marketing authorisation holders proportionally to the number of chargeable units-human corresponding to products included in the procedure which are held by each of those marketing authorisation holders;

(b) by subsequently applying, where relevant, the fee reduction laid down in point 1 of Annex V.

16. Post-authorisation safety studies

16.1. A fee of EUR 88 200 shall apply to an assessment carried out under Articles 107n to 107q of Directive 2001/83/EC and Article 28b of Regulation (EC) No 726/2004 of post-authorisation safety studies as referred to in Article 21a, point (b), or Article 22a(1), point (a), of Directive 2001/83/EC, or in Article 9(4), point (cb), or Article 10a(1), point (a), of Regulation (EC) No 726/2004, that are conducted in more than one Member State.

16.2. The fee shall be charged in two instalments, as follows:

16.2.1. EUR 44 100 shall be due on the date of the start of the procedure for the assessment of the draft protocol referred to in Article 107n of Directive 2001/83/EC; the remuneration shall be EUR 17 800 for the rapporteur.

16.2.2. EUR 44 100 shall be due at the date of the start of the procedure for the assessment of the final study report, as referred to in Article 107p of Directive 2001/83/EC, by the Pharmacovigilance Risk Assessment Committee; the remuneration shall be EUR 17 800 for the rapporteur.

16.3. Where the obligation to conduct a post-authorisation safety study is imposed by the Commission on more than one marketing authorisation holder, the same concerns apply to more than one medicinal product and the marketing authorisation holders concerned conduct a joint post-authorisation safety study, the Agency shall calculate the amount payable by each marketing authorisation holder in two steps, as follows:

(a) by evenly dividing the total amount of the fee among those marketing authorisation holders;

(b) by subsequently applying the fee reduction as set out in point 1 of Annex V, where relevant.

ANNEX II

Fees, charges and remuneration for assessment procedures and services relating to veterinary medicinal products

SI NOTE:

According to JAZMP a general increase in fees related to veterinary medicinal products is welcome.

We are also in agreement with the reduction of fees for certain new fee categories (e.g. immunologicals and medicines for limited markets).
Since the Regulation (EU) 2019/6 has been applied for only one year, it isn't clear:

- how the new fees will affect the income of NCAs,

- whether the foreseen reductions are going to be a sufficient incentive for development of new veterinary medicines and improvement of their availability across EU.

1. Scientific advice in accordance with Article 57(1)(n) of Regulation (EC) No 726/2004

1.1. A fee of EUR 33 100 shall apply to any of the following requests:
(a) a request on quality, safety and clinical development;
(b) a request on quality and clinical development;
(c) a request on safety and clinical development;

The remuneration shall be EUR 15 800 for the scientific advice co-ordinator.

1.2. A fee of EUR 24 300 shall apply to any of the following requests:
(a) a request on clinical development;
(b) a request on quality and safety development;
(c) a request on quality and bioequivalence studies for generic veterinary medicinal products as defined in Article 4(9) of (EU) 2019/6.

The remuneration shall be EUR 10 100 for the scientific advice co-ordinator.

1.3. A fee of EUR 21 300 shall apply to a request related to any of the following:
(a) a request on quality development;
(b) a request on safety development;
(c) a request on bioequivalence studies for generic veterinary medicinal products as defined in Article 4(9) of (EU) 2019/6;
(d) a request for preliminary risk profile;
(e) a request related to setting a new maximum residue limit.

The remuneration shall be EUR 6 100 for the scientific advice co-ordinator.

2. Request for classification of a veterinary medicinal product as intended for a limited market as defined in Article 4, point (29), of Regulation (EU) 2019/6 and for consideration for eligibility for authorisation in accordance with Article 23 of that Regulation

A charge of EUR 5 200 shall apply to a request for classification of a veterinary medicinal product as intended for a limited market within the meaning of Article 4(29) of Regulation (EU) 2019/6 and for consideration for eligibility for authorisation pursuant to Article 23 of Regulation (EU) 2019/6.

3. Establishment, modification or extension of a maximum residue limit (MRL) in accordance with the procedure laid down in Regulation (EC) No 470/2009 of the European Parliament and of the Council[15]

3.1. A fee of EUR 84 700 shall apply to an application to set an initial MRL for a given substance. The remuneration shall be EUR 21 400 for the rapporteur and EUR 10 300 for the co-rapporteur.

3.2. A fee of EUR 53 000 shall apply to each application to modify or to extend an existing MRL. The remuneration shall be EUR 10 600 for the rapporteur and EUR 9 700 for the co-rapporteur.

3.3. A fee of EUR 24 300 shall apply to the assessment to determine whether a chemical- unlike biological substance requires a full MRL evaluation or not pursuant to Annex I, Section 1.7, to Commission Regulation (EU) 2018/782[16]. The remuneration shall be EUR 10 100 for the rapporteur.

4. Authorisation to market veterinary medicinal products falling within the scope of the centralised marketing authorisation procedure pursuant to Article 42 of Regulation (EU) 2019/6

4.1. A fee of EUR 295 500 shall apply to an application for a marketing authorisation for a veterinary medicinal product pursuant to Articles 8, 23 or Article 25 of Regulation (EU) 2019/6 where the applicant claims a new active substance. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application, irrespective of the number of target species. The remuneration shall be EUR 107 000 for the rapporteur and EUR 38 100 for the co-rapporteur.

