Study supporting the Impact Assessment of the Revision of the EMA Fee System

SANTE/2019/B5/043

Methodology note to support the targeted consultation

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Contact: EMA Fees Team

E-mail: SANTE-EMA-FEES@ec.europa.eu

European Commission
B-1049 Brussels

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1. INTRODUCTION

This is a methodology note to support the targeted consultation as part of the 'Study supporting the Impact Assessment of the Revision of the EMA Fee System'. The methodology note provides information about the financial modelling undertaken as part of the study. It is intended to be read alongside the targeted stakeholder survey questionnaire, which presents preliminary modelling results for a set of options to support potential revisions to the Fee System.[1]

This document provides:

- A brief overview of the approach to the financial modelling and how the model is used in the current study;
- An explanation of the key elements of the updated model;
- Details regarding implementation of the policy options in the model; and
- A summary of the key input data used in the modelling.

The financial modelling used in the current study builds on a model (hereafter, the '2016 model') developed for the 'Study for the Evaluation of the Fee System' conducted on behalf of the European Commission, Directorate General for Health and Food Safety (DG SANTE).In the following sections, only the key elements of the financial model and the extensions that have been made to support the impact assessment are presented. More details are provided in Appendix 1 to this report.[2]

The results of the financial modelling presented in the targeted consultation are based on the data, assumptions and implementation of the policy options outlined in this document. These may be amended after the targeted consultation following analysis of the feedback received.

2. MODEL OVERVIEW

2.1. Financial model

The financial model is designed to calculate cost-based fees and to quantify the impact of different options for the revision of the Fee System on the costs and/or revenues of stakeholders. It is not intended to replicate the financial accounting systems of stakeholders. It also does not and cannot take account of the impact of the timing of payments on stakeholders. In practice, this means that the model considers that for all EMA procedures started in a given year the fee is levied and the remuneration is paid, as relevant, during the same year.

The financial model consists of two parts:

[1] This is a preliminary output developed for the purposes of testing policy options for potential changes to the legislation pertaining to the EMA fee system. It is not intended for wider public release.

[2] Further information is available in the detailed methodology note for the 2016 model that was provided as a formal deliverable alongside the final report. Available at: https://ec.europa.eu/health/sites/default/files/files/fees/evaluation_ema_fee_methodology_en.pdf

a) A **cost** model of the costs for NCAs to undertake EMA activities and for EMA to undertake its activities (NCA costs for other, non EMA activities are not included).

- A **costing methodology** was developed to calculate costs for all procedural activities undertaken by EMA and NCAs using information on salary costs, overhead costs and direct non-staff costs, time spent on individual activities and the numbers of activities undertaken. In this approach costs are allocated to one 'average scientific staff type' and one 'average administrative staff type' only in each organisation. This is explained in more detail in Appendix 1.

- Other costs are included in the model as inputs. Costs for horizontal activites undertaken by EMA are provided by EMA. Costs for eligible additional activities undertaken by NCAs have also been calculated separately (see Appendix 2).

b) A **revenue** model of the remuneration income that NCAs receive from EMA for the eligible EMA scientific activities they undertake, and the share of total net fee revenue that EMA retains (i.e. EMA fee income), as well as the European Union (EU) / European Economic Area (EEA) budget contributions to the EMA budget. [3]

- NCA income in this model consists of the payments for scientific work they receive from EMA[4] (NCA income from other sources, such as national fees or national budget contributions was not included).

- EMA fee income consists of the fee revenue it receives less the payments NCAs receive from EMA (remuneration). The fees paid by the pharmaceutical industry enter the model as the total fee revenue that is received by EMA. This revenue is net of incentives that are applied to fees for some activities and/or organisations.[5]

Two rules are implemented in the model:

a) A **fee rule** that establishes the unitary EMA fees. Such fees are calculated by the model under each **option**, taking into account the estimated cost of EMA and NCAs and the frequency of procedures. The model takes into account the EU budget contribution and implements the budgetary principle that all revenues cover all costs for EMA. EMA fee income depends on the fee rules and the incentives that are applied to the fees. For the **do-minimum**, the unitary fees are inputs to the model rather than calculated by the model and updated by inflation for future years.

b) An **NCA remuneration rule** that establishes NCA unitary remuneration for eligible EMA activities. Such remuneration is calculated by the model under each **option**, taking into account the estimated NCA costs for such activities. For the **do-minimum**, remuneration is based on the existing fee system.[6] NCA income depends on the remuneration rule. EMA net fee income after making payments to

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[3] In any year EMA may receive miscellaneous revenue from outstanding invoices, staffing changes and minor corrections. As this revenue is small (circa €370,00 p.a.) and difficult to forecast, it has not been included in the model.

[4] Reimbursement of travel and hotel costs, the travel allowance in case of arrival/departure outside of the meeting days and the daily allowance for each day of the meeting are not included as these are transfers from EMA to NCAs (and would be included in both the cost and revenue sides of the model for NCAs).

[5] Incentives are targeted reductions applied to unitary fees.

[6] Please see Appendix 1 for more explanation of the existing system.

NCAs also depends on the remuneration rule as this rule determines the EMA costs for remuneration to NCAs for scientific services.

In the model, costs and income associated with an activity are assumed to occur within the same year and are presented as yearly totals.

2.2. Model scope

In order to support the impact assessment of the revision of the fees system, the financial model for the current study extends the 2016 evaluation model[7] in a number of ways.

Firstly it takes account of changes to the existing fee system that have been implemented since the 2016 model and changes in legislation, in particular the forthcoming Veterinary Medicines Product (VMP) Regulation that come into force from 2022 and the changes to the EMA Founding Regulation. It also takes account of the proposed Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (hereinafter called proposal for EMA reinforced role). The financial statement of that proposal includes three objectives, of which objective 3 has a future impact on EMA fees (relating to EMA as a node in the European Health Data Space, i.e. DARWIN[8]).

In the study the model is used to quantify the impacts of three policy options and a set of sub-options on EMA, NCAs[9] and industry stakeholders. These options were first presented in the Inception impact assessment high level. The options as implemented by the model for this study are described in the survey of the targeted stakeholder consultation, with additional detail of their implementation provided in Section 4 of this document. The options introduce different possibilities for changes to the current EMA fee and remuneration system. The way in which fees are charged and fees and NCA remuneration are calculated are explained in this note.

In order to factor in the impact of the changes related to the Veterinary Medicines Regulation, the EU budget contribution and the proposal for EMA reinforced role separately from the impact of the policy options, a 'do minimum' scenario is also modelled. This scenario represents a continuation of the current system but with the inclusion of new legislation and the proposal for EMA reinforced role and updated EU budget contribution. The impacts of options is thus assessed after taking into account the impact of these changes to the baseline.

Secondly, the list of procedural activities included in the 2016 model has been extended so that procedural fees can be calculated for all procedural activities undertaken by EMA and NCAs, where applicable, as well as annual fees. New or amended activities introduced as a result of the VMP Regulation, the changes to the EMA Founding Regulation and the proposal for EMA reinforced role in relation to EHDS/Darwin have also been included. These apply in the do-minimum scenario and all policy options. The full list of activities included is presented in the fee grid provided for each option on the

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[7] Available at : https://ec.europa.eu/health/sites/default/files/files/fees/evaluation_ema_fee_methodology_en.pdf

[8] See Appendix 4.

[9] The UK Medicines and Healthcare products Regulation Agency (MHRA) and the Veterinary Medicines Directorate (VMD) are not included in the data inputs or model calculations for NCAs. PLEASE REVIEW

dedicated website for this study.[10] Activities for which procedures are not expected to be undertaken every year and the volume is low are designated 'infrequent' activities. This means that unitary fees and remuneration are calculated for these activities but they are not included in the yearly cost and income calculations for EMA and NCAs (see Section 2.3).

In addition, some changes to activities for which procedural fees can be charged are proposed as part of the options. These are explained in Section 4. The list of activites and corresponding data on the forecast number of procedures are provided in Section 5.

Finally, the model has been extended to cover the period 2022 to 2026. This five year period was selected because: i) the VMP Regulation starts to apply in 2022, ii) EMA EHDS node activities under the proposal for EMA reinforced role is expected to be funded through fee income as of 2024 and iii) it balances the need to consider impacts over the MFF budget period against the robustness and reliability of the forecast activity for EMA and NCAs. The existing system was also modelled using data for 2020. This provides fee, cost and revenue data for the fees system before any changes resulting from the VMP Regulation, the EMA Founding Regulation and the proposal for EMA reinforced role are introduced.

2.3. Model outputs

The financial impacts are calculated for each year over a five year period from 2022 to 2026.

For each year, the model generates the EMA costs and NCA costs for EMA activities undertaken. These costs are independent of the fee and NCA remuneration rules and are the same for both the do-minimum scenario and the policy options tested.

The model generates the following outputs, which depend on the fee and NCA remuneration rule applied:

- EMA unitary fees: that is, fees both before and after incentives are applied.
- NCA unitary remuneration (payments from EMA) for EMA eligible activities undertaken;
- EMA yearly fee income, to identify whether the EMA's costs are balanced in the budget by all sources of revenue including the agreed EU/EEA budget contributions;
- Total NCA yearly remuneration (for NCAs undertaking human medicine activities only, veterinary medicine activities only, and both human and veterinary medicine activities' and
- Total yearly fees paid to EMA (EMA fee income).

In the survey, the impacts of the policy options are quantified by comparing percentage changes in these outputs for each year between policy options and with the do-minimum scenario.

Supplementary/supporting data can be found on the dedicated website for this study. These include a detailed fee grid for each option with unit fees, NCA unit remuneration and corresponding incentives applicable for each activity. The fee grids are presented for

[10] http://icfeurope.com/ema-fees-IA-study/

2024. A table with extended EMA budgetary data is also provided for each policy option and each year of the modelling period.

3. KEY ELEMENTS OF THE FINANCIAL MODEL

3.1. Cost model

The cost model includes the costs for EMA to undertake its own activities and costs for NCAs to undertake EMA activities.

EMA costs

EMA costs cover the scientific and administrative work they undertake as part of fee- and non-fee-generating services they provide to industry and other activities, some of which also involve NCAs. They also cover horizontal activities that do not have a specific procedural fee attached.

Costs for scientific and administrative work of EMA staff on procedural activities are calculated using hourly cost data, time taken to complete a procedure and the number of procedures undertaken for each activity. These include paediatric and orphan medicines activities.

Hourly cost data for EMA has been derived from budget forecast data provided to the study team by EMA for 2020 and over the period 2022 to 2026.[11] These costs increase by 5% per annum for labour costs and 2% per annum for non-labour costs in accordance with EMA forecasts.

The numbers of procedures for each activity for each year from 2022 to 2026 have been provided by EMA based on historic data and projections. These are disaggregated by incentive type.

The Management Board Data Gathering (MBDG) exercise carried out from 2015 to 2017 by the EMA Management Board is the main source of data on time taken to undertake procedural activities. Suitable 'comparator' activities were agreed with EMA and the time taken for those activities used for those where data is not available from the MDBG, including new and amended activities as a result of the VMP regulation. This approach ensures that a consistent estimate of the time taken is used for EMA and NCAs for activities where both are involved.

