Study for the evaluation of the EMA fee system

Summary Report

SANTE/2016/B5/021

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List of acronyms

Acronym	Description
AMR	Antimicrobial resistance
CAP	Centrally authorised product
DG SANTE	Directorate General for Health and Food Safety
ECHA	European Chemicals Agency
EEA	European Economic Area
EMA	European Medicines Agency
EMA MB	EMA Management Board
EU	European Union
FDA	U.S. Food and Drug Administration
HMA	Heads of Medicines Agencies
IT	Information technology
MBDG	EMA Management Board Data Gathering
MUMS	Minor-use-minor-species
NAP	Nationally authorised product
NCA	National Competent Authority
PAES	Post-authorisation efficacy study
PAM	Post-authorisation measure
PASS	Post-authorisation safety study
PO	Purchase order
PSUR	Periodic safety update report
PSUSA	Periodic safety update report (PSUR) single assessment
SME	Small and medium-sized enterprise

Glossary of terms

Term	Definition
Additional activities	Both EMA and NCAs undertake additional activities, which are not categorised as procedural activities or time spent in committees and working groups, as defined in the NCA survey[1] (Questions 17-19). For EMA, these activities were provided as a separate list.[2] For NCAs, costs of these activities are calculated as a residual cost in the model.
Administrative staff	The definition used in the EMA Management Board Data Gathering (MBDG) exercise (EMA, 2017 Annex III[3]) is applied in NCA survey, data provided by EMA and model. Administrative staff is defined as 'staff other than scientific/technical providing direct administrative support to procedures'. The same definition is applied to committee, working group and additional EMA-related activities.
Average incentive rate	The average discount rate applied to the full or theoretical industry fee for a given activity. It depends on the nature of the product and the industry organisation (e.g. whether an SME) making the application, among other things and is assumed to be fixed for the typical year.
Committee and working group activities	Time spent in and preparing for EMA committee and working group meetings.
Cost-based	In a cost-based system fees reflect the average cost of undertaking a procedure for an activity. In this study, cost-based is defined as cost-based in aggregate, not at the individual organisation level.
Cost per hour of EMA activities	The cost per hour of EMA activities is calculated based on the annual costs divided by the annual hours worked for each staff type. Overheads and non-staff costs are allocated to the annual costs for two different staff types (scientific and administrative staff).
EMA budget	The EMA budget consists of fee revenue from industry; EU and EEA budget contributions; EMA costs; payments EMA makes to NCAs for procedural activities (NCA remuneration) and reimbursements to NCAs for working group and committee-related travel and subsistence costs.
EMA costs	Costs to EMA for all the activities they undertake, which include the activities EMA undertakes as an organisation and reimbursement of NCAs for travel and subsistence costs. EMA also makes payments to NCAs for the procedural activities they undertake; these are not considered to be EMA costs, but rather enter the revenue model as a reduction in the EMA share of fee income from industry.
EMA fee income	EMA fee income is fee revenue from industry minus the NCA remuneration.

[1] The NCA survey is included as Appendix 7 to the Interim Report.

[2] Data provided by EMA is available in spreadsheet form as an electronic supplement.

[3] Annex III only provides an example of how the definition applies to scientific advice and protocol assistance activities. Time spent by scientific and administrative staff was recorded for all activities covered in the MBDG exercise.

Term	Definition
EMA revenue	EMA revenue consists of the fee revenue from industry and EU and EEA budget contributions minus NCA remuneration.
EMA-related activities	These are all the cost-generating activities undertaken by NCAs that are reported in the NCA survey.
EU and EEA budget contributions	In the model, the actual EU and EEA budget contributions are used in the baseline and synthetic baseline. An additional term, denoted 'other income', is calculated in the synthetic baseline model. It corresponds to income from administrative operations, such as sale of publications and organisation of seminars, and is calculated as the EMA fee income plus EU and EEA budget contributions minus EMA costs. For scenarios where the EU budget contributions are used as a funding mechanism, additional EU budget contributions are calculated.
Procedural activities with NCA involvement	These comprise a specific number of procedural activities for which data were gathered during the MBDG exercise agreed with EMA and HMA and which formed the basis for two questions listed in Questions 17 and 18 in the NCA survey.
Fee revenue from industry	This is the total amount received from industry by EMA for services undertaken and annual fees. It depends on the number of procedures invoiced and the average incentive rate applied for each activity. The fee revenue further depends on the number of centrally authorised products (CAPs) and nationally authorised products (NAPs) holding a valid marketing authorisation (MA). The fee revenue received from the annual CAP fee and annual pharmacovigilance (PhV) fee depend respectively on the number of CAP and NAP MAs.
Fee rule	Determines the full fees paid by industry for the services they receive. Incentives are not part of the fee rule. EMA income depends on the fee rules and the incentives that are applied.
Procedural activities without NCA involvement	These are a set of activities undertaken by EMA without NCA involvement and for which fees are charged to industry.
Fixed inputs	These comprise the number and type of procedures, average incentive rates and times taken to undertake activities. They have been determined for a 'typical year' and remain constant in the model calculations. They are independent of the fee and NCA remuneration rules.
Full fee	The full fee is the average fee paid under a given fee rule per procedure of a given activity over the reporting year, prior to the application of incentives. Full fees were obtained from data provided by EMA.
NCA budget	The NCA budget covers EMA-related activities only and consists of NCA costs and NCA remuneration. Other sources of costs or income not related to EMA activities are not included.
NCA costs	Costs to NCAs to undertake EMA-related activities. Costs from other activities that NCAs undertake are not included.
NCA income	Income that NCAs receive from EMA for the EMA-related activities they undertake. NCA income from other sources is not included.

Term	Definition
NCA reimbursement	NCA reimbursement consists of travel costs and substance allowances paid to experts travelling to London to take part in committees and working groups. Under the existing system such travel costs are reimbursed by the EMA under the relevant rules. They are included in the EMA costs only. Additional travel and subsistence costs for member state experts have been declared by NCAs in the survey and are taken into account in the cost calculation.
NCA remuneration	Payments NCAs receive from EMA for undertaking EMA-related activities.
NCA remuneration rule	This rule determines the payments NCAs receive from EMA for undertaking EMA-related activities. EMA fee income depends in part on the remuneration rule as that determines the payments they make to NCAs. NCA income depends on the remuneration rule.
NCA roles	Committee rapporteur, committee co-rapporteur, peer reviewer or member of a multi-national assessment team. Rapporteur could also encompass a coordinator or inspector role depending on the type of activity involved.
Non-EMA activities	These are activities undertaken by NCAs that contribute to their total costs but are not EMA-related and not included in the NCA survey.
Other income	This is an additional term calculated in the baseline and synthetic baseline to balance the EMA budget. It corresponds to income from administrative operations, such as sale of publications and organisation of seminars.
Overhead costs	Overhead costs: e.g. depreciation, information technology (IT), administration. These costs cannot be directly allocated to an activity as is salary or other non-staff costs. Overheads are allocated to salary costs in the model according to a specified rule based on staff time.
Procedure	The term ‘ procedure’ is used by the study team, for the purposes of the report, as instances of the activities listed in Questions 17 and 18 of the NCA survey and the procedural activities without NCA involvement listed by EMA. It is acknowledged that there are a wider range of activities not included in our definition for which procedures may be undertaken. In the study, unit fees are defined per procedure. Several procedural roles may be associated with a single procedure.
Procedural activities with NCA involvement	These comprise a specific set of procedural activities listed in Questions 17 and 18 of the NCA survey.

Term	Definition
Procedural role	The term 'procedural role' is used by the study team to refer to each instance that an NCA undertakes a particular activity in a given role for which data were reported in the NCA survey. There are three classifications of roles that correspond to the data requested in Q17 and Q18 of the NCA survey. These are: • Rapporteur or equivalent lead role (column 1) • Co-rapporteur or equivalent support (column 2) • Other role that is required for completion of a procedure (column 3). Other roles include PRAC rapporteur and co-rapporteur and peer-reviewer, as well as members of multi-national teams. For example, NCA X could report carrying out a co-rapporteur procedural role ten times for the activity 'type II variation – level I'.
Purchase orders	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. POs do not cover non-remunerated roles, such as peer review.
Scaling factor	In the synthetic baseline it is assumed that the 29 respondent NCAs in the model undertake all the invoiced procedural activities reported by EMA. To achieve this, each procedural role reported by an NCA for a given procedural activity is multiplied by a scaling factor so that the total number of rapporteur and co-rapporteur roles is equal to the number of POs reported by EMA. This scaling factor is equal to the ratio of the total number of purchase orders reported by EMA to the total sum of the number of rapporteur and co-rapporteur roles or equivalent remunerable roles reported in the NCA survey by the 29 respondent NCAs included in the model.
Scientific staff	The definition used in the EMA Management Board Data Gathering (MBDG) exercise (EMA, 2017 Annex III[4]) is applied in the NCA survey, data provided by EMA and model. Scientific staff is defined as 'Scientifically qualified staff acting as co-ordinator, quality, safety, efficacy assessor, peer reviewer, QA, External Expert, SA officer, EPL/Specialist, Secretariat and Regulatory and in addition legal support.'
Staff salary costs/hour	These are costs before overheads and direct (non-staff) costs are added.

[4] Annex III only provides an example of how the definition applies to scientific advice and protocol assistance activities. Time spent by scientific and administrative staff was recorded for all activities covered in the MBDG exercise.

