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

Below is a summary of your responses

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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: emafeesystem_study@icf.com.

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:

Par Tellner

Email:

par.tellner@efpia.eu

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 association you represent

- ○ Healthcare association
- ○ Patient association
- ○ Consumer association
- ◉ **Pharmaceutical association**
- ○ Veterinary association
- ○ Other - please specify

What is the scope of your expertise/interest?

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

What is the name of your organisation?

European Federation of Pharmaceutical Industries and Associations (EFPIA)

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.

38526121292-88

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.

The options may not fully address necessary improvements EFPIA previously raised (e.g. administrative complexity, adapting to regulatory science advances, future proofing). We do not believe that fees should be introduced for orphan and paediatric regulatory activities. While understanding DARWIN EU's potential benefits, we have reservations with the proposed funding approach (see attached paper).

Characters remaining: 0

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.

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

In your opinion, what impact would this policy option for legislative action have on your organisation and/or those groups represented by your organisation?

- ○ Very positive – this option will be very beneficial for my organisation and/or the groups my organisation represents
- ○ Somewhat positive – this option will be beneficial for my organisation and/or the groups my organisation represents
- ○ No impact – this option will be neither beneficial or nor disadvantageous for my organisation and/or the groups my organisation represents as under the 'do minimum' scenario
- ◉ **Somewhat negative – this option will be disadvantageous for my organisation and/or the groups my organisation represents**
- ○ Very negative – this option will be very disadvantageous for my organisation and/or the groups my organisation represents
- ○ Do not know
- ○ Not applicable

Please name or describe the impacts on your organisation and/or those you represent:

As described in IA, EFPIA considers that Option 1 will have limited impact on innovative human medicine procedures or procedural fees other than new fees applied from 2024 to support the recent proposal for a reinforced role of EMA. Option 1 would not address resource requirements to support any increased regulatory procedural activities.

Characters remaining: 60

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:

As described in IA, EFPIA considers that Option 1 will have limited impact on innovative human medicine procedural fees other than new fees applied from 2024 to support the recent proposal for a reinforced role of EMA.

Characters remaining: 182

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:

As described in IA, EFPIA considers that Option 1 will have limited impact on innovative human medicine procedural fees other than new fees applied from 2024 to support the recent proposal for a reinforced role of EMA.

Characters remaining: 182

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:

As described in IA, EFPIA considers that Option 1 will have limited impact on innovative human medicine procedural fees other than new fees applied from 2024 to support the recent proposal for a reinforced role of EMA.

Characters remaining: 182

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):

EFPIA believes that changes to the fee structure should be based on a comprehensive, transparent and independent evaluation of the underlying costs of the services provided, projections of future developments, and strengths and weaknesses of the current system. As Option 1 does not seem to address cost-based human medicines fees, for this and other reasons, EFPIA does not support it.

Characters remaining: 14

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.

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

In your opinion, what impact would this policy option for legislative action have on your organisation and/or those groups represented by your organisation?

- ○ Very positive – this option will be very beneficial for my organisation and/or the groups my organisation represents
- ○ Somewhat positive – this option will be beneficial for my organisation and/or the groups my organisation represents
- ○ No impact – this option will be neither beneficial or nor disadvantageous for my organisation and/or the groups my organisation represents as under the 'do minimum' scenario
- ◉ **Somewhat negative – this option will be disadvantageous for my organisation and/or the groups my**

organisation represents

- Very negative – this option will be very disadvantageous for my organisation and/or the groups my organisation represents
- Do not know
- Not applicable

Please name or describe the impacts on your organisation and/or those you represent:

While noting that Option 2 would introduce welcomed cost-based approaches, as previously mentioned, EFPIA does not support the addition of fees for paediatric and orphan products. Also, while understanding DARWIN EU's potential benefits, EFPIA has reservations with the proposed funding approach. Option 2 would also not adequately address the needed simplification to the EMA fee system.

Characters remaining: 11

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:

With cost-based analyses, fees should be recalculated at least annually based on the inflation rate and workload with expected efficiency gains, and the resulting assessment should be communicated for public consultation. In EFPIA's opinion, efficiencies and appropriate regulator resourcing based on cost-based fees could result in a slightly positive effect on authorisation timelines.

Characters remaining: 13

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:

As previously mentioned, in EFPIA's opinion, efficiencies gained from introducing a more transparent, cost-based approach to fees calculations could result in a somewhat positive effect on authorisation timelines and thus speed of availability. A cost-based approach should enable better resourcing.