Meeting costs data were provided for each year at an aggregrate activity level (e.g. scientific advice, marketing authorisations). These reflect the cost to EMA of reimbursing NCA representatives for attending meetings. They are allocated to disaggregated activities in proportion to the number of procedures and added to the procedural activity costs. To avoid calculating excessive fees for veterinary activities, meeting costs have been combined and distributed equally across for human and veterinary activities where appropriate.

A scaling factor was used to match the procedural costs calculated in the model to costs provided by EMA at the aggregrate activity level for 2020. The reported costs are based on data from EMA's financial accounting system, which has a more detailed cost specification than the model used in this study. This calibration takes account of differences in actual time spent and the type of staff working on different activities.

[11] These forecasts may not fully align with financial budget forecasts as the full costs of procedures are assumed to be covered in a single year, while in reality some costs are distributed over a loner period.

These effects may give rise to further small fluctuations in costs in future forecast years that result in a small divergence in the calculated model costs and costs forecast by EMA.

Horizontal activities of EMA are shown in Table 1. These include costs associated with the extended proposal for EMA reinforced role [12], knowing that costs stemming from this proposal are covered by a corresponding increase of the EU budget contribution, except for EHDS/Darwin operating expenditure (maintenance phase), as of 2024. The approach to covering the costs of EMA horizontal activities is discussed in Section 4.

NCA costs

NCA costs for undertaking EMA activities cover procedural activities for EMA level procedures and eligible additional activities.

Costs for scientific and administrative work on procedural activities are calculated using hourly cost data, time taken and the number of procedures undertaken in rapporteur and co-rapporteur or equivalent roles for each activity. These include paediatric and orphan medicines activities. Costs for other activities, that are undertaken in addition to the remunerated roles for a given activity, but do not have a legal base to be remunerated under the current system are not included.

Hourly cost data for each NCA has been derived from aggregate organisational cost data collected for the 2016 model using the methodology from that model. To determine hourly costs for the period 2022 to 2026, these data have been increased by 5% per annum for labour costs and 2% per annum for non-labour costs. For NCAs that did not provide data for the 2016 model, these have been assigned the average cost from the reporting NCAs altogether.

The distribution of rapporteur and co-rapporteur roles across NCAs is derived from actual 'purchase order' data (i.e. data on actually recorded procedures) provided by EMA, supplemented by information reported in the survey of NCAs for the 2016 model.[13] This distribution is scaled to the forecast total number of procedures for each activity provided by EMA according to available inforamtion.

The MBDG exercise is the main source of time data for procedural activities for NCAs. For the 2016 model, data from the exercise was used to calculate times for rapporteurs and co-rapporteurs separately – in the MBDG report, time data for these roles is combined.[14] As discussed for EMA, time data from comparator activities for both EMA and NCAs has been used where appropriate.

The additional EMA activites of NCAs that are considered eligible for remuneration from EMA fee revenue for the current study are based on the findings of the evaluation study and a consultation exercise carried out by DG SANTE services with NCAs after the evaluation study.[15] These costs are allocated across NCAs in proportion to the rapporteur and co-rapporteur 'purchase orders' for CAP annual fees for human and veterinary products. The rationale for this allocation is based on the observation of the evaluation

[12] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020PC0725

[13] Purchase orders (POs) are a commitment for future payment to NCAs by EMA. Under the existing fee system, one purchase order is sent out for each rapporteur, co-rapporteur or equivalent remunerable role undertaken by NCAs for a given procedure.

[14] The MBDG data includes data from MHRA and VMD and this has not been excluded from the time data used due to the limited sample size.

[15] The results of the consultation exercise can be found in Appendix 2.

study that the level of additional activities increases in proportion to the level of involvement in procedural activities.

For veterinary medicines NCAs, the introduction of the VMP regulation rules is expected to result in additional pharmacovigilance-related costs for updates by NCAs to the Union pharmacovigilance database and less pharmacovigilance cost due to the discontinuation of Periodic Safety Update Reports for CAPs (PSUR) activities. The total yearly PSUR costs that NCAs incur under the existing system have been used as a proxy for the additional costs and are allocated across NCAs in proportion to the co-rapporteur 'purchase orders' for CAP annual fees for veterinary products.

3.2. Revenue model

The revenue model includes

- EMA fee income, which is the share of total fee revenue that EMA retains after remunerating NCAs for the EMA activities they undertake, and
- EU/EEA budget contributions.

NCA income is also calculated for the remuneration they receive from EMA for their EMA activities. In budgetary terms for EMA, it is considered as equivalent to EMA expenditure for NCA remuneration.

EMA fees

Under the current fee system, there exists a single basic fee for each activity that is updated for inflation each year.[16] For each policy option, a single fee is also determined and used in the targeted consultation. To do this the fees that balance the EMA budget for 2024 (the central estimate for the study model) are calculated.[17] These are then adjusted for inflation and used to calculate the stakeholder impacts for each year modelled.[18] As a further step, based on the analysis of these impacts and feedback from the targeted consultation, single fees may be replaced by fee bands for some activities, provided that the legal instrument could accommodate such a choice.

For activities, for which fees can be increased under the current system based on additional presentation and strength, these have not been calculated for the cost-based options as no data are available on the additional time taken for these. This is in line with the approach followed by the MBDG exercise.

There are a number of activities for which different fee levels apply under the existing system but for which it has only been possible to calculate a single cost-based fees. For these activities, the ratio of fees pertaining under the existing system has been used to derive different fee levels from the cost-based fee.[19]

Fee reductions

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[16] The fee may be increased for additional strengths and presentations for some activities or number of active substances. The fee grids presented under each option represent the detailed fee grid that would be implemented under the legislation for that option.

[17] For option 1, only part of the EMA budget deficit that is allocated to veterinary medicines based on their share of additional EMA activities is balanced as the existing system still applies for human medicines under this option.

[18] Inflation rates are based on ECB staff macroeconomic projections for the euro area, March 2021 (europa.eu) with the 2024 forecast of 1.4% assumed to apply to 2025 to 2026.

[19] Scientific services – PMF, scientific services traditional herbal, scientific services certification for advanced therapies, pharmacovigilance referrals and annual CAP fees.

Reduction rates from the current fee system are applied to the do-minimum and all options for human medicines. For veterinary medicines, the existing system applies in the do-minimum but changes to these incentives are applied in the options. This is because a number of sub-options with different combinations of specific and general reductions are implemented in option 1.

Under the current fee system nearly all incentives are borne by the EMA budget (NCA remuneration is not reduced by incentives), except for pharmacovigilance fees. In the cost-based policy options, two sub-options are implemented: one in which the cost of incentives is borne by EMA budget alone and one in which the cost of incentives is shared with NCAs, i.e. NCA remuneration is reduced in the same proportion as the fee reduction and the burden of the fee reduction is shared proportionately between EMA and NCAs.

The incentives in the do-minimum and policy options are presented in the corresponding fee grids.

EMA income

EMA has two sources of income in the model. These are fee income and EU/EEA budget contributions.[20] The EU budget contributions are shown in Table 2. EMA fee income is calculated from the unit fee, the number of procedures (or number of products for the annual fees) and the incentive rates. The EU/EEA budget contributions include a specific component for objective 3 of the proposal for EMA reinforced role (EHDS/ DARWIN) [21] in 2022 and 2023 to offset the costs incurred by EMA for that purpose (project phase). This is replaced by fee income as of 2024.

Annual CAP fees are calculated to balance the EMA budget after taking into account cost-based procedural and pharmacovigilance fees and EU/EEA contributions.

NCA remuneration

EMA makes payments to NCAs to remunerate them for scientific service provision. Under the existing system these payments are covered by specific rules which are implemented in the model for the do-minimum scenario. These remuneration rates are also adjusted for inflation each year.

Remuneration is allocated across NCAs based on the distribution of rapporteur and co-rapporteur roles, which is determined from "purchase order" data, and, for activities where purchase order data is not available, NCA survey data collected during the 'Study for the Evaluation of the Fee System' is used.

In line with the approach to the fee calculations, a corresponding NCA remuneration amount is first identified for each relevant procedural activity under each policy option; this is the cost-based unit remuneration for 2024. These figures are adjusted for inflation and used to calculate the stakeholder impacts for each year modelled. An inflation rate of 1.2% per annum has been adopted for future years.

Under the policy options, when cost-based remuneration is introduced, the calculated remuneration for rapporteur and co-rapporteur roles may be different if they do not, on

[20] As noted earlier, miscellaneous revenue is not included in the model because it is considered marginal.

[21] Data Analytics and Real World Interrogation Network: allow timely access and analysis of EU-wide health data to support better decision-making throughout the product lifecycle on medicines with valid and reliable real world evidence

average, spend the same amount of time on an activity. However, all NCAs continue to receive the same level of payment for each of these roles.

Remuneration is then allocated across NCAs in the same way as under the existing system for procedural activities, i.e. to the NCA of the rapporteur/co-rapportuer or similar role. Remuneration for eligible additional costs is covered by the annual CAP fees remuneration and is allocated in proportion to the corresponding rapporteur and co-rapporteur purchase orders.

For veterinary medicines, given the overhaul of the pharmacovigilance system, the remuneration also covers in addition pharmacovigilance related costs that are proxied by the PSUR costs incurred by NCAs under the current system. This is because NCAs could not declare such activities in the evaluation.

NCA unitary remuneration for rapporteur and co-rapporteur (or equivalent) roles are presented in the fee grids for the policy options.

Two possible adjustments to NCA remuneration are considered as part of the policy sub options:

- NCAs share the cost of incentives applied to fee income with EMA, so that remuneration is reduced accordingly.

- NCA remuneration is scaled by a country specific coefficient so that NCAs receive a different level of remuneration. Coefficients available from the European Chemicals Agency (ECHA) have been adopted for this study as these cover almost all NCAs. The coefficients are presented in Table 3.[22]

These adjustments to NCA remuneration affect fees because they change the EMA budget deficit in the model that has to be balanced. In the results presented in the consultation, only the annual CAP fees are used to balance the EMA budget and therefore only these fees change; procedural fees remain as calculated under the cost based principle as explained above.

4. DETAILED IMPLEMENTATION OF THE DO-MINIMUM SCENARIO AND POLICY OPTIONS

In this section details of the implementation of the do-minimum scenario and the policy options are presented. This implements the policy options that were outlined in the Inception Impact Assessment (IIA)[23] , taking account of feedback received on that exercise (see Appendix 3).

Do-minimum scenario

The do-minimum scenario represents the fee system in the forecast years when no legal action is undertaken in relation to the fee system. It provides the baseline against which the impacts of the cost-based policy options can be assessed. Under the do-minimum scenario, changes are limited to ensuring that the fee system aligns with the 2018 VMP Regulation and revised EMA Founding Regulation. The costs and EU budget contributions

[22] ECHA Country coefficients. Available at: https://echa.europa.eu/documents/10162/2792271/FINAL_MB_36_2017_Transfer_of_Fees_revised_decision_signed_at_MB48_en.pdf/235fdafe-6652-6c44-dc60-2412e504903c. For Lichenstein, a value of 100 was assumed.

