We thank you for your time spent taking this survey.
Your response has been recorded.

Below is a summary of your responses

Download PDF

The European Medicines Agency (EMA) undertakes centralised pre-authorisation and post-authorisation procedures and other activities for medicinal products for human and veterinary use across the EU and the European Economic Area (EEA).

The EMA charges for the services it provides and remunerates National Competent Authorities (NCAs) for the scientific assessments that they undertake in support of the EMA's pre- and post-authorisation services.

Specific rules regarding EMA revenue, fees charged and NCA remuneration are established in EU legislation and through implementing arrangements:

- The EMA Founding Regulation specifies the Agency's revenue sources and general rules on NCA remuneration for certain services.
- The main Fee Regulation and its rules for implementation establish the fee-earning services provided by the EMA and related fees payable to the Agency and remuneration paid by EMA to NCAs.
- The Pharmacovigilance Fee Regulation provides the rules and amounts for fees charged to industry and remuneration paid to NCAs for pharmacovigilance activities for centrally and, where relevant, nationally authorized medicines for human use.
- The SME Regulation provides the rules for and levels of fee incentives for micro, small or medium-sized enterprises (SMEs).
- Finally, fee incentives (i.e. reductions), such as exemptions, partial and full waivers and deferrals, are laid down in pharmaceutical legislation for advanced therapies, orphan medicines, and paediatric medicines.

Recent changes to the legal framework affect the fee system, specifically:

- Changes to the regulatory framework for veterinary medicines following the entry into force of the Veterinary Medicinal Product (VMP) Regulation, which becomes applicable in January 2022; and
- Changes to the EMA Founding Regulation that provide for the possibility of introducing a new potential source of revenue for the EMA (i.e. charges) and place an obligation on the Commission to pay attention to potential risks related to fluctuation in the fee revenue of the Agency when it reviews the fee system (Art.86a).

The Commission has also issued recently a legal proposal for an extension of the EMA mandate, including EMA activities to access and analyse EU-wide health data in support of decision-making on medicines. These EMA activities are projected to affect the fee system as of 2024 and are therefore taken into account in the impact assessment study (the effect is presented separately).

In light of these changes, and the results of an evaluation of the EMA Fee System, as well as feedback received to the Inception Impact Assessment, the European Commission is conducting an impact assessment of potential revisions to the EMA fee system, which is supported by an ongoing study carried out by ICF and RAND Europe. The objectives of the impact assessment are to analyse a set of options:

- Aligning the main categories of fees and charges with the EMA Founding Regulation,
- Allowing for adequate financing of veterinary procedures,
- Achieving a simplification of the system, and
- Ensuring a fair distribution of fees and NCA remuneration, while respecting fee incentives established in existing policies

The options and sub-options that are the subject of the impact assessment are summarized in Figure 1 below. Details of the options and sub-options can be found here.

Further changes to the fee system may be needed in future as the pharmaceutical legislation evolves, for example as a result of review of that legislation under the Pharmaceutical Strategy for Europe. However, this is not a reason to delay acting on the fee legislation in order to address the issues identified by the evaluation.

This targeted survey conducted in the framework of the study supporting the impact assessment aims to elicit information, views and concerns of all interested stakeholders regarding the impact of the potential revision to the legislation governing the EMA fee system under a set of policy options for legislative action. The financial impacts under the options have been modelled over a five-year period from the time when the VMP Regulation becomes applicable (2022). The results of the modelling exercise conducted within the ongoing study presented in this survey are based on the previous evaluation of the EMA fee system and legislation and on further information provided by DG SANTE, EMA and NCAs. A methodology note explaining the data sources and assumptions underlying the modelling results of the study presented for this consultation is available. The results presented in the survey are *preliminary* outputs from the first run of the model and do not represent a position of the European Commission. The final figures of the study may change as the model is refined over the course of the study, for example, as a result of the analysis of justified feedback provided during the consultations.

Your input, along with other information gathered through desk research, interviews and analysis, will inform the assessment of the impacts of potential revisions to the EMA fee system. **This consultation is strictly limited to the EMA fee system. The underlying legislation governing the activities and incentives of the EMA is not within the scope of the impact assessment.**

A dedicated study microsite has been developed to assist you in completing this questionnaire. Please refer to the supporting information that can be found there as you work through the survey.

If you are unable to use the online questionnaire, please contact us at: _____

The information provided will be anonymised by type of respondent prior to analysis and then reported in the Impact Assessment study report of the Revision of the Union legislation pertaining to the EMA fee system. The final study report itself and the consultations outcome will be published by the European Commission when the impact assessment is finalised.

The questionnaire is available in English. You may respond in any EU language, but the study team would prefer to receive responses in English.

Figure 1 : Summary of the impact assessment options and sub-options

Policy	Veterinary fees	Human fees	Veterinary incentives	Human incentives	Fee system structure	NCA remuneration	Legislative action on fees
Do minimum	Procedural fees introduced for new VMP activities. Current fees and remuneration amounts used, adapted to VMP Regulation.	No change	No change	No change	No change	No change	No
Option 1	Cost-based fees. PhV annual fee introduced.	No change. Annual fees will be impacted from 2024 due to extended EMA mandate proposal.	No change; see sub-options	No change	No change	No change	Yes, minimum required to adjust to basic legislation.
Option 2	Same as Option 1	Cost-based fees. New procedural fees for activities not previously charged for.	No change; see sub-options	No change	No change	Full cost-based remuneration per procedure.	Yes
Option 3	Same as Option 1, but fewer procedural fees for post-authorisation, non-PhV activities. CAP annual fee covers broader costs. PhV annual fee covers EMA PhV horizontal activities on NAPs.		No change; see sub-options	No change	Simplified	Full cost-based remuneration per procedure. CAP procedures charged under annual fee are also remunerated via annual fee.	Yes

Sub-options (may be applied to any of the three main options):
(a) 50% general fee reduction
(b) 50% general fee reduction + incentives for limited markets
(c) Incentives for limited markets (no general reduction)

Sub-option: Partial simplification

Sub-option: Country coefficient applied to remuneration

Sub-option: Cost of incentives shared between EMA and NCAs

About You

Please provide your publication privacy preference

The Commission will publish the responses to this consultation. You can choose whether you would like your details to be made public or to remain anonymous.

○ **Anonymous**
Only your respondent type, country and contribution will be published. All other details (organisation name and size, transparency register number) will not be published.

◉ **Public**
Your details (organisation name and size, transparency register number) will be published with your contribution.

☑ **I agree with the personal data protection provisions**

☑ **I agree to being contacted regarding my responses for additional information or clarification**

Please provide a contact name and email address. This information will not be published.

Contact name:

Email:

Please indicate the language of your contribution

English

How are you are providing your contribution?

I am a representative of a[n]

- ○ Academic / research institution
- ○ Company
- ◉ **Government institution**
- ○ Non-governmental organisation (NGO)
- ○ Representative association
- ○ Other – please specify

Please select the type of institution you represent

- ◉ **Central government/ministry or public authority at national or regional level in a Member State or EEA country (not a medicines regulatory authority)**
- ○ Member State/EEA medicines regulatory authority
- ○ European Medicines Agency
- ○ Inspectorate
- ○ Other – please specify

What is the scope of your expertise/interest?

- ☐ International
- ☑ **EU/EEA**
- ☑ **National**
- ☐ Regional
- ☐ Local

What is the name of your organisation?

Ministry of Health, Welfare and Sport

What is the size of your organization?

- ○ Micro (1 to 9 employees)
- ○ Small (10 to 49 employees)
- ○ Medium (50 to 249 employees)
- ◉ **Large (250 or more)**

What is your transparency register number?

You can check whether your organisation is on the transparency register. The register is a voluntary database for organisations seeking to influence EU decision-making.

In what country is your place of work?

Austria
Belgium
Bulgaria
Croatia
Cyprus
Czechia
Denmark
Estonia
Finland
France

Where is your organisation headquartered?

Austria
Belgium
Bulgaria
Croatia
Cyprus
Czechia
Denmark
Estonia
Finland
France

Assesment of the Options

This question asks you to consider the extent to which the options for potential revision to the EMA fee system, as presented in this survey, take into account the outcome of the preceding evaluation, the options for action on the EMA fee legislation as defined in the inception impact assessment, and the feedback received to the IIA.

In your opinion, are the major aspects identified by the evaluation and the feedback to the inception impact assessment sufficiently addressed in the options as presented in this survey?

- ○ Yes – the major aspects identified in the preceding evaluation and IIA are reflected in the options presented in this survey.
- ◉ **No – the major aspects identified in the preceding evaluation and IIA are not reflected in the options presented in this survey.**
- ○ I don't know

Please indicate the aspects that are not included in the options as presented.

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

ASSESSMENT OF IMPACTS OF POTENTIAL CHANGES TO THE EMA FEE SYSTEM

The European Commission is considering revisions to the legislation governing the EMA fee system. These revisions include:

1. Options to better align fees to costs.
2. Options to further simplify the fee system and ensure a fair distribution of fees and remuneration, while respecting fee incentives set in existing policies.

At a minimum, the EMA fee system will need to be aligned with the 2018 VMP Regulation as of 2022. These changes will occur regardless of the option(s) that may be implemented following this assessment. The 'do minimum' scenario is summarised here.

The next part of the survey presents the implementation of the policy options and sub-options under consideration by the European Commission to revise the EMA fee system.
A detailed description of each policy option can be found here.