Term	Definition
Synthetic baseline	A 'synthetic baseline' is used to determine NCA costs and EMA costs excluding NCA remuneration. The synthetic baseline relies on assumptions about a common set of activities for both EMA and NCAs. That is, for procedural activities involving NCAs, the number of procedural activities that EMA undertakes in a typical year is the same as the number of activities undertaken by NCAs at EMA's request. Both the fee revenue and NCA remuneration are then based on this number of activities. For procedural-activities involving EMA only, the number of invoiced procedures is the same as the number of procedures undertaken by EMA.
Theoretical fees	The full fee per activity under a cost-based fee system.
Types of cost generating activities undertaken by EMA	Three types: (i) costs for the scientific and administrative work they undertake as part of procedural activities they provide which also involve NCAs; (ii) costs for the scientific and administrative work they undertake as part of procedural activities they provide which do not involve NCAs; (iii) costs for additional activities they undertake.
Types of cost generating activities undertaken by NCAs	Three types for EMA related activities only: (i) costs for the scientific and administrative work they undertake as part of procedural activities for EMA; (ii) costs associated with committees and working groups excluding costs associated with rapporteur, co-rapporteur and equivalent remunerable roles; and (iii) costs for additional activities they undertake.
Typical year	The typical year is based on data from the reporting years for NCAs and EMA and the MBDG sample year. In this year it is assumed that, for procedural activities involving NCAs or carried out by EMA only, the number of invoiced procedures is the same as the number of procedures undertaken. Data for all other activities remains the same as in the baseline year. The typical year is used in the synthetic baseline.
Unitary fee	This is the fee per procedure for a given activity.

1. EXECUTIVE SUMMARY

1.1. Introduction and context to the Study

The European Medicines Agency (EMA) is the European Union's (EU) central regulatory body to enable centralised authorisation procedures for medicinal products for use in humans and food-producing animals across the European Economic Area (EEA). The agency is funded by general EU and EEA contributions as well as fees paid by industry for obtaining and maintaining marketing authorisations and providing other authorisation-related services. The EMA works in close collaboration with national competent authorities (NCAs) in EEA Member States, which undertake activities related to assessments aimed at granting, maintaining and monitoring EU marketing authorisations, and other services related to medicinal products for human and veterinary use including pharmacovigilance activities for medicines for human use at EU level. NCAs are remunerated by the EMA for undertaking these activities.

The fee and remuneration system is defined in Council Regulation (EC) No 297/95, which establishes the services provided by the EMA and related fees payable to the agency for undertaking authorisation procedures, as well as through a set of implementing rules and Regulation (EU) No 658/2014 for pharmacovigilance activities. The fee system also provides fee incentives and reductions for specific types of products including orphan designated medicines, veterinary medicines, products for paediatric use, and advanced therapy medicinal products and for specific user groups such as micro, small and medium-sized enterprises (SMEs).

1.1.1. Objectives and scope

This is a study of the fee and remuneration system and its relationship to the underlying costs associated with its services. It assesses the strengths and weaknesses of the fee system to show the extent to which fees and remuneration are founded on a sound economic basis, whether they are fair and proportionate, and whether the fee system avoids unnecessary administrative burden on fee payers. It addresses these questions with reference to four main evaluation criteria, effectiveness and efficiency, relevance, coherence, and sustainability. This analysis provides a basis from which to consider the need for reform of the fee and remuneration system, and to consider which elements of the fee system might be specifically targeted for reform.

This is a summary report for the 'Study for the evaluation of the European Medicines Agency fee system'. The study was commissioned by the Directorate General for Health and Food Safety (DG SANTE) and was delivered by RAND Europe.

1.1.2. Methodology

The study applied a mixed-methods approach using both quantitative and qualitative methods in order to address the evaluation questions set out in the study terms of reference and to ensure that all relevant stakeholders have been consulted. The approach includes:

- Extensive **desk research and review** of relevant documents and information resources relevant to the fee and remuneration system, including legislative documents, EMA annual reports and budgets, European Court of Auditors reports, final report of an evaluation of the EMA in 2010 and EU policies, as well as a review of fee-based approaches in other EU agencies and the U.S. Food and Drug Administration (FDA).
- A **review of cost and time data** covering EMA and NCA activities, collected by a data gathering initiative of the EMA Management Board (MDBG exercise) and through a survey of NCAs.

- Two **online surveys**, targeting (i) all NCAs to provide cost and time data and insights into perceived strengths and weaknesses of the fee system, and (ii) wider stakeholders, covering European level industry, research, healthcare, patient, consumer and other relevant associations and representative groups.
- **In-depth interviews** with representatives of the EMA and ten selected NCAs.
- **Validation of the time data** provided by the EMA MBDG exercise to identify which, if any, data should be excluded from the cost estimates to be undertaken in this study.
- Development of a **costing methodology and financial modelling** for the fee and remuneration system.
- An **open public consultation** to elicit information, views and concerns of all groups having an interest in the EMA fee system and its implementation.

Financial modelling was used as the primary analytical method for the study, in order to calculate EMA and NCA costs for each category of EMA services and activities, including those for which no fee is currently charged. The modelling approach consists of two parts. A cost model was developed by the study team using an activity based costing methodology to allocate overheads to salary costs. Cost data from EMA and the NCA survey and time data from the MBDG exercise were used to calculate costs of EMA-related work undertaken at activity level. Costs were divided into three types: costs of EMA-requested, procedural activities,[5] costs of participation in EMA working groups and committees, and costs of additional EMA-related activities. A full list of the activities considered in the modelling exercise is contained in Appendix 1 to this summary report.

The second part is a revenue model that calculates the income NCAs receive from EMA for the EMA-related activities they undertake – that is, NCAs' share of fee income – and the share of total revenue that EMA retains (EMA fee income). EMA fee income consists of the fee revenue it receives from industry less NCA income. The fees paid by the pharmaceutical industry enter the model as the fee revenue that is received by EMA. Two rules were applied in the fee model to specify NCA remuneration and industry fees.

As well as fee income, EMA receives revenue from EU and EEA budget contributions. In the model, the actual EU and EEA budget contributions are used in the baseline and synthetic baseline. An additional term, denoted 'other income', was calculated as the difference between the EMA costs and revenues from fees and EU budget contributions. It corresponds to income from administrative operations, such as sale of publications and organisation of seminars.. For NCAs, the cost and revenue modelling only covers EMA-related activities and all other NCA activities were excluded.

In addition to the remuneration and fee rules, incentives and reductions are applied by the EMA to some industry fees. These reduce the fees paid by some applicants. The industry fees per procedure before any incentives are applied to them are referred to as the unitary full fees and are presented in the fee grid for each of the activities considered in the cost model. The fee grid is provided as a separate document with this report.

Finally, scenarios were developed based on different assumptions about which services may or may not be charged for. In order to use the model to compare different theoretical fee system scenarios in a consistent manner, the study team had to make assumptions and, in particular, develop a synthetic baseline to represent a 'typical' year, for which the incentive rates and numbers of procedures are fixed. This is the synthetic baseline year and all the results presented in the study refer to the synthetic baseline. Changes to the number of procedures and incentive rates for a given activity will have an impact on the cost and fee calculations. Costs depend directly on the number of

[5] Some procedural activities are undertaken by EMA only.

procedures and fees paid by industry, and the EMA share of fee income depends on the number of procedures and the incentives and reductions applied. To take account of these effects without needing to test many combinations of incentives and numbers of procedures for different activities, we used average costs per procedure, unitary fees per procedure and full fees before incentives or reductions for some of the analysis of specific activities.

An evaluation framework presented in **Error! Reference source not found.** was used to guide the assessment of judgement criteria for each evaluation question. The data collection tasks described above targeted the sets of indicators for each of the judgement criteria. Information collected under each approach (including desk research, stakeholder consultation and the modelling work) was aggregated and analysed separately to identify the main findings emerging from each. The results were then drawn together to allow for a synthesis of findings for each judgement criterion across all of the evaluation questions.

1.1.3. Limitations

The study relied on the best available data and information to arrive at the findings and conclusions presented in this report. The reported results do not aim to reproduce costs and fees reported in EMA and NCA accounts, but are estimated values based on data provided by EMA and NCAs using an activity based costing approach and the current fee implementing rules. However, there are several issues that limit the conclusions that can be drawn:

- Additional activities are a large component of overall EMA and NCA costs modelled in the synthetic baseline. However, no data is available to analyse in any detail the additional activities reported by NCAs in the survey; data available from EMA on its additional activities was also highly limited. Further research is required to assess the specific costs in this category, which is beyond the scope of the present study.
- The centralised system was acknowledged by NCAs as having considerable benefits; however, this study could not quantify or in other respects assess in detail the implied benefits of the centralised system vis-à-vis national markets, such as provision of access to products without individual countries needing to undertake national procedures.

For veterinary medicines, data samples were small, with a large degree of variation across the reported values for some activities. This is to be expected, given the small volume of activities undertaken relative to human medicines during the period of the MBDG exercise. The small samples mean that there is a higher degree of uncertainty associated with the calculated average time values that are used in the cost estimates, and hence with the cost estimates themselves.

1.2. Findings

1.2.1. Criterion 1: Effectiveness and Efficiency

For this study, the assessment of effectiveness is based on the extent to which the objectives of the fee system have been achieved in relation to the general needs of the fee system. This includes an assessment of the extent to which the fee system: allows the EMA to perform its tasks, allows the EMA to remunerate NCAs adequately, is fair and transparent, is flexible to take into account exceptional circumstances, and supports SMEs. Efficiency is assessed by examining the relationship between costs and fees for the activities covered by the EMA. Effectiveness is closely tied to efficiency and so these evaluation criteria are considered together.

1.2.1.1. EQ1: To what extent do the fees charged correspond with EMA costs?

Overall, the analysis of correspondence between the fees charged and EMA and NCA costs shows that the fees charged to industry enable EMA to: undertake the procedural activities within its remit; provide remuneration to NCAs for their activities in line with the legislative requirements; and to cover some additional cross-cutting and horizontal activities.[6] Equally, the total remuneration provided to NCAs covers the aggregate costs of the procedural activities that they undertake, as well as in aggregate their involvement in working groups and committees; however, alignment with individual NCAs varies.

The total fees are not, however, sufficient to cover all of EMA's activities. The additional EU and EEA budget contributions in effect finance additional activities that EMA undertakes. For NCAs, the total value of remuneration they receive from EMA does not cover all of the additional EMA-related activities that they report undertaking in addition to procedural activities and time spent in working groups and committees.