[23] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/2091-Revision-of-EMA-fees

associated with the proposal for EMA reinforced role are also included as of 2024 (EHDS node). The structure of the fee system is otherwise unchanged.

The main changes to procedural activities for veterinary medicines from 2022 as a result of the VMP Regulation are:

- Classification of Initial market authorisations (MA), both in terms of the new legal basis and further sub-classifications for fee levels ;
- Classification of variations requiring assessment and not requiring assessment, covering line extensions, Type IA, Type IB and Type II variations ;
- Classification of referrals ;
- Procedural activity in relation to renewals and PSURs are no longer undertaken ;[24]

The Pharmacovigliance database and the Union Product database are introduced and a small change is made to the supplier database (EUDRA GMP) by adding veterinary wholesalers. The mechanism of remuneration to NCAs, as well as fees for human and veterinary medicines procedures and the incentives applied to fees remain unchanged from the existing system.

Aggregate fee revenue may change due to the change of classification and frequency of procedures under the VMP regulation.

For new and amended procedural activities under the VMP Regulation, the fee from the closest matching existing procedural activity is applied (no cost-based fees are implemented because there is no legislative action on fees under this scenario).

Costs to EMA resulting from the veterinary databases implemented under the VMP Regulation and from the proposal for EMA reinforced role are included in the EMA horizontal costs (Table 1).

Regarding EHDS node reuse data activities under objective 3 of the proposal to reinforce EMA's mandate (EHDS/DARWIN), please refer to Appendix 4. It is understood that the use will be proportional to the number of products on the market and therefore likely to support more NAPs than CAPs. For 2022 and 2023, the objective 3 project phase costs will be fully covered by the EU/EEA budget contributions (Table 2)[25]. Thereafter, as there is no legal action under the do-minimum, these maintenance costs will not be covered under the do-minimum scenario. For all the policy options described below, objective 3 maintenance costs are allocated to the human PhV annual fee and human CAP annual fee in proportion to the number of NAPs (75%) and CAPs (25%).

Under the do-minimum scenario, no further changes to annual fees or to procedural fees are permitted. The model calculates the impact on the EMA budget variance (whether income is sufficient to cover costs) of the costs to EMA, payments to NCAs and income from fees and EU and EEA budget contributions given the forecast frequency of procedural activities, EMA horizontal activities and eligible NCAs additional activities.

[24] The costs for renewals that may need to be undertaken for products approved prior to 2022 under the existing legislation are already included in EMA horizontal costs.

[25] Objectives 1 and 2 of the proposal for EMA reinforced role are fully covered by the EU budget contributions for the entire period covered by the study.

Policy option 1: Introduce cost-based fees for veterinary medicines only

Policy option 1 was designed to introduce the minimum legislative action required to address recent changes to EU legislation affecting EMA activities. In addition to the changes made to procedural activities under the VMP Regulation and as a result of the proposal for EMA reinforced role under objective 3, the following changes to fees and remuneration are introduced in option 1:

- Cost-based fees are implemented for **all** fee-paying veterinary medicines procedural activities. This includes new and amended activities under the VMP Regulation. Fee paying procedural activity in relation to renewals and PSURs is discontinued in line with underlying VMP regulation provisions.

- An annual fee for veterinary CAPs is maintained. In addition to EMA horizontal veterinary costs (Table 1), this fee will also cover the eligible NCA additional costs for veterinary activities including eligible pharmacovigilance costs as a result of the VMP Regulation to the extent that they contribute to the EMA mandate (Appendix 2). The fee is calculated to balance the EMA budget after taking into account cost-based procedural and pharmacovigilance fees and EU/EEA contributions.

- In view of the EMA pharmacovigilance mandate in the VMP regulation, a pharmacovigilance annual fee for veterinary NAPs, based on an estimated number of chargeable units[26], is introduced to cover the cost to EMA of non-procedural veterinary pharmacovigilance activities, namely veterinary databases and veterinary public health activities in relation to product availability, MUMS, AMR and EU co-operation. These activities are marked in grey in Table 1.

- The mechanism of remuneration to NCAs for veterinary medicines remains unchanged from the do-minimum for procedural activities. NCAs will also receive a flat annual remuneration to cover the costs of eligible NCA additional costs for veterinary activities including eligible pharmacovigilance costs as a result of the VMP Regulation to the extent that they contribute to the EMA mandate.

- Cost-based fees are introduced for a small number of veterinary activities for which fees are not currently charged and to which incentives are not applied, namely pre-submission and re-examination activities. Cost-based remuneration for NCAs is introduced for these activities.[27]

- For human medicines, the majority of fees and NCA remuneration remain unchanged from the do-minimum, i.e. as in the current system. Only the annual fees, both CAP and Pharmacovigilance, will be adjusted as of 2024 to allow EMA to recuperate operational costs of DARWIN (maintenance phase).

- Under this policy option, only SME fee reductions from the existing system are first applied with no other specific fee incentives or general reductions on fees. Different combinations of fee incentives and general reductions to fees are tested as per the inception impact assessment to determine the most appropriate levels. Options 1a,1b and 1c are used to test the impact of the following incentive and general reduction combinations. Specifically:

[26] defined for the purpose of the model estimations following the same principle as for the pharmacovigilance annual fee for human NAPs

[27] if the respective procedural fees, included in the fee grid for information, were to be created, the remuneration amount linked to the annual fee would need to be reduced in order to avoid double charging.

- Sub-option (a) introduces cost-based fees for veterinary medicines with a general fee reduction only. This sub-option is the same as Option 1, but a 50% general reduction for veterinary medicines is applied to all veterinary fees. No additional incentives are applied.

- Sub-option (b) introduces cost-based fees for veterinary medicines with a 50% general fee reduction and incentives. This sub-option is the same as Sub-option 1a, but it also includes specific incentives that are applied for limited markets.[28]

- Sub-option (c) introduces cost-based fees for veterinary medicines with incentives only. This sub-option is the same as Option 1, but specific incentives are also applied for limited markets. No general reduction is applied to veterinary medicines cost-based fees.

Policy Option 2: A cost-based fee system for human and veterinary activities

In addition to the changes implemented to the fee system under option 1, policy option 2 introduces a cost-based system for both human and veterinary activities. Some further changes to human and veterinary procedural activities are also implemented.

- Cost-based fees reflecting EMA and NCAs costs are also implemented for human medicine procedural activities.

- In addition to EMA horizontal costs including a proportion of EHDS/DARWIN costs, the CAP annual fee-human will also cover remuneration for the eligible NCA additional costs for human activities.

- The annual pharmacovigilance fee covers EMA horizontal pharmacovigilance costs and a proportion of EHDS/DARWIN costs.

- The annual CAP fee income is then matched to procedural fee income and the EU budget contributions to ensure the EMA income after cost-based payments to NCAs is sufficient to cover its costs.

- For human medicines, relevant fee incentives continue to apply in line with existing legislation and rules (implementing rules, EMA decisions, sectorial legislation, SME regulation). For veterinary medicines, the SME incentives from option 1 only are implemented.[29]

- Cost-based fees are calculated for all procedural activities but these may be fully waived in accordance with the applicable legislation for activities such as paediatric and orphan medicines. In these cases, NCA remuneration is still maintained and is calculated as part of EMA's remuneration costs.

- NCA remuneration for human and veterinary procedural activities is cost based. NCAs also receive a flat annual remuneration, also cost-based. For human and veterinary medicines, this remuneration covers eligible addtional NCA costs.[30]

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[28] In addition to the MUMS incentives from the existing system, reductions of 50% are applied all other limited market applications.

[29] These can be compared with the results for the policy option 1 sub-options.

[30] For veterinary medicines, the current PSUR assessment revenue of NCAs is used as a proxy to remunerate NCAs for relevant additional activities under the VMP regulation (updates of products under databases), for which no data are otherwise available.

- Fees for Type II variations for human medicines are re-classified to align with patterns stemming from analysis of the data collected during the MBDG data gathering exercise (only fees are concerned, not the variations themselves). Fees and remuneration are determined for Type II variations in Quality, Clinical safety, and Clinical indication, respectively.

- Cost-based fees are introduced for a small number of human and veterinary activities for which fees are not currently charged and to which incentives are not applied in addition to paediatric and orphan designation activities, namely pre-submission and re-examination activities. Cost-based remuneration for NCAs is introduced for these activities.[31]

Policy Option 3: A cost-based fee system with a simpler, more efficient structure

The purpose of this option is to simplify the cost-based fee system implemented in option 2 for both human and veterinary medicines by applying a reduced number of procedural fees for post-authorisation activities (human and veterinary). Following the feedback from the IIA, two versions are considered under this option, namely:

- **'Full' version of option 3**

    - A reduced number of procedural fees are applied for post-authorisation non-pharmacovigilance activities for human and veterinary medicines. Procedural fees are levied only for pre-authorisation activities (human and veterinary), inspections and only some major post-authorisation activities (e.g. referrals). Due to technical complexities linked to the variety of products included in pharmacovigilance procedures and activities, pharmacovigilance procedures continue to attract procedural fees.

    - The annual fee for Centrally Authorised Products covers a broader set of costs as compared to the current system including those non-pharmacovigilance post-authorisation procedures that would no longer levy a procedural fee.

    - The annual fees for pharmacovigilance cover costs of EMA horizontal pharmacovigilance activities in both the human and veterinary sectors.

    - NCA remuneration for procedures charged under the Centrally Authorised Products (CAP) annual fee is no-longer per-procedure and is included in the annual remuneration paid to NCAs via the CAP annual fee.

- **Policy sub-option for a 'light' version of option 3**. This sub-option implements only a partial simplification of the fee system structure (i.e. a reduced version of Option 3). This option is the same as Option 3 'full', but a more limited set of activities are covered by annual fees (mainly minor variations) and procedural fees are retained for a larger number of activities (mainly major variations). This responds to feedback received to the inception impact assessment regarding the design of the policy options.

[31] if the respective procedural fees, included in the fee grid for information, were to be created, the remuneration amount linked to the annual fee would need to be reduced in order to avoid double charging.