Based on this information and your own views and experience of the EMA fee system, we will then ask you to respond to a series of questions about the potential impact of the options and related sub-options. Each option will be presented separately for your consideration.

POLICY OPTION 1: INTRODUCE COST-BASED FEES FOR VETERINARY MEDICINES ONLY

Policy option 1 is expected to result in some changes to fees, NCA remuneration and EMA cost recovery. A description of the option can be found here.

Unitary cost-based fee and remuneration tables for each option and sub-option are provided on the project microsite for your reference.

Please refer to the fee grids[1] as well as the EMA budget summary tables.

The results presented are *preliminary* outputs from the first run of a model developed for the purposes of testing the options for potential changes to the EMA fee system. The figures may change as the model is refined over the course of the study.

In your opinion, what impact would this policy option have on financial predictability for your organisation, with regards to centralised activities[2]?

- ○ Very positive – financial predictability would be much better for my organisation
- ○ Somewhat positive – financial predictability would be better for my organisation
- ◉ **No impact – financial predictability would be the same for my organisation as under the do minimum scenario**
- ○ Somewhat negative – financial predictability would be worse for my organisation
- ○ Very negative – financial predictability would be much worse for my organisation
- ○ Do not know
- ○ Not applicable

Please provide additional information that will help us to understand your response:

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

---

[1]theoretical cost-based unitary fee amounts and NCA remuneration amounts, calculated by the study model according to the methodology note

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[2]Centralised activities are those undertaken at the level of the EMA for centrally authorised medicinal products, that is, medicinal products authorised or to be authorised by the European Commission in the EU.

In your opinion, what impact would this policy option have on the ability of your NCA to undertake procedural and additional EMA activities eligible for EMA remuneration compared to the current situation (please refer to the list of additional activities provided in the appendix to the methodology note)?

- ○ Very positive – my NCA would be much more able to undertake other EMA-related activities
- ○ Somewhat positive – my NCA would be more able to undertake other EMA-related activities
- ◉ **No impact – my NCA would be able to undertake the same number of other EMA-related activities as under the do minimum scenario**
- ○ Somewhat negative – my NCA would be less able to undertake EMA-activities eligible for remuneration
- ○ Very negative – my NCA would be much less able to undertake other EMA activities
- ○ Do not know
- ○ Not applicable

Please provide additional information and justification that will help us to understand your response, and in particular identifying the EMA activities eligible for remuneration that your response refers to:

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

The objectives of a potential review of the EMA fee system, as stated in the inception impact assessment, are to

- align the main categories of fees and charges with the EMA Founding Regulation,
- allow for proper financing of new veterinary procedures,
- to achieve a simplification of the system, and
- ensure a fair distribution of fees and remuneration, while respecting fee incentives set in existing policies.

Taking these objectives into account, in your opinion, what impact would this policy option have on the likelihood of new medicines being authorised in the EU?

- ○ Very positive – new medicines are likely to be authorised in the EU much faster than they do currently
- ○ Somewhat positive – new medicines are likely to be authorised in the EU market faster than they do currently
- ○ No impact – new medicines are likely to be authorised in the EU market at the same pace as under the 'do minimum' scenario
- ○ Somewhat negative – new medicines are likely to be authorised in the EU market more slowly than they do currently
- ◉ **Very negative – new medicines are likely to be authorised in the EU market much more slowly than they do currently**
- ○ Do not know
- ○ Not applicable

Please provide additional information that will help us to help us understand your response:

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

In your opinion, what impact will this policy option have on the availability of medicines in the EU as compared to the impact of other EU policies?

- ○ Very positive – medicines will be much more available than they are currently
- ○ Somewhat positive – medicines will be more available than they are currently
- ○ No impact – there will be no change in the availability of medicines are as under the 'do minimum' scenario
- ○ Somewhat negative – medicines will be less available than they are currently
- ◉ **Very negative –medicines will be much less available than they are currently**
- ○ Do not know
- ○ Not applicable

Please provide additional information that will help us to help us understand your response:

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

In your opinion, what impact will this policy option have on the financial stability and sustainability of the operation of the EMA and NCAs as a regulatory network?

- ○ Very positive – the EMA fee and remuneration system will have much greater financial stability and sustainability
- ○ Somewhat positive – the EMA fee and remuneration system will have greater financial stability and sustainability
- ○ No impact – the EMA fee and remuneration system will have the same financial stability and sustainability as under the 'do minimum' scenario
- ○ Somewhat negative – the EMA fee and remuneration system will have less financial stability and sustainability
- ◉ **Very negative – the EMA fee and remuneration system will have much less financial stability and sustainability**
- ○ Do not know
- ○ Not applicable

Please provide additional information that will help us to understand your response:

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

Overall, after considering the potential impacts, do you support or oppose this policy option to revise the EMA fee system?

- ○ My organisation strongly supports this policy option to revise the EMA fee system
- ○ My organisation support this policy option to revise the EMA fee system to some extent
- ○ My organisation neither supports nor opposes this policy option
- ○ My organisation opposes this policy option to revise the EMA fee system to some extent
- ◉ **My organisation strongly opposes this policy option to revise the EMA fee system**
- ○ Do not know
- ○ Not applicable

Please specify any particular elements of the policy option that you/your organisation support(s) or oppose(s):

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

POLICY OPTION 2: INTRODUCE COST-BASED FEES FOR ALL EMA ACTIVITIES

Policy option 2 introduces a cost-based fee system for all EMA activities, i.e. in both veterinary and human sectors. A description of the option can be found here.

Unitary cost-based fee and remuneration tables for each option and sub-option are provided on the project microsite for your reference.

Please refer to the fee grids[1] as well as the EMA budget summary tables.

The results presented are *preliminary* outputs from the first run of a model developed for the purposes of testing the options for potential changes to the EMA fee system. The figures may change as the model is refined over the course of the study.

In your opinion, what impact would this policy option have on financial predictability for your organisation, with regards to centralised activities[2]?

- ○ Very positive – financial predictability would be much better for my organisation
- ○ Somewhat positive – financial predictability would be better for my organisation
- ○ No impact – financial predictability would be the same for my organisation as under the do minimum scenario
- ○ Somewhat negative – financial predictability would be worse for my organisation
- ◉ **Very negative – financial predictability would be much worse for my organisation**
- ○ Do not know
- ○ Not applicable

Please provide additional information that will help us to understand your response:

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

---

[1]theoretical cost-based unitary fee amounts and NCA remuneration amounts, calculated by the study model according to the methodology note

---

[2]Centralised activities are those undertaken at the level of the EMA for centrally authorised medicinal products, that is, medicinal products authorised or to be authorised by the European Commission in the EU.

In your opinion, what impact would this policy option have on the ability of your NCA to undertake procedural and additional EMA activities eligible for EMA remuneration compared to the current situation (please refer to the list of additional activities provided in the appendix to the methodology note)?

- ○ Very positive – my NCA would be much more able to undertake other EMA-related activities
- ○ Somewhat positive – my NCA would be more able to undertake other EMA-related activities
- ○ No impact – my NCA would be able to undertake the same number of other EMA-related activities as under the do minimum scenario
- ○ Somewhat negative – my NCA would be less able to undertake EMA-activities eligible for remuneration
- ◉ **Very negative – my NCA would be much less able to undertake other EMA activities**
- ○ Do not know
- ○ Not applicable

Please provide additional information and justification that will help us to understand your response, and in particular identifying the EMA activities eligible for remuneration that your response refers to:

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

The objectives of a potential review of the EMA fee system, as stated in the inception impact assessment, are to

- align the main categories of fees and charges with the EMA Founding Regulation,
- allow for proper financing of new veterinary procedures,
- to achieve a simplification of the system, and
- ensure a fair distribution of fees and remuneration, while respecting fee incentives set in existing policies.

Taking these objectives into account, in your opinion, what impact would this policy option have on the likelihood of new medicines being authorised in the EU?

- ○ Very positive – new medicines are likely to be authorised in the EU much faster than they do currently
- ○ Somewhat positive – new medicines are likely to be authorised in the EU market faster than they do currently
- ○ No impact – new medicines are likely to be authorised in the EU market at the same pace as under the 'do minimum' scenario
- ○ Somewhat negative – new medicines are likely to be authorised in the EU market more slowly than they do currently
- ◉ **Very negative – new medicines are likely to be authorised in the EU market much more slowly than they do currently**
- ○ Do not know
- ○ Not applicable

Please provide additional information that will help us to help us understand your response:

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

In your opinion, what impact will this policy option have on the availability of medicines in the EU as compared to the impact of other EU policies?

- ○ Very positive – medicines will be much more available than they are currently
- ○ Somewhat positive – medicines will be more available than they are currently
- ○ No impact – there will be no change in the availability of medicines are as under the 'do minimum' scenario
- ○ Somewhat negative – medicines will be less available than they are currently
- ◉ **Very negative –medicines will be much less available than they are currently**
- ○ Do not know
- ○ Not applicable

Please provide additional information that will help us to help us understand your response:

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

In your opinion, what impact will this policy option have on the financial stability and sustainability of the operation of the EMA and NCAs as a regulatory network?