4.2. A fee of EUR 267 700 shall apply to an application for a marketing authorisation for a veterinary medicinal product pursuant to Articles 8, 20, 22, 23 or Article 25 of Regulation (EU) 2019/6 where the applicant claims a known active substance. That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application, irrespective of the number of target species. The remuneration shall be EUR 82 100 for the rapporteur and EUR 35 300 for the co- rapporteur.

4.3. A fee of EUR 136 800 shall apply for any of the following applications:

(a) an application for a marketing authorisation for a generic veterinary medicinal product pursuant to Article 18 of Regulation (EU) 2019/6;

(b) an application for a marketing authorisation for a hybrid veterinary medicinal product pursuant to Article 19 of Regulation (EU) 2019/6;

(c) an application based on informed consent for a marketing authorisation for a veterinary medicinal product pursuant to Article 21 of Regulation (EU) 2019/6.

That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application, irrespective of the number of target species. The remuneration shall be EUR 30 800 for the rapporteur and EUR 17 900 for the co- rapporteur.

5. Re-examination of a marketing authorisation for limited markets

A fee of EUR 19 000 shall apply to an application for a re-examination of a marketing authorisation for a limited market pursuant to Article 24(3) of Regulation (EU) 2019/6.

The remuneration shall be EUR 3 100 for the rapporteur and EUR 2 400 for the co- rapporteur.

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[16] Commission Regulation (EU) 2018/782 of 29 May 2018 establishing the methodological principles for the risk assessment and risk management recommendations referred to in Regulation (EC) No 470/2009 (OJ L 132, 30.5.2018, p. 5).

6. Variations to the terms of a marketing authorisation, requiring assessment in accordance with Articles 64, 65 and 66 of Regulation (EU) 2019/6

6.1. A fee of EUR 87 800 shall apply to a variation requiring assessment introducing changes of active substance(s), strength, pharmaceutical form, route of administration or food-producing target species, which are to be assessed within 90 days in accordance with Article 66(3) of Regulation (EU) 2019/6. That fee shall be charged for each single pharmaceutical form or each single associated strength/potency. The remuneration shall be EUR 28 600 for the rapporteur and EUR 8 600 for the co-rapporteur.

6.2. A fee of EUR 47 500 shall apply to variations requiring assessment that introduce changes to safety, efficacy or pharmacovigilance, which are to be assessed within 60 or 90 days, as the case may be, in accordance with Article 66(3) of Regulation (EU) 2019/6. The remuneration shall be EUR 9 800 for the rapporteur and EUR 7 600 for the co-rapporteur.

6.3. A fee of EUR 23 900 shall apply to variations requiring assessment introducing quality changes only, which are to be assessed within 60 days in accordance with Article 66(3) of Regulation (EU) 2019/6. The remuneration shall be EUR 3 600 for the rapporteur and EUR 3 600 for the co-rapporteur.

6.4. Where several variations requiring assessment are grouped in a single application under Article 64 of Regulation (EU) 2019/6, the corresponding fee as set out in points 6.1, 6.2 and 6.3 of this Annex shall apply to each of the first two variations. Remuneration shall be paid in accordance with those points. For the third and subsequent variations, the fee shall be EUR 12 000 per variation and the remuneration shall be EUR 1 800 per variation for the rapporteur and EUR 1 800 for the co-rapporteur.

6.5. Where a work-sharing application pursuant to Article 65 of Regulation (EU) 2019/6 includes more than one centrally authorised product, the fees and remuneration specified in points 6.1, 6.2 and 6.3 of this Annex shall apply for each variation to the first centrally authorised product, whereas a charge of EUR 800 shall apply for each variation to the second and subsequent centrally authorised product included in the same application.

7. Referrals and arbitration procedures

7.1 A fee of EUR 152 700 shall apply to an assessment carried out in the context of a procedure initiated under Article 54(8) of Regulation (EU) 2019/6. Such fee shall be waived in full. The remuneration shall be EUR 21 100 for the rapporteur and EUR 9 600 for the co-rapporteur.

7.2. A fee of EUR 209 300 shall apply to the assessment carried out in the context of a procedure initiated under Article 70(11) of Regulation (EU) 2019/6. Such fee shall be waived in full. The remuneration shall be EUR 29 200 for the rapporteur and EUR 12 900 for the co-rapporteur.

7.3. A fee of EUR 147 200 shall apply to the assessment carried out pursuant to Article 141(1), points (c) and (e), of Regulation (EU) 2019/6. Such fee shall be waived in full. The remuneration shall be EUR 17 500 for the rapporteur and EUR 7 700 for the co-rapporteur.

7.4. A fee of EUR 209 300 shall apply to the assessment carried out in the context of a procedure initiated under Article 82 of Regulation (EU) 2019/6. The remuneration shall be EUR 29 200 for the rapporteur and EUR 12 900 for the co-rapporteur.

7.5. A fee of EUR 147 200 shall apply for the assessment carried out in the context of a procedure initiated under Article 129(3) or Article 130(4) of Regulation (EU) 2019/6. The remuneration shall be EUR 17 500 for the rapporteur and EUR 7 700 for the co-rapporteur.

7.6. Where two or more marketing authorisation holders are involved in the procedures referred to in points 7.4 or 7.5, the amount payable by each marketing authorisation holder shall be calculated by the Agency in two steps, as follows:

(a) by dividing the total amount of the fee among the marketing authorisation holders proportionally to the number of chargeable units – veterinary corresponding to products included in the procedure which are held by each of those marketing authorisation holders;

(b) by subsequently applying the fee reduction laid down in point 1 of Annex V, where relevant.

8. Certification of compliance with Union legislation for vaccine antigen master files (VAMF)

8.1. A fee of EUR 23 900 shall apply to an application for review of a VAMF and its certification pursuant to point V.2 of Annex II to Regulation (EU) 2019/6 when it is submitted simultaneously with an initial application for marketing authorisation for a veterinary medicinal product under the centralised procedure containing the named antigen. The remuneration shall be EUR 3 600 for the rapporteur and EUR 3 600 for the co-rapporteur.

8.2. For multiple VAMF applications submitted simultaneously in the context of the same initial marketing authorisation application, a fee of EUR 23 900 shall apply per VAMF. The maximum total amount charged by the Agency shall not exceed EUR 71 700. The remuneration shall be EUR 3 600 for the rapporteur and EUR 3 600 for the co-rapporteur. For multiple VAMF applications submitted simultaneously in the context of the same initial marketing authorisation application, the remuneration shall not exceed EUR 10 800 for the rapporteur and EUR 10 800 for the co-rapporteur.

8.3. A fee of EUR 33 100 shall apply to an application for the review of a VAMF and its certification when submitted as a separate application for an antigen in vaccine(s) already authorised under the centralised, decentralised or mutual recognition procedure. The remuneration shall be EUR 5 000 for the rapporteur and EUR 5 000 for the co-rapporteur.

8.4. Section 6 [of this Annex] shall apply by analogy to variations to a certified VAMF.

9. Certification of compliance with Union legislation for vaccine platform technology master files (vPTMF)

9.1. A fee of EUR 23 900 shall apply to an application for review of a vPTMF and its certification pursuant to point V.4 of Annex II to Regulation (EU) 2019/6 when submitted simultaneously with an initial application for marketing authorisation for a veterinary medicinal product under the centralised procedure containing the named
platform. The remuneration shall be EUR 3 600 for the rapporteur and EUR 3 600 for the co-rapporteur.

9.2. A fee of EUR 33 100 shall apply to an application for review of a vPTMF and its certification when submitted as a separate application for a platform in vaccines already authorised under the centralised, decentralised or mutual recognition procedure. The remuneration shall be EUR 5 000 for the rapporteur and EUR 5 000 for the co-rapporteur.

9.3. Section 6 of this Annex shall apply by analogy to variations to a certified vPTMF.

10. Assessment of post-marketing surveillance studies

10.1. A fee of EUR 37 800 shall apply to the assessment of post-marketing surveillance studies pursuant to Article 76(3) of Regulation (EU) 2019/6 that are conducted in more than one Member States.

10.2. The fee shall be charged as follows:

(a) EUR 18 900 shall be due at the date of the start of the procedure for the approval of the draft study protocol as referred to in Article 15(3) of Commission Implementing Regulation (EU) 2021/1281[3]. The remuneration shall be EUR 7 700 for the rapporteur;

(b) EUR 18 900 shall be due at the date of the start of the procedure for the assessment of the final study report as referred to in Article 15(5) of Implementing Regulation (EU) 2021/1281. The remuneration shall be EUR 7 700 for the rapporteur.

10.3. Where the obligation to conduct a post-authorisation surveillance study is imposed on more than one marketing authorisation holder and the marketing authorisation holders concerned conduct a joint post-authorisation safety study, the Agency shall calculate the fee to be charged in two steps, as follows:

(a) by evenly dividing the total amount of the fee among those marketing authorisation holders;

(b) by subsequently applying the fee reduction as set out in Annex V, point 1, where relevant.

11. Scientific opinions in the context of cooperation with international organisations for animal health for the evaluation of veterinary medicinal products intended exclusively for markets outside the Union

A fee and corresponding remuneration as specified in points 1, 3, 4 and 6 of this Annex and in points 1, 3, 4 and 5 of Annex IV and points 6.1, 6.2 and 6.4 of that Annex to this Regulation shall apply for an application for a scientific opinion for the evaluation of veterinary medicinal products intended exclusively for markets outside the Union pursuant to Article 138 of Regulation (EU) 2019/6.

ANNEX III

Annual fees and remuneration

SI NOTE :

JAZMP supports the increase in annual fees as regulated in Annex III since the increased costs of review of medicines.

To be considered:

NCAs receive part of annual fee only for those CAPs for which have been appointed as Rapp or Co-Rapp.

NCAs should also receive compensation for other activities (e.g. monitoring) for all CAPs that are placed on the market within each Member State. This would cover also the costs of monitoring the medicine after its release on the market within each MS (the importance of which was shown during covid-19 pandemic, e.g. through intensive pharmacovigilance activities of each MS).

Besides regulating the fees as explained above would place EMA and NCAs in equal position.

1. Annual fee for medicinal products for human use authorised in accordance with Regulation (EC) No 726/2004

1.1. An annual fee of EUR 48 900 shall apply to each marketing authorisation of a medicinal product for human use authorised on the basis of an application submitted under Article 10(1) and (3) and Article 10c of Directive 2001/83/EC. The remuneration shall be EUR 6 400 for the rapporteur

1.2. and EUR 5 600 for the co- rapporteur.

1.3. An annual fee of EUR 95 600 shall apply to each marketing authorisation of a medicinal product for human use authorised on the basis of an application submitted under Article 10(4) of Directive 2001/83/EC. The remuneration shall be EUR 12 900 for the rapporteur and EUR 11 400 for the co-rapporteur.