5. SUMMARY KEY INPUT DATA TABLES

Table 1 Yearly cost (€) for EMA horizontal activities

EMA activity list	Total (€)					
	Typical budget (2020)	**2022**	**2023**	**2024**	**2025**	**2026**
Product maintenance activities and Pharmacovigilance (CAPs) - human	5,902,000	6,577,000	6,873,000	7,182,000	7,682,000	8,202,000
Signal detection (CAPs)	5,667,000	5,979,000	6,318,600	6,673,616	7,052,545	7,447,301
Genral PhV (data management and databases) (NAPs) - (PHV) - human	11,745,000	12,487,000	12,839,000	13,204,000	13,743,000	14,223,000
Literature monitoring (PhV)	1,980,000	2,081,000	2,130,000	2,179,000	2,238,000	2,293,000
DARWIN (investment and maintenance expenditure)		8,000,000	8,000,000	16,000,000	16,000,000	16,000,000
Expenditure (objective 1 & 2)		14,090,000	14,700,000	15,300,000	15,300,000	15,300,000
Product maintenance activities and Pharmacovigilance (CAPs) - Vet	1,923,000	2,501,000	2,586,000	2,675,000	2,900,000	3,136,000
Vet public health -product availability/MUMS (CAPs)	285,000	306,000	317,000	330,000	346,077	362,746
Signal management (vet) (CAPs)		440,000	466,400	494,384	522,455	551,699
Vet public health - AMR - Total expenditure	626,000	1,163,000	1,214,000	1,268,000	1,340,884	1,416,902
Vet databases (PhV)	2,500,000	2,652,250	2,731,818	2,813,772	2,908,910	2,996,302
Databases for use outside EMA: EudraVigilance, EudraPharm - Corporate	28,524,000	30,125,750	30,904,183	31,701,228	32,773,090	33,757,698
Guidelines for good practice (including working parties)	10,745,000	11,587,000	11,983,000	12,396,000	12,902,000	13,362,000
(Non-Guideline) Published information for healthcare professionals, patients and general public	7,487,000	8,230,000	8,597,000	8,981,000	9,314,000	9,640,000
EU Network Training Centre	490,000	528,000	546,000	565,000	588,000	609,000
Public Health activities: eg AntiMicrobialResistance , Stakeholders, PRIME(Priority Medicines) , Health Technology Assessment, and SME etc.	13,272,000	14,500,000	15,252,000	15,909,000	16,590,443	17,288,889

Vet public health - Eu Co-Operation Costs	527,000	571,000	595,000	620,000	652,596	686,464
Projects which create costs – Innovation Medicines Initiatives (IMI), GRIP, European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)	5,829,000	6,383,000	6,658,000	6,945,000	7,276,000	7,511,000
Transparency on non-fee generating areas e.g. Access to documents and publication of clinical trials	6,848,000	7,716,000	8,150,000	8,601,000	9,071,000	9,565,000
International Activities	4,466,000	4,842,000	5,025,000	5,218,000	5,458,000	5,672,000
Coordination Group (Cmd) Human & Vet	2,774,000	2,934,000	3,009,000	3,085,000	3,159,000	3,243,000

Table 2 EU/EEA yearly budget contributions (€) to EMA

EU/EEA budget contributions	2022	2023	2024	2025	2026
Initial MFF proposal non-orphan	22,500	22,500	18,700	18,700	18,700
Initial MFF proposal - orphan medicines contribut	14,000	14,000	14,000	14,000	14,000
EMA Reinforced Role proposal (objectives 1&2)	22,090	22,700	15,300	15,300	15,300
EMA Reinforeced Role proposal, specifically for Node reuse data* (specific objective 3)	8,000	8,000	0	0	0
TOTAL	44,590	45,200	34,000	34,000	34,000

Table 3 Country specific scaling coefficients

Country	Coefficient
Austria	105
Belgium	100
Bulgaria	51
Croatia	74
Cyprus	74
Czech Republic	73
Denmark	133
Estonia	78
Finland	119
France	114
Germany	96
Greece	79
Hungary	70
Ireland	118
Italy	98
Latvia	73
Lithuania	70
Luxembourg	100
Malta	86
Netherlands	108
Poland	67
Portugal	81
Romania	64
Slovakia	76
Slovenia	81
Spain	88
Sweden	127
Norway	136
Iceland	134

ECHA Country coefficients. Available at: https://echa.europa.eu/documents/10162/2792271/FINAL_MB_36_2017_Transfer_of_Fees_revised_decision_signed_at_MB48_en.pdf/235fdafe-6652-6c44-dc60-2412e504903c. For Lichenstein, a value of 100 was assumed.


Publications Office

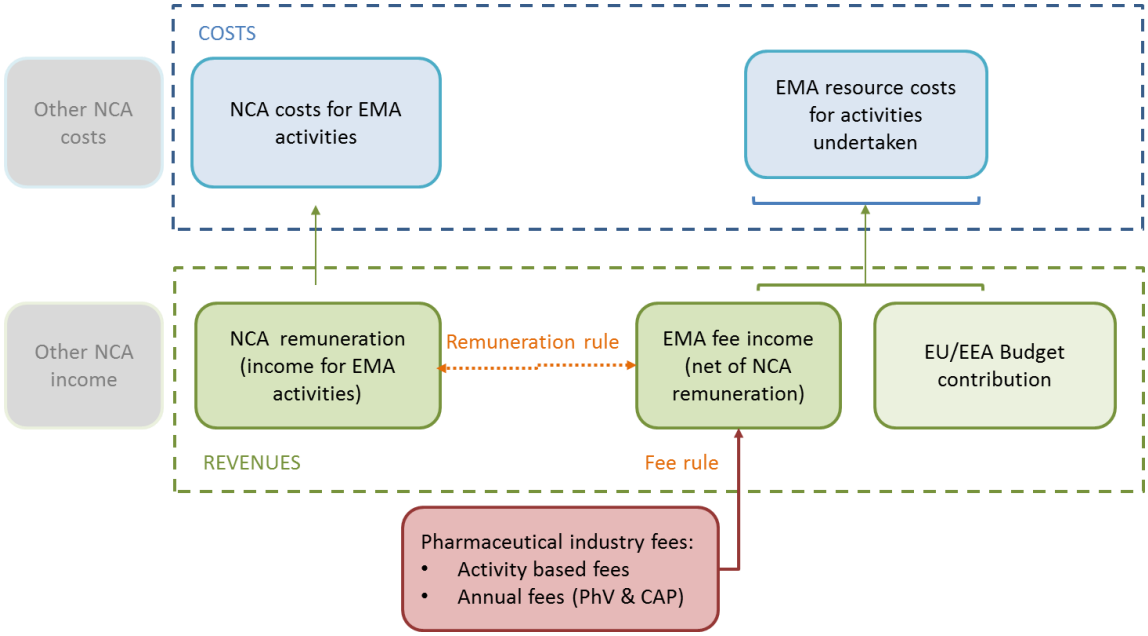
Appendix 1. Additional information on the financial model

This appendix presents excerpts from the methodology note that accompanied the Study for the Evaluation of the Fee System, updated to reflect changes made to the model for the current study.

Model overview

The model is illustrated in Figure A1. Costs and income not included in the model have been greyed out. NCAs receive their remuneration for EMA activities from EMA rather than directly from industry: the payment is treated as a transfer of income and is therefore included in the revenue model only.

Figure A1: Schematic presentation of the cost and revenue model



Components of the financial model

The EMA resource cost model

This section describes the costing methodology applied to EMA. EMA costs can be broadly categorised as the costs of activities they undertake as an organisation (including direct non-staff costs), the costs of remunerating NCAs for EMA-related activities they undertake, and overhead costs.

The EMA activity costs consist of three types:

i) Costs for the scientific and administrative work they undertake as part of fee- and non-fee-generating services they provide to industry, which also involve NCAs.
ii) Costs for the scientific and administrative work they undertake as part of fee-generating services they provide to industry which do not involve NCAs, plus costs incurred for the administration of annual fees.
iii) Costs for additional non-fee-generating activities.

For each of the above cost types, EMA provided granular data for activities for the calendar year 2020 and 2022-26.[32]

EMA costs were provided as scientific and administrative staff salary costs, meeting costs, other direct (non-staff) costs and overhead costs. Staff costs that were not directly related to activities were included in overhead costs.

In the data provided by EMA, staff costs related to the plenary meetings of committees were included under the relevant activity – for example, COMP was included under "orphan designation" and PDCO was included in the Paediatrics activities – whereas the staff costs for the CHMP and CVMP were re-allocated to the relevant activities using "staff" as the allocation key. This approach was applied to the reported costs because almost all EMA time spent in committees is related to procedural activities.

An activity-based costing methodology was used to determine costs for the EMA's procedural activities involving NCAs (i.e. costs for the scientific and administrative work EMA undertakes as part of fee- and non-fee-generating services they provide to industry that also involve NCAs). This approach allocates overhead costs as well as non-staff direct costs and staff costs to individual activities, thus enabling fees to be compared with full costs for individual activities in the modelling.

The study team followed a two-step procedure to calculate the costs of the activities undertaken by EMA at a disaggregate level:

- Step 1: Determine the full cost per hour of an activity. Salary costs per hour for two staff types (scientific and administrative) were calculated from total EMA salary costs divided by total annual number of hours worked (number of FTEs x annual hours per FTE). Overhead and direct costs were then allocated to each of these staff types according to staff numbers because direct costs are more likely to be aligned with staff numbers than to, say, staff costs. Meeting costs were allocated separately.
- Step 2: Multiply full cost per hour by hours spent on an activity. The total time spent on an activity by each staff type was determined from the time taken to carry out a procedure for the given activity and the number of procedures undertaken. Total costs were calculated by multiplying the time taken by the costs per hour for each staff type and activity.

The following assumptions were used:

- EMA staff were categorised as one of two staff types - scientific or administrative staff – these definitions were consistent with those used by EMA in the MBDG Exercise. This categorisation was made by EMA.
- The number of FTEs of each staff type was provided to the study team by EMA.
- The annual number of hours worked per FTE is based on 41 working weeks per year (after allowing for holidays, sick leave etc.) of 40 hours per week for both staff types. This is based on data provided by EMA.
- The hourly cost of each staff type was assumed to be independent of the type of activity they undertake (e.g. the salary cost of scientific staff time is the same for all activities). Costs of staff not involved in scientific activities were included as overhead costs.

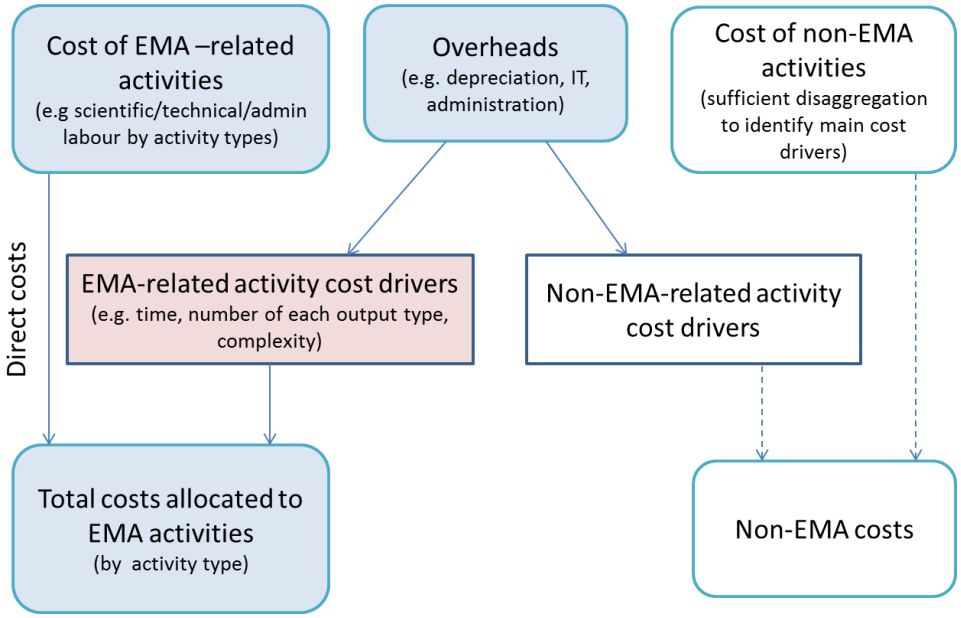
[32] The EMA data is available in a spreadsheet as a separate electronic supplement.