- ○ Very positive – the EMA fee and remuneration system will have much greater financial stability and sustainability
- ○ Somewhat positive – the EMA fee and remuneration system will have greater financial stability and sustainability
- ○ No impact – the EMA fee and remuneration system will have the same financial stability and sustainability as under the 'do minimum' scenario
- ○ Somewhat negative – the EMA fee and remuneration system will have less financial stability and sustainability
- ◉ **Very negative – the EMA fee and remuneration system will have much less financial stability and sustainability**
- ○ Do not know
- ○ Not applicable

Please provide additional information that will help us to understand your response:

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

Overall, after considering the potential impacts, do you support or oppose this policy option to revise the EMA fee system?

- ○ My organisation strongly supports this policy option to revise the EMA fee system
- ○ My organisation support this policy option to revise the EMA fee system to some extent
- ○ My organisation neither supports nor opposes this policy option
- ○ My organisation opposes this policy option to revise the EMA fee system to some extent
- ◉ **My organisation strongly opposes this policy option to revise the EMA fee system**
- ○ Do not know
- ○ Not applicable

Please specify any particular elements of the policy option that you/your organisation support(s) or oppose(s):

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

POLICY OPTION 3: INTRODUCE COST-BASED FEES FOR ALL EMA ACTIVITIES WITH A SIMPLER SYSTEM STRUCTURE

Policy option 3 introduces a cost-based fee system for human and veterinary activities, with a simpler system structure. A description of the option can be found here.

Unitary cost-based fee and remuneration tables for each option and sub-option are provided on the project microsite for your reference.

Please refer to the fee grids[1] as well as the EMA budget summary tables.

The results presented are *preliminary* outputs from the first run of a model developed for the purposes of testing the options for potential changes to the EMA fee system. The figures may change as the model is refined over the course of the study.

In your opinion, what impact would this policy option have on financial predictability for your organisation, with regards to centralised activities[2]?

- ○ Very positive – financial predictability would be much better for my organisation
- ○ Somewhat positive – financial predictability would be better for my organisation
- ○ No impact – financial predictability would be the same for my organisation as under the do minimum scenario
- ○ Somewhat negative – financial predictability would be worse for my organisation
- ◉ **Very negative – financial predictability would be much worse for my organisation**
- ○ Do not know
- ○ Not applicable

Please provide additional information that will help us to understand your response:

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

---

[1]theoretical cost-based unitary fee amounts and NCA remuneration amounts, calculated by the study model according to the methodology note

---

[2]Centralised activities are those undertaken at the level of the EMA for centrally authorised medicinal products, that is, medicinal products authorised or to be authorised by the European Commission in the EU.

In your opinion, what impact would this policy option have on the ability of your NCA to undertake procedural and additional EMA activities eligible for EMA remuneration compared to the current situation (please refer to the list of additional activities provided in the appendix to the methodology note)?

- ○ Very positive – my NCA would be much more able to undertake other EMA-related activities
- ○ Somewhat positive – my NCA would be more able to undertake other EMA-related activities
- ○ No impact – my NCA would be able to undertake the same number of other EMA-related activities as under the do minimum scenario
- ○ Somewhat negative – my NCA would be less able to undertake EMA-activities eligible for remuneration
- ◉ **Very negative – my NCA would be much less able to undertake other EMA activities**
- ○ Do not know
- ○ Not applicable

Please provide additional information and justification that will help us to understand your response, and in particular identifying the EMA activities eligible for remuneration that your response refers to:

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

The objectives of a potential review of the EMA fee system, as stated in the inception impact assessment, are to

- align the main categories of fees and charges with the EMA Founding Regulation,
- allow for proper financing of new veterinary procedures,
- to achieve a simplification of the system, and
- ensure a fair distribution of fees and remuneration, while respecting fee incentives set in existing policies.

Taking these objectives into account, in your opinion, what impact would this policy option have on the likelihood of new medicines being authorised in the EU?

- ○ Very positive – new medicines are likely to be authorised in the EU much faster than they do currently
- ○ Somewhat positive – new medicines are likely to be authorised in the EU market faster than they do currently
- ○ No impact – new medicines are likely to be authorised in the EU market at the same pace as under the 'do minimum' scenario
- ○ Somewhat negative – new medicines are likely to be authorised in the EU market more slowly than they do currently
- ◉ **Very negative – new medicines are likely to be authorised in the EU market much more slowly than they do currently**
- ○ Do not know
- ○ Not applicable

Please provide additional information that will help us to help us understand your response:

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

In your opinion, what impact will this policy option have on the availability of medicines in the EU as compared to the impact of other EU policies?

- ○ Very positive – medicines will be much more available than they are currently
- ○ Somewhat positive – medicines will be more available than they are currently
- ○ No impact – there will be no change in the availability of medicines are as under the 'do minimum' scenario
- ○ Somewhat negative – medicines will be less available than they are currently
- ◉ **Very negative –medicines will be much less available than they are currently**
- ○ Do not know
- ○ Not applicable

Please provide additional information that will help us to help us understand your response:

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

In your opinion, what impact will this policy option have on the financial stability and sustainability of the operation of the EMA and NCAs as a regulatory network?

- ○ Very positive – the EMA fee and remuneration system will have much greater financial stability and sustainability
- ○ Somewhat positive – the EMA fee and remuneration system will have greater financial stability and sustainability
- ○ No impact – the EMA fee and remuneration system will have the same financial stability and sustainability as under the 'do minimum' scenario
- ○ Somewhat negative – the EMA fee and remuneration system will have less financial stability and sustainability
- ◉ **Very negative – the EMA fee and remuneration system will have much less financial stability and sustainability**
- ○ Do not know
- ○ Not applicable

Please provide additional information that will help us to understand your response:

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

Overall, after considering the potential impacts, do you support or oppose this policy option to revise the EMA fee system?

- ○ My organisation strongly supports this policy option to revise the EMA fee system
- ○ My organisation support this policy option to revise the EMA fee system to some extent
- ○ My organisation neither supports nor opposes this policy option
- ○ My organisation opposes this policy option to revise the EMA fee system to some extent
- ◉ **My organisation strongly opposes this policy option to revise the EMA fee system**
- ○ Do not know
- ○ Not applicable

Please specify any particular elements of the policy option that you/your organisation support(s) or oppose(s):

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

The objectives of a potential review of the EMA fee system, as stated in the inception impact assessment, are to

- align the main categories of fees and charges with the EMA Founding Regulation
- allow for proper financing of new veterinary procedures,
- to achieve a simplification of the system, and
- ensure a fair distribution of fees and remuneration, while respecting fee incentives set in existing policies.

From your perspective, which policy option is most likely to deliver on these objectives (please bear in mind that suboptions are the subject of separate questions)?

- ○ Option 1
- ○ Option 2
- ○ Option 3
- ○ Do not know
- ◉ **Not applicable**

Please provide additional information that will help us understand your response,:

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

Sub-options assessment

The European Commission is considering a series of sub-options to the main options. A description of each policy sub-option can be found here.

Based on this information and your own views and experience of the EMA fee system, we will ask you to respond to questions about the potential impact of the sub-options.

POLICY SUB-OPTIONS FOR VETERINARY MEDICINES ONLY

Three sub-options are being considered for veterinary medicines only, introducing general fee reductions and/or incentives.

Please refer to the summary tables of expected changes under these sub-options.

The results presented are *preliminary* outputs from the first run of a model developed for the purposes of testing the options for potential changes to the EMA fee system. The figures may change as the model is refined over the course of the study.

The objectives of a potential review of the EMA fee system, as stated in the inception impact assessment, are to inception impact assessment, are to

- align the main categories of fees and charges with the EMA Founding Regulation,
- allow for proper financing of new veterinary procedures to achieve a simplification of the system, and
- ensure a fair distribution of fees and remuneration, while respecting fee incentives set in existing policies.

From your perspective, which policy sub-option is most likely to deliver on these objectives?

- ○ Sub-option a, with a general fee reduction only (no incentives)
- ○ Sub-option b, with a general fee reduction and incentives for limited markets
- ○ Sub-option c, with incentives for limited markets (no general fee reduction)
- ○ Do not know
- ◉ **Not applicable**

The proposed general fee reduction is 50% of the full fee. In your view, is this the appropriate level?

- ○ Yes, 50% is the appropriate level for a general reduction
- ○ No, the general reduction should be set at a different level
- ○ Do not know
- ◉ **Not applicable**

How do the veterinary medicines incentives implemented in the study model for the centralized system compare to incentives applied for veterinary medicines at national level in your Member State?

- ○ Similar – the proposed veterinary incentives for the centralised system are the same or nearly the same as those applied at national level in my member state
- ○ Different – the proposed veterinary incentives for the centralised system are not the same or nearly the same as those applied at national level in my member state
- ○ Do not know
- ◉ **Not applicable**

Please provide additional information that will help us understand your response. In particular, if incentives are different in your member state, please indicate what incentives are applied at national level.

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

POLICY SUB-OPTION FOR THE DISTRIBUTION OF INCENTIVES BETWEEN EMA AND NCAS

A sub-option is being considered under options 2 and 3, which applies incentives to cost-based fees before remuneration to NCAs. A description of the options can be found here.

The objectives of a potential review of the EMA fee system, as stated in the inception impact assessment, are to

- align the main categories of fees and charges with the EMA Founding Regulation,
- allow for proper financing of new veterinary procedures to achieve a simplification of the system, and
- ensure a fair distribution of fees and remuneration, while respecting fee incentives set in existing policies.