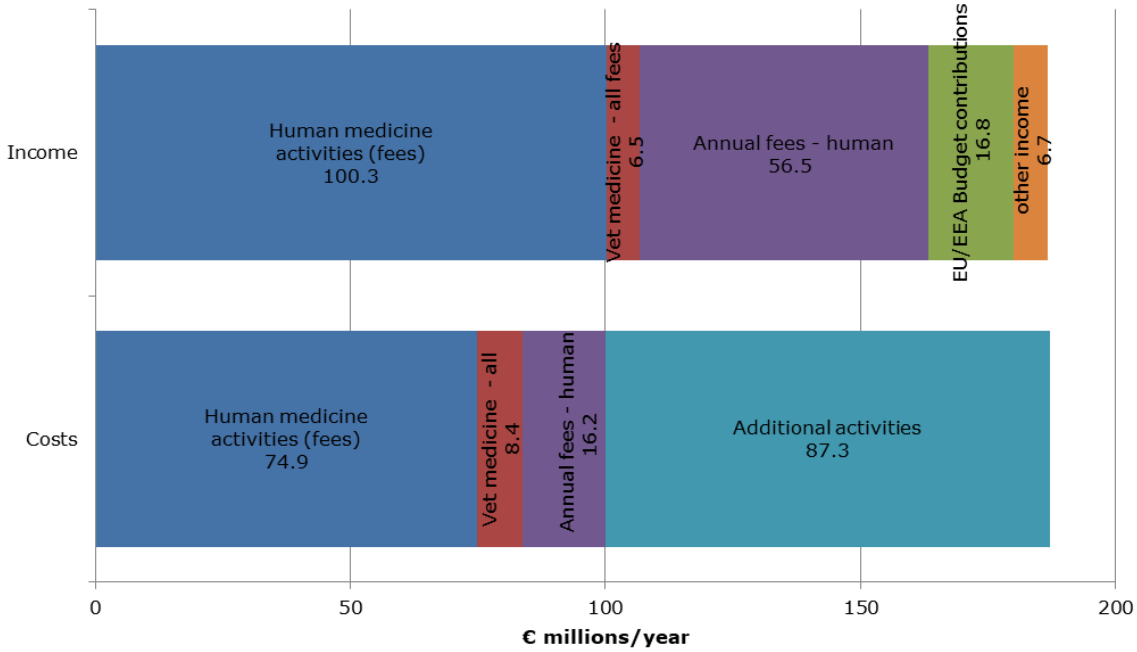
Specifically, the total EMA share of industry fees for procedural activities (excluding annual fees) for both human and veterinary medicines (€103.7 million/year) is sufficient to cover the costs to EMA for these activities (€81.6 million/year). These figures exclude NCA remuneration. These cost figures do not necessarily imply that industry fees are too high or that NCA remuneration is too low as EMA undertakes additional activities for which they receive no fee income.

The total NCA share of fees for procedural activities (excluding annual fees) for both human and veterinary medicines (€92.1 million/year) exceeds their aggregate costs for these activities (€87.3 million/year). These costs are within 5 per cent of the fees. This does not necessarily imply that NCAs were overpaid, however, they undertake additional activities for EMA for which they currently receive no remuneration. Furthermore, at the level of individual NCAs (as opposed to all NCAs in aggregate), some NCAs are able to meet their costs for procedural activities while others are not.

The EMA share of fees for procedural activities (excluding annual fees) for human medicines (€100.3 million/year) is sufficient to cover the costs to EMA of these activities (€74.9 million/year). However, the EMA share of fees for procedural activities for veterinary medicines (€3.4 million/year) is not sufficient to cover the costs to EMA for these activities (€6.7 million/year). An overview of EMA fee income and costs over one synthetic year under the current financial model is provided in Figure 1.

[6] The costs, fees and number of procedures used in the results reported in this section all refer to the synthetic baseline. They do not aim to reproduce costs and fees reported in EMA and NCA accounts but are estimated values based on data provided by EMA and NCAs using an activity based costing approach and the current fee implementing rules.

Figure 1: EMA income (fee revenue and EU/EEA budget contributions) and costs over one synthetic year under the current financial model (€millions/year)

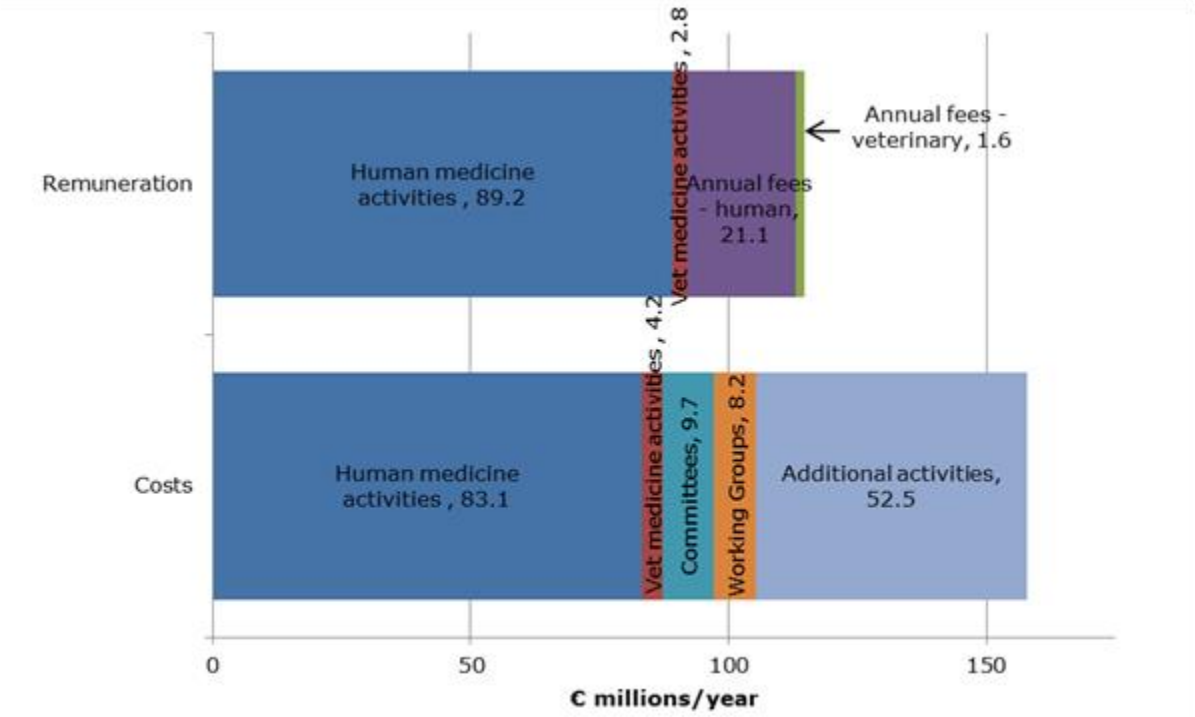


Note: EMA fee income is equal to total fee income net of incentives and NCA remuneration. The depiction used in this figure makes the EMA share of fee income clear. The EMA budget could be presented with total fee income net of incentives in the income bar and NCA remuneration as a cost. The EMA share of fee income would not be immediately apparent in that case. * A full list of additional activities undertaken by EMA is provided in the appendices to the main report.

The total remuneration received by NCAs for undertaking procedural activities for human medicines activities (€89.2 million/year) is sufficient to cover the total costs of these activities (€83.1 million/year). The total remuneration received by NCAs for undertaking procedural activities for veterinary medicines activities (€2.8 million/year) is less than 70 per cent of the costs they incur for veterinary medicines activities (€4.2 million/year). When annual fees are taken into account, NCA remuneration (€4.4 million/year) is approximately equal to costs. An overview of total NCA remuneration and costs over one synthetic year under the current financial model is provided in Figure 2.

Figure 2: Total NCA remuneration and costs over one synthetic year under the current financial model (€millions/year)

* **Error! Reference source not found.** contains a categorisation of additional activities reported by NCAs.

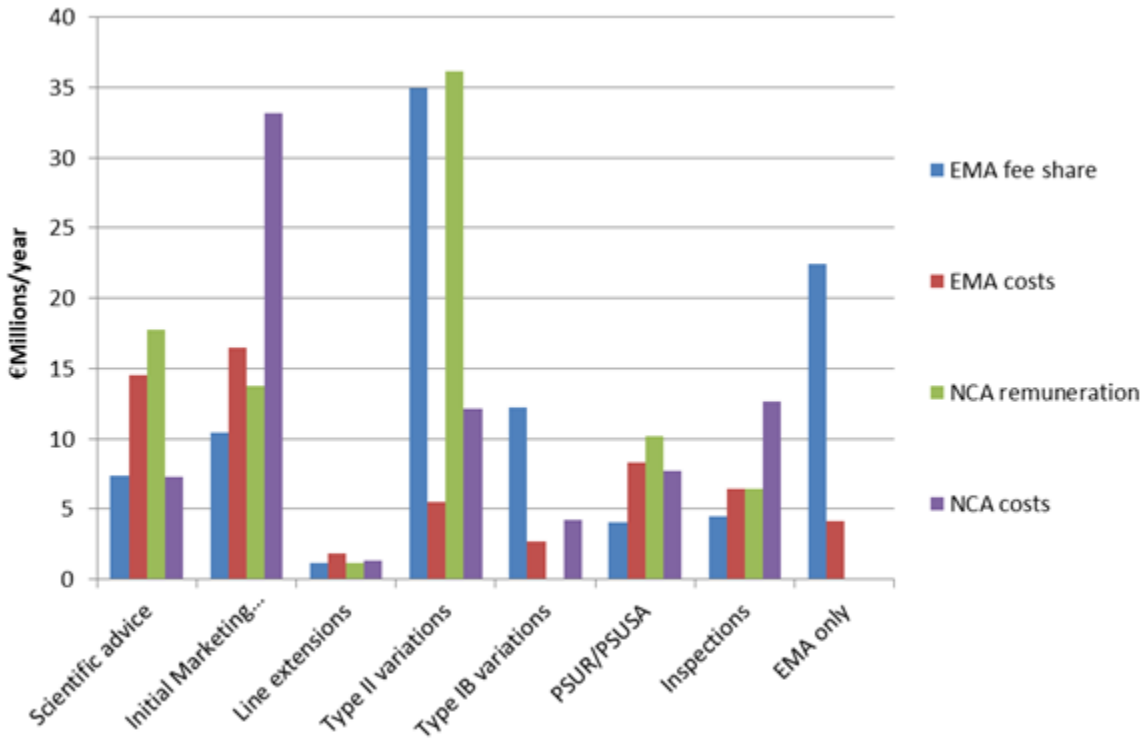


* A categorisation of additional activities reported by NCAs is provided in the appendices to the main report.