- The allocation of overheads in relation to staff time was specified in the model. EMA also provided its own allocation of overheads and direct costs to activities. This was used for procedural activities involving EMA only and additional activities.

The NCA cost model

NCA costs can be considered to consist of three types: costs for EMA-related activities, costs for other (non-EMA-related) activities they undertake, and overhead costs. The current study is concerned only with costs from EMA-related activities by NCAs and the proportion of NCA overheads that can be attributed to these. Costs associated with all other non-EMA-related activities undertaken by NCAs were explicitly excluded from the model. This is illustrated in Figure-A2.

Figure-A2: Cost allocation for NCAs



The cost calculations for NCAs followed a similar approach to that used for EMA.

The hourly costs of EMA-related activities and the cost of EMA-related activities by activity type were calculated for each NCA. The following steps were applied to each NCA separately:[33]

1. determine hourly costs of EMA-related activities
2. determine the cost of EMA-related activities by activity type

Step 1: determine hourly costs of EMA-related activities

Overheads and non-staff costs were allocated to the annual salary costs to determine the annual costs of undertaking EMA activities for two different staff types: administrative and scientific. The cost per hour of EMA activities for each staff type was calculated by

[33] The model is based on cost data from 27 respondent NCAs excluding MHRA and VMD. Average values are applied to NCAs for which no data were reported in the 2016 survey.

dividing the annual costs by the annual hours worked. The cost per hour was (as for EMA) multiplied by a factor of 1.2 to allow for FTEs working on EMA-related activities spending some time on non-assessment activities. This is in line with the approach taken in the pilot costing exercise (EMEA 2009).

The following data sources and assumptions were used:

- NCAs provided data for two staff types - scientific and administrative staff – in order to ensure consistency with the time data provided by the EMA MBDG Exercise, which refers to these two employee types only.
- The number of FTEs of each staff type involved in EMA activities was provided by NCAs in the survey. For NCAs that did not provide any data, 1640 annual hours per FTE was assumed.
- The hourly cost of each staff type was assumed to be independent of the type of activity they undertake (e.g. the salary cost of scientific staff time is the same for EMA and non-EMA related activities and for rapporteur, co-rapporteur or other, unremunerated roles). Costs of staff not involved in scientific activities were included as overhead costs.
- To ensure consistency in the model, however, overheads were allocated in relation to staff time for all NCAs (and EMA).[34] Explicitly this means that all reported overhead costs (scientific staff, administrative staff and non-staff) were summed. These were first allocated between EMA-related and other NCA activities in proportion to the number of FTEs working on these two types of activities. For EMA related activities, the overheads were then further allocated between scientific and administrative staff in proportion to the number of these staff types working on these activities.
- 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.

[34] 15 NCAs reported a cost based overhead allocation rule, 11 a staff time or staff numbers based rule; i.e. consistent with the overhead allocation rule. Two NCAs specified a different rule but it was not clear how this would be implemented. One NCA did not specify a rule. In these cases, the staff numbers rule was used as the default. If overheads were already allocated by staff type, then both rules would allocate the same proportion between EMA and non-EMA activities.

Step 2: determine the cost of EMA-related activities by activity type

The cost of EMA-related activities was calculated based on a categorisation according to three different types of activities:

1. Procedural activities (NCA involvement)
2. Additional activities

For a given activity and role, the total cost was calculated based on the time taken multiplied by the number of procedures undertaken. These costs were summed across the different roles (rapporteur, co-rapporteur and other) and activities to provide the total yearly procedural activity cost of a given NCA. The total yearly activity costs are presented separately for human and veterinary medicines.[35] A weighted yearly average cost per procedure for each procedural activity was calculated from the total yearly cost divided by the number of procedures.

The distribution of roles across NCA is determined from purchase orders for 2019 provided by EMA. The distribution of rapporteurs was scaled to the number of procedures for each activity in each year. In addition to this scaling, the co-rapporteur distribution was determined by the number of co-rapporteurs per procedure ; normally zero (no co-rapporteur) or one (always a rapporteur and co-rapporteur), but for a small number of activités, this was less than one (co-rapporteur sometimes required). For activities where purchase order data could not be used, data reported by NCAs for 2016 provided the distribution across NCAs and was scaled to the total number of procedures. For infreguent activities, where only one procedure is implemented, this is assigned to an 'average NCA' with costs calculated as the simple average of NCAs.

The revenue model

In this section the revenue model and the different fee and remuneration rules that are applied under the existing fee system and in the scenarios are presented.

There are three stages to the revenue model as follows.

First, EMA receives fees from the pharmaceutical industry for the services it provides. The total fees paid by industry depend on the fee rule and the incentive rate and the number of procedures for a given activity. The fee rule determines the full fee, which is the maximum fee that could be paid. Incentives (discounts or waivers) are applied to the full fees depending on the nature of the product and the industry organisation (e.g. whether an SME) making the application, as well as for other reasons. A procedure is the smallest chargeable unit used in the model and, for a given activity, the model calculates the unit full fee, which is the full fee per procedure (before any incentive, i.e. discount or waiver), as well as the total fees paid by industry. Three types of fees may be covered by the fee rule. These are procedural-activity based fees for CAPs, annual fees for CAPs and annual PhV fees for nationally authorised products.

Second, NCA income takes the form of a payment from EMA to recompense it for the EMA-related activities it has undertaken. The amount of this payment is determined by the **remuneration rule**. NCA delegates are additionally also reimbursed by EMA for travel and

[35] Keeping costs for human and veterinary medicines separate is in line with the study's terms of reference and enabled the implications of cost-based fees for different stakeholders to be better understood. Only data for inspections and EMA activities not involving NCAs include human and veterinary activities. These are included in the human medicines totals but are presented separately in the fee grids.

subsistence costs for attending meetings. The EMA's net fee income was calculated as the total fee revenue minus the NCA remuneration. For both NCAs and EMA, fee income from annual fees and procedural-activity based fees are provided separately for both human and veterinary medicines.

Finally, in the financial model for EMA, the budget is balanced so that EMA costs do not exceed the revenue it receives. In addition to revenue from its share of industry fee income, EMA receives EU and EEA budget contributions.

Fee and remuneration rules under the existing fee system

Under the current fee system, each procedural activity (or service) for which a fee can be charged has a full fee associated with it. This is the maximum fee that an organisation could be asked to pay for a given activity (i.e. if there were no discount or waiver) and has a specific legal basis. The different full fees were the main basis for the level of disaggregation of procedural activities in the NCA survey and hence in the model. In addition, there are a number of procedural activities for which no fees are charged currently.

In the model, the unitary full fees were derived from the total theoretical full fee revenue from industry before incentives are applied divided by the number of invoiced procedures. These may differ from published values because:

- A yearly inflationary adjustment is applied to the fees charged.
- The fee charged for some procedures (full application for marketing authorisation and line extensions) contains a fixed and a variable fee. The variable part is linked to the requests from the applicants for additional "strength, pharmaceutical forms and presentations, so the higher the number of additional requests the higher fee charged.

For procedural activities, detailed data on incentives was provided. From this, the study team calculated the average incentive rate for a given activity, in percentage terms, which was implemented in the model to calculate EMA and NCA incomes.

The rule for the remuneration of NCAs under the existing fee system is as follows:

1) For a rapporteur or co-rapporteur role for a non-pharmacovigilance, fee generating procedural-activity,[36] the NCA receives 50 per cent of the full fee before incentives are applied. Where more than one NCA undertakes a remunerated role for the same procedure, the remuneration is distributed equally between them. For pharmacovigilance activities, NCAs are remunerated a fixed amount, which is reduced in proportion to the incentive applied to the full fee.[37]
2) Rapporteurs and co-rapporteurs of eligible procedures receive 30 per cent (15 per cent each) of the CAP annual fees for human and veterinary medicines. NCAs do not receive a share of pharmacovigilance annual fees.

[36] PRAC rapporteur and co-rapporteur roles, as well as peer-reviewers, are not remunerated under the current fee system, where they appear in conjunction with other rapporteur or co-rapporteur roles (e.g. CHMP).

[37] The combined NCA remuneration for rapporteurs and co-rapporteurs for PASS is €7280 for the draft report and a further €10920 for the final report. For PSURs and PSUSAs, it is €13100. The remuneration is scaled proportionally to the incentive rate applied to the full fee (EU Regulation 658/2014).

The net fee income that EMA receives from fee-generating activities is the remainder of the full fee income less NCA remuneration and the incentives applied. Hence, for procedural activities, other than pharmacovigilance activities, they receive:

Full fee x (100% – 50% paid to NCAs – incentive rate (%))

For pharmacovigilance activities, EMA fee income is calculated as:

(Full fee – NCA remuneration) x (100% – incentive rate (%))

EMA receives 70 per cent of the annual fees for CAPs and 100 per cent of the annual pharmacovigilance fees. In both cases the EMA fee income is net of incentives.

Based on the above rules, the fee income for EMA and remuneration for NCAs was calculated as follows:

- The total theoretical full fee income was calculated as the product of the full fee per activity and the number of invoiced procedures for a given activity.
- Data on the number of CAP and PhV annual fee procedures, the incentive rates and the number of POs for CAP annual fees sent to individual NCAs was provided by EMA. These data were used to determine the share of CAP annualfee income they received.
- The EMA net fee income is the total fee income net of the NCA share and incentives.
- NCA remuneration was calculated for a given activity according to the rules outlined above. The remuneration was allocated across NCAs according to the number of rapporteur/co-rapporteur roles undertaken and the number of POs per procedure. (The formula is modified slightly for pharmacovigilance activities.)

  Remuneration of NCA X = NCA share of fee x unit full fee x (no. rap + no. co-rap NCA X)

  /(no. rap + no. co-rap per procedure)

Fee and remuneration rules for cost-based scenarios

Fees for a given procedural activity are calculated from the total costs incurred by EMA and NCAs combined and divided by the number of procedures.

Remuneration for NCA is allocated between rapporteur and co-rapporteur roles in proportion to the weighted average for each rôle. The average-cost remuneration is allocated across NCAs in proportion to the number and type of roles they undertake.
EMA fee income is calculated as the industry fee income (net of incentives) minus NCA remuneration.

Appendix 2. NCAs: participation in EMA committees and working parties and activities declared in addition to procedures – analysis of relevance to the EMA fee and remuneration system

The analysis presented in this appendix has been provided to the study team by DG SANTE services and has been reviewed for consistency with the evaluation and the impact assessment study study model and its outputs presented for this consultation.

The evaluation of the EMA fee system found that, overall and at an aggregate level, the remuneration paid by the Agency to NCAs exceeds the total costs calculated for undertaking procedures for human and veterinary medicines, if the two sectors are taken together.

Beyond this group of NCAs activities, i.e. procedural activities, the EMA Management Board data gathering also considered time spent on two other groups of NCAs' activities: (1) Attending EMA's committees and working groups, outside procedures[38] and (2) Additional activities declared by NCAs as potential EMA activities, beyond the assessment procedures and the committee and working groups non-procedural time. These two groups of NCAs activities were considered in the evaluation study and their cost was estimated, but their relevance was not analysed with regard to the remuneration that EMA pays to NCAs.