From your perspective, does this policy sub-option deliver on these objectives?

- ○ Yes
- ○ To some extent
- ◉ **No**
- ○ Do not know
- ○ Not applicable

Please provide additional information that will help us understand your response:

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

POLICY SUB-OPTION FOR A 'LIGHT' VERSION OF OPTION 3

A sub-option is being considered under option 3 only, which implements a 'light' version of the main option. A description of the options can be found here.

Please refer to the fee grids[1] for details of the full Option 3 and the 'light' version of Option 3

The objectives of a potential review of the EMA fee system, as stated in the inception impact assessment, are to

- align the main categories of fees and charges with the EMA Founding Regulation,
- allow for proper financing of new veterinary procedures to achieve a simplification of the system, and
- ensure a fair distribution of fees and remuneration, while respecting fee incentives set in existing policies.

From your pespective, which version of option 3 best delivers on these objectives?

- ○ Option 3 (i.e. the full version)
- ○ Sub-option d (i.e. the 'light' version of Option 3)
- ○ Do not know
- ◉ **Not applicable**

In your opinion, what impact would the application of a country coefficient (i.e. an adjustment linked to real salary costs and cost of living in each Member State) have on the ability of your NCA to undertake EMA activities?

- ○ Very positive – my NCA would be much more able to undertake EMA activities
- ○ Somewhat positive – my NCA would be more able to undertake EMA activities
- ○ No impact – my NCA would be able to undertake the same number of EMA activities as under policy option 1
- ○ Somewhat negative – my NCA would be less able to undertake EMA activities
- ○ Very negative – my NCA would be much less able to undertake EMA activities
- ○ Do not know
- ◉ **Not applicable**

Please elaborate your response, specifying any impacts foreseen:

For our response to this question and the previous one see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 267

Please select the impacts that you foresee for your NCA as a result of applying a country coefficient to your NCA's remuneration

(select all that apply)

- ☐ Financial considerations might be taken into account when appointing rapporteurs
- ☐ Funding for my NCA's scientific contribution might increase
- ☐ Funding for my NCA's scientific contribution might decrease
- ☐ My NCA might be more likely to be selected for multinational teams
- ☐ My NCA might be less likely to be selected for multinational teams
- ☐ Financial planning for my NCA may become easier
- ☐ Financial planning for my NCA may become more difficult
- ☐ Other, please specify

- [x] **None of the above**

Please provide additional details to help us understand your response:

For our response see the explanatory note (Annex II) attached at the end of this questionnaire.

Characters remaining: 305

In your opinion, does the list of **procedures** presented in the fee grid capture all EMA procedures?

- ( ) Yes, the fee grid reflects all EMA procedures
- ( ) No, the fee grid is missing some EMA procedures
- ( ) Do not know
- (•) **Not applicable**

Collection of data on an annual or other regular basis from the EMA and NCAs contributing to the EMA mandate could be used to monitor the attainment of the objectives of the EMA fee system, which are: (i) a sound financial basis for activities in the EMA mandate; (ii) fairness; (iii) adaptability; and (iv) proportionate administrative burden.

In your opinion, what indicators should be monitored in respect of each objective of the EMA fee system, in particular in view of future amendments to the fee system?

Please answer for each objective in turn using the table below. Please also provide your recommendations for any other indicators you think should be used for annual monitoring of the EMA fee system. Please consider in your reply also the operational feasibility.

Please tick at least one box in each row.

	Sound financial basis for activities in the EMA mandate
Annual EMA and NCA activity data	
	☐
Annual EMA financial data:	
staff costs	☐
staff full-time equivalent numbers	☐
annual contracted hours per staff full-time equivalent	☐
non-staff costs	☐
Periodically, data on time taken per activity, similar to that collected in the 2016 MBDG exercise	
	☐
Is there another indicator you recommend for monitoring?	
	☐

Is there another indicator you recommend for monitoring?

Sound financial basis for activities in the EMA mandate

Is there another indicator you recommend for monitoring?

Fairness

Annual EMA and NCA activity data

Annual EMA financial data:

- staff costs
- staff full-time equivalent numbers
- annual contracted hours per staff full-time equivalent
- non-staff costs

Periodically, data on time taken per activity, similar to that collected in the 2016 MBDG exercise

Is there another indicator you recommend for monitoring?

Is there another indicator you recommend for monitoring?

Is there another indicator you recommend for monitoring?

Adaptability

Annual EMA and NCA activity data

Annual EMA financial data:

- staff costs
- staff full-time equivalent numbers
- annual contracted hours per staff full-time equivalent
- non-staff costs

Adaptability

Periodically, data on time taken per activity, similar to that collected in the 2016 MBDG exercise

Is there another indicator you recommend for monitoring?

Is there another indicator you recommend for monitoring?

Is there another indicator you recommend for monitoring?

Proportionate administrative burdens

Annual EMA and NCA activity data

Annual EMA financial data:

- staff costs
- staff full-time equivalent numbers
- annual contracted hours per staff full-time equivalent
- non-staff costs

Periodically, data on time taken per activity, similar to that collected in the 2016 MBDG exercise

Is there another indicator you recommend for monitoring?

Is there another indicator you recommend for monitoring?

Is there another indicator you recommend for monitoring?

Don't know

Annual EMA and NCA activity data

	Don't know
Annual EMA financial data:	
staff costs	☑
staff full-time equivalent numbers	☑
annual contracted hours per staff full-time equivalent	☑
non-staff costs	☑
Periodically, data on time taken per activity, similar to that collected in the 2016 MBDG exercise	☑
Is there another indicator you recommend for monitoring?	☑
Is there another indicator you recommend for monitoring?	☑
Is there another indicator you recommend for monitoring?	☑

With what frequency should the indicators that you have selected be monitored?

	Every year (annually)
Annual EMA and NCA activity data	○
Annual EMA financial data:	
staff costs	○
staff full-time equivalent numbers	○
annual contracted hours per staff full-time equivalent	○
non-staff costs	○
Periodically, data on time taken per activity, similar to that collected in the 2016 MBDG exercise	○

	Every 2 years
Annual EMA and NCA activity data	○

Annual EMA financial data:

	Every 2 years
staff costs	○
staff full-time equivalent numbers	○
annual contracted hours per staff full-time equivalent	○
non-staff costs	○
Periodically, data on time taken per activity, similar to that collected in the 2016 MBDG exercise	○

	Every 5 years
Annual EMA and NCA activity data	○
Annual EMA financial data:	
staff costs	○
staff full-time equivalent numbers	○
annual contracted hours per staff full-time equivalent	○
non-staff costs	○
Periodically, data on time taken per activity, similar to that collected in the 2016 MBDG exercise	○

	Every 6-10 years
Annual EMA and NCA activity data	○
Annual EMA financial data:	
staff costs	○
staff full-time equivalent numbers	○
annual contracted hours per staff full-time equivalent	○
non-staff costs	○
Periodically, data on time taken per activity, similar to that collected in the 2016 MBDG exercise	○

	Don't know
Annual EMA and NCA activity data	◉

Annual EMA financial data:	Don't know
staff costs	◉
staff full-time equivalent numbers	◉
annual contracted hours per staff full-time equivalent	◉
non-staff costs	◉

Periodically, data on time taken per activity, similar to that collected in the 2016 MBDG exercise

◉

You are invited to upload a concise document, such as a position paper related to your responses (max. 2 pages)

The document is an optional complement and serves as additional background reading to better understand your position.

Please upload your file here. The maximum file size is 1 MB.

NL response - IA targeted survey EMA fee system_20210820.pdf

0.2 MB

application/pdf

If you wish to add further information within the scope of the questions asked in this questionnaire, please do so here.

In addition to our replies to the survey questions, the Netherlands provides a general statement with additional considerations in order to further substantiate and clarify our vision for a future EMA fee system. Please see Annex I attached to this survey. Further, an explanatory note (Annex II) has been attached to explain the diffuclties encountered when replying to this questionnaire and the approach we have taken. This annex also provides additional information to the survey questions as the text boxes proved too small and the questions are not numbered making cross-referring very difficult.

Characters remaining: 397

The Hague, 20-08-2021

Annex I

General statement from the Netherlands in relation to the targeted consultation for the impact assessment of a potential revision of the legislation governing the EMA fee system

Summary

In order to guarantee European citizens have access to safe and effective medicines, the EU regulatory network needs to be able to carry out their tasks with the highest level of (scientific) expertise. This requires a fee and remuneration system that is fair, flexible and responsive, relatively simple and predictable, and sustainable. More specifically, this means a fee system that: (1) is based on actual costs in regard to both fees for EMA and remuneration for NCAs; (2) responds adequately to foreseen and unforeseen changes in the regulatory, scientific and technological environment the EMA and NCAs operate in; (3) is stripped of unnecessary complexities whilst still being transparent and offering a good balance between income and costs; (4) enables EMA and NCAs to execute their operations to the highest possible standards not only now but also in the future.

In the view of the Netherlands, the proposed policy (sub)options and quantitative fee and remuneration amounts as calculated by the Commission contractor regrettably fail to meet any of these requirements, both for the veterinary and human sector. Although it is very positive that NCA remuneration is proposed for several currently uncompensated procedural activities under some of the policy options, overall the NCA remuneration projected for procedural activities and the NCAs' share in annual fee are a complete mismatch with the increase in NCA workload and the capacity issue the regulatory network currently faces. In addition, none of the proposed policy (sub)options explain how a future fee system would be able to respond in a timely and adequate manner to foreseen and unforeseen regulatory, scientific or technological circumstances. This will have a negative effect on future NCA engagement in (especially non-remunerated) EMA-level activities and the sustainability of the regulatory system as a whole.