1.4. An annual fee of EUR 188 000 shall apply to each marketing authorisation of a medicinal product for human use not covered by point 1.1 or 1.2. The remuneration shall be EUR 25 700 for the rapporteur and EUR 22 700 for the co-rapporteur.

2. Annual fee for veterinary medicinal products authorised through the centralised procedure in accordance with Regulation (EU) 2019/6

21. An annual fee of EUR 21 500 for shall apply for each marketing authorisation of a veterinary medicinal product authorised pursuant to Article 18, 19 or 21 of Regulation (EU) 2019/6. The remuneration shall be EUR 5 000 for the rapporteur and EUR 4 600 for the co-rapporteur.

22. An annual fee of EUR 87 500 shall apply to each marketing authorisation not covered by point 2.1. The remuneration shall be EUR 20 400 for the rapporteur and EUR 18 800 for the co-rapporteur.

SI NOTE:

Introduction of a new fee for veterinary medicinal products for pharmacovigilance tasks performed by EMA means that companies would have to pay a double fee (at national and EU level) but there is no remuneration for MS for pharmacovigilance activities related to the monitoring and regulation of centrally authorised veterinary medicines at national level.

3. Annual pharmacovigilance fee for medicinal products for human use authorised in accordance with Directive 2001/83/EC and for veterinary medicinal products authorised by competent authorities of the Member States in accordance with Regulation (EU) 2019/6

31. For medicinal products for human use authorised in accordance with Directive 2001/83/EC, a fee of EUR 190 per chargeable unit-human, shall apply once per year for the Agency's pharmacovigilance activities including analysis of Union-wide health data to support better decision-making with real world evidence. The Agency shall retain the fee revenue from the annual pharmacovigilance fee.

32. For veterinary medicinal products authorised by competent authorities of the Member States in accordance with Chapter III, Sections 2 to 5 of Regulation (EU) 2019/6, a fee of EUR 80 per chargeable unit-veterinary shall apply once per year for the Agency's pharmacovigilance activities. The Agency shall retain the fee revenue from the annual pharmacovigilance fee.

33. The total payable amount of the annual fees referred to in points 3.1 and 3.2 for each marketing authorisation holder shall be calculated by the Agency on the basis of the number of chargeable units-human and chargeable units-veterinary, respectively, which correspond to the information recorded on 1 July of each year.

34. The annual fees referred to in points 3.1 and 3.2 shall be due on 1 July of every year and shall cover the period from 1 January to 31 December of that calendar year.

ANNEX IV

Other fees and charges for medicinal products for human use, veterinary medicinal products and consultations on medical devices

SI NOTE :

The fees for pharmaceutical inspection have increased, but they still remain low when speaking in absolute terms. For example supervisions in third countries may demand presence of usually two inspectors for several weeks. The proposed fee does not cover the full cost of NCAs.

Based on the collected calculations, 90% of the scope of work for GMP inspections is completed by the NCAs, while their reimbursement for services in the proposal is valued at only 66% of proposed fee. The currently proposed level of fees for GMP inspections does not reflect the actual costs incurred by NCAs compared to EMAs.

Furthermore the distribution ratio is not properly defined.

1. Inspections pursuant to Article 8(2), 19 and Article 57(1), point (i) of Regulation (EC) No 726/2004

1.1. Inspections in relation to medicinal products for human use and veterinary medicinal products

1.1.1. For any distinct Good Manufacturing Practice inspection within the Union a fee of EUR 24 800 shall apply. The remuneration shall be EUR 8 600 for the leading supervisory authority and EUR 5 200 for the supporting supervisory authority.

1.1.2. For any distinct Good Manufacturing Practice inspection outside the Union a fee of EUR 37 800 shall apply. The remuneration shall be EUR 15 600 for the leading supervisory authority and EUR 9 400 for the supporting supervisory authority.

1.1.3. For any distinct Good Clinical Practice inspection within the Union a fee of EUR 37 100 shall apply. The remuneration shall be EUR 14 700 for the leading supervisory authority and EUR 9 100 for the supporting supervisory authority.

1.1.4. For any distinct Good Clinical Practice inspection outside the Union a fee of EUR 44 200 shall apply. The remuneration shall be EUR 19 600 for the leading supervisory authority and EUR 10 400 for the supporting supervisory authority.

1.1.5. For any distinct Plasma Master File inspection within or outside the Union a fee of EUR 36 100 shall apply. The remuneration shall be EUR 13 400 for the leading supervisory authority and EUR 8 200 for the supporting supervisory authority.

1.1.6. For any consecutive Plasma Master File inspection within or outside the Union a fee of EUR 36 100 shall apply. The remuneration shall be EUR 13 400 for the leading supervisory authority and EUR 8 200 for the supporting supervisory authority.

1.1.7. For any distinct Good Laboratory Practice inspection within or outside the Union a fee of EUR 34 900 shall apply. The remuneration shall be EUR 13 200 for the leading supervisory authority and EUR 8 700 for the supporting supervisory authority.

1.1.8. For any distinct pharmacovigilance inspection within or outside the Union a fee of EUR 52 700 shall apply. The remuneration shall be EUR 16 200 for the leading supervisory authority and EUR 10 100 for the supporting supervisory authority.

1.2. If a scheduled inspection is cancelled 30 calendar days or less before the first day of the inspection for reasons attributable to the applicant, the applicable fee referred to in point 1.1 shall apply.

1.3. If a scheduled inspection is cancelled more than 30 calendar days before the first day of the inspection, a charge of EUR 840 shall apply.