NCAs' time for attending EMA committees and working parties when not in charge of a procedure

The evaluation estimated the cost of time for participating in committees and working parties outside procedures at €17.9 million/year for all NCAs in aggregate. This figure did not take into account the reimbursement of travel and subsistence costs.

This time relates to taking part in common EU-level structures and is therefore seen as part of the overall setting of the EU regulatory system, consistent with the model of the EU in general. Without a relation to a specific assessment procedure, and in common with many other sectors, this is part of the collective responsibility of all Member States within the centralised regulatory system, which is combined with their collective benefit of having medicines authorised and monitored throughout the Union via a single centralised assessment procedure and a single centralised authorisation adopted by the Commission. Therefore, being part of these EU-level structures is not consistent with the remuneration paid by EMA, as an EU decentralised agency, specifically for the work carried out by the national competent authorities of the Member States which act as rapporteurs and, where applicable, co-rapporteurs in accordance with Articles 61(6) and 62(1) of Regulation (EC) No 726/2004. Moreover, calculating a monetary equivalent of benefits associated with the EU centralised system is also not considered appropriate for the purpose of this exercise. This rationale is applied as an overarching matter of principle.
Separately, NCAs receive in principle reimbursement of travel and hotel costs, a travel allowance in case of arrival/departure outside of the meeting days, and a daily allowance for each day of the meeting. The reimbursement in principle of travel and subsistence costs is not affected by the above considerations.

[38] EMA committees' and working parties' time related to procedural activities has been taken into account in the procedural time

NCAs' declared activities in addition to procedures

In relation to the EMA fee system evaluation, NCAs have declared broader 'additional activities', i.e. other than procedural activities. Examples of such additional activities, as declared by NCAs, included: work related to IT and databases, participation in the EMA Management Board, surveillance of safety of medicines, giving or attending scientific training sessions, actions on AMR, providing comments to draft assessment reports when not in the role of co-/rapporteur, updating national registries and publishing information on medicinal products, national implementation of EU decisions, national inspections related to EMA requests, work related to EU presidency, work on ICH (International Conference on Harmonisation), WHO work, etc.
The evaluation study[39] estimated the overall costs of this type of activities at €52.5 million/year for all NCAs in aggregate, based on the overall cost declarations by NCAs. According to the estimations of the evaluation, €22.7 million/year are currently paid to the NCAs via a share of the annual fee in the current system.[40] However, whether and to what extent such 'additional activities' should be remunerated by EMA in a cost-based system was not analysed by the evaluation and has therefore been subject to further analysis by DG SANTE services.

Analysis of NCAs additional activities and relevant costs
Up to 88 activities were declared by NCAs, with a very high level of variation in the number of activities declared and in the level of precision of the description. This called for a pragmatic approach of the analysis. After the evaluation, NCAs were surveyed to provide further detail and to specify a relative distribution of the estimated time spent on those declared activities. The outcome allowed for a relative distribution of the overall aggregated costs estimated by the evaluation, across the various activities (see table below).

Further, an assessment of potential eligibility for remuneration by EMA consistent with calculating such remuneration in the level of EMA fees was carried out, based on the activities and additional exaplanations on content of activities provided by the NCAs respondents and a preliminary analysis of the principles established by the legislation[41]. The resulting amount of such additional activities eligible for a remuneration calculated in the annual fee was added to the overall costs used as a basis for the calculation of the CAP annual fee and respective NCA remuneration. The fee amount and the NCA remuneration amount presented in the fee grids take these costs into account. This approach to remunerating eligible additional activities of NCAs on an annual basis, through an amount calculated in the annual fee is consistent with the trend observed in the evaluation study estimations that the level of possible additional activities is proportionate to the level of procedural activities of NCAs.

[39] https://ec.europa.eu/health/human-use/legal-framework/ema_fees_en

[40] The Implementing Rules of the Fee Regulation provide that NCAs of the rapporteur and co-rapporteur receive 15% each of the annual fee.

[41] Further legal scrutiny may be needed for the purpose of a legislative proposal.

The general criterion for the assessment of eligibility for remuneration by EMA which is consistent with calculating the EMA fees paid by undertakings, is whether the activity is in support of the EMA's scientific services, at central level, or, whether it is instead an activity that EMA fees are not called to fund, e.g. a national activity (such as implementation of EU legislation at national level).[42]
The Founding Regulation of the EMA provides in general that the Agency is responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products (Article 55). Further, it stipulates (Article 67) that fees are paid by undertakings:
(i) for obtaining and maintaining Union marketing authorisations for medicinal products for human use and for veterinary medicinal products and for other services provided by the Agency, as provided for in this Regulation and in Regulation (EU) 2019/6; and
(ii) for services provided by the coordination group as regards the fulfilment of its tasks in accordance with Articles 107c, 107e, 107g, 107k and 107q of Directive 2001/83/EC

In addition, it stipulates (Article 62) that the provision of services by rapporteurs or experts shall be remunerated.
In the most recent EMA fee legislation, i.e. Regulation 658/2014, the legislator stated that any revisions of fees levied by the Agency should be based on a transparent and independent evaluation of the costs of the Agency and the costs of the tasks carried out by the national competent authorities (recital 7). It also clarified that such costs cover the work carried out by the national competent authorities of the Member States which act as rapporteurs and, where applicable, co-rapporteurs in accordance with Articles 61(6) and 62(1) of Regulation (EC) No 726/2004 (recital 6). Similar provisions exist in Regulation 297/95. Further, Regulation 2019/6 confirmed (Article 2(8) that it is without prejudice to national provisions on fees..

In light of the above, three cumulative conditions can be established to guide the assessment of the eligibility for remuneration calculated in the level of EMA fees of each of the so-called 'additional activities' considered by the evaluation: **(1)** the activity must be of scientific nature, consistent with Articles 61(6) and 62(1) of Regulation (EC) No 726/2004 **(2)** it must be part of EMA's services, consistent with Articles 67(3)(c) of Regulation (EC) No 726/2004 and **(3)** it must be a service provided to the EMA consistent with Articles 61(6) and 62 of Regulation (EC) No 726/2004. In addition, for a fair and proportionate EMA fee system, any risk of double charging between the Agency's fee system and the national fee systems in Member States should be eliminated.

Examples of activities potentially eligible for remuneration under the annual fee
Activities such as for example work on the additional monitoring list, or checking national translations of safety communications on centralised procedures and annual reassessment of a marketing authorisation under exceptional circumstances may qualify for remuneration in accordance with the eligibility criteria and the analytical conditions.

Examples of activities potentially non-eligible for remuneration under the annual fee
Some activities declared are at national level or do not constitute a service to the EMA and/or can be charged for at national level and, therefore, are not eligible. Examples include updates

[42] This does not exclude a priori such activities from eligibility for financing through EU financial instruments.

of national drug registries, DSURs, adverse drug reaction reporting, signal management[43], national safety communication following a pharmacovigilance procedure of a centrally authorised product, participation in IT projects relating to databases and portals, and participation in ICH/VICH meetings (which are reimbursed by the Commission).

Regarding the provision of comments to scientific reports from non-rapporteur NCAs and IT activities of NCAs, following the same reasoning as for committee and working parties time, remuneration is not consistent. These activities are part of the overall setting of the EU regulatory system, which is based on the collective responsibility of all Member States and which provides a collective benefit to all.

Examples of activities potentially non-eligible for remuneration under the annual fee but eligible under a procedural fee

Another group of activities are considered as "non eligible" for remuneration through the annual fee not because they do not fulfil the criteria but because, instead, the proposed fee and remuneration grids (see consultation materials) comprise a procedural remuneration, calculated in a procedural fee.

The following activities (totalling €3.9mln) appear thus in the table below as "non eligible for remuneration through EMA annual fee", because it is considered to charge instead a cost-based procedural fee. Such fee could be potentially reduced or fully exempted; however, a fee level could be calculated and a remuneration for NCAs could be included.

- Pre-submission meetings -to cover Qualification Opinion meeting, Pre-submission meetings/hearings, Eligibility requests (including Eligibility requests, PRIME requests, Letter of intent, Accelerated assessment/ review requests, ATMP certification, notification changes and withdrawals, total requests and notifications: *procedural fee Pre-submission activities* Compassionate use programme: *procedural fee for Scientific services - Compassionate use opinions (Scientific services compassionate other than MA)*
- Paediatric Investigation Plan (PIP) modifications: *procedural fee for Paediatrics - PIPs (modification)*
- Orphan designation, review of maintenance of an orphan designation at the time of the initial marketing authorisation, including assessment of significant benefit criteria: *procedural fee for Orphan medicinal product designation procedures*
- Classification MUMS/limited markets: *procedural fee for Limited market classification*
- HMPC operation and associated procedures: *procedural fee for centralised herbal application*
- Plasma Master File (PMF) – initial certification, *procedural fee for Scientific services PMF*
- PMF - annual updates, procedure aligned with *Scientific services PMF Type IA/IB*
- ATMP classification/ certification- *procedural fee for Scientific Services - Certification for Advanced Therapies (Scientific services ATMP certification)*

[43] The Council working party's discussions in relation to Regulation 658/2014 on fees for pharmacovigilance indicated that national fees may apply for this type of activities and there should be no risk of creating legal grounds for double charging as Member States would keep that possibility.

- Establishment, modification or extension of maximum residue limits (MRLs) – *procedural fee Maximum residual limit (MRL) applications (Establishment of MRL)*
- Re-examination procedure: *procedural re-examination fee*
- Art. 5(3) procedure (Regulation (EC) No 726/2004): *procedural fee for referral – Article 5(3)*
- Annual renewal of a conditional marketing authorisation – *new procedural fee*[44]

The total estimated average cost (of NCAs) for those activities which are considered at the current stage eligible for remuneration calculated in the CAP annual fee is ca. €8.3 mln, while the cost of those activities eligible for remuneration calculated in procedural fees is ca. €3.9mln.

[44] A fee has not been calculated for this activity for the consultation.