Characters remaining: 101

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:

As previously mentioned, in EFPIA's opinion, the cost-based approach to fees calculations and NCA remuneration should allow for better reflections of actual EMA and NCA costs. A cost-based approach should enable better resourcing.

Characters remaining: 170

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):

EFPIA considers that the fee system has become increasingly complex since its introduction and does not believe that

Option 2 adequately addresses the Commission's objective of "(a)chieving a simplification of the system". EFPIA does not believe that fees should be introduced for orphan and paediatric regulatory activities and has key reservations with the proposed DARWIN EU funding approach.

Characters remaining: 5

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.

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

In your opinion, what impact would this policy option for legislative action have on your organisation and/or those groups represented by your organisation?

- ○ Very positive – this option will be very beneficial for my organisation and/or the groups my organisation represents
- ◉ **Somewhat positive – this option will be beneficial for my organisation and/or the groups my organisation represents**
- ○ No impact – this option will be neither beneficial or nor disadvantageous for my organisation and/or the groups my organisation represents as under the 'do minimum' scenario
- ○ Somewhat negative – this option will be disadvantageous for my organisation and/or the groups my organisation represents
- ○ Very negative – this option will be very disadvantageous for my organisation and/or the groups my organisation represents
- ○ Do not know
- ○ Not applicable

Please name or describe the impacts on your organisation and/or those you represent:

Overall, Option 3 would have a somewhat positive effect by reducing the number of procedural fees in some areas while broadening the CAP annual fee, although this may result in increased company costs depending on the CAP annual fee approach finally implemented. EFPIA does not support new fees for paediatric and orphan activities and has reservations for the proposed DARWIN EU funding approach.

Characters remaining: 2

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:

EFPIA supports a simpler, broader CAP fee which would free EMA resources previously administering a complex fee system. A cost-based approach should also enable better resourcing of EMA. As a result, resources could be redirected to advancing implementation of the EMA's regulatory science strategy and infrastructure, which should result in a somewhat positive effect on authorisation timelines.

Characters remaining: 3

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:

In EFPIA's opinion, efficiencies gained from introducing a more cost-based approach to fees calculations could result in a somewhat positive effect on authorisation timelines and thus the timeline of availability on the market. Perhaps, some of the resources conserved through these efficiency gains could be directed towards infrastructure expenditures such as for DARWIN EU maintenance costs.

Characters remaining: 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?

- (●) **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:

As previously mentioned, in EFPIA's opinion, the cost-based approach to fees calculations and NCA remuneration should allow for better reflections of actual EMA and NCA costs. A cost-based approach should enable better resourcing of EMA. In addition, under Option 3, the broader CAP annual fees should provide more stable and predictable income.

Characters remaining: 54

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):

EFPIA supports a cost-based approach to fees calculations and simplification of post-authorisation procedural fees by broadening the scope of the CAP annual fee. However, EFPIA does not believe that fees should be introduced for orphan and paediatric regulatory activities. Additionally, EFPIA has important reservations with the proposed DARWIN EU funding approach (see attached paper).

Characters remaining: 13

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,:

EFPIA considers that Option 3 is most consistent with its principles and position for improving EMA fees, but would need to evaluate precise details for implementation before providing full support. We reiterate our concerns with orphan and paediatric fees and the DARWIN EU funding approach. Finally, it is unclear how Agency resources conserved by administrative simplification would be redirected.

Characters remaining: 0

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**

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:

Adequate and appropriate funding of the EMA and NCAs is essential to support the effective operation of the European Medicines Regulatory Network and to ensure public health. However, EFPIA does not offer comment on the sub-options presented within the IA related to renumeration and distribution of budget between EMA and NCAs since this is a matter for agreement between the Agencies concerned.

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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

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

Fees for Type IA/IAIN and IB variations are relatively low, but these variations numerically comprise the majority of submissions made to EMA that attract a fee. EFPIA considers that Option 3 “light” would offer predictable and equitable fee structure which significantly reduces the administrative fee processing burden, while supporting the appropriate level of regulatory oversight.

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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.

EFPIA additional note on EMA fees impact assessment_final draft.docx

52.3 KB

application/vnd.openxmlformats-officedocument.wordprocessingml.document

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

EFPIA welcomes the opportunity to offer comment on the EU Commission’s IA. EFPIA considers that the scope of questions was fit-for-purpose for offering these preliminary comments on the Options and additional supportive file.

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