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Study supporting the Evaluation of the European Medicines Agency Fee System

Fields marked with * are mandatory.

I. Introduction

The European Medicines Agency (EMA) is the European Union's (EU) central regulatory body operating centralised pre-authorisation and post-authorisation procedures for medicinal products for human and veterinary use across the EU and the European Economic Area (EEA). The Agency is funded by EU and EEA contributions as well as fees paid by industry for obtaining and maintaining marketing authorisations and providing other services. The EMA works in close collaboration with national competent authorities (NCAs) in EU and EEA Member States. NCAs are represented in the EMA committees and in this setting they carry out assessments of medicinal products for human and veterinary use in the context of EU marketing authorisations. Other activities related to centrally-authorised medicinal products are also undertaken, including pharmacovigilance activities at EU level. NCAs receive remuneration by the EMA for activities for centralised procedures at EU level.

The EMA fee system is set up by (Council Regulation (EC) No 297/95 and Regulation (EU) No 658/2014) and implementing arrangements. It provides fee incentives for specific types of products (including medicines for rare diseases, medicines for children, advanced therapies, and veterinary medicines for minor use/minor species) and specific applicants and marketing authorisation holders such as micro, small and medium-sized enterprises (SMEs).

This public consultation is part of a study supporting the evaluation of the EMA fee system. The consultation aims to elicit information, views and concerns of all groups having an interest in the EMA fee system and its implementation, including the remuneration to NCAs. In particular, it seeks to gather input from groups having experience with the fee and remuneration system on its effectiveness and efficiency, relevance, coherence and sustainability.

Your input will help the study team to assess the extent to which the current fee and remuneration system is cost-based, fair, proportionate and not unduly complex. It will complement information from other sources, particularly time and cost data provided by the EMA and NCAs, insights gained from EMA and NCA representatives as well as views provided by wider stakeholders, covering European level industry, research, healthcare, patient, consumer and other relevant associations and representative groups.

You can contribute to this public consultation by filling in the online questionnaire below. The questionnaire is available in English, French and German, and responses can be submitted in any EU language.

The final question of the questionnaire allows you to upload one supplementary document (max. 2 pages).

Please **only** include any personal data or any other information that can lead to your direct identification in your replies **where specifically requested in the questionnaire**. Please **do not** enter such data in any of your other replies, in particular in the free text boxes of the questionnaire. See further the privacy statement attached to this consultation for information on how your personal data and contribution will be dealt with.

*[NOTE: * represents questions that are mandatory for the respondent]*

II. About you

*** 1. Publication of your contribution**

Note that, whatever option chosen, your answers may be subject to a request for public access to documents under Regulation (EC) No 1049/2001.

- (●) **My contribution can be published with my personal information** (I consent the publication of all information in my contribution in whole or in part including my name or my organisation's name, and I declare that nothing within my response is unlawful or would infringe the rights of any third party in a manner that would prevent publication).
- ( ) **My contribution can be published only without my identification and contact details** (i.e. name, surname and e-mail address) (I consent to the publication of any information in my contribution in whole or in part (which may include quotes or opinions I express) provided that it is done without publishing my name, surname and e-mail address. I declare that nothing within my response is unlawful or would infringe the rights of any third party in a manner that would prevent the publication).

2. Please provide your:

* First name:

Christiane

* Last name:

Abouzeid

* E-mail address (Your e-mail address is needed in case we have questions about your reply and need to ask for clarifications. If you do not have an email address or do not wish to be contacted by us for further clarifications, please write "Not available").

*Please write your **full** email address in the field below.*

cabouzeid@bioindustry.org

*** 3. You are welcome to answer the questionnaire in any of the 24 official languages of the EU. Please indicate in which language you are replying**

- ( ) Bulgarian

- Croatian
- Czech
- Danish
- Dutch
- (•) English
- Estonian
- Finnish
- French
- Gaelic
- German
- Greek
- Hungarian
- Italian
- Latvian
- Lithuanian
- Maltese
- Polish
- Portuguese
- Romanian
- Slovak
- Slovenian
- Spanish
- Swedish