Table A2-1 Additional activities declared by NCAs

'Additional activities', declared by NCAs	*Estimated average cost for all NCAs (€)*
Total	52.634.924 €
Not eligible under annual fee because does not meet eligibility criteria	***40.349.325 €***
(Work related to being a) member of the EMA Management Board	730.881 €
Member of and work related to EMA-hosted boards and forums (e.g. Scientific Coordination Board (SciCoBo))	586.721 €
Member of and work related to ad-hoc working groups for organisational matters	277.537 €
Participation in multi-stakeholder meetings/forums (e.g. European Forum for Good Clinical Practice (EFGCP)) ; Stakeholder engagement (e.g. patients and healthcare professionals, industry, European and International partners)	337.080 €
Attending and presenting at Drug Information Association (DIA) events	99.151 €
Patient Registries Initiative, e.g. member of Cross-Committee Task Force and/or of one of the Cross-Committee Task Force Working groups, or participation in their workshops	243.269 €
Member of and work related to EU Telematics Management Board and Telematics Working Group (e.g. meetings for Clinical Trials Interface Working groups (Application Programming Interface), Consultative Group for Veterinary Product Data Systems (CGVPS, former TIG), Consultative Group for Veterinary Pharmacovigilance Systems (CGVPhS, former JIG));	2.197.168 €
EMA Strategic Review & Learning Meeting (SRLM)	289.628 €
PDCO Non-clinical Working Group (NcWG) and PDCO Formulation Working Group (FWG)	298.378 €
ICH or VICH (Expert) Working Group (EWG) (meetings and other related work)	391.015 €
Medical dictionary for regulatory activities (MedDRA) or Veterinary Dictionary for Drug Regulatory Activities (VeDDRA): establishment and maintenance of terminology standards	115.715 €

EudraLex - Volume 8 of the publications "The Rules Governing Medicinal Products in the European Union" ('Volume 8'), titled: 'Notice to applicants and Guideline – Veterinary medicinal products – Establishment of maximum residue limits (MRLs) for residues of veterinary medicinal products in foodstuffs or animal origin'	221.023 €
WHO collaboration, other than related to antimicrobial resistance	134.925 €
Reaction of EFSA	155.908 €
Lumpy skin disease (focus group) and FishMed	301.106 €
Transparency: access to documents (ATD) (Policy/0043)	68.722 €
Transparency: proactive publication of clinical trial data (CDP) (Policy/0070)	101.693 €
Transparency: reviewing of the contents of documents made public on the EMA website (e.g. review of the European Public Assessment Report (EPAR) for human or veterinary medicinal products and the Assessment Report Summaries for the Public (ARSPs) for herbal medicinal products)	72.138 €
Transparency: linguistic review of documents made public on the EMA website (e.g. product information or the EPAR summary for the public)	2.230.843 €
Transparency: preparation of responses to queries related to referral procedures	663.620 €
Coordination of safety communication	533.021 €
Communication	591.853 €
Attendance, organisation or giving training, presentations, webinars or workshops (outside working parties/committees) in the framework of the EU Network Training Centre (EU NTC)	1.892.036 €
Attendance, organisation or giving training, presentations, webinars or workshops (outside working parties/committees), other than EU NTC-related activities	800.922 €
Work related to EU presidency	512.557 €
Data gathering, EMA or EC surveys	600.285 €
OMCL laboratory projects, incl. taking samples from the market	1.472.747 €

Signal management human medicines (this includes the following actions: 1. Signal detection (incl. review e-RMR), 2. Signal validation, 3. Signal confirmation, 4. Signal analysis and prioritisation, 5. Signal assessment, 6. Recommendation for action) ; Signal detection and surveillance veterinary medicines	1.625.948 €
Adverse drug reaction (ADR) reporting	4.900.673 €
GLP inspection	719.795 €
GMP/GDP inspection: national	3.832.751 €
Speeding up access to medicines	356.985 €
Assessment of invented names	212.024 €
Comments on non-(co)rap procedures (concerned comments)	3.489.140 €
Monitoring of the advertising of all medicinal products	2.098.283 €
Checking of the content of the QR (quick response) code	52.860 €
National implementation of EC decisions (e.g. after safety referrals)	932.278 €
Update of national drug registry and publishing of drug information	1.927.568 €
Work related to product defects ; Rapid Alert (RA)/Non-Urgent Information (NUI)/Incident Management Plan (IMP)	770.357 €
Medicine shortages	1.518.487 €
Parallel distribution activities	323.511 €
EMA Guidance dev rapporteur	429.653 €
Herbal legislation	28.601 €
WHO collaboration, other than related to antimicrobial resistance	134.925 €
Development Safety Update Report (DSUR)	1.075.544 €
	40.349.325€
Eligible under annual fee	**8.292.438 *€***
Post-authorisation measures (PAMs) (REC, MEA, ANX, LEG, SOB) / follow-up measures (FUM)	1.024.082 €
Annual reassessment of a marketing authorisation under exceptional circumstances	88.981 €
List of Union reference dates and frequency of submission of period safety update reports (the EU reference dates (EURD) list)	32.687 €
Pharmacovigilance audit, including (non)conformity reports	641.750 €

Checking of national translations of additional risk minimization materials (educational materials etc.) and DHPC letters	2.183.163 €
Drafting, peer-review and commenting on herbal monographs and list entries	209.826 €
Modification of a herbal monograph	105.502 €
Regular revision of a herbal monograph (every five years)	116.486 €
Member of and work related to (smaller) (ad-hoc) working groups for scientific matters (e.g. for review and implementation of ICH guidelines or those related to the different annual Committee Work Plans (e.g. improving the full MA/AR-documentation process and templates))	660.040 €
CODEX	134.187 €
HTA collaboration	118.377 €
Additional monitoring list	267.950 €
Work related to addressing antimicrobial resistance (AMR), including JIACRA, AMEG, RONAFA, ESVAC, CADVVA	1.701.743 €
European Pharmacopoeia work and corresponding laboratory work	821.439 €
Post-Authorisation Efficacy Studies (PAES): PAES protocol	186.225 €
	8.292.438 €
Not eligible for annual fee because procedural fee remuneration either exists or is to be created	**3.993.161 €**
Qualification Opinion meeting	87.763 €
Compassionate use programme	113.875 €
Paediatric work-sharing in accordance with Article 45 and 46 of Regulation (EC) No 1901/2006 (Paediatric Regulation) in case of centrally authorised products	475.691 €
Paediatric Investigation Plan (PIP) modifications	335.843 €
Orphan designation, review of maintenance of an orphan designation at the time of the initial marketing authorisation, including assessment of significant benefit criteria; orphan derogation	263.217 € + 106.242€
Classification at the request of the MAH on MUMS/limited markets	20.021 €
HMPC operation and associated procedures	62.016 €
National GCP inspection linked to EMA request (MA), including preparation of supporting documents for sanctions imposed for GCP non-compliance	502.268 €

Plasma Master File (PMF) – initial certification	72.032 €
PMF - annual updates	75.137 €
ATMP certification	23.040 €
Pre-submission meetings/hearings	532.818 €
Establishment, modification or extension of maximum residue limits (MRLs)	93.203 €
PRIME	363.965 €
Accelerated assessment, including eligibility requests	161.024 €
Eligibility assessment for the centralised procedure	9.772 €
ATMP classification	63.619 €
Re-examination procedure	477.784 €
Annual renewal of a conditional marketing authorisation	101.523 €
Art. 5(3) procedure (Regulation (EC) No 726/2004):	52.308 €
	3.993.161 €
TOTAL ALL	**52.634.924 €**

Appendix 3. Overview of the feedback received on the Inception Impact Assessment for the future amendment of the EMA fee system

The analysis presented in this appendix has been provided to the study team by DG SANTE services.

1. Introduction

The evaluation of the EMA fee system found that, although the system is generally effective and efficient, it is not cost-based on the procedural level (both fees and NCA remuneration). In addition, it may need to be revised to be more flexible to adapt to future developments, including the implementation of the new veterinary legislation, and also be more sustainable in the long term. Based on this, a draft IIA was created presenting three incremental policy options and a few sub-options. Option 1 only addressed veterinary fees to accommodate for the new veterinary legislation, option 2 aimed at making both veterinary and human fees cost-based without changing the fee system structure, and option 3 concerned a simplification of the fee system structure by including fees of several post-authorisation procedures into the annual fee. Sub-options concern the application of a country coefficient to NCA remuneration levels, the distribution of the burden of costs for fee incentives between EMA and NCAs, and the application of a general reduction and/or specific incentives to veterinary fees.

The draft IIA was published for feedback. Responses were received from the following 14 parties:

- Public authorities (regulators and governments):
  (1) EMA

  (2) HMA

  (3) USKVBL, CZ (NCA V)

  (4) AESMP, ES (NCA H/V)

  (5) FMA, FI (NCA H/V)

  (6) MPA, SE (NCA H/V)

  (7) DKMA, DK (NCA H/V)

  (8) PEI, DE (NCA H/V)

  (9) German public authority (anonymous)

  (10) Ministry of Health, Welfare and Sports and Ministry of Agriculture, Nature and Food, NL

- Industry associations:
  (11) Medicines for Europe

(12) EFPIA

(13) ECHAMP

- Other:
  (14) Prescrire

The feedback received as well as actions proposed to address this feedback are presented below.

2. Feedback received

A. Feedback on the main policy options

Even though it was not the aim of the exercise, many respondents indicated which of the policy options would be their preferred option or which option, in their view, would best address the issues identified during the evaluation. The following comments were received:

1. **Updated, cost-based veterinary fees to take account of the new veterinary legislation - policy option 1**
   This option was generally not supported by respondents, because it does not provide a solution for any of the problems identified during the evaluation, with the exception of the necessary adjustments of veterinary fees.
2. **Cost-based human and veterinary fees – policy option 2 (comments from 3 respondents from regulatory bodies)**
   In general, respondents agreed with making fees cost-based, including cost-based remuneration for NCAs (with different amounts for the rapporteur and co-rapporteur). However, respondents commented as follows:
   - Policy option 2 doesn't address all identified issues, i.e.: more complex vs more simple procedures and the complexity of the fee system.
   - The annual fee is critical to finance horizontal activities. It is assumed that under a cost-based system all fees are assigned to specific tasks. It is unclear how the annual fee will be allocated under option 2.
   - Only option 2 can be established within a reasonable timeframe, but it will partly result in inadequate fees. Introducing cost-based fees whilst keeping the existing fee structure may lead to weighted averages that will have a negative impact on the sustainability of some NCAs.
3. **Simplification of the fee system – policy option 3 (comments from 7 respondents from regulatory bodies or ministries, 2 industry associations)**
   In general, respondents find the current fee system fairly easy to understand and apply. However, with the exception of one respondent, they still called for simplification. The extent to which respondents felt the fee system should be simplified however differed:

   Comments favouring policy option 3 came from industry associations and some NCAs:

- Policy option 3 is most consistent with its principles and position. Simplification of the fee system would make it more efficient and less costly, since significant levels of resources are currently being diverted to processing and invoicing of the simplest administrative submissions. These resources could be better utilised to advance innovation and patient health.
- Policy option 3 increases financial predictability for all stakeholders.

Some regulators expressed some uncertainties:

- A more comprehensive annual fee may increase the mismatch between income and costs, especially for NCAs without critical mass of CAPs.
- Policy option 3 requires further elaboration:
  - The impact on EMA and NCAs is unclear and more granularity is required on procedures covered by the annual fee.
  - Flexibility is required to accommodate unexpected circumstances, implementation of legislation, expertise, new IT developments etc.

B. Feedback on policy sub-options

Some of the respondents disagreed with the sub-options presented in the IIA:

1. **The application of a country coefficient for NCA remuneration (6 respondents from regulatory bodies):**
   - It leads to financial unpredictability:
     In case of fixed fees, EMA's fee income per procedure would depend on the origin of the rapporteur. This creates unforeseeable fluctuations in EMA's budget and, as such, increases the risk to EMA's financial stability and the complexity towards EMA's financial planning. In case of non-fixed fees, the level of fees would be based on the origin of the rapporteur.
   - It may negatively impact the multinational assessment team (MNAT) concept[45]:
     The MNAT concept is crucial to address the increasing workload due to the UK leaving the regulatory network and due to increased complexity of products. A country coefficient would destroy the successful MNAT, because authorities with a high coefficient would no longer be willing to take part in assessments conducted by rapporteurs from countries with a low coefficient.
   - It may affect the appointment of rapporteurs:
     The distribution of centralised procedures may no longer be based on scientific expertise but on financial considerations in order to balance expenses.
   - It is inherently unfair and divisive:
     The scientific contribution should be remunerated; all parties are expected to deliver the same quality of work.
     In addition, countries with lower costs already struggle with funding and contributing to the regulatory network. A country coefficient will negatively impact their possibility to participate and, as such, further contribute to a two-tier network.