1.4. The supervisory authorities shall charge the applicant the travel expenses separately from the fee specified in this Annex, based on actual cost. In case of a cancelled inspection as per points 1.2 or 1.3, the applicant shall be charged for any travel expenses already incurred by the inspecting authority on the date of cancellation for which that authority is not able to obtain reimbursement.

2. Transfer of a marketing authorisation

A charge of EUR 3 700 shall apply to an application for the transfer of a marketing authorisation pursuant to Article 3 of Commission Regulation (EC) No 2141/96[1]. This covers all authorised presentations of a given medicinal product.

The charge shall be levied to the marketing authorisation holder that requested the transfer, according to the application submitted to the Agency.

3. Pre-submission requests by a prospective applicant prior to a potential submission of an application for a marketing authorisation falling within the scope of the centralised procedure

3.1. A fee of EUR 7 100 shall apply to each eligibility request submitted with a notification of intention to submit an application for a marketing authorisation falling within the scope of Regulation (EC) No 726/2004 or the scope of the centralised marketing authorisation procedure pursuant to Article 42 of Regulation (EU) 2019/6. The fee shall cover any costs related to pre-submission activities up until the potential submission of the marketing authorisation application. The fee shall apply irrespective of whether or not a marketing authorisation application for the concerned product is subsequently submitted. If an eligibility request has not been submitted, the fee shall apply in addition to the applicable authorisation fee.

The remuneration of the national competent authority, where applicable, shall be EUR 1 300 for the rapporteur and EUR 1 300 for the co-rapporteur.

3.2. Where the applicant changes the intended submission date by more than 60 days, an additional fee of EUR 3 500 shall apply. The additional remuneration of the national competent authority, where applicable, shall be EUR 600 for the rapporteur and EUR 600 for the co-rapporteur.

4. Re-examination of an opinion of the Committees referred to in Article 56(1) of Regulation (EC) No 726/2004 and in Article 139(1) of Regulation (EU) 2019/6

The fee for the re-examination of an opinion of any of the committees referred to in Article 56(1) of Regulation (EC) No 726/2004 and in Article 139(1) of Regulation (EU) 2019/6 shall be 30% of the fee applicable to the initial opinion in accordance with points 3, 4, 5 and 6 of Annex I and points 3, 4, 6 and 7 of Annex II to this Regulation. The remuneration to the rapporteur and the co-rapporteur shall be calculated based on the same proportion of the respective remuneration.

5. Scientific services referred to in Article 4(1)

The range for fees for scientific services referred to in Article 4(1) shall be EUR 4 100 to EUR 684 500. The range for the remuneration shall be EUR 1 000 to EUR 217 300 for the rapporteur and the co-rapporteur. The applicable amounts of the fee and the remuneration within the above ranges shall be determined in accordance with Article 8.

6. Administrative services

6.1. Administrative charge

A charge of EUR 3 700 shall apply for applications subject to a fee set out in Annex I or II in any of the following situations:

(a) the application is withdrawn after 24 hours of its submission and prior to completion of the administrative validation;

(b) the application has been rejected following the conclusion of the administrative validation.

In the cases referred to in the previous subparagraph, the corresponding fee shall not be levied.

In addition to the applicable fee or charge set out in Annexes I, II or Annex III, a charge of EUR 3 700 shall also apply to applications where a marketing authorisation holder or an applicant claiming, or having claimed, to be entitled to a fee reduction, fails to demonstrate that it is entitled to such a reduction.

6.2. Certificates of medicinal products as referred to in Article 127 of Directive 2001/83/EC and in Article 98 of Regulation (EU) 2019/6

6.2.1. A charge of EUR 140 shall apply to each request for a set of certificates issued by the Agency for a medicinal product, using the standard procedure for issuing the certificate.

6.2.2 A charge of EUR 420 shall apply to each request for a set of certificates issued by the Agency for a medicinal product, using the urgent procedure for issuing the certificate.

6.3. Notification of parallel distribution in accordance with Article 57(1), point (o), of Regulation (EC) No 726/2004

6.3.1. A charge of EUR 1 200 shall apply to each initial notification for each presentation of a medicinal product, for one Member State of destination having one or more official languages or for several Member States of destination having the same official language. That charge shall cover any subsequent safety update notification relating to the initial notification.

6.3.2. A charge of EUR 350 shall apply to each notification of a bulk change. That charge shall cover all initial notifications approved by the date of submission of the notification of bulk changes.

6.3.3. A charge of EUR 350 shall apply to each annual update notification. That charge shall cover all the presentations belonging to the same pharmaceutical form of the same medicinal product for one Member State of destination having one or more official languages, or for several Member States of destination having the same official language. No charge shall apply if there have been no regulatory updates in the past twelve months or if the product was dormant.

6.4. Administrative services referred to in Article 4(2)

The range of charges for other administrative services referred to in Article 4(2) shall be from EUR 100 to EUR 10 000. The applicable amounts of the charge within the above range shall be determined in accordance with Article 8.

7. Consultation on medical devices

7.1. Ancillary substances incorporated in medical devices

7.1.1. A fee of EUR 94 000 shall apply to a consultation on one or more ancillary medicinal substances pursuant to section 5.2 of Annex IX to Regulation (EU) 2017/745, where the medicinal substance(s) from the specified manufacturer has not been evaluated by the Agency or a competent authority designated by the Member States in accordance with Directive 2001/83/EC (hereafter 'medicinal products authority') in connection with a previous marketing authorisation or through a previous consultation by a notified body. One application may include a range of strength or concentrations of the ancillary substance(s) or a range of similar devices from the same medical device manufacturer incorporating the same substance(s) or both. The remuneration shall be EUR 23 500 for the rapporteur and EUR 23 500 for the co-rapporteur.