Therefore, the Netherlands urges the Commission to have further in-depth discussions with the EMA and the HMA/NCAs on their needs and the issues they are facing, and to take these duly into account when adopting a Commission legal proposal for a future EMA fee system.

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1. Introductory remarks

The Netherlands thanks the Commission and the Commission contractor for the opportunity to respond to the targeted consultation supporting the impact assessment for a potential revision of the fee system of the European Medicines Agency (EMA). The Netherlands recognises the effort and work that has already gone into the evaluation and impact assessment of the EMA fee system and the complexity of the subject matter.

Ensuring that citizens have access to safe and effective medicines and to innovative technological and scientific treatments requires that both EMA and national competent authorities (NCAs) are able to carry out their tasks with the highest possible level of competence and that they are in the position to continuously invest both quantitatively and qualitatively in their capacity and necessary expertise. This is recognised by the Pharmaceutical Strategy for Europe [1], which states that one important factor therein is the availability of sufficient funding at all levels and that the Commission will consider this in the upcoming revision of the EMA fee system. However, in the view of the Netherlands, the data and documents provided via the microsite of the Commission contractor in support of this targeted consultation do not seem to fully align with this notion. In this regard, the Netherlands fully supports the comments of the Heads of Medicines Agencies (HMA) on this targeted consultation. In addition to HMA's comments, the Netherlands wishes to share a few general observations in relation to a future fee system and the quantitative data provided in support of the questionnaire. These observations are in addition to and in support of our responses to the individual survey questions and apply to both medicines for human and veterinary use, unless stated otherwise.

2. Characteristics of a future fee system

To guarantee European citizens have access to safe, effective and innovative medicines, EMA and NCAs need to be enabled financially to adapt to new scientific and technological developments by continuously

[1] COM(2020)761

investing in necessary expertise and achieving operational excellence. In the view of the Netherlands, this calls for a fee and remuneration system that is fair, flexible and responsive, relatively simple and predictable, and sustainable.

Fair

A fair system implies that both fees to be paid to EMA and remuneration for NCAs are based on actual costs incurred for their operations. This, to not create a financial shortfall for regulators or, alternatively, overcharge industry for services provided. It also implies that NCAs are not just able to cover their aggregate costs, but also their individual costs. A fair system further means no cross-subsidisation is required between different types of procedures (e.g. initial marketing authorisation applications vs type II variations) or products (e.g. innovative vs generic), between the veterinary and human regulatory sector or between non-central and central procedures.

In this regard, it is first noted that the "cost-based" fee and remuneration amounts calculated by the contractor are based on time and cost data from 2016. Although page 24 of the Methodology Note [2] states that NCA costs reported for 2016 were updated for the study period by 5% per annum for labour costs and 2% for non-labour costs, in line with the increases underpinning the EMA forecast data, this is deemed insufficient to reflect actual current costs NCAs incur per EMA-related operation. The overall workload for the regulatory network has increased significantly since 2016, both in volume and in type and complexity of tasks. This is due to an increase in more complex therapeutic innovations, the redistribution of UK's large portfolio following Brexit, and most recently the Covid-19 pandemic. The regulatory network has notified the Commission on several occasions, both orally and in writing, of the continuously increasing capacity issue it faces and how this endangers the sustainability of the network, most recently by letter of EMA's Executive Director Emer Cooke dated 29 June 2021. In this regard the Netherlands finds it astounding that the fee and remuneration grids provided by the Commission contractor underlying policy options 2 and 3 foresee a significant decrease in NCA income. It is recognised that, as found by the evaluation study, some of the current fee and remuneration amounts exceed actual costs for EMA and NCAs, most notably for type II variations, and the Netherlands believes this should be corrected in order to create a fair fee system not just for regulators but also for payers. However, the projected reduction in total NCA remuneration is a complete mismatch with the experienced increase in workload and capacity issue. In this regard, it should be noted that already in 2010 the European Court of Auditors (EC A) repeatedly noted the need for an NCA remuneration system based on real costs [3].

In addition, the Commission evaluation study of the EMA fee system found that a substantial number of NCAs were unable to cover their costs for procedural activities with the remuneration they receive, and that this is still the case for some NCAs when remuneration from annual fees is included [4]. A further reduction in income means that even more NCAs would have to cross-finance their EMA-related operations from national income, which is not allowed by law in several Member States including the Netherlands. It additionally creates a system that is less fair for payers, as holders of national marketing authorisations would have to pay for the costs incurred by regulators for centrally authorised products.

A fair fee system also implies that all NC A operations relevant for the functioning of the medicines regulatory network and the regulatory system as a whole are adequately financed through a share in the procedural and annual fee. In this regard, the Netherlands finds it very positive that under some of the policy options the Commission contractor envisions several of the currently unremunerated activities for NCA remuneration, such as MUMS/limited market classifications upon request of the MAH, paediatric investigation plan related procedures and PRIME. At the same time, the Netherlands notes the projected significant reduction in the NC As' total share of the procedural and annual fee. In the view of the Netherlands, this reduction negatively impacts the fairness and sustainability of the fee system and needs re-evaluation and, as stated before, does not reflect actual costs incurred and increase in workload. As regards NCAs' share of the annual fee, the projected reduction is the result of an exercise by the Commission or Commission contractor assessing the potential eligibility of NCAs' reported additional activities for remuneration, as explained in appendix 2 of the Methodology Note. The annual fee is critical to finance horizontal activities required for the operation of the network. Therefore, such exercise should be based on the correct assumptions and starting points, and not lead to an imbalance between NC A remuneration and costs for essential horizontal activities. In this regard, it is noted that

[2] SANTE/2019/B5/043

[3] European Court of Auditors reports on the annual accounts of the European Medicines Agency for the financial years 2006 (OJ C 309, 19.12.2007, p. 34–39), 2010 (OJ C 366, 15.12.2011, p. 27–32) and 2011 (OJ C 388, 15.12.2012, p. 116–122).

[4] Chapter 5.1 of the Commission evaluation report (SWD(2019)335)

the eligibility criteria mention relevance for EMA services but not Commission services. Since the Commission is part of the regulatory network, scientific services provided by NCAs to and upon request by the Commission should be considered for remuneration, e.g. expertise provided in relation to the (V)ICH. In addition, the operation of the network and regulatory system as a whole not only depends on scientific services, but also on for instance IT-related services provided by NCAs to EMA (e.g. SPOR). Without adequate EMA databases and portals, not only the current regulatory system would come to a halt but also the implementation of new pieces of legislation such as the Veterinary Regulation [5]. Also, adequate explanation of the application of the eligibility criteria to each of the additional activities is lacking, leaving it unclear for several activities why they are not considered eligible for remuneration. Also, although the list of activities considered by the Commission (contractor) is extensive, it may not be complete. For instance, the methodology note does not make mention of the essential and currently uncompensated task of chairing EMA's scientific committees. For most committees, this is a full-time task which also requires additional (administrative) NCA support. Without adequate chairing, the regulatory system would fail to function and, therefore, this essential task deserves proper compensation. The Netherlands therefore urges the Commission to discuss with HMA and EMA the relevance of the eligibility criteria as well as the list of additional activities reported by NCAs and their eligibility for inclusion in the annual fee and NCA remuneration.

Finally, a fair fee system implies that when costs are shared between different regulators, income to cover these costs is shared too. Whereas under the Fee Regulation [6] incentives are applied to the fee after NCA remuneration, incentives are deducted from the fee before NCA remuneration under the Pharmacovigilance Fee Regulation [7]. One of the policy sub-options aims to align this by having the EMA and NCAs share the costs of incentives. However, currently the EMA receives a general EU budget contribution and a dedicated orphan budget contribution to cover its shortfall caused by fee incentives, whereas NCAs do not receive a share of this EU contribution. The Netherlands therefore views that, in order for a future fee system to be fair, the costs of incentives should not be equally covered by EMA and NCAs, unless NCAs in future receive part of the EU contribution.

Special mention is made of the veterinary sector. With no actual time and cost data of the operations under the New Veterinary Regulation being available (yet), projected fee and remuneration amounts are based on assumptions. The Netherlands views that those amounts should be reassessed based on (f)actual data sometime after the veterinary legislation becomes applicable (e.g. after one year) and readjusted as needed in order to ensure a fair fee system.

Flexible and responsive

In order for a fee system to be sustainable, it should be able to respond timely to foreseen and unforeseen changes in the regulatory, scientific and technological environment the EMA and NCAs operate in. The Commission evaluation of the EMA fee system found that it provides a level of flexibility that is sufficient for the current operations of the regulatory network but it may not be enough to guarantee future sustainability of these operations. In this regard, the evaluation specifically mentioned scientific innovations as a future challenge due to an increase in workload they entail.