[45] MNAT = Multinational assessment teams

Finally, a country coefficient is notoriously hard to apply fairly in that they are generalised coefficients based on country costs that may be irrelevant for assessment costs (e.g. the inflation rate of salary costs, the most relevant costs for NCAs' scientific assessment, may be significantly different than the inflation rate of other, irrelevant costs (e.g. food, fuel) that are factored into the coefficient).

- Legality:
  The application of a country coefficient seems to exceed the legal remit foreseen in the EMA Founding Regulation[46].

2. **The sharing of the costs of fee incentives between EMA and NCAs (6 respondents from regulatory bodies and ministries); the application of a general reduction to veterinary fees (4 respondents from regulatory bodies):**
   Although all parties inherently support the application of fee incentives to certain products or actors, they object to the above proposals for the following reasons:
   - EU policy based fee incentives should be funded by EU budget:
     Fee incentives, including a flat reduction for veterinary products, would follow EU level health care policies and/or industry support policies and should therefore not be financed by EMA or NCAs but by EU budget (or, failing so, by industry).
   - It leads to problematic funding mechanisms for NCAs:
     Since centralised fees will be made cost-based, fee incentives should then be financed from national funds. For self-financing NCAs this may not be sustainable.
     Also, this means that pharmaceutical companies operating at the national level would fund incentives for centralised applications, for which there seems to be no basis.
     Further, respondents stated that in some Member States (e.g. NL) it is not allowed by law to finance centralised/EMA-related work from national funds.
     For government-funded NCAs, the funding of incentives should then come from government interventions. This should be agreed explicitly with those governments and not be hidden through reduced non-cost covering fees.
   - It leads to unfair distribution of costs of incentives:
     Sharing of costs of incentives between EMA and NCAs does not meet the objective of a fair distribution of fees and remuneration according to some respondents, because, it was claimed, NCAs don't have other sources of income (i.e. budget contributions) to cover the shortfall. This may also lead to economic considerations by NCAs impacting rapporteurships.
   - Fees should be based on costs:
3. Veterinary fees should not be based on the size of the market but reflect costs, because the aim of the assessment is to safeguard quality, safety and efficacy of products, and the amount and quality of the assessments are driven by legislative requirements. Any flat reduction is an incentive which requires a separate funding model and should be financed from the EU budget and/or other charges (see further the comments above). **No fee for veterinary variations not requiring assessment under the new Veterinary Medicinal Products (VMP) Regulation[47] (2 respondents from regulatory bodies):**
   - Also variations not requiring assessment incur costs:
     Even for administrative procedures authorities are obliged to execute responsibilities under the VMP Regulation related to that task (Art. 61(2) and (3)), which should be funded.

[46] Regulation (EC) No 726/2004

[47] Regulation (EU) 2019/6

C. Other comments

In addition to the above, several other comments were made:

4. **The increasing complexity of products/procedures should be taken into account (5 respondents from regulatory bodies and 1 respondent from industry associations):**
   The new fee system should take account of increasing complexity of tasks due to advances in science, which result in higher complexity of medicine development and regulatory oversight, and new technologies requiring investments in large telematics projects benefiting the whole network and new legislation. None of the draft policy options offer solutions for this increasing complexity.
   The new fee system should be flexible to (1) take account without delay of scientific innovation or new legislative requirements, (2) allow for different fee levels for more complex procedures (e.g. distinction between chemical, biological, gene-based therapies for new applications, Type II variations, line-extensions and pharmacovigilance referrals), and (3) address future scenarios which require incentives. Different fee levels would avoid massive misalignment and the need for cross-financing (which is currently the case) and the lack of bidding for highly complex procedures.
5. **Data gathered for the evaluation are outdated (3 regulatory bodies):**
   The evaluation was based on 2016 time and cost data. However, costs of procedures have increased since due to increasing complexity. In addition, very limited data were gathered for meetings, and costs will be understated. Further, data gathered on NCAs' additional activities covers the last 12 months when activities were kept at a minimum due to EMA's business continuity plan.
6. **The new fee system should ensure financing of general public health activities (1 regulatory body):**
   The new fee system should ensure financing of general public health activities:
   - The EU budget contribution in the next MFF will be gradually reduced so that public health activities would no longer be financed by the EU contribution but by income from fees or charges.
   - Extended EMA activities should be considered as well (framework for accessing and analysing healthcare data, funding of industry-independent post-authorisation studies, health digitalisation etc.).
7. **Provisions of the Fee Regulation related to scientific services and fee incentives should be kept (1 regulatory body):**
   The Fee Regulation allows for the introduction of fees for scientific services and fee incentives for specific cases by the EMA Management Board (on a favourable opinion from the Commission) and fee reductions in exceptional circumstances and imperative public and animal health reasons by the EMA Executive Director.[48] Currently, these are included in the Implementing Rules of the Fee Regulation. These provisions should be kept.
8. **NCA remuneration for additional activities (5 respondents from regulatory bodes and 1 respondent from ministries):**
   NCA funding is needed for at least some of the cross-cutting activities:
   - Funding is needed to support and sustain the EMA and the network (e.g. telematics) and to recognise the need to fund public health issues, developing expertise and development of the network into a world class regulator (currently, the EU is lagging in authorisation and research as compared to other regions).

[48] Articles 8(2) and Article 9 of the Fee Regulation.

- Recognition is needed that EMA's role in respect national products has significantly increased (pharmacovigilance). Some of the additional activities are therefore for the benefit of national products.
- Running an organisation brings significant ancillary costs (e.g. EMA Management Board) which fees must cover.
- To the extent that the work relates to centrally authorised products (CAP) or the CAP framework, it is inappropriate that additional activities should be funded from national fees. Therefore, in a new fee system these costs can be included in fees as overhead costs.
- Currently, NCAs provide non-reimbursed additional services for the network for more than €50 million per year. Any future fee-adjustment increasing this imbalance will have a negative impact on the sustainability of the network.
- All NCAs should receive a part of the annual fee to cover additional (non-procedural) activities. This part is smaller than for the (co-)rapporteur.

9. **Introduction of a system for annual fee adjustment (1 regulatory body):**
   There is a need for a specific mechanism for annual fee adjustment and introduction of new fees/charges to correct for changing costs (including inflation rate) and new tasks, whereby efficiency gains should also be considered.
10. **Introduction of a time-slot fee (1 regulatory body):**
    Introduction of a time-slot fee to improve predictability of new applications and future resource planning. In case of delay or cancellation of the submission, the fee would not be returned to the company.
11. **Three-tier annual fee and lower annual fee for duplicates (1 industry association):**
    The annual fee under option 3 should reflect the actual workload. This workload decreases over the years, which could be reflected by introducing a three-tier level annual fee with a decrease after 5 and 10 years (e.g. renewal). Further, true duplicates should have lower annual fees due to lower workload.
12. **EMA should be solely financed by EU funding (1 respondent from wider stakeholders):**
    EMA's budget should not be based on a fee-for-service basis but solely on EU funding to ensure its independence from industry so that public health interests override industry interests.

Appendix 4. DARWIN EU, its interplay with the European Health Data Space (EHDS) and expected annual maintenance cost

The analysis presented in this appendix has been provided to the study team by DG SANTE services.

The creation of the EHDS is one of the main priorities of the Commission in the area of health. The EHDS will enable the cross-border exchange of and access to different types of health data originating from real-world data sources such as electronic health records, administrative databases or patient registries. The EHDS will not only support healthcare delivery but also health research and innovation, public health policy-making and regulatory activities. The EHDS is an overarching initiative that covers four key strands of work:

a) a governance framework and rules for the secure exchanges of health data for primary and secondary purposes;
b) the deployment of the interoperable digital infrastructure for such exchanges;
c) specific actions for improved quality and semantic interoperability of health data;
d) capacity building activities in Member States, including on digital skills of competent authorities and health workforce.

The Commission is currently working on the preparation of a legal framework for the governance, rules and requirements for a common EHDS. A legal proposal is expected to be adopted by the end of the year of the beginning of 2022. The Commission, together with relevant stakeholders, and including the EMA, is preparing a pilot that aims at demonstrating the added-value of the EHDS, among others in use cases related to EMA's regulatory activities at the level of the Union. The integration of DARWIN EU in the EHDS (as a node in the digital infrastructure for secondary use of health data) will facilitate the EMA's and national agencies' ability to launch cross-countries observational studies.

The Data Analysis and Real World Interrogation Network (DARWIN EU) is the future EMA's infrastructure that will support regulatory decision-making by:

a) establishing and expanding a catalogue of observational data sources for use in medicines regulation;
b) providing a source of high-quality, validated real world data on the uses, safety and efficacy of medicines;
c) addressing specific questions by carrying out high-quality, non-interventional studies, including developing scientific protocols, interrogating relevant data sources and interpreting and reporting study results.

DARWIN EU will connect EMA and the European medicines regulatory network to the European Health Data Space (EHDS), an initiative to promote better exchange of and access to different types of health data. DARWIN EU will include a coordination centre for the exchange of queries and information across European medicines agencies and the EMA, and it will be integrated in the broader EHDS infrastructure network for access to real-world health data.

DARWIN would also support FAIRification of datasets[49], which can also be made available to other re-users.

The DARWIN EU infrastructure and organisational structure are expected to be developed, deployed and operated in two phases:

a) A project phase (Phase 1), which covers the development and deployment of the core components of the DARWIN EU infrastructure (2021-2023);
b) A maintenance phase (Phase 2), which covers the operations and further development of the DARWIN EU infrastructure (from 2024 onwards).

Phase 1 is expected to be funded through the Union budget contribution allocated to the EMA under its revised mandate. Phase 2 is expected to be covered annually by fees collected by the EMA. The EMA has estimated the yearly amount for Phase 2 at 16 million EUR (see Table below). This yearly amount includes the operation of the Coordination Centre and its integration in the EHDS, the operation of the associated infrastructure, and the execution of routine and complex data analysis studies.

EXPECTED ANNUAL MAINTENANCE COST (PHASE 2)

Type	Category	Amount EUR
Analysis and Studies	**Analyses and Studies**	**7,200,000**
Operational	**Governance**	**3,750,000**
	Training & Missions	**258,000**
	Maintaining Data Sources	**2,998,187**
Infrastructure	**Technology Infrastructure**	**1,720,713**
Total expected annual maintenance cost		**15,926,900**

[49] FAIR data sets are those that meet principles of **f**indability, **a**ccessibility, **i**nteroperability and **r**eusability. FAIRification is the process through which data sets are made compliant with FAIR principles.