At a granular level, the picture becomes more complex. There are many different procedural activities, some of which are charged full fees, some of which have reductions applied, some of which have the fees waived, and some of which are exempted from fees. Incentives and exemptions result in activities for which costs cannot be covered (fully or at all) by fees and so fees charged for other procedural activities and annual fees fund these costs, both for EMA and for NCAs.

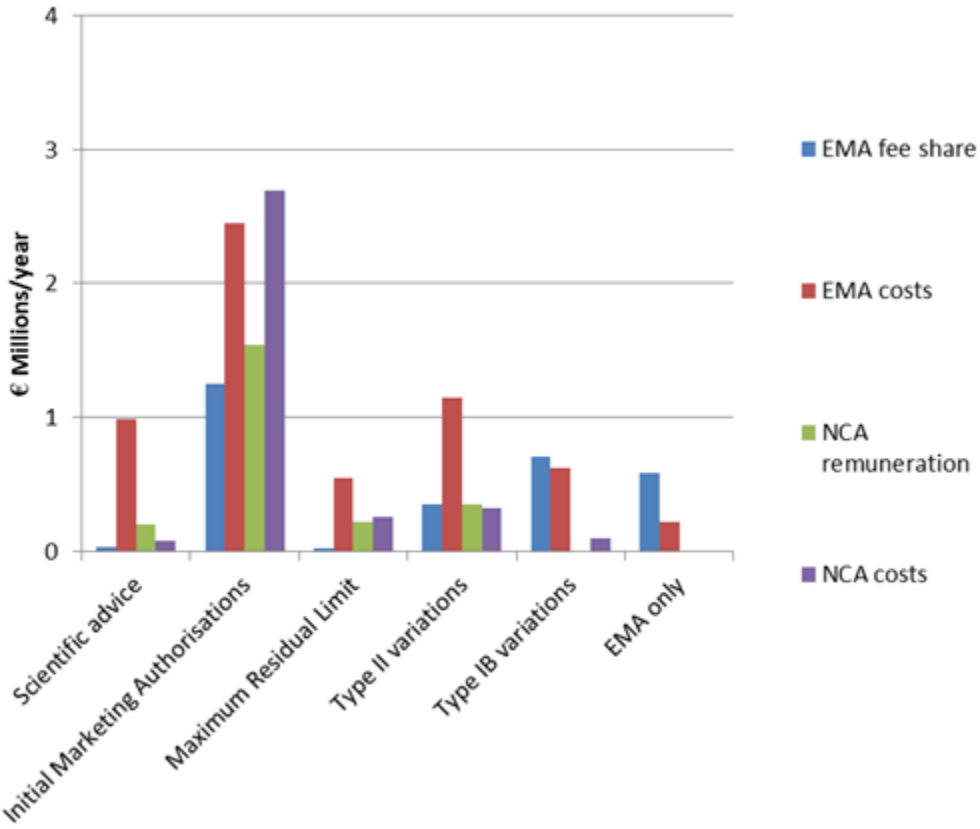
In particular, costs are not covered for EMA or NCAs for initial marketing authorisations, although they are currently associated with the highest fees. For other activities, such as scientific advice, fees cover costs for NCAs but do not fully cover EMA costs. For yet other procedures, such as inspections, fees cover EMA costs, but do not cover the costs incurred by NCAs. Finally, some activities have fees that are higher than the cost of the activity. Type II variations are the most notable example of this; fees for these activities well exceed costs both for EMA and NCAs. The EMA and NCA shares of costs and fees for one year after incentives are applied under the current financial model are illustrated in Figure 3 (human medicines) and Figure 4 (veterinary medicines).

Figure 3: EMA and NCA shares of costs and fees over one synthetic year after incentives have been applied under the current financial model – human medicines[7]



[7] Inspections were reported separately by NCAs for veterinary medicines and human medicines. They were combined in the EMA data reporting. In the synthetic baseline, these were allocated to human and veterinary medicines for EMA in proportion to the procedures reported by NCAs.

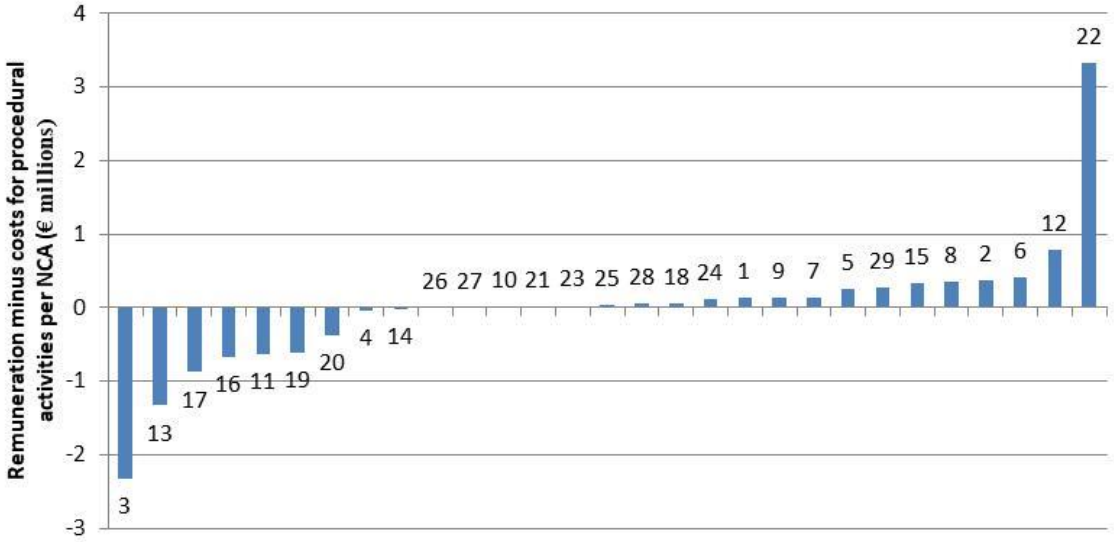
Figure 4: EMA and NCA shares of costs and fees revenue/income over one synthetic year with incentives applied under the current financial model – veterinary medicines



Thus, the more granular-level finding is that the current fee system is not cost-based.

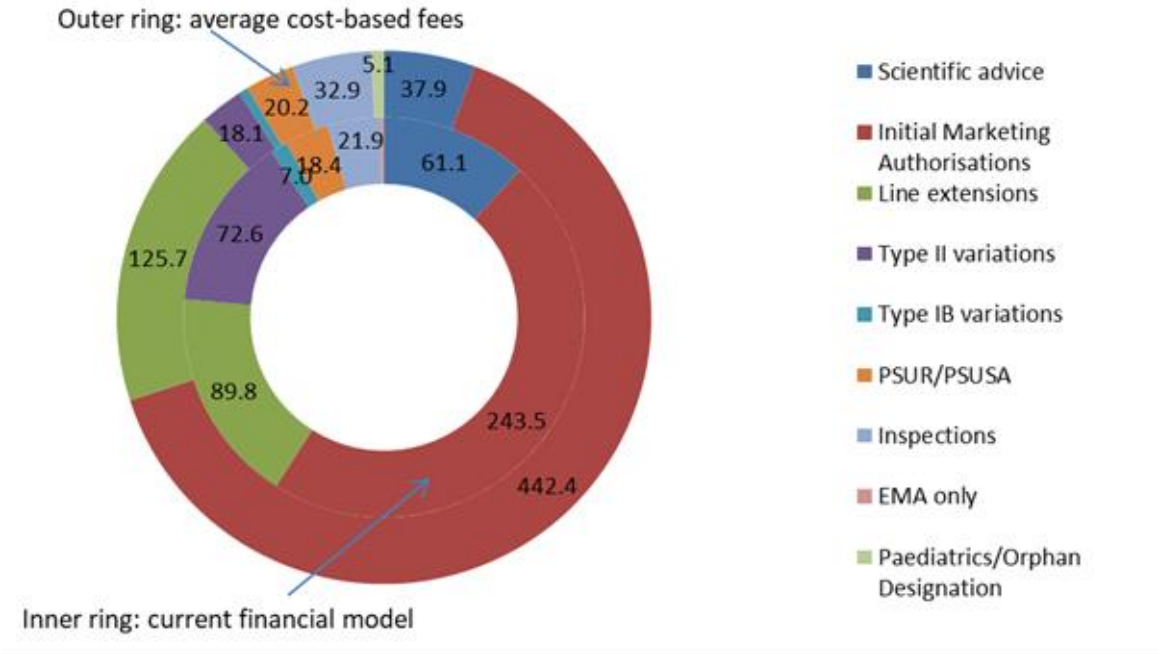
Under the current financial model fees are not always shared between EMA and NCAs in proportion to their costs. Scenarios that tested an average cost-based approach show that this approach would result in NCAs receiving less remuneration for some activities and more for others. Figure 5 illustrates this issue by comparing the distribution of procedural remuneration minus costs for individual NCAs relative to average NCA costs.