*** 4. You are replying as a(n)**

- Individual citizen in your personal capacity
- Member of a central government/ministry or public authority at national or regional level in a Member State or the EEA
- Member of a central government or public authority at EU level
- Member of an inter-governmental organisation
- Member of a non-governmental organisation (NGO)
- Member of a civil society organisation
- (•) Member of a representative organisation
- Member of a Member State/EEA medicine regulation agency
- Member of a non-EU medicine regulation agency
- Member of a think-tank/consultancy
- Member of a research organisation/academic institution
- Representative of a company with direct relevance to the EMA (e.g. pharmaceutical company)
- Representative of a company with no direct relevance to the EMA
- Legal professional
- Other

Type of organisation:

- Healthcare organisation
- Patient association
- Consumer association

- (●) Other representative group/organisation

Please specify:

200 character(s) maximum

The BioIndustry Association (BIA) is the trade association for innovative UK life science enterprises. Members including emerging and established biotech companies and pharmaceutical companies.

*** 5. Is your organisation included in the Transparency Register?**

[If you do not respond as a representative of an organisation, please click 'Not applicable']

If your organisation is not registered, we invite you to register here, although it is not compulsory to be registered to reply to this consultation. Please also read: Why a transparency register?

- ( ) Yes
- (●) No
- ( ) Not applicable

*** 6. Country of your residence**

- ( ) Austria
- ( ) Belgium
- ( ) Bulgaria
- ( ) Croatia
- ( ) Cyprus
- ( ) Czech
- ( ) republic
- ( ) Denmark
- ( ) Estonia
- ( ) Finland
- ( ) France
- ( ) Germany
- ( ) Greece
- ( ) Hungary
- ( ) Iceland
- ( ) Ireland
- ( ) Italy
- ( ) Latvia
- ( ) Liechtenstein
- ( ) Lithuania
- ( ) Luxembourg
- ( ) Malta
- ( ) Netherlands
- ( ) Norway
- ( ) Poland
- ( ) Portugal
- ( ) Romania
- ( ) Slovakia

- Slovenia
- Spain
- Sweden
- (●) United Kingdom
- Other

***7. Country of your organisation's headquarters**

[If you do not respond as a representative of an organisation, please click 'Not applicable']

- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czech republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Italy
- Latvia
- Liechtenstein
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Norway
- Poland
- Portugal
- Romania
- Slovakia
- Slovenia
- Spain
- Sweden
- (●) United Kingdom
- Other
- Not applicable (responding as an individual citizen)

III. Awareness

This part of the questionnaire aims to assess the extent to which you are familiar with the European Medicines Agency, and specifically the EMA fee system.

*** 8. To what extent are you familiar with the EMA?**

- (●) 1 – I am very familiar with the EMA
- ( ) 2 – I am familiar with the EMA
- ( ) 3 – I am not very familiar with the EMA
- ( ) 4 – I am not at all familiar with the EMA

*** 9. To what extent are you familiar with the EMA fee system for medicinal products?**

- (●) 1 – I am very familiar with the EMA fee system
- ( ) 2 – I am familiar with the EMA fee system
- ( ) 3 – I am not very familiar with the EMA fee system
- ( ) 4 – I am not at all familiar with the EMA fee system

*** 10. Have you ever had direct contact or engagement with the EMA?**

- (●) Yes
- ( ) No
- ( ) Do not know

* If yes, please specify:

- [ ] As an employee/former employee of the EMA
- [ ] As a representative of an EU medicines regulatory agency
- [x] As a representative of a pharmaceutical company
- [ ] As an academic / researcher
- [x] Other

Please specify:

200 character(s) maximum

As representative of an European industry association

IV. Experience

11. To what extent do you agree with the following statements related to the EMA fee system for medicinal products?

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree	Do not know
* The EMA fee system rules are clear and easy to understand	( )	( )	(●)	( )	( )	( )
* The operation of the EMA fee system is transparent	( )	(●)	( )	( )	( )	( )

* The EMA fee system rules are easy to apply in practice	○	○	◉	○	○	○
* The EMA fee system reflects the overall costs of the services charged for	○	○	◉	○	○	○
* The EMA fee system provides adequate incentives and support (e.g. SMEs, orphan, paediatric, advanced therapy medicinal products, veterinary medicines for minor use/minor species, academia)	○	◉	○	○	○	○

Note: Any additional comments to your reply can be provided under Question 16.