7.1.2. A fee of EUR 46 900 shall apply to a consultation on one or more ancillary medicinal substance(s) pursuant to section 5.2 of Annex IX to Regulation (EU) 2017/745, where the medicinal substance(s) from the specified manufacturer has been evaluated by a medicinal products authority in connection with a previous marketing authorisation or through a previous consultation by a notified body. One application may include a range of strengths or concentrations of the ancillary substance(s) or a range of similar devices from the same medical device manufacturer incorporating the same substance(s) or both. The remuneration shall be EUR 11 500 for the rapporteur and EUR 11 500 for the co-rapporteur.

7.1.3. For the purpose of 7.1.1. and 7.1.2., a fee of EUR 4 100 shall apply to a consultation, pursuant to section 5.2, point (f), of Annex IX to Regulation (EU) 2017/745, regarding a change with respect to an ancillary medicinal substance incorporated in a device. The remuneration shall be EUR 1 400 for the rapporteur.

7.2. Medical devices composed of a substance or a combination of substances that are systemically absorbed to achieve their intended purpose.

A fee of EUR 70 600 shall apply to a consultation on a medical device or a range of similar devices composed of a substance or a combination of substances that are absorbed by or locally dispersed in the human body, pursuant to section 5.4 of Annex IX, to Regulation (EU) 2017/745. The remuneration shall be EUR 17 500 for

the rapporteur and EUR 17 500 for the co-rapporteur.

7.3. *Companion diagnostic*

7.3.1. A fee of EUR 46 900 shall apply to a consultation on the suitability of a companion diagnostic in relation to a concerned medicinal product, pursuant to Article 48(3) or (4), of Regulation (EU) 2017/746, and section 5.2 of Annex IX, or section 3, point (k), of Annex X to that Regulation. The remuneration shall be EUR 11 800 for the rapporteur.

A fee of EUR 4 100 shall apply to a consultation on a change affecting the suitability of the companion diagnostic in relation to the medicinal product concerned, pursuant to section 5.2, point (f), of Annex IX to Regulation (EU) 2017/746. The remuneration shall be EUR 1 400 for the rapporteur.

7.4. The fees set out in points 7.1, 7.2 and 7.3 shall be charged to the medical device manufacturer that, according to the application form submitted to the Agency, requested the assessment of conformity of the medical device for which the notified body is consulting the Agency.

ANNEX V

Fee reductions

SI NOTE :

SI fully supports the following proposition.

1. Fee reductions granted to micro, small- and medium-sized enterprises

1.1. The following total or partial reductions to the fees laid down in this Regulation shall be granted to micro, small and medium-sized enterprises:

1.1.1. for a small or medium-sized enterprise, a fee reduction of 40 % of the applicable amount shall apply to the following fees:

(a) extension of a marketing authorisation for medicinal products for human use pursuant to section 4 of Annex I;

(b) major type-II variations for medicinal products for human use pursuant to section 5 of Annex I, excluding point 5.4 of that section;

(c) referral procedures for medicinal products for human use pursuant to points 6.4 to 6.7 of Annex I;

(d) request for scientific support and advice by the Committee on Herbal Medicinal Products related to traditional herbal medicinal products pursuant to section 7 of Annex I;

(e) certification of compliance with Union legislation for plasma master files pursuant to section 9 of Annex I;

(f) certification of compliance with Union legislation regarding vaccine antigen master files (VAMF) pursuant to section 10 of Annex I;

(g) assessment of periodic safety update reports for medicinal products for human use pursuant to section 15 of Annex I;

(h) assessment of post-authorisation safety studies for medicinal products for human use pursuant to section 16 of Annex I;

(i) variations requiring assessment pursuant to section 6 of Annex II, excluding point 6.5 of that section;
(j) referral procedures for veterinary medicinal products pursuant to points 7.4 to 7.7 of Annex II;
(k) certification of compliance with Union legislation regarding VAMF pursuant to section 8 of Annex II;
(l) certification of compliance with Union legislation regarding vaccine platform technology master files (vPTMF) pursuant to section 9 of Annex II;
(m) assessment of post-marketing surveillance studies for veterinary medicinal products pursuant to section 10 of Annex II;
(n) annual fee, for medicinal products for human use or for veterinary medicinal products, or both, pursuant to section 1 or 2, respectively, of Annex III;
(o) pharmacovigilance annual fee, for medicinal products for human use or veterinary medicinal products pursuant to Annex III;
(p) transfer of a marketing authorisation to another micro-, small- or medium-sized enterprise, both for medicinal products for human use and veterinary medicinal products pursuant to section 2, point 2 of Annex IV;

1.1.2. for a small or medium-sized enterprise, a fee reduction of 90 % of the applicable amount shall apply to a consultation on medical devices pursuant to section 7 of Annex IV, where the medical device manufacturer has been assigned the small and medium-sized enterprise status by the Agency;

1.1.3. for a micro enterprise, a reduction of 100 % shall apply to the fees set out in points 1.1.1. and 1.1.2.

1.1.2. The fee reductions set out in point 1.1.1 shall apply in addition to fee reductions and incentives provided for in Regulation (EC) No 2049/2005 or in the Union pharmaceutical legislation.