Figure 5: Distribution of remuneration for procedural activities minus costs for individual NCAs when modelling average cost based remuneration



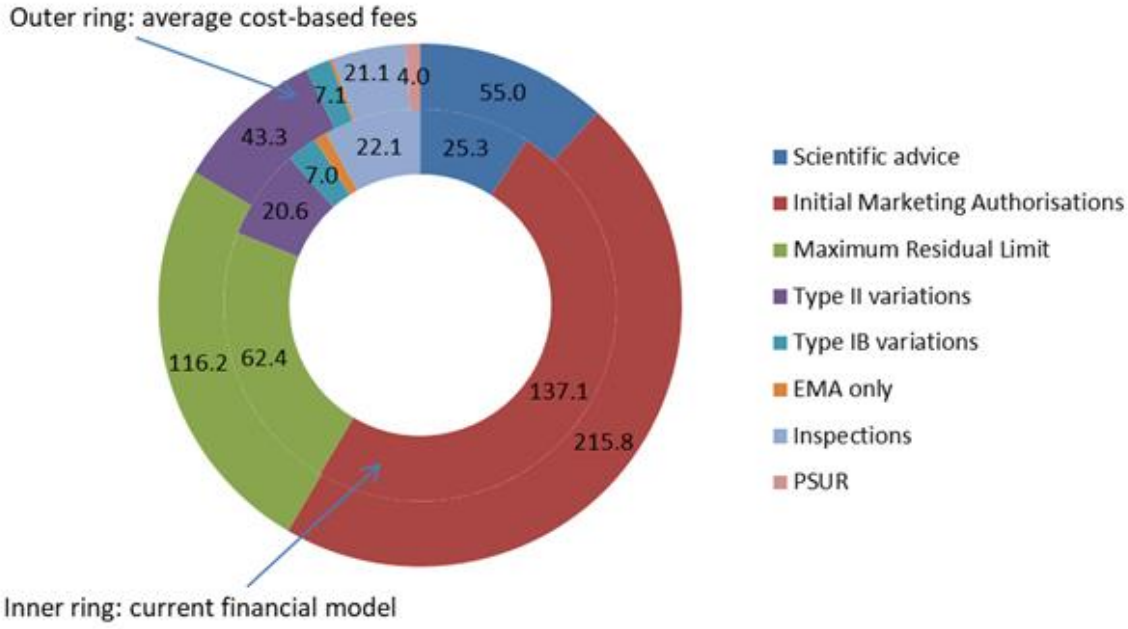
NCA costs vary across individual NCAs, with the consequence that some NCAs receive fees that cover their costs, while others experience a shortfall. This situation remains under scenarios that test an average cost-based fee system, as wage and other cost levels vary considerably between countries. However, the principle of applying average cost-based fees for procedural activities would by definition mean that total NCA remuneration would be equal to the total costs of these activities. Any individual NCA might be left with a financial deficit or surplus depending on their individual costs compared to the average NCA cost. A comparison of unitary full fees for the main activities under the current financial model and average cost-based fees is provided in Figure 6 (human medicines) and Figure 7 (veterinary medicines).

Figure 6: Comparison of unitary full fees for human medicine procedural activities for current financial model and when modelling average cost-based fees (€ thousand/procedure)



Note: Outer ring represents average cost-based fees. Inner ring represents the current financial model.

Figure 7: Comparison of unitary full fees for veterinary medicine procedural activities for current financial model and when modelling average cost-based fees (€ thousand/procedure)



Note: Outer ring represents average cost-based fees. Inner ring represents the current financial model.

1.2.1.2. EQ2: To what extent does the current financial model allow the EMA to effectively perform the activities in its remit?

The current financial model enables the EMA to undertake procedural activities as well as other tasks, and there is evidence that the current financial model enables the EMA to perform these additional tasks effectively. According to EMA representatives, one of the key pillars of the fee and remuneration system is that it allows the EMA to take on new or different aspects of their work as well as to undertake cross-cutting activities. In addition, EMA interviewees emphasised that the current financial model provides sufficient flexibility in terms of the budget principle of universality, which ensures stability of their work. As pointed out above, in the current model this is particularly important in the case of waived or reduced fees for SMEs and for specific types of products.

1.2.1.3. EQ3: To what extent does the current financial model allow the EMA to remunerate the NCAs adequately for the activities they perform?

The study found that there is alignment between remuneration to NCAs and NCA procedural activities, and committee and working group activities, while it is insufficient to fund other unremunerated activities. At individual NCA level, remuneration is also sufficient to cover the costs of procedural activities, as well as committee and working group activities, for some but not all NCAs. At activity level, remuneration is sufficient to cover the costs of some but not all activities. However, remuneration is not sufficient to cover all of the additional activities that NCAs reported to be EMA-related.

1.2.1.4. EQ4: To what extent is a balance struck between a fee and remuneration system based on actual costs and simplicity of the fee system?

Overall, the study showed that there is a balance between a cost-based system and simplicity when considering its size and scope. Changes to legislation have improved this balance to some extent in several cases (e.g. pharmacovigilance legislation in 2010/2012/2014, Clinical Trials Regulation in 2014). There is evidence that several procedures follow simpler and more structured processes as a result of amended legislation, such as periodic safety update reports (PSURs). However, there is also evidence of increasing complexity with regard to implementing the procedures resulting from legislative amendments. In addition, changes to legislation made the system less flexible in some cases (e.g. the amended pharmacovigilance legislation does not allow fee reductions after 30 calendar days from the date of the invoice).

The fee system is also generally clear and transparent. However, there are areas in need of more clarity and transparency, such as fee breakdowns for industry and NCAs, the basis for each fee, and criteria for fee exemptions and reductions. The fee system is considered to be proportionate between the fees charged to industry and the services provided. The evaluation found specific areas within the system that are disproportionate, particularly at the level of fees charged for specific activities, where the costs in some cases are much higher than the fees and in others where the reverse is the case.

1.2.1.5. EQ5: To what extent does the fee system enable needs to be met in exceptional circumstances or under particular priorities/imperatives?

The evaluation found that key elements of the current fee system are its ability to respond to exceptional circumstances and related to that a certain degree of flexibility to allow doing so. This flexibility is particularly important in the context of activities related to orphan designated medicines, products for paediatric use and advance therapies. The system of having a Fee Regulation (Council Regulation (EC) No 297/95) and

implementing rules is considered to be important to enable a certain degree of flexibility. However, as outlined above, changes to the pharmacovigilance legislation impeded fee reductions under exceptional circumstances.

The current fee system does not enable enough flexibility regarding the time NCAs need for activities (time needed for accomplishing an activity of the same kind often varies). Related to that, the current fee system is not flexible enough to meet time and budget needs regarding increasing complexity of activities. The study identified activities related to the following areas which already include and will likely include even more complexity in the future for both the EMA and NCAs: companion diagnostic reviews, activities related to big data, raw data analysis, highly innovative products without sufficient clinical data, health technology assessments and novel therapies.

Overall, stakeholders from industry, academia and representative organisations are satisfied with the provisions made in exceptional circumstances or under particular priorities/imperatives. Stakeholders highlighted that more incentives are needed for academic and non-profit institutions as well as patient organisations.

1.2.1.6. EQ6: To what extent are SMEs supported through effective reductions in their costs to use the centralised system?

Commission Regulation (EC) No 2049/2005 defines specific fee incentives (reductions and exemptions) and administrative support for micro enterprises and SMEs Overall, the study found that current support provided to micro enterprises and SMEs (fee incentives and administrative support) allows smaller businesses to use the current centralised system. Indicators such as numbers of registered SMEs and authorisations to SMEs support this finding.

Comparisons to the European Chemicals Agency (ECHA) show that the EMA offers greater fee reductions for SMEs. The EMA fee system also offers fee exemptions, which are not provided for SMEs in the ECHA fee system. However, ECHA breaks its reductions down by the size of the enterprise (micro, small and medium-sized enterprises), providing significantly higher reductions to micro-sized businesses. Compared to the U.S. FDA, the EMA offers more incentives to micro-sized businesses and SMEs. Unlike the EMA, the FDA does not have individual definitions for micro, small or medium-sized enterprises.

1.2.2. Criterion 2: Relevance

The assessment of relevance refers to the relationship between the EU intervention being evaluated and the needs and problems related to activities that fall within the remit of EMA. The assessment includes identification of any possible mismatch between the problems and needs that the EMA fee and NCA remuneration system was designed to address and compares this with existing needs and any problems identified to determine whether the system is still fit for purpose and if any changes are needed.

1.2.2.1. EQ7: To what extent does the fee system address the problems and needs originally identified to fund the relevant legislative tasks of the EMA, including NCA remuneration?

The analysis showed that the current fee and remuneration system responds to needs originally identified at the time the fee system was established. In particular, the underlying legislation and the fee system itself address the requirement of a funding model based both on fee income paid by industry applicants and general EU and EEA contributions.

The fee system is also relevant regarding the need to remunerate NCAs for undertaking EMA-related activities, although the fee charged and remuneration provided are not cost-based across all activities. The study also found that the current fee system overall meets the need to provide lower fees for activities for veterinary medicinal products; however, there are indications that such lower fees are not aligned with present needs.

Alignment was also found between the original requirement to offer incentives to respond to public or animal health threats and the current fee system. Additional fee incentives introduced in later years indicate that the fee system responds to the requirement to allow fee reductions and exemptions under exceptional circumstances.

1.2.2.2. EQ8: Is the fee system relevant in terms of current needs?

While the fee and remuneration system is still relevant in relation to originally identified needs, the study identified problems that are currently not taken into account. In particular, there are indications that the fee and remuneration system does not account for increasing complexity of the fee system as well as of activities. For instance, activities related to innovative medicines are expected to not only change the way medicines are developed, but also change approval processes, which might have an impact on EMA's and NCAs' ability to meet their costs in the future.

The current fee and remuneration system does not address potential future changes related to proposed changes to the EMA legislation, such as a new regulation on veterinary medicinal products (Proposal Regulation COM(2014) 558)[8] and potential changes to the orphan and paediatric medicines legislation (Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006; see European Commission (2017)).

A particular requirement of this study was to assess the need for a dispute settlement procedure between EMA and industry. The analysis showed that there is no such need at this time.

1.2.3. Criterion 3: Coherence

Coherence refers to how well or not different aspects of a system work together (e.g. to achieve common objectives). This can take place at several levels, including: (i) internally, (ii) with other EU interventions, and (iii) with non-EU interventions. In this study, the assessment of fee system coherence focuses: (i) internally (e.g. fee structure, remuneration levels), (ii) nationally, with Member State fee systems, and (iii) at EU level, with other EU policies and programmes.

1.2.3.1. EQ9: To what extent is the fee system coherent internally?

Broadly, the fees charged for procedural activities align with the costs for undertaking the activities; however, the fee system is not cost-based at the level of specific activities and this contradicts Council Regulation (EC) No 297/95 which requires that 'the calculation of the amount of fees charged by the Agency must be based on the principle of the service actually provided'. Additionally, it does not take into account changes since 2005 resulting from additional legislation (e.g. medicinal products for paediatric use and advanced therapy medicinal products).

The study shows overall internal coherence of Council Regulation (EC) No 297/95 and the implementing rules (EMA 2017). Minor aspects of incoherence were found between

[8] Changes related to the new veterinary legislation are outside of the scope of the study because there is no available data on the changes; therefore, the changes were not taken into consideration.

documents. Regulation (EU) No 658/2014 and Council Regulation (EC) No 297/95 on the general fees payable are also internally coherent. However, some EMA representatives indicated that they would prefer an overall revision of all legislative documents and consolidating them into one coherent piece of legislation.

The study did not find any incoherence regarding the fee system, remuneration provided and the legislation determining the remuneration to NCAs. Overall, the fee system is coherent with the EMA's strategy and objectives. However, there are some areas where more coherence is needed: in particular, flexibility in the case of pharmacovigilance activities and financing of innovation-related activities

1.2.3.2. EQ10: To what extent is the fee system coherent with Member State fee systems?

The analysis of the alignment of the EMA fee system with Member State fee systems showed that the EMA fee system is coherent with Member State fee systems. There is no evidence regarding an overlap or gaps between fees for EMA-requested activities and fees charged for national activities. In addition, the study showed that national-level fee systems and the EMA fee and remuneration system differ in their financing structures and in the amount of fees charged. Considering the complexity of the EMA fee system resulting from its size and scope, EMA's comparatively higher fees are considered to be fair.

1.2.3.3. EQ11: To what extent is the fee system coherent at EU level with other EU policies?

The study analysed the coherence of the fee and remuneration system with requirements set out in EU policies considered particularly relevant to the fee system:

- Third EU health programme (2014-2020), in particular requirements set out in Regulation (EU) No 282/2014;
- DG Health & Food Safety's Strategic Plan 2016-2020 (DG Health & Food Safety 2016);
- EU policy on the support of micro, small and medium-sized enterprises:
  - Commission Communication COM(2008) 394.
  - Commission Recommendation 2003/361/EC.

Overall, there is external coherence of the fee system with priorities set out in other EU policies. The EMA fee system is coherent with the third EU health programme (2014-2020). It shows strong synergies with the programme's four main objectives. It is also coherent with the priorities set out in the Strategic Plan of DG Health & Food Safety for 2016 to 2020, and with EU policy on the support of micro, small and medium-sized businesses.

1.2.4. Criterion 4: Sustainability

Sustainability was assessed with reference to the likelihood that an intervention will succeed over time. This study focused on the extent to which the fee system is based on costs, taking into account the need to finance some activities (i.e. reductions and exemptions), cross-cutting activities and the needs of the EMA and NCAs to meet evidence-based trends. The assessment includes analysis of the system's flexibility to adjust to changing trends.

1.2.4.1. EQ12: To what does the current financial model ensure the financial stability of the EMA?

The study found that the current fee system has important elements that contribute to its sustainability. In particular, the flexibility to support unremunerated activities, as well as incentives for specific medicinal products and SMEs are considered to be essential.

However, the study also identified elements of the fee system that create challenges for its long-term sustainability. The current fee system enables EMA and NCAs overall to meet their costs for procedural activities, although some flexible funding across procedures is needed where incentives and exemptions are applied. The current financial model does not enable NCAs to cover all costs for undertaking cross-cutting activities. The remuneration and payments provided to NCAs are not sufficient to compensate for all costs of EMA-related activities. The current fee system does not address the increasing complexity of existing and new procedures (e.g. specialised/personalised medicine).

Exemptions and reductions for SMEs and exemptions for specific products and procedures (e.g. orphan medicinal products, medicinal products for paediatric use, advanced therapy medicinal products) are considered to be important elements of the current fee system and contribute to the fee system's sustainability. Such incentives enable relevant stakeholders who otherwise might not be able to use the centralised system to do so.

Finally, an increase in transparency in the areas highlighted above would likely contribute to more sustainability of the fee system.

The current fee and remuneration system does not consider potential future changes related to proposed changes to the EMA legislation, such as a new regulation on veterinary medicinal products (Proposal Regulation COM(2014) 558) and potential changes to the orphan and paediatric medicines legislation (Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006; see European Commission (2017)).

1.3. Cross-cutting conclusions

In addition to the answers to the 12 questions linked to the study criteria prescribed by the Better Regulation guidelines for evaluations, some key, cross-cutting messages were also identified.

1.3.1. The current fee system is generally efficient and effective but it is not cost-based at a granular level

The current EMA fee and NCA remuneration system enables EMA to meet its costs after remunerating NCAs, and there is no evidence that the EMA is hindered in its activities by the existing charging and remuneration arrangements. EMA relies on both industry fees and EU and EEA budget contributions to meet its costs.

NCA remuneration covers the aggregate costs of their procedural activities as well as, in aggregate, their involvement in working groups and committees. Alignment of remuneration with costs for individual NCAs varies, however, and in some cases there is a high degree of variation for NCAs in the extent to which remuneration aligns with costs. There are also differences in the extent to which remuneration covers costs for organisations that undertake human medicine activities only, human and veterinary medicine activities, and veterinary medicine activities only. NCAs that undertake veterinary activities only are less likely to cover their costs. Moreover, the total value of remuneration NCAs receive from EMA does not cover all of the additional EMA-related activities that NCAs report undertaking. A closer analysis of the additional EMA-related activities reported by NCAs would be required in order to better assess whether and to what extent these activities might require additional remuneration.

At a granular level, the current fee system is not cost-based. There are many different procedural activities. Fees for some procedures exceed the total EMA and NCA costs of delivering them. Fees for some other procedures fall short of costs. Furthermore, there are no fees for some activities.

Some fees may have 'incentives' applied, or be exempted, for certain types of medicines and certain types of company. Incentives and exemptions result in activities for which costs cannot be covered (fully or at all) by fees, and so fees charged for other activities and annual fees support covering the costs for undertaking these activities, both for EMA and for NCAs. For veterinary medicines, average incentives are generally higher than for human medicines.

Fees are not always shared between EMA and NCAs in proportion to their respective costs incurred for delivering the activities.

The purpose of the modelling exercise was to provide cost-based benchmarks for comparison with the current fee system. The exercise shows that using average cost pricing and remuneration could help to balance unitary fees against costs. But the overall effect would be that EMA income would need to increase to balance its costs, due to the effect of incentives and exemptions which are absorbed by EMA and not passed on to NCAs. The mechanism used to achieve this would have an impact either on EU and EEA budget contributions or industry fees (or potentially both, if the shortfall is met by a combination of increased fees and EU and EEA budget contribution). Average cost pricing would by definition cover costs for procedural activities for NCAs overall (with the assumption that their remuneration continues to be based on full fees without incentives applied), but it would not cover costs for all individual NCAs.

If NCAs were also remunerated to take into account costs for their time spent in committees and working groups, and for additional EMA-related activities that are currently unreimbursed, the additional revenue required by EMA would increase. In the scenarios, the overall budget of the EMA would only be larger than its existing budget under the current system if NCAs were remunerated for all activities they reported undertaking. This would include additional activities that have not been analysed in detail in the study.

1.3.2. The existing fee and remuneration system provides for a certain degree of flexibility, which is beneficial to its current operation; in other respects, the system is less flexible, which creates challenges for its current operation

The current fee system provides flexibility that enables EMA and NCAs to fund some of their activities. In particular, the flexibility to fund unremunerated activities, as well as incentives for specific medicinal products and SMEs are considered to be essential. Flexibility is important in relation to incentives and exemptions, which respondents to the consultation for this study largely view as important in order to support the development of veterinary medicines; facilitate the development of orphan designated medicines, products for paediatric use and advanced therapies; and support SMEs to participate in the centralised system.

Additionally, the current system of having a Fee Regulation and implementing rules provides further flexibility in regards to the introduction and implementation of reductions and exemptions, for example, to respond to needs under exceptional circumstances. EMA representatives noted that Regulation (EU) No 658/2014 on fees payable for pharmacovigilance activities does not have implementing rules, resulting in less flexibility with regard to fee exemptions and reductions.

1.3.3. The fee system responds to needs originally identified at the time the system was established

The current fee system responds to needs originally identified at the time the fee system was established. In particular, the underlying legislation and the fee system itself address the requirement of a funding model based both on fee income paid by industry

applicants and general EU and EEA contributions. The fee system is also relevant regarding the need to remunerate NCAs for undertaking EMA-related activities, although the fee charged and remuneration provided are not cost-based across all activities. The study also found that the current fee system overall meets the need to provide lower fees for activities for veterinary medicinal products; however, there are indications that such lower fees are not aligned with present needs. Alignment was also found between the original requirement to offer incentives to respond to public or animal health threats and the current fee system.