12. For the next set of questions, please consider how the EMA fee system compares to the fee system for medicinal products in the following countries.

12. 1. Thinking first about the EMA fee system for medicinal products compared to the fee system of the Food and Drug Administration in the United States:

* Considering the clarity of the rules of each fee system:
- ○ The EMA fee system rules are clearer and easier to understand than those of the U.S. fee system.
- ○ The EMA fee system rules and the U.S. system's rules are comparably clear and easy to understand.
- ◉ The U.S. fee system rules are clearer and easier to understand than those of the EMA fee system.
- ○ Do not know

* Considering the transparency of each fee system:
- ○ The EMA fee system is more transparent than the U.S. fee system.
- ◉ The EMA fee system and the U.S. fee system are comparably transparent.
- ○ The U.S. fee system is more transparent that the EMA fee system.
- ○ Do not know

* Considering the ease of applying the rules in practice for each fee system:
- ○ The EMA fee system rules are easier to apply in practice than those in the U.S. fee system.
- ○ The EMA fee system and the U.S. fee system have rules that are comparably easy to apply in practice.
- ◉ The U.S. fee system rules are easier to apply in practice than those in the EMA fee system.
- ○ Do not know

* Considering the extent to which each fee system is cost-based:
- ◉ The EMA fee system is more cost-based than the U.S. fee system.
- ○ The EMA fee system and the U.S. fee system are comparably cost-based.
- ○ The U.S. fee system is more cost-based than the EMA fee system.
- ○ Do not know

* Considering the appropriateness of the incentives provided by each fee system (e.g. SMEs, orphan, paediatric, advanced therapy medicinal products, veterinary medicines for minor use/minor species, academia):

- (●) The EMA fee system provides more appropriate incentives than the U.S. fee system.
- ( ) The EMA fee system and the U.S. fee system provide comparably appropriate incentives.
- ( ) The U.S. fee system provides more appropriate incentives than the EMA fee system.
- ( ) Do not know

Note: Any additional comments to your reply can be provided under Question 16.

12.2. Thinking next about the EMA fee system for medicinal products compared to the fee system of the Pharmaceuticals and Medical Devices Agency in Japan:

* Considering the clarity of the rules of each fee system:

- ( ) The EMA fee system rules are clearer and easier to understand than those of the fee system in Japan.
- (●) The EMA fee system rules and the fee system rules in Japan are comparably clear and easy to understand.
- ( ) The fee system rules in Japan are clearer and easier to understand than those of the EMA fee system.
- ( ) Do not know

* Considering the transparency of each fee system:

- ( ) The EMA fee system is more transparent than the fee system in Japan.
- (●) The EMA fee system and the fee system in Japan are comparably transparent.
- ( ) The fee system in Japan is more transparent that the EMA fee system.
- ( ) Do not know

* Considering the ease of applying the rules in practice for each fee system:

- ( ) The EMA fee system rules are easier to apply in practice than those in the fee system in Japan.
- ( ) The EMA fee system and the fee system in Japan have rules that are comparably easy to apply in practice.
- (●) The fee system rules in Japan are easier to apply in practice than those in the EMA fee system.
- ( ) Do not know

* Considering the extent to which each fee system is cost-based:

- (●) The EMA fee system is more cost-based than the fee system in Japan.
- ( ) The EMA fee system and the fee system in Japan are comparably cost-based.
- ( ) The fee system in Japan is more cost-based than the EMA fee system.
- ( ) Do not know

* Considering the appropriateness of the incentives provided by each fee system (e.g. SMEs, orphan, paediatric, advanced therapy medicinal products, veterinary medicines for minor use/minor species, academia):

- (●) The EMA fee system provides more appropriate incentives than the fee system in Japan.
- ( ) The EMA fee system and the fee system in Japan provide comparably appropriate incentives.
- ( ) The fee system in Japan provides more appropriate incentives than the EMA fee system.
- ( ) Do not know

Note: Any additional comments to your reply can be provided under Question 16.