Although the Netherlands fully supports this finding, we are of the opinion that the fee system not just lacks flexibility in relation to scientific progress in therapeutics but also in relation to other areas. First, the Covid-19 pandemic brought along a significant amount of additional work for the regulatory network, most recognisably in the form of rolling reviews of Covid-19 vaccines and therapeutics and work related to the monitoring of shortages. So far, NC As have not received any funding for this essential work. This shows that the current EMA fee system is insufficiently capable of responding to unexpected challenges, thereby not meeting its objective of taking into account exceptional circumstances and imperative public or animal health reasons [8]. The Netherlands warmly welcomes the recent EMA initiative to establish additional payments to NCAs for activities related to Covid-19 procedures, but notes that it took considerable pressure from to network to make urgently needed changes and that only temporary measures have been put in place so far. Although the policy options in the impact assessment make mention of the draft regulation on the extension of the EMA mandate in crisis preparation and response[9], this does not ensure that the future fee system is sufficiently capable to (timely) accommodate an unforeseen change of circumstances different from the current pandemic.

[5] Regulation (EU) 2019/6
[6] Council Regulation (EC) No 297/95
[7] Regulation (EU) No 658/2014
[8] Fig. 1 of the Commission evaluation report (SWD(2019)335).
[9] COM(2020)725

Apart from unforeseen circumstances, the current fee system has also proven to be inadequate in responding to foreseen changes in the relevant regulatory framework. In this regard, the Netherlands points to the situation as occurred with the pharmacovigilance and paediatric legislation. The Pharmacovigilance Fee Regulation for the funding of the relevant tasks under the new pharmacovigilance legislation [10] only came into force two years after the application of that new legislation. As a result, during a period of two years NC As did not receive remuneration for services provided in accordance with the pharmacovigilance legislation. Further, the Paediatric Regulation stipulates that the general Union contribution should cover the work of not only the EMA but also the Paediatric Committee (PDCO); this includes scientific support provided by experts, the assessment of paediatric investigation plans, scientific advice and any fee waivers provided for in that Regulation. [11] However, specific provisions for the remuneration of experts for their scientific support within this committee were never put in place, and currently the work on procedures undertaken by the NC As under this remit remains unremunerated, contrary to the spirit of this legislative provision. Both undesirable situations were recognised by the evaluation report of the Commission [12]. In this regard, it is noteworthy that the EMA Founding Regulation and the Orphan and Paediatric Regulation [13] are currently reviewed for future revision and that a revised Commission proposal for the variation framework [14] is planned by 2023 [15], likely requiring further amendments to the fee system. However, the proposed policy (sub)options do not explain how they would prevent in the future situations as described above. Equally, they do not clarify how they would accommodate other changing circumstances, such as new IT developments.

Currently, the flexibility and responsiveness of the fee system mainly come from the Implementing Rules adopted by the EMA Management Board and Decisions of the EMA Executive Director. During the evaluation study of the fee system, EMA representatives noted that the combination of the fee legislation and Implementing Rules is key in order to enable them to provide fee reductions and exemptions not foreseen in the legislation [16]. The documents provided via the Commission contractor's microsite do not mention whether these important tools are foreseen within the framework of a revised fee system and, if not, how flexibility and responsiveness are built into the future system. The Netherlands therefore calls upon the Commission to provide clarity on this matter.

Relatively simple and predictable

The evaluation of the EMA fee system found that it is complex. The Netherlands is of the opinion that simplification would make it more efficient and less costly and would provide for more financial predictability for all stakeholders involved. This would increase financial stability of the regulatory network. Policy option 3 (light) aims to achieve this by transferring certain procedure-related costs to the annual fee. However, simplification also comes with the risk of a mismatch between income and costs and of decreased transparency of the fee system. That risk is highest for more expensive procedures with a large recorded range of time spent by the regulators and with a high range of yearly volume. The Netherlands therefore advocates a modest level of simplification along the lines of option 3 light. However, which fees would be most suitable for inclusion in the annual fee would need further discussion with EMA and HMA. Also the overall split of the annual fee in part to be attributed to the EMA and the NCAs respectively would need reconsideration, as also indicated further above in this statement.

The Netherlands further notices that the projected fee grids do not include additional ("top-up") fees. The Methodology Note states that these have not been calculated for the cost-based options as no data are available on the additional time taken for these, and in line with the approach taken for the EMA Management Board Data Gathering (MBDG) exercise supporting the preceding evaluation of the fee system. It is however unclear whether top-up fees are nevertheless envisioned for all or any of the proposed policy options. The Netherlands could imagine these fees are reconsidered when aiming for simplification and streamlining.

Sustainable

In order to be sustainable, a future fee system needs to be fair, flexible and responsive, reasonably simple and predictable, as explained above. The Netherlands stresses that to safeguard the sustainability of the regulatory network, adequate funding is required for both EMA ánd NCAs. A system is sustainable if it not only enables the EMA and NCAs to execute their operations to the highest standard now, but also in the future. Without sufficient, sustainable funding, EMA and NCAs will not be able to

[10] Regulation (EU) No 1027/2012, Regulation (EU) No 1235/2010, Directive 2012/26/EU and Directive 2010/84/EU
[11] Article 48 of Regulation (EC) No 1901/2006
[12] Chapter 3.2 of the Commission evaluation report (SWD(2019)335)
[13] Respectively Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006.
[14] Regulation (EC) No 1234/2008
[15] Page 16 of the Pharmaceutical Strategy for Europe (COM(2020)761).
[16] Chapter 5.1 of the Commission evaluation report (SWD(2019)335)

invest both quantitatively and qualitatively in their capacity, and the EU will not be able to maintain its leading position globally in the field of therapeutic and preventive medicines. In this regard, it is noteworthy that the 2010 study on the evaluation of the EMA [17] already commented on an imbalance between NCAs' costs and remuneration received, and the potential effects of this imbalance on future NCA engagement in (especially non-remunerated) EMA-level activities and the sustainability of the regulatory system as a whole. In 2010, the same concerns were raised by the HMA [18], and, as stated before, ECA also commented several times on such imbalance.

As regards sustainability, specific attention is needed for veterinary medicines. With the scope of the central procedure being extended via the new veterinary legislation to all medicines, it is foreseen that more products will follow the central marketing authorisation procedure. This means that income via non-central procedures will decrease. Depending on the degree to which a shift from non-central to central will take place, the proposed policy options and underling fee grids will, to a smaller or larger extent, be inadequate in providing mixed and veterinary-only NCAs with sufficient funding to cover their EMA-related veterinary operations. In this regard, it should be kept in mind that even if an NCA is not leading the assessment as (co-)rapporteur or reference member state, it incurs costs related to assessment and (IT and product) maintenance. Whereas with mutual recognition and decentralised procedures NCAs are able to cover such costs by charging procedural and annual fees at the national level, this is not a possibility under the current EMA fee system where only rapporteurs receive remuneration. Hence, a shift to central procedures could impact the sustainability of the veterinary regulatory system. The Netherlands therefore urges the Commission to weigh in on this and assess the impact of the extension of the scope for central procedures and to take necessary measures to offset any negative impact.

Final mention in relation to sustainability is made of the projected country-coefficient. Application of average cost-based fees punishes more expensive NCAs, and those also happen to be among the most active. However, applying a country-coefficient to NCA remuneration does not offer the desired solution and may even be counter-productive. First, it adds to the complexity and financial unpredictability of the fee system as the level of the fee would be based on the rapporteur Member State. Second, it endangers the multinational assessment team (MNAT) concept, since NCAs with a high coefficient may no longer be willing to take part in assessments by low coefficient countries [19]. Finally, it may lead to financial considerations (also) impacting the choice of rapporteur rather than (just) basing it on relevant scientific expertise. The Netherlands therefore calls upon the Commission to come up with a different solution to offset the shortfall some NCAs may face if choosing average cost-based remuneration.

3. Final remarks

Ensuring that citizens have access to safe and effective medicines and to innovative technological and scientific treatments requires that both the EMA and NC As are able to carry out their tasks with the highest possible level of competence and that they are in the position to continuously invest both quantitatively and qualitatively in their capacity and necessary expertise. This calls for a fee system that is fair, flexible and responsive, relatively simple and predictable, and sustainable. As provided above, the data and documents underlying the policy (sub)options do not fully support this vision. Therefore, the Netherlands urges the Commission to have further in-depth discussions with the EMA and HMA/NCAs on their needs and the issues they are facing, and to take these duly into account when adopting a Commission legal proposal for a future EMA fee system.

This statement is submitted by:
The Ministry of Agriculture, Nature and Food Quality (LNV),
The Ministry of Health, Welfare and Sport (VWS), and
The Medicines Evaluation Board (CBG-MEB)
of the Netherlands

See the next page for our explanatory note to our response to the questionnaire.

[17] Evaluation of the European Medicines – Final report - January 2010 by Ernst & Young
[18] HMA position paper: Role of the European regulatory m edicines network and its relation to a revision of the fee regulation, December 15, 2010.
[19] By m aximising the use of available resources and expertise and allowing for building up know-how, MNAT is one of the im portant tools in safeguarding future sustainability of the regulatory network in an environment with incre asing workload and product co mplexity. Hence , any revision of the fee system should support the MNAT, not je opardise it.

Annex II

Explanatory note from the Netherlands to our response to the questionnaire in support of the impact assessment of a potential revision of the legislation governing the EMA fee system

1. Introductory remark

Via this explanatory note, the Netherlands wishes to clarify our chosen approach towards the questionnaire and the difficulties encountered when drafting our response. In addition, we have chosen to provide all additional information to substantiate our responses under section 3 of this annex instead of in the survey text boxes. Reasons for this are that in many instances the survey text boxes proved too small to provide an adequate response to the questions and that the survey questions are not numbered, which makes cross-referring very difficult.