1.3.4. The system is complex and increasing complexity across many dimensions is viewed as a challenge for a well-functioning system

The EMA fee and NCA remuneration system has become more complex over time, which has created challenges for its effective operation and this complexity is expected to increase in the future.

Both EMA and NCA representatives observed that a perpetual challenge in the fee system is the increasing complexity of their activities. In both cases, this is a result of changes in the field of medicine; for example, highly innovative products may lack sufficient clinical data and novel therapies present assessment challenges as well. Other changes in the regulatory system, such as companion diagnostic reviews, activities related to big data, and real-world data analysis, add to the complexity of EMA and NCA work. In some cases this means that there can be wide variation in the costs associated with undertaking any given procedure

For the EMA, increasing complexity is also related to its coordination activities and to managing a fee system that has a large number of activities, all of which have different associated fees, and related incentives and exemptions. Legislative amendments and the introduction of new legislation have meant that the fee system has changed considerably since its implementation in 2005. EMA representatives generally reported a highly complex fee system to coordinate and manage, and one that is growing ever-more complex.

NCAs, conversely, reported that given the complexities in the fee system, the current fee and remuneration system itself is generally simple to understand and implement. Legislative changes in recent years have generally contributed to the fee system's simplicity. Any additional simplifications (e.g. with respect to the legislation) would be welcomed by all stakeholders.

EMA, NCAs and industry are generally satisfied that the fee system is clear and transparent, although NCAs and industry would like to see more information from EMA regarding the basis for each fee.

1.3.5. The fee system has elements that contribute to its sustainability but there are some challenges in the long-term

The flexibility in the fee system to fund unremunerated activities, as well as incentives for specific medicinal products and SMEs are considered to be important for the fee system's long-term sustainability.

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3. APPENDICES

Appendix 1. List of agreed activities

The activities presented below were agreed with EMA and HMA for the purposes of undertaking the modelling exercise and were divided into two groups. These activities are listed in the fee grid provided separately with this report.

The first set of activities consists of procedural activities that involve EMA and NCAs. There are 35 procedural activity types for human medicines and 26 procedural activity types for veterinary medicines that involve both EMA and NCAs. Five further inspection activities were combined for human and veterinary medicines. The activities are mainly fee-generating but also include non-fee-generating activities for which NCAs do not receive remuneration under the current system (e.g. paediatrics and orphan designations).

The activities are differentiated either in the legal basis for the associated fee or because of the time taken to undertake a procedure. The activities can be grouped into more aggregate categories that reflect the type of work undertaken. The aggregate activities, which are used to illustrate the main results described in the summary report, are shown in **Error! Reference source not found.**. **Error! Reference source not found.**The remuneration rule for NCAs under the current financial model is also included.

The second set of activities involves seven fee-generating, procedural activities undertaken by EMA only (without NCA involvement). These are also combined in the analysis.

In addition to fees generated from procedural activities, there are two types of annual fees: annual fees for CAPs for human and veterinary medicines and annual pharmacovigilance fees for NAPs for human use. EMA incurs costs for the administration of both of these fees. NCAs receive a share of annual centrally authorised procedure (CAP) fee income but EMA retains all of the fee income from the annual pharmacovigilance fees.

Table 1. Summary of procedural activities included in the financial modelling

Type		Aggregate activity	NCA remuneration under current financial model*
Activities involving EMA and NCAs	Human	Scientific Advice/Protocol Assistance (initial request and follow-up request (Level I, II and III))*	50% of full fees
		Initial marketing authorisations (new active substance, known active substance, fixed-dose combination, generic, hybrid, biosimilar, informed consent, well-established use)	
		Line extensions (Level I, II and III)	
		Scientific services (PMF, VAMF, ancillary medicinal substances consultation, ATMP certification, traditional herbals; compassionate use opinions; Art.58)	
		Renewals	
		Referrals of disputes from decentralised and mutual recognition procedures (Art.29(4), Art.30, Art.31, Art.20)	
		Type II variations (Level I, II and III)	
		Type IB variations	Not remunerated
		Pharmacovigilance referrals (Art.31, Art.20, Art.107i)	€119,333, scaled according to incentives applied
		Post-Authorisation Safety Studies (PASS)	Fixed amount, scaled according to incentives applied (€18,200 in total for PASS, €13,100 for PSUR/PSUSA)
		Periodic Safety Update Reports for CAPs (PSUR)	
		Periodic Safety Update Reports for NAPs & CAP/NAP (PSUSA)	
		PIP (phase I and II), , PIP waiver, PIP compliance check (PIP modifications were not included in the list agreed for the NCA survey)	Not remunerated
		Orphan Designation	
	Human/veterinary	Inspections (GMP, GCP, GVP)	50% of full fee
	Veterinary	Scientific Advice/Protocol Assistance (initial request and follow-up request (Level I, II and III))	50% of full fee
		Initial marketing authorisations (new active substance, known active substance, generic (phase I, II and III)	
		Line extensions (Level I, II and III))	
		Maximum residue limits (phase I, II and III)	

Type		Aggregate activity	NCA remuneration under current financial model*
		Renewals	
		Referral procedures (Art. 34 and Art. 35 (phase I, II and III) and Art. 45 (total procedure))	
		Type II variations (Level I, II and III)	
		Type IB variations	Not remunerated
		MUMS	
EMA only	Human and Veterinary	Type IA variations, MAH transfers, issuing certificates, parallel distribution	Not applicable

* Rapporteur and co-rapporteur roles, or equivalent receive an equal share of the remuneration.

Appendix 2. Evaluation matrix

Effectiveness & efficiency

Evaluation Criterion	Effectiveness & efficiency
Definition	Effectiveness: Assessment of progress made towards achieving the objectives of the intervention, looking for evidence of why, whether or how these changes are linked to the EU intervention. Identification of factors driving or hindering progress and how they are linked (or not) to the EU intervention. Efficiency: Assessment of the relationship between the resources used by an intervention and the changes generated by the intervention and of both the costs and benefits of the EU intervention as they accrue to different stakeholders.
Approach proposed	In this study, effectiveness was closely tied to efficiency and so these evaluation criteria were considered together. Effectiveness in general was based on the extent to which the objectives of the fee system have been achieved in relation to the general needs of the fee system. This included an assessment of the extent to which the fee system: allows the EMA to perform its tasks, allows the EMA to remunerate NCAs adequately, is fair and transparent, is flexible to take into account exceptional circumstances, and supports SMEs. Linked to this, efficiency (cost-effectiveness) was assessed by examining the relationship between costs and fees for the activities covered by the EMA.
Risks and challenges	A challenge for addressing this evaluation criterion identified at the inception stage of the study was the availability of data from the EMA and NCAs in relation to the costs and time data for various activities – in terms of the quality, quantity and timeliness in receiving the data. In order to mitigate against these challenges, we requested the opportunity to review the time data already collected at an early stage in the study so that we could identify where we will need to collect additional data through the consultation. Interviews served as a means of both validating data gathered through desk research and the surveys, and to address any gaps identified. We used more than one data source wherever possible and as many data sources as possible to triangulate the findings and ensure the most robust response possible. We indicated where possible the data sources that provided the most robust evidence and used these as the basis for our answers to the study questions, supplemented and supported by other data sources.

Evaluation question	Judgement criteria	Indicators	Data sources	Methods
Q1. To what extent do the fees charged correspond with EMA and NCA costs?	JC.1.1 Fees charged are aligned with the services performed JC.1.2 Total fees earned enable the EMA to meet its costs, taking into consideration the availability of EU and EEA contributions; the remuneration paid to NCAs allow them to meet the costs of EMA-requested activities	I.1.1 Specific fees charged align with costs identified by the EMA and by the NCAs with regard to their remuneration I.1.1a Specific fees charged align with legislative requirements (e.g. exemptions and reductions) where the fees do not align with the costs identified by the EMA	DS.1.1 Time data collected by the EMA MB Data Gathering exercise DS.1.2 Cost data collected by the study team DS.1.3 Fee grid of EMA fees and remuneration to NCAs DS.1.4 EU legislation that sets specific requirements for fee exemptions and reductions DS.1.5 Comparison of fees system approach in other EU agencies and third countries	M.1.1 Time data analysis M.1.2 Cost data analysis M.1.3 Interviews with EMA and with NCAs M.1.4 Desk research of EU legislation and supporting documents: EU2020 budget; EMA budget; NCA budgets M.1.5 Analysis of approach taken in other EU agencies and countries, notably, ECHA and the U.S. FDA, as well as Canada, Japan and Australia, where appropriate
Q2. To what extent does the current financial model allow the EMA to effectively perform the activities in its remit?	JC.2.1 The financial model enables the EMA to perform procedural tasks within its remit JC.2.2 The financial model enables the EMA to perform other (i.e. cross-cutting, horizontal and related) tasks within its remit	I.2.1 The financial model enables EMA to perform procedural and other tasks effectively I.2.2 The EMA is not hindered by their charging and remuneration arrangements	DS.2.1 Views of EMA DS.2.2 Views of NCAs DS.2.3 Views of stakeholders DS.2.4 Documents that comment on the ability of EMA to perform their tasks effectively DS.2.5 EU Court of Auditors reports regarding EMA fee system	M.2.1 Interviews with EMA and NCAs and survey of stakeholder representatives M.2.2 Document review of EMA annual reports, 2010 EMA evaluation, NCAs and HMA