12.3. Thinking next about the EMA fee system for medicinal products compared to the system of Health Canada in Canada:

* Considering the clarity of the rules of each fee system:
- ○ The EMA fee system rules are clearer and easier to understand than those of the fee system in Canada.
- ◉ The EMA fee system rules and the fee system rules in Canada are comparably clear and easy to understand.
- ○ The fee system rules in Canada are clearer and easier to understand than those of the EMA fee system.
- ○ Do not know

* Considering the transparency of each fee system:
- ○ The EMA fee system is more transparent than the fee system in Canada.
- ◉ The EMA fee system and the fee system in Canada are comparably transparent.
- ○ The fee system in Canada is more transparent that the EMA fee system.
- ○ Do not know

* Considering the ease of applying the rules in practice for each fee system:
- ○ The EMA fee system rules are easier to apply in practice than those in the fee system in Canada.
- ○ The EMA fee system and the fee system in Canada have rules that are comparably easy to apply in practice.
- ◉ The fee system rules in Canada are easier to apply in practice than those in the EMA fee system.
- ○ Do not know

* Considering the extent to which each fee system is cost-based:
- ○ The EMA fee system is more cost-based than the fee system in Canada.
- ◉ The EMA fee system and the fee system in Canada are comparably cost-based.
- ○ The fee system in Canada is more cost-based than the EMA fee system.
- ○ Do not know

* Considering the appropriateness of the incentives provided by each fee system (e.g. SMEs, orphan, paediatric, advanced therapy medicinal products, veterinary medicines for minor use/minor species, academia):
- ◉ The EMA fee system provides more appropriate incentives than the fee system in Canada.
- ○ The EMA fee system and the fee system in Canada provide comparably appropriate incentives.
- ○ The fee system in Canada provides more appropriate incentives than the EMA fee system.
- ○ Do not know

Note: Any additional comments to your reply can be provided under Question 16.

12.4. Thinking next about the EMA fee system for medicinal products compared to the system of the Therapeutic Goods Administration in Australia:

* Considering the clarity of the rules of each fee system:
- ◉ The EMA fee system rules are clearer and easier to understand than those of the fee system in Australia.
- ○ The EMA fee system rules and the fee system rules in Australia are comparably clear and easy to understand.
- ○

The fee system rules in Australia are clearer and easier to understand than those of the EMA fee system.

- ○ Do not know

* Considering the transparency of each fee system:

- ○ The EMA fee system is more transparent than the fee system in Australia.
- ◉ The EMA fee system and the fee system in Australia are comparably transparent.
- ○ The fee system in Australia is more transparent that the EMA fee system.
- ○ Do not know

* Considering the ease of applying the rules in practice for each fee system:

- ○ The EMA fee system rules are easier to apply in practice than those in the fee system in Australia.
- ◉ The EMA fee system and the fee system in Australia have rules that are comparably easy to apply in practice.
- ○ The fee system rules in Australia are easier to apply in practice than those in the EMA fee system.
- ○ Do not know

* Considering the extent to which each fee system is cost-based:

- ○ The EMA fee system is more cost-based than the fee system in Australia.
- ○ The EMA fee system and the fee system in Australia are comparably cost-based.
- ◉ The fee system in Australia is more cost-based than the EMA fee system.
- ○ Do not know

* Considering the appropriateness of the incentives provided by each fee system (e.g. SMEs, orphan, paediatric, advanced therapy medicinal products, veterinary medicines for minor use/minor species, academia):

- ◉ The EMA fee system provides more appropriate incentives than the fee system in Australia.
- ○ The EMA fee system and the fee system in Australia provide comparably appropriate incentives.
- ○ The fee system in Australia provides more appropriate incentives than the EMA fee system.
- ○ Do not know

Note: Any additional comments to your reply can be provided under Question 16.

*** 13. In your experience, have you ever encountered difficulties related to the EMA fee system for medicinal products?**

- ◉ Yes
- ○ No
- ○ Do not know
- ○ Not applicable

If yes, please indicate the areas where you experienced difficulties (multiple choice possible):

- ☐ Lack of transparency of the fee system (rules and/or implementation).
- ☑ Complexity of the fee system.
- ☑ Misalignment between fees charged and services provided.
- ☑ Lack of flexibility of the fee system
- ☐ Insufficient focus on the needs of particular users (e.g. SMEs, orphan medicinal products, paediatric medicinal products, ATMPs, academia)
- ☐ Other

Please explain the difficulties you have experienced with respect to the complexity of the fee system:

1000 character(s) maximum

The following are examples of where the fee system can be complex.

For product X, a member company had 5 strengths of tablets and blister packs of 14, 56 and 3x56 tablets, and 100 single unit dose tablets. A variation was submitted to add a pack of 14 single unit dose tablets and the company was required to pay a variation fee for each strength. The blisters were of the same material and the same stability data applied to all blisters. It only required one review of one submission so it is unclear why each strength attracted a fee.

For a grouping or worksharing, a company needs to check with EMA beforehand on the appropriateness of the grouping and to obtain a special procedure number in advance of filing.

Please explain the difficulties you have experienced with respect to the misalignment between fees charged and services provided:

1000 character(s) maximum

The following are examples of where the fees charged and the service provided are misaligned.

With regard to the transfer of a marketing authorisation, the process is administrative and so the fee should reflect this; it should be closer to Type IA fee and not Type IB.

For grouped variations containing multiple type II and related Type IA/IB variations (for example a new indication with a new dosing device and a new pack to include the new device), each variation attracts a fee and yet it is typically the same data package under review for the entire variation.

Worksharing administrative fees for Type II variations are relatively high.

Please explain the difficulties you have experienced with respect to the lack of flexibility of the fee system:

1000 character(s) maximum

The following is an example of where the fee system lacks flexibility.

With regard to a GMP inspection of a member company, originally it was planned that the inspection would cover three products. However, the company advised the EMA that the process to be inspected was no longer performed at the site, in accordance with an approved CMC variation, and that the Agency should remove that one product from the inspection. The EMA insisted that the fee for all three products should be paid.

*** 14. Based on your experience, have you ever had a need for a dispute settlement procedure between the EMA and industry?**

- ○ Yes
- ◉ No
- ○ Do not know

- ○ Not applicable

*** 15. For a typical year for your organisation, please indicate what is the proportion of your total annual expenditure on EMA fees of, respectively, pre-authorisation fees (i.e. scientific advice and initial marketing authorisation) and post-authorisation fees (e.g. variation, extension, renewal, pharmacovigilance procedure, annual fee)**

- ○ The percentages of pre-authorisation fees and post-authorisation fees are as follows:
- ◉ Do not know
- ○ Not applicable

V. Document upload and final comments

16. If you wish to provide additional comments or information within the scope of this questionnaire, including possible recommendations, please do so here.

2000 character(s) maximum

We would like to provide some additional proposals and recommendations.

Annual maintenance fee to optimise product lifecycle management
We would like the Commission, along with EU regulators and industry associations, to explore whether the introduction of an annual maintenance fee would be appropriate and what activities such a fee would cover. A maintenance fee could be required per marketing authorisation and could be applied to all marketing authorisation holders. An analysis of the appropriateness of a maintenance fee could help to determine whether this approach will reduce administration for both the regulators and applicants so that resources can be targeted to more value-add activities.

Pharmacovigilance (PV) and safety related changes
Applicants do have a responsibility to protect patients and to contribute to the pharmacovigilance system. However, where a submission is the result of an obligation, e.g., under a post approval measure, then a reduced fee should be considered. Given that PV activities are core to the European Union's role in protecting public health there is an expectation that significant funding would come from the Union.

Products that have been on the market for more than 10 years
Consideration should be given to reducing the fee for a product that has been on the market 10+ years after which timeframe there is likely to be less regulatory activity. This reduction could be applied to both the originator and generic products.

17. If you wish to provide additional supporting information within the scope of this questionnaire you may also upload a document, such as a position paper, related to your responses (max. 2 pages):

The maximum file size is 1 MB

Please note that the uploaded document will be published alongside your response to the questionnaire which is the essential input to this open public consultation. The document is an optional complement and serves as additional information to better understand your position.

Contact

EMA-fees-eval@RAND.org