1.1.3. The reductions set out in point 1.1 shall not be granted to SMEs acting as applicant or marketing authorisation holder for the relevant medicinal product by virtue of a contractual arrangement with a non-SME legal entity. Such contractual arrangements shall be declared to the Agency ahead of any service listed under point 1.1.1.

2. Applications relating to core dossier medicinal products to be used in a human pandemic situation

2.1. The payment of the fee for an application for a marketing authorisation of a medicinal product to be used in a human pandemic situation shall be deferred until the pandemic situation is duly recognised, either by the World Health Organisation or by the Union in accordance with Decision No 1082/2013/EU.
Such deferral shall not exceed 5 years.

2.2. In addition to the deferral provided for in point 2.1, for regulatory activities within the framework of the submission of a core dossier for a pandemic influenza vaccine and the follow-up submission of a pandemic variation, a fee reduction of 100 % shall apply in the following cases:
(a) pre-submission activities pursuant to section 9 of Annex IV;
(b) scientific advice pursuant to section 1 of Annex I;
(c) extension of marketing authorisation pursuant to section 4 of Annex I;
(d) major type-II variation pursuant to section 5 of Annex I;
(e) annual fee pursuant to section 1 of Annex III.
Those reductions shall apply until the human pandemic situation is duly recognised.

2.3. Where reductions apply pursuant to point 2.2, no remuneration shall be paid to the national competent authorities for the annual fees referred to in point 2.2(e).

3. Applications submitted under Article 30 of Regulation (EC) No 1901/2006

A 50 % fee reduction shall apply to paediatric use marketing authorisation applications submitted under Article 30 of Regulation (EC) No 1901/2006 for the following services:

(a) initial marketing authorisation application pursuant to section 3 of Annex I, to this Regulation;
(b) pre-authorisation inspection pursuant to section 1 of Annex IV, to this Regulation;
(c) extension of a marketing authorisation pursuant to section 4 of Annex I, to this Regulation, in the first year from granting of the marketing authorisation;
(d) major type-II variation pursuant to section 5 of Annex I, to this Regulation, in the first year from granting of a marketing authorisation;
(e) annual fee pursuant to section 1 of Annex III, to this Regulation, in the first year from granting of a marketing authorisation;
(f) post-authorisation inspection pursuant to section 1 of Annex IV, to this Regulation, in the first year from granting of a marketing authorisation.

4. Immunological veterinary medicinal products

A fee reduction of 50 % shall apply to immunological veterinary medicinal products for the following activities:

(a) scientific advice pursuant to section 1 of Annex II;
(b) request for classification of a veterinary medicinal product as intended for a limited market as defined in Article 4, point 29 of Regulation (EU) 2019/6 and for consideration for eligibility for authorisation according to Article 23 of that Regulation, pursuant to section 2 of Annex II, to this Regulation;
(c) authorisation to market veterinary medicinal products falling within the scope of the centralised marketing authorisation procedure pursuant to Article 42 of Regulation (EU) 2019/6, pursuant to section 4 of Annex II, to this Regulation;
(d) variations to the terms of a marketing authorisation requiring assessment in accordance with Article 66 of Regulation (EU) 2019/6, pursuant to Annex II, section 6, to this Regulation. In the specific case of point 6.5 of Annex II, the reduction shall apply to the variations subject to a fee and shall not apply to the variations subject to a charge;
(e) certification of compliance with Union legislation for VAMF pursuant to section 8 of Annex II;
(f) certification of compliance with Union legislation for vPTMF pursuant to section 9 of Annex II;
(g) assessment of post-marketing surveillance studies pursuant to section 10 of Annex II;
(h) annual fee pursuant to section 2 of Annex III;
(i) pre-submission services pursuant to section 3 of Annex IV.

5. Veterinary medicinal products for limited markets

5.1. A fee reduction of 50 % shall apply to veterinary medicinal products classified as intended for a limited market within the meaning of Article 4(29) of Regulation (EU) 2019/6 and considered eligible for authorisation or authorised pursuant to Article 23 of that Regulation, for the following activities:

(a) scientific advice pursuant to section 1 of Annex II, to this Regulation;
(b) applications for establishment, modification or extension of a maximum residue limit pursuant to section 3 of Annex II, to this Regulation;
(c) authorisation to market veterinary medicinal products falling within the scope of the centralised marketing authorisation procedure pursuant to Article 42 of Regulation (EU)

2019/6 pursuant to Article 23 of that Regulation, pursuant to point 4.1 or 4.2 of Annex II, to this Regulation;

(d) variations to the terms of a marketing authorisation requiring assessment in accordance with Article 66 of Regulation (EU) 2019/6, pursuant to section 6 of Annex

II. In the specific case of point 6.5 of Annex II, the reduction shall apply to the variations subject to a fee and shall not apply to the variations subject to a charge;

(e) certification of compliance with Union legislation for VAMF pursuant to section 8 of Annex II to this Regulation;

(f) certification of compliance with Union legislation for vPTMF pursuant to section 9 of Annex II to this Regulation;

(g) assessment of post-marketing surveillance studies pursuant to section 10 of Annex II, to this Regulation;

(h) annual fee pursuant to section 2 of Annex III, to this Regulation;

(i) pre-submission services pursuant section 3 to Annex IV, to this Regulation.

5.2. A reduction of 100 % shall apply to the fee for extension of maximum residues limits set out in section 3 of Annex II, when such extension does not require assessment of data.