2. Difficulties encountered and approach taken towards the questionnaire

First, in order to be able to indicate which policy option or options will meet the necessary objectives of a future fee system, a full-fletched impact assessment is required identifying and weighing in on the most significant quantitative and qualitative effects of each of the policy (sub)options on the operation of the fee system and the regulatory network, which depends on it for its funding. When assessing the identified impacts, not only the design of each policy (sub)option should be taken into account but also the underlying proposed fee and remuneration amounts. This is an absolute necessity, because the impact of a particular policy (sub)option not only depends on its design, but also on the actual quantitative elaboration pertaining to it. Although the Commission contractor has provided for each (sub)option quantitative elaborations in the form of fee and remuneration grids, an actual impact assessment is lacking at this stage, leaving the assessment of the impact(s) of each policy (sub)option to the survey respondents. Obviously, the deadline given for completing the survey is too short for such an exercise. Although it is recognised that in order to conduct a full-fletched impact assessment qualitative input from the relevant stakeholders (as provided via this targeted consultation) is required, an initial assessment of the main impacts including preliminary conclusions based on evaluation findings and quantitative calculations would have been useful at this stage.

Also, the Netherlands finds it unclear what we are responding to when completing the survey; just the design of each policy (sub)option or also the quantitative fee and remuneration grids provided via the supporting microsite of the Commission contractor? Whereas an option may seem to meet all required objectives of a future fee system in design, it still won't allow for a sustainable system if the foreseen fee and remuneration amounts pertaining to it do not provide for adequate funding for EMA and NCAs. Hence, the reply to the survey questions may change depending on what information and data the questions actually encompass. Where deemed necessary, we have tried to clarify in our response whether we are commenting on the design of the policy (sub)option and/or the quantitative projections pertaining to each (sub)option as provided by the Commission contractor in the form of fee and remuneration grids.

Finally, the documents and data provided via the Commission contractor's microsite leave several uncertainties. For instance, how will the actual regulatory framework be constructed; will there be implementing or delegated acts and/or implementing rules? How will 'charges for other services provided by the Agency' [20] be applied? The survey mentions that the extension of the EMA mandate has been projected to affect the fee system as of 2024 and is therefore taken into account in the impact assessment study; it is however unclear how the required calculations are made and on which assumptions, data and foreseen activities they are based. It is equally unclear how veterinary fee and remuneration amounts applicable to the new veterinary legislation [21] are calculated, since the only available time and cost data apply to the current regulatory framework, not the New Veterinary Regulation. The Netherlands urges the Commission (contractor) to provide further clarification on these matters, in order to support any further discussions with HMA/NCAs/the Member States during the Impact Assessment study.

[20] Art. 67.3(d) of Regulation (EC) No 726/2004
[21] Regulation (EU) 2019/6

3. More detailed responses to some of the survey questions

ASSESSMENT OF THE OPTIONS

Question 1: In your opinion, are the major aspects identified by the evaluation and the feedback to the inception impact assessment sufficiently addressed in the options as presented in this survey?

Additional information: The policy (sub)options only partially reflect the feedback provided by the NCAs. The options are still set on the basis of a methodology that disregards horizontal costs of NCAs for activities without which the centralised system cannot function. The level of the remuneration amounts in the different options does not compensate for this shortcoming. All options outside of Do Minimum or Option 1 will worsen the already existing imbalances in the system.

POLICY OPTION 1: INTRODUCE COST-BASED FEES FOR VETERINARY MEDICINES ONLY

Question 2: In your opinion, what impact would this policy option have on financial predictability for your organisation, with regards to centralised activities?

Additional information: Option 1 compares positively to the Do Minimum scenario, for veterinary especially, because of the introduction of fees for Referrals, PASS/PSUR and New Activities. The option takes no account, however, of what the NCA-part of the network needs in order to finance its activities to contribute to the centralised part of the system. In relation to the New Veterinary Regulation (NVR) and the proposed changes to the veterinary fees (300% increase for MAHs), it is completely unpredictable as to what impact this will have on how companies will approach new authorisations going forward and finally also on workload and fee income for NCAs. The same applies for Options 2, 3 and 3 light.

Option 1 is clearly unfair in its distribution of veterinary annual fees (90% EMA vs. 10% NCAs). Option 1 has no features for compensating NCAs for their share in horizontal cross network activities while the EMA is 100% compensated for these activities. The proposed distribution of veterinary annual fees is also unfair because CAPs have a marketing authorisation in all Member States. Member State NCAs are the national points of contact for any issue related to CAPs (e.g. pharmacovigilance). A more balanced and fair distribution of veterinary annual fees over all NCAs would help to cover the costs that NCAs make to contribute to both procedure related and non-procedure related cross network activities in the centralised part of the system.

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Question 3: In your opinion, what impact would this policy option have on the ability of your NCA to undertake procedural and additional EMA activities eligible for EMA remuneration compared to the current situation (please refer to the list of additional activities provided in the appendix to the methodology note)?

Additional information: Policy option 1 is substantially the same as the current model for human medicines and therefore any limitation in the current system will remain. In relation to veterinary medicines, Option 1 compares positively to the Do Minimum scenario, while Options 2, 3 and 3 light will result in a negative financial outcome for the Dutch medicines agency. The increase in fee income to be expected under Option 1 may help the veterinary part of the Dutch medicines agency as the current fees are very low. However, concerns remain in relation to the methodology and the complete uncertainty as to how companies will react to the options and the new fees under the NVR.

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Question 4: Taking these objectives into account, in your opinion, what impact would this policy option have on the likelihood of new medicines being authorised in the EU?

Additional information: NC As are already facing a negative financial result on their contribution to the work for CAPs and the workload may increase further. Without a significant increase of the

remuneration for NCAs the availability of new products reaching the market as soon as possible may be hampered and the sustainability of the network cannot be guaranteed.

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Question 5: In your opinion, what impact will this policy option have on the availability of medicines in the EU as compared to the impact of other EU policies?

Additional information: See the additional information provided for questions 2, 3 and 4.

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Question 6: In your opinion, what impact will this policy option have on the financial stability and sustainability of the operation of the EMA and NCAs as a regulatory network?

Additional information: While some of the new fees better align with the EMA Founding Regulation and have proposed fees required under the NVR, we do not consider that the proposals have met the objective of a fair distribution of the fees. Without a fee system that covers the real costs of NCAs, including compensation for their horizontal costs in support of the centralised part of the system, the sustainability of the network will become critical. The distribution of the fees between EMA and the NCAs seems to be disproportionate, certainly for the veterinary domain (in aggregate EMA 71%, NCAs 29%).

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Question 7: Overall, after considering the potential impacts, do you support or oppose this policy option to revise the EMA fee system?

Additional information: Although Option 1 addresses some of the issues that the NVR causes for the veterinary domain and the option compares positively to both the Do Minimum scenario and Options 2, 3 and 3 light, the fees are set in such a way that undesirable and unjustifiable effects in the fee division between the EMA and the NCAs are introduced. This option is therefore unacceptable. In general, while Option 1 doesn't cause major new shortcomings in the EMA fee system compared to the other policy options, all policy options, including Option 1, fall short of addressing the shortcomings in the current fee system that have been identified in the evaluation phase. This is in part the result of the definitions and the methodology chosen for the evaluation, the inception impact assessment and the impact assessment and in part of the levels of the fees as presented in the fee grids. This combination seems to produce the poor outcomes we now see in the impact assessment phase.

We think it's undesirable that options that change relatively little (Do Minimum and Option 1) compared to options that change more (Options 2, 3 and 3 light) will come out as most favoured options in the impact assessment phase. The overall outcomes of all options are extremely poor for the NCA-part of the network.

POLICY OPTION 2: INTRODUCE COST-BASED FEES FOR ALL EMA ACTIVITIES

Question 8: In your opinion, what impact would this policy option have on financial predictability for your organisation, with regards to centralised activities?

Additional information: As all policy options, this option is based on a very strict and incorrect definition of EMA-related activities. It causes shifts between fee categories that could be justified if the overall outcome of the option would be positive and major shortcomings of the current fee system would be addressed. Apart from a few relatively minor improvements, this is not the case. It's not so much the principle of cost-based fees that is at stake but the definitions chosen and the fee levels set that fail to produce a healthy outcome for NCAs and therefore for the network as a whole.
Option 2 causes more uncertainty and unpredictability because stabilising factors as the fees for scientific advice and the annual fees are lower, while the fees that will be raised are connected to less predictable and controllable procedures and these fees will still not offer any financial compensation for real costs of NCAs that fall outside of the definition of EMA-related activities chosen.

Additional note on the methodology: the costing exercise on which the options are based is flawed as it is based on pre-Brexit, pre-Covid time data from 2016 and also does not reflect the emergence of more complex procedures. It is based on summary costs that are incorrectly averaged (e.g. scientific staff), it does not reflect the role of the NCAs as the providers of the scientific assessments and it embeds staff shortages and underfunding of the NCAs into the model going forward. It only addresses future proofing the EMA, not of the NCAs and rewards high cost of the EMA to the detriment of the NCAs. In this regard, we refer to the HMA comments.

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Question 9: In your opinion, what impact would this policy option have on the ability of your NCA to undertake procedural and additional EMA activities eligible for EMA remuneration compared to the current situation (please refer to the list of additional activities provided in the appendix to the methodology note)?