Evaluation question	Judgement criteria	Indicators	Data sources	Methods
Q3. To what extent does the current financial model allow the EMA to remunerate NCAs adequately for the activities they perform?	JC.3.1 Remuneration provided to NCAs aligns with the actual costs to NCAs for the activities they perform JC.3.2 Evidence of any issues regarding the current model's ability to adequately remunerate NCAs	I.3.1 Remuneration to NCAs aligns with the time spent and overhead costs identified by NCAs to perform activities within their remit I.3.2 The current model allows adequate remuneration to NCAs	DS.3.1 Information on remuneration currently provided to NCAs (fee grid) DS.3.2 Time data on actual time spent by NCAs, collected by the EMA MB data gathering DS.3.3 Overheads and other costs for NCAs to undertake the work, collected by the study team DS.3.4 EU Court of Auditors reports regarding EMA fee system DS.3.5 Views of EMA and NCAs	M.3.1 Desk research of EU Court of Auditors reports and other data sources M.3.2 Time data analysis M.3.3 Cost data analysis M.3.4 Interviews with EMA representatives M.3.5 Interviews with NCAs M.3.6 Survey of NCAs
Q4. To what extent is a balance struck between a fee and remuneration system based on actual costs and simplicity of the fee system?	JC.4.1 Evidence of satisfaction (or dissatisfaction) with the balance between costs and simplicity	I.4.1 EMA, NCAs and payers are satisfied that the fee system is balanced between costs and simplicity I.4.2 The fee system is clear, transparent and proportionate, and aligned with the underlying legislation	DS.4.1 Views of EMA, NCAs and stakeholders DS.4.2 Documents that comment on the balance between simplicity and cost basis	M.4.1 Interviews with EMA and NCAs M.4.2 Survey of NCAs and stakeholder representatives M.4.3 Public consultation M.4.5 Document review of position papers and other supporting information that indicates satisfaction

Evaluation question	Judgement criteria	Indicators	Data sources	Methods
Q5. To what extent does the fee system enable needs to be met in exceptional circumstances or under particular priorities/imperatives?	JC.5.1 The reductions and exemptions enable authorisations for special categories of medicinal products that are prioritised by the EU JC 5.2 Fee system provides flexibility for exceptional circumstances JC 5.3 Evidence of satisfaction with the provisions made in exceptional circumstances or under particular priorities/imperatives	I.5.1 Number of authorisations under exceptional circumstances or to meet particular needs (e.g. public health or animal health emergencies, orphan medicines, paediatric medicines, advanced therapy medicines) I.5.2 Other evidence that the fee system enables needs to be met in exceptional circumstances or to meet particular needs I.5.3 Stakeholders are satisfied with the provisions	DS 5.1 Applicable fee rules DS.5.2 Authorisations data held by the EMA DS.5.3 Views of stakeholders DS.5.4 Views of EMA and NCAs DS.5.5 Comparison of authorisation data in other countries	M.5.1 Analysis of applicable fee regulations and implementing rules M.5.2 EMA authorisation data analysis M.5.3 Interviews with EMA, NCAs and survey of stakeholders (targeted consultation) M.5.4 Public consultation M.5.5 Comparative Information on authorisations for special circumstances in third countries
Q6. To what extent are SMEs supported through effective reductions in their costs to use the centralised system?	JC.6.1 SMEs are able to participate in the centralised system without undue burdens	I.6.1 Number of authorisations to SMEs I.6.2 SMEs are able to access the centralised system given the costs	DS.6.1 Authorisations data held by the EMA DS.6.2 Views of SMEs DS.6.3 Comparison of SME provisions and any information on views of SMEs to obtain authorisation in other countries DS.6.4 SME regulation	M.6.1 Analysis of EMA authorisations data and SME office activities M.6.2 Interviews with SME representatives M.6.3 Public consultation M.6.4 Information on SME provisions in other EU agencies and third countries

Relevance

Evaluation Criterion	Relevance
Definition	Assessment of the relationship between the EU intervention and the needs/problems related to activities that fall within EMA's remit. Identification of any possible mismatch between the objectives of the intervention and the (current) needs or problems.
Approach proposed	The problems and needs that the fee system was designed to address were assessed and compared with existing needs and any problems identified to determine whether the system is still fit for purpose and if any changes are needed.
Risks and challenges	The main challenge for this criterion identified at the inception stage was related to collecting and synthesising the views of a wide range of stakeholders in relation to the main needs relating to the EMA fee system, taking into account the different priorities set by various groups of stakeholders. In order to address this challenge, the study team gathered the information collected into an evidence grid which enabled comparison of responses to the questions asked in interviews, surveys and gathered through document review. This internal document enabled the team to analyse the responses of numerous groups of stakeholder in a synthetic way and compare current needs and problems with those existing when the system was first developed.

Evaluation question	Judgement criteria	Indicators	Data sources	Methods
Q7: To what extent does the fee system address the problems and needs originally identified to fund the relevant legislative tasks of the EMA, including NCA remuneration?	JC.7.1 Needs identified when the fee system was developed are addressed by the fee system.	I.7.1 Alignment between the fee system and the problems and needs originally identified I.7.2 Divergence between the fee system and the problems and needs originally identified	DS.7.1 EMA and NCA views DS.7.2 Stakeholder views DS.7.4 Supporting documents	M.7.1 EMA and NCA interviews M.7.2 NCA and stakeholder survey M.7.3 Public consultation M.7.4 Desk research of supporting documents
Q8: Is the fee system relevant in terms of current needs?	JC.8.1 Needs identified by EMA, NCAs and stakeholders as relevant currently are addressed by the fee system.	I.8.1 Alignment between the fee system and current problems and needs I.8.2 Divergence between the fee system and current problems and needs	DS.8.1 EMA and NCA views DS.8.2 Stakeholder views DS.8.3 Supporting documents	M.8.1 EMA and NCA interviews M.8.2 NCA and stakeholder survey M.8.3 Public consultation M.8.4 Desk research of supporting documents

Coherence

Evaluation Criterion	Coherence
Definition	Assessment of how well or not different aspects of the system work together (e.g. to achieve common objectives). This can take place at several levels, including: (i) internally, (ii) with other EU interventions, and (iii) with non-EU interventions
Approach proposed	The study assessed the coherence of the fee system: (i) internally (e.g. fee structure, remuneration levels), (ii) nationally, with Member State fee systems, (iii) at EU level, with other EU policies and programmes.
Risks and challenges	The main challenge identified at inception stage was to identify the synergies and potential overlaps between national fee systems and the EMA fee system. This point was raised through interviews with the EMA and with stakeholders and cross checked in interviews with the NCAs in order to validate findings.

Evaluation question	Judgement criteria	Indicators	Data sources	Methods
Q9: To what extent is the fee system coherent internally?	JC.9.1 The EMA fee system is internally coherent in terms of the fees charged JC.9.2 The EMA fee system is internally coherent in terms of the remuneration provided JC.9.3 The EMA fee system is coherent in terms of the agency's strategy and objectives	I.9.1 The internal components of the fee system work well together, including: • with the legal basis and other related rules, • between the fees charged to industry and the remuneration provided to NCAs, and • the funding required for the EMA to conduct the activities in its remit taking into consideration EU and EEA contributions	DS.9.1 Views of EMA, NCAs and industry representatives DS.9.2 Time and cost data provided by EMA and collected by the study team DS.9.3 EU legislation on medicines DS.9.4 Supporting documents, as appropriate	M.9.1 EMA and NCA interviews; survey of stakeholders M.9.2 Analysis of time and cost data M.9.3 Desk research of EMA-related EU legislation and supporting documents
Q10: To what extent is the fee system coherent with Member State fee systems?	JC.10.1 The EMA fee system is consistent with and does not overlap with national fees	I.10.1 Synergies observed between national fee systems and the EMA system I.10.2 Risks of overlaps observed between national fee systems and the EMA fee system	DS.10.1 Views of EMA and NCA representatives DS.10.2 Views of other stakeholders, as appropriate	M.10.1 EMA and NCA interviews M.10.2 NCA and stakeholders' survey
Q11: To what extent is the fee system coherent at EU level, with other EU policies?	JC.11.1 The fee system is coherent with requirements set out in other EU policies	I.11.1 Synergies observed between EU policies and the EMA fee system I.11.2 Overlaps observed between EU policies and the EMA fee system	DS.11.1 Views of EMA and COM representatives DS.11.2 EU policy documents	M.11.1 EMA and COM interviews M.11.2 Document review of EU policies, including legislation and supporting materials

Sustainability

Evaluation Criterion	Sustainability
Definition	Assessment of the likelihood that the intervention will succeed over time.
Approach proposed	The study focused on the extent to which the fee system is based on costs, taking into account the need to finance some activities (i.e. reductions and waivers), cross-cutting activities and the needs of the EMA and NCAs to meet evidence-based trends. The study team assessed the flexibility of system to adjust to changing trends.
Risks and challenges	The main challenge identified at inception stage was to identify the long-term costs associated with EMA and NCA activities. In order to mitigate against this, consultees were asked to reflect on how costs may change in the future.

Evaluation question	Judgement criteria	Indicators	Data sources	Methods
Q12: To what extent does the current financial model ensure the financial stability of the EMA including its ability to remunerate NCAs?	JC.12.1 Fees charged correspond with EMA and NCA costs JC.12.2 Total fees earned enable the EMA to meet its costs, taking into consideration the availability of EU and EEA contributions	I.12.1 Specific fees charged align with all costs identified by the EMA and NCAs I.12.2 Specific fees charged align with legislative requirements (e.g. exemptions and reductions) where fees do not align with the costs identified by the EMA I.12.3 Fees charged enable cross-cutting activities I.12.4 EU and EEA contributions are sufficient and will continue to be available to the EMA where fees collected do not meet actual costs, taking into consideration the reductions and exemptions required under EU law	DS.12.1 Time data collected by the DGSG DS.12.2 Cost data collected by the study team DS.12.3 EU legislation that sets specific requirements for fee exemptions and reductions DS.12.4 Information on cross-cutting activities funded by fees or that could be funded by fees DS.12.5 Information on EMA and NCA needs with regard to ongoing and medium to long-term investments	M.12.1 Analysis of time data provided by DGSG M.12.2 Analysis of cost data collected by the study team M.12.3 Interviews with EMA and NCAs M.12.4 NCA and stakeholders' survey M.12.5 Public consultation M.12.6 Desk research of EU legislation and supporting documents

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