6. Veterinary vaccines against certain major epizootic diseases

6.1. A fee reduction of 100 % shall apply to the annual fee for vaccines against bluetongue, pandemic avian influenza, foot and mouth disease and classical swine fever, where the vaccine is authorised under normal circumstances and the product has not been marketed within the Union at any time during the totality of the period covered by the fee.

6.2. Where a reduction applies pursuant to point 6.1, no remuneration shall be paid to the national competent authorities for the annual fees referred to in point 6.1.

7. Annual fee for veterinary medicinal products

A fee reduction of 25 % shall apply to the annual fee for veterinary medicinal products set out in section 2 of Annex III, with the exclusion of those products already listed in sections 4 and 5 of this Annex.

8. Annual pharmacovigilance fee for generic, homeopathic and herbal medicinal products

A fee reduction of 20 % shall apply to the annual pharmacovigilance fee set out in section 3 of Annex III for the following medicinal products:

(a) medicinal products for human use as referred to in Article 10(1) and Article 10a of Directive 2001/83/EC;

(b) homeopathic medicinal products for human use;

(c) herbal medicinal products for human use;

(d) veterinary medicinal products as referred to in Articles 18 and 22 of Regulation (EU) 2019/6;

(e) homeopathic veterinary medicinal products;

(f) homeopathic veterinary medicinal products registered in accordance with Article 87 of Regulation (EU) 2019/6.

ANNEX VI

Performance information

SI NOTE :

SI can supports the following proposition, however also further amendments for the sake of clarity might be supported.

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;

(2) number of Agency staff involved and the overall costs for obtaining and maintaining a Union authorisation to market medicinal products for human use and veterinary medicinal products and for other services of the Agency;

(3) number of procedures for obtaining and maintaining a Union authorisation to market medicinal products for human use and veterinary medicinal products and for other services of the Agency;

(4) number of fee reductions granted per type of fee reduction as set out in Annex V;

(5) attribution of rapporteurs, co-rapporteurs, or roles considered as equivalent for the purposes of this regulation as referred to in the Annexes to this regulation, per Member State, per type of procedure;

(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 based on a proposal by the Agency.

ANNEX VII

Correlation table

SI NOTE:

One of the objectives of the proposal of the Regulation is to simplify the calculation of fees and to eliminate unnecessary complexity of the existing legal framework by uniting all rules on fees in only one regulation.

A more complex dual legal basis is therefore abandoned, which is adequately reflected in the prepared correlation table, as a result of which SI has no comments on the proposed text.

Regulation 297/95	This Regulation
Article 8(1)	Annex I, point 1 and Annex II, point 1
Article 3(1)	Annex I, point 3
Article 7	Annex II, point 3
Article 5(1)	Annex II, point 4
Article 3(4)	Annex IV, point 1
Article 5(4)	Annex IV, point 1
Article 8(2)	Annex IV, point 5
Article 8(3)	Annex IV, points 6.1, 6.2 and 6.4

Comments from the Spanish delegation

Comments from Spain on Presidency Working Document

(ST06007)

1. Targeted approach:

ES agrees with the approach of the Presidency working document (targeted approach) that includes:

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

We would like **to include the following categories in the targeted approach**:

- **GMP´s inspections in and out of the European Union**
- **Referrals: Art. 30 and 31**

2. Article 11

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 justified 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; **we think this point is too broad and we suggest to narrow down it.**

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

Comments from Spain 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)

Comments on Annexes to the proposed regulation:

1. **Veterinary medicines (Annex II, related points in Annex III, IV and V)**

   Annex II:

   - Point 1: Although the remunetarion for the Rapp is increased, the figure of the CoRapp dissapears.

   - A general comment on some points of the proposal is the equalisation of the remuneration between the Rapp y CoRapp (e.g. 6.3, 6.4, 8.1, 8.2, 8.3). The workload of the Rap pis higher than the workload of the CoRapp and should be higher in remuneration.

2. **Annex III: Annual Fees and remuneration**

   3.Annual pharmacovigilance fee for medicinal products for human use authorised in accordance with Directive 2001/83/EC and for veterinary medicinal products authorised by competent authorities of the Member States in accordance with Regulation (EU) 2019/6

   3.1 For medicinal products for human use authorised in accordance with Directive 2001/83/EC, a fee of EUR 190 per chargeable unit-human, shall apply once per year for the Agency's pharmacovigilance activities including analysis of Union-wide health data to support better decision-making with real world evidence. The Agency shall retain the fee revenue from the annual pharmacovigilance fee.

   3.2 For veterinary medicinal products authorised by competent authorities of the Member States in accordance with Chapter III, Sections 2 to 5 of Regulation (EU) 2019/6, a fee of EUR 80 per chargeable unit-veterinary shall apply once per year for the Agency's pharmacovigilance activities. The Agency shall retain the fee revenue from the annual pharmacovigilance fee.

   3.3 The total payable amount of the annual fees referred to in points 3.1 and 3.2 for each marketing authorisation holder shall be calculated by the Agency on the basis of the number of chargeable units-human and chargeable units-veterinary, respectively, which correspond to the information recorded on 1 July of each year.

   3.4 The annual fees referred to in points 3.1 and 3.2 shall be due on 1 July of every year and shall cover the period from 1 January to 31 December of that calendar year.

Rationale:

Regarding point 3 on 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

Interinstitutional files:
2022/0417 (COD)

Brussels, 27 February 2023

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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.