Additional information: See the additional information provided for question 8. The overall fee income under this option for the Dutch medicines agency will drop considerably compared to the current situation. A general underfunding of NCAs may lead to lower willingness to take on centralised work, which could lead to increased difficulties in assigning coordinators for scientific advice, rapporteurs and co-rapporteurs. NCAs that take a large share in EMA-related activities may be forced to reduce their level of centralised activities. The data and arguments presented in this respect during the phases of evaluation and inception impact assessment seem to have not been taken seriously at all. This seems to reflect a general gross underestimation of the role that NCAs play in the overall performance of the centralised part of the EU medicines regulatory system.

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Question 10: Taking these objectives into account, in your opinion, what impact would this policy option have on the likelihood of new medicines being authorised in the EU?

Additional information: See the additional information provided for questions 7, 8 and 9. In principle a cost-based fee system could be acceptable, provided that the definitions of EMA-related activities and the levels of the fees in the fee grids are set right and fair. While this is not the case, Policy Option 2 is likely to undermine the stability and sustainability of the centralised part of the EU medicines regulatory system. We also do not consider that this policy option – like all options presented - meets the objective of a fair distribution of the fees between EMA and NCAs.

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Question 11: In your opinion, what impact will this policy option have on the availability of medicines in the EU as compared to the impact of other EU policies?

Additional information: See the additional information provided for question 10.

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Question 12: In your opinion, what impact will this policy option have on the financial stability and sustainability of the operation of the EMA and NCAs as a regulatory network?

Additional information: See the additional information provided for question 10.

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Question 13: Overall, after considering the potential impacts, do you support or oppose this policy option to revise the EMA fee system?

Additional information: See the additional information provided for the previous questions and see also our general statement attached as Annex 1.

POLICY OPTION 3: INTRODUCE COST-BASED FEES FOR ALL EMA ACTIVITIES WITH A SIMPLER SYSTEM STRUCTURE

Question 14: In your opinion, what impact would this policy option have on financial predictability for your organisation, with regards to centralised activities?

Additional information: As all policy options, this option is based on a very strict and incorrect definition of EMA-related activities. It causes shifts between fee categories that could be justified if the overall outcome of the option would be positive and major shortcomings of the current fee system would be addressed. This is not the case. As a general principle the Netherlands is in favour of reducing the complexity of the fee system, but the definitions chosen and the fee levels set in all policy options, including Option 3, fail to produce a healthy outcome for NCAs and therefore for the network as a whole. Like Option 2, Option 3 causes uncertainty and unpredictability. For human medicines NCA fee income for Renewals and Variations is replaced by a – from an individual NCA perspective – less predictable higher annual fee. For veterinary medicines NCA fee income for Variations (apart form Line Extensions – where Option 3 compares favourable to Option 1) is replaced by a modest and – from an individual NCA perspective – less predictable annual fee. The raised annual fees will still not offer any financial compensation for real costs of NCAs that fall outside of the definition of EMA-related activities chosen. For a more elaborate analysis of why annual fees as defined in the study are less suitable for compensating individual NCAs for their costs for centralised activities we refer to the HMA comments.

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Question 15: In your opinion, what impact would this policy option have on the ability of your NCA to undertake procedural and additional EMA activities eligible for EMA remuneration compared to the current situation (please refer to the list of additional activities provided in the appendix to the methodology note)?

Additional information: As a general principle the Netherlands supports a reduction of the complexity of the fee system. Option 3 causes two sorts of problems however. Firstly the overall fee income under this policy option for the Dutch medicines agency will drop considerably compared to the current situation and compared to the outcomes of Policy Options 1 and 2. Secondly, it creates a larger risk of imbalance between costs and fee revenue on an individual NCA basis. That is why we cannot support Option 3 as designed and as instrumented with fee amounts. The network is currently struggling to resource centralised activities and any proposal that reduces fees is not acceptable.

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Question 16: Taking these objectives into account, in your opinion, what impact would this policy option have on the likelihood of new medicines being authorised in the EU?

Additional information: See previous answers.

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Question 17: In your opinion, what impact will this policy option have on the availability of medicines in the EU as compared to the impact of other EU policies?

Additional information: See previous answers.

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Question 18: In your opinion, what impact will this policy option have on the financial stability and sustainability of the operation of the EMA and NCAs as a regulatory network?

Additional information: See previous answers. In addition: any option that reduces the fees of the NCAs (all NCAs or a significant number of NCAs doing multiple procedures and procedure-related activities) will result in far less financial stability and sustainability for the NCAs, which will be detrimental to the network and the EU regulatory system as a whole.

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Question 19: Overall, after considering the potential impacts, do you support or oppose this policy option to revise the EMA fee system?

Additional information: See previous answers and our general statement provided as Annex I.

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Question 20: From your perspective, which policy option is most likely to deliver on these objectives (please bear in mind that suboptions are the subject of separate questions)?

Additional information: As explained earlier, none of the policy options presented are likely to deliver on the objectives, most notably not on the objective of fair distribution. Simplification of the system could in itself be attractive, but Policy Option 3 fails to stabilize the system and to make it more sustainable. All policy options suffer from the same methodological weaknesses in their design, most notably the failure to account for horizontal and non-procedure based costs that NCAs incur for their role in EMA-related activities, as explained in previous answers. This problem is not in any way offset by the fee levels as presented in the fee grids.

POLICY SUB-OPTIONS FOR VETERINARY MEDICINES ONLY

Question 21: From your perspective, which policy sub-option is most likely to deliver on these objectives?
Question 22: The proposed general fee reduction is 50% of the full fee. In your view, is this the appropriate level?
Question 23: How do the veterinary medicines incentives implemented in the study model for the centralized system compare to incentives applied for veterinary medicines at national level in your Member State?

Additional information: The boxes 'Not applicable' have been ticked for questions 21-23 because these question are difficult to answer how they are phrased. The Netherlands is of the opinion that it is highly doubtful if a 50% general reduction can be upheld on the basis of the real costs for veterinary procedures. Any incentives that may be needed (See sub-option c) should be financially compensated by the EMA/European Commission. This burden cannot be bared by NCAs.
The Netherlands has no national incentive scheme in place outside of scientific advice for small academic groups. This incentive has so far never been applied to veterinary requests.

POLICY SUB-OPTION FOR THE DISTRIBUTION OF INCENTIVES BETWEEN EMA AND NCAS

Question 24: From your perspective, does this policy sub-option deliver on these objectives?

Additional information: As long as none of the policy options provides an NCA share in the EU budget contribution that compensates EMA for the financial shortfall caused by incentives and also no other compensating mechanisms are set in place, the Netherlands is of the view that the incentives should be funded from the EU budget contribution and not the NCA remuneration. See also our general statement provided as Annex I.

POLICY SUB-OPTION FOR A 'LIGHT' VERSION OF OPTION 3

Question 25: From your perspective, which version of option 3 best delivers on these objectives?

Additional information: As presented before, we do not think that either version of option 3 is feasible. Although post-authorisation fees that are removed seem to have been offset by an increase in the annual fee, the increase is minimal for the NCAs and there is no match (because NCAs have different portfolios of centralised products and thus annual fees) between the work carried out by an individual NCA and the uplift in the annual fees they receive. This model only works where the uplift in annual fees

in total matches the costs absorbed into the annual fee. While this works for the EMA who receives an annual fee for all centralised products, it does not work at NCA level where a significant mismatch will exist.

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Question 26: In your opinion, what impact would the application of a country coefficient (i.e. an adjustment linked to real salary costs and cost of living in each Member State) have on the ability of your NCA to undertake EMA activities?

Additional information: The Netherlands supports the position taken by the HMA in its response to the inception impact assessment. In that response it was stated that the introduction of a country co-efficient was not supported. This position is unchanged. Key issues include that it devalues the contribution of low cost countries, which also may be less experienced, and will act as a disincentive for those countries becoming more involved in the network, which is necessary due to the shortage of resources already identified within the network. Another key issue is that the fee should be for services provided by the best available expertise regardless where that expertise is located. A country coefficient also introduces an economical factor into a decision that should be founded on scientific grounds. Please also refer to our general statement provided as Annex I.

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Question 27: Please select the impacts that you foresee for your NCA as a result of applying a country coefficient to your NCA's remuneration

Additional information: Please see our additional information provided for question 26.

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Question 28: In your opinion, does the list of procedures presented in the fee grid capture all EMA procedures?

Additional information: The problem is not that procedures are missing in the fee grids but that the projected general compensation for horizontal and cross-network activities that NCAs perform in support of the centralised part of the system is highly inadequate, while EMA is 100% compensated for these costs. EMA cannot function without NCA support for their horizontal and cross-network activities.

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Question 29: In your opinion, what indicators should be monitored in respect of each objective of the EMA fee system, in particular in view of future amendments to the fee system?
Question 30: With what frequency should the indicators that you have selected be monitored?

Additional information: The Netherlands is of the opinion these questions cannot be answered at present. First, in our view all of the options including their underlying fee and remuneration grids presented here are so weak and fail to address fundamental issues that have been raised during the evaluation phase, that it would be misleading to go into details as requested in these two questions. Clearly outlined updated options and amended set of fee grids actually addressing all problems raised are needed before any decision can be taken on which indicators are best suited to monitor the performance of the fee system in regards its objectives.