Annex I

TERMS OF REFERENCE – Evaluation of the EMA fee system

Contracting Authority: European Commission

1. CONTEXT/INTRODUCTION

1.1 Background

The general purpose of this request is an evaluation support study of the fee system by which the activities of the European Medicines Agency, a decentralised Agency of the EU, are financed.

The evaluation will take place in the policy area of public health and more specifically in the context of the pharmaceutical legislation of the EU and the tasks assigned to the European Medicines Agency ('EMA' or 'the Agency') related to medicinal products for human and veterinary use. The Agency plays a pivotal role in the evaluation, supervision and pharmacovigilance[1] of medicinal products in the European Union. In this context, it coordinates scientific resources put at its disposal by Member States.

A medicinal product may only be placed on the market in the EU when a marketing authorisation has been issued by the competent authority of a Member State for its own territory or when an authorisation has been granted by the European Commission for the entire Union.

Under the **centralised** procedure, the applicant for a marketing authorisation submits an application dossier to the EMA which is assessed by the relevant scientific committee(s) of the Agency typically composed by members and alternates appointed by each Member State and a scientific opinion is prepared. The scientific opinion on whether a marketing authorisation should be granted is sent to the European Commission which is responsible for granting the authorisation. If an authorisation is granted, it is valid throughout the EU and the applicant becomes the marketing authorisation holder.

Under the **decentralised** procedure (authorisation of a new medicine in several Member States in parallel) or the **mutual recognition** procedure (a medicine is authorised in several Member States based on an already existing authorisation in one Member State), the scientific assessment is performed by the competent authority of one Member State and is recognised by the other concerned Member States. The EMA provides the secretariat, i.e. it provides technical and administrative support to a coordination group (composed of the Member States' authorities) dealing with the decentralised and mutual recognition procedures.

Under **national** procedures, the authorisation is granted by the authority of the Member State and is valid only on its territory.

Under the new legislation on post-authorisation safety monitoring (pharmacovigilance) the EMA plays an important coordinating role in the life-cycle management of medicinal products, independent of the specific procedure under which they were authorised. It acts a central hub for all pharmacovigilance procedures.

The scientific assessment of the EMA committees is performed by experts from the Member States ('rapporteurs and co-rapporteurs') which are represented in the different scientific committees of the Agency. The EMA provides technical, scientific and administrative support for all the committees and working parties and ensures appropriate coordination between them. The

[1] Pharmacovigilance is the post-authorisation safety monitoring of medicines in the EU.

Agency has also other technical, scientific and administrative tasks defined in its **founding regulation**[2]**,** facilitating the development of medicinal products.

The Agency's revenue consists of:

-fees paid by the private sector for obtaining and maintaining Union marketing authorisations and for other services; and

- contributions from the Union budget to implement Union policies.

EMA charges fees for the assessment of applications for a marketing authorisation under the centralised procedure, for changes to marketing authorisations, as well as annual fees for the authorised medicines. Pharmacovigilance activities for human medicines conducted at EU level in the EMA are also financed by fees paid by marketing authorisation holders. Overall, the vast majority of the EMA's activities are currently funded through fees, charged to pharmaceutical companies in their capacity of applicants and holders of marketing authorisations. EMA remunerates the national competent authorities (NCAs) for the scientific assessment work of 'rapporteurs and co-rapporteurs' appointed by the EMA scientific committees.

Article 12(3) of Council Regulation (EC) No 297/95 on fees payable to the EMA (hereinafter 'the Fees Regulation')[3] states that the Commission shall present a report to the Council by 24 November 2010 on the implementation of this Regulation including an analysis of the need for including a dispute settlement procedure into the Regulation. The data and analysis produced by the evaluation will feed into this analysis, which has been postponed due to the urgent need to introduce fees for pharmacovigilance activities laid down in the pharmacovigilance legislation following its revision in 2010 and in 2012. As a result, the Regulation on Fees for Pharmacovigilance activities relating to medicinal products for human use was adopted in 2014 (Regulation No 658/2014). Recital 3 of that Regulation provides for a pending overall legislative revision of the fees regimes in the medicinal products sector. Moreover, Recital 7 provides that any future revisions of the pharmacovigilance fees or other 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 NCAs. This is line with a similar provision in Article 12(4) of the Fees Regulation, which provides that any review of the fees shall be based on an evaluation of the Agency's costs and on the basis of the related costs of the services provided for by the Member States. It further stipulates that those costs shall be calculated in accordance with generally accepted international costing methods.
In addition, EMA has to comply with the Financial Regulation, see:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000158.jsp&mid=WC0b01ac0580029337

[2] Regulation (EC) No 726/2004, OJ L 136, 30.4.2004, p. 1.

[3] Regulation (EC) No 297/95, OJ L 35, 15.2.1995, p. 1.

Finally, it should be noted that the outcome of the ongoing legislative process following the 2014 legislative proposals[4] to revise the veterinary medicines legislation[5] may have an impact on the future setup of the fees for veterinary medicinal products. However, the full impact on the fee system may only be known once the co-legislators (the European Parliament and the Council) finalise the current legislative process.

1.2 Objectives of the initiative/intervention and intervention logic

General objective

The main objective of the EMA fee system was to establish a sound financial basis for the Agency's activities related to assessments aimed at granting, maintaining and monitoring of Union marketing authorisations and for other services provided by the Agency related to medicinal products for human and veterinary use including pharmacovigilance activities for medicines for human use carried out at EU level. The activities of the Agency are understood as including the provision of services of the highly qualified experts from national competent authorities .

Specific objectives

The initial specific objectives stemming from the legislation relate overall to the need to ensure that fees are based on a sound economic basis, that they are fair and proportionate and that the system is as simple as possible in order to avoid unnecessary administrative burden for payers.

In particular:

- the amount of fees charged and of the remuneration of the National Competent Authorities ('NCAs') must correspond to the service actually provided;
- the amount of fees must be justified by the corresponding work and cost;
- the amount of the fees should not be a determining factor for the applicant for an authorisation where there is a choice between a centralised procedure and a national procedure;
- flexibility should be allowed by having the possibility to apply justified reductions for certain categories of medicinal products (such as products for the treatment of rare diseases in the human sector or products for minor species in the veterinary sector), as well as case by case reductions in exceptional circumstances and for imperative reasons of public or animal health;
- the structure of the fees should be as simple as possible to apply in order to minimise the related administrative burden;
- fees should be set at a level that avoids a deficit or a significant accumulation of surplus of the budget of the Agency, and should be revised when this is not the case;
- the amount of remuneration for the services provided by national competent authorities should be based on generalised estimations of the workload involved;

[4] COM(2014) 558 final and COM(2014) 557 final.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2014:0558:FIN
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2014:0557:FIN

[5] Regulation (EC) No 726/2014 (the founding regulation of EMA) and Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, OJ L 311, 28.11.2001,

- fees should be levied on marketing authorisation holders and applicants on a fair basis;
- fee incentives should be provided for micro-, small and medium-sized enterprises (and, consequently, these incentives need to be financed).

1.3 Description of the initiative/intervention

1.3.1 Actions/Measures

The main legislative provisions of relevance for this evaluation are laid down in:

- the founding regulation of EMA;
- the general fee regulation of EMA[6];
- the pharmacovigilance fee regulation of EMA[7] and
- the SME regulation[8].

A number of other sectorial legislative acts (such as, but not limited to, the legislation on orphan medicinal products, paediatric medicines or on advanced therapy medicinal products) and further texts have an impact on the fee system of the Agency, providing notably for specific fee reductions and/or non-fee based activities.

The implementing rules of the general fee regulation of EMA (see http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000327.jsp for this and other relevant EMA documents on fees) is adopted by the Management Board of EMA and is and important element of the detailed EMA fee system.

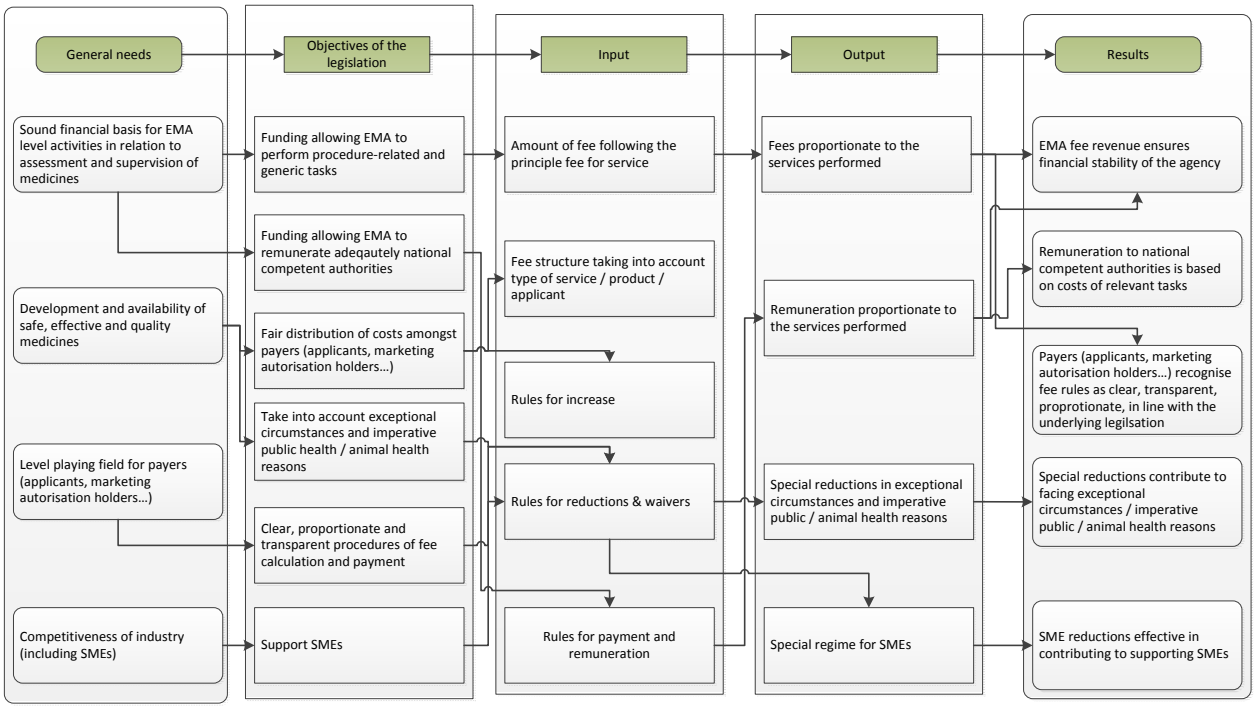
Any other relevant applicable text that will be further provided will be taken into account by the contractor. In particular, the contractor will consult EMA on other texts having a bearing on the EMA fee system and will take them into account in the analysis in agreement with the Commission.

[6] Regulation (EC) No 297/1995, OJ L 35, 15.2.1995

[7] Regulation (EC) No 658/2014, OJ L 189 27.06.2014

[8] Commission Regulation (EC) No 2049/2005, OJ L 329, 16.12.2005

1.3.2 Intervention logic



1.3.3 EU budget contribution

EMA receives a balancing subsidy of the EU budget for approximately 10% of its revenue. A separate specific budget line for activities related to orphan medicines exists. The analysis will include the way these budget subsidies are used, e.g. to finance Union policies. The relevant figures, at least for the period covered by the evaluation, will be provided by the EMA. Some information is already available on the web page of EMA under Home - About Us- How we work - Governance and reporting – Funding

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000130.jsp&mid=WC0b01ac0580029336

1.4 Implementation – State of Play

For 2016, the total budget of the EMA amounts to € 324 million of which € 277 million derive from fees payable by the pharmaceutical industry. The remainder is mainly financed by the EU budget of which the EU subsidy is a balancing contribution. There is also a relatively small EEA contribution. Over the years, the share of this contribution has diminished and is currently approximately 10-15% of the EMA budget, whereas it used to be 25%. Of the overall EMA fee income, an important share is paid to the NCAs of the Member States for the work they carry out. In 2016, it is estimated that € 120 million (i.e. 43% of the EMA fee revenue) will be paid to the NCAs from the Agency's budget.

The fees of the EMA are laid down in two main pieces of legislation, the Fees Regulation and the Pharmacovigilance Fees Regulation. In addition, there is the Regulation on SMEs that includes provisions on fees. The Fees Regulation was introduced in 1995, i.e. at the same time as the establishment of the Agency and the Regulation was last substantially amended in 2005. After that time, new legislation has been introduced with new tasks attributed to the Agency. While some of these tasks are covered by the Pharmacovigilance Fee Regulation, others are not subject to fees or are exempted from fees and hence the need to analyse whether the Fees Regulation and the budgetary contribution cover sufficiently all the tasks of the Agency.

In addition, some work is currently carried out by the NCAs for which there is no remuneration which is leading to difficulties in terms of sustainability of the Network. Recently, some improvements have been introduced, such as the use of multinational teams (involving several NCAs sharing the work).

Downstream rules have an important impact on the operational aspects of the current fee system. For example, the implementing rules of the Fees Regulation provide that 50% of the fee are repaid to the NCAs (e.g. to 2 NCAs when there is a rapporteur and a co-rapportuer) for the work they carry out.

1.5 Evaluation and Monitoring Provisions

1.5.1 Monitoring Provisions

The main monitoring tools are the EMA annual report, and the EMA annual activity report and the annual budgets of the EMA. The Agency will provide them to the contractor, covering at least the period assessed. Some information is already available on the EMA web page under:

Home-About Us-How we work-Governance and reporting-Annual reports and work programmes

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000208.jsp&mid=WC0b01ac058002933a#section3

In order to provide input for the evaluation of the EMA fee system, the Management Board of the EMA set up a Data Gathering Steering Group in June 2014, i.e. shortly after the adoption of the Pharmacovigilance Fee Regulation (which refers to the pending evaluation), to collect time data about the work carried out by the NCAs and by the EMA. This Group is expected to finalise its work by the end of 2016. It has focused on collecting data on the time spent on various procedures and relevant non-procedural activities activities (both remunerated and non-remunerated; both fee-financed and non- fee financed).

1.5.2 Previous evaluations and other reports

In terms of collecting data about the costs, an attempt was made through a pilot project in 2008-2009 of the Management Board to collect such data (in the so-called costing group) but this did not lead to any changes in the level of remuneration of the NCAs.

In 2009, an external evaluation of the EMA was undertaken. One of the recommendations thereof was the need to simplify the fee structure which has become very complex, whilst ensuring the fairness of the fees. [9]

As regards the repartition of the EMA fees between the EMA and the NCAs, the European Court of Auditors has repeatedly stated that the remuneration for services provided by the NCAs should be based on costs. [10] The audit reports are available on the web-site of the European Court of Auditors:

http://www.eca.europa.eu/en/Pages/AuditReportsOpinions.aspx?ty=Specific annual report&tab=tab3

Also the European Parliament has called for this, e.g. in the context of granting discharge to the EMA.

In 2013 the impact assessment report accompanying the Commission's proposal for pharmacovigilance fee legislation provided volume and workload estimations which were expected to correspond to a reasonable degree to the real activity. [11]

2. SPECIFICATIONS OF THE ASSIGNMENT

2.1 Objectives of the evaluation

This evaluation shall provide a sound basis to consider the possible review of the entire fee system of EMA based on needs for such a review identified and described in the evaluation process.

The objective of this evaluation is to examine in a comprehensive way the functioning of the fee system of the EMA as laid down in the relevant body of legislation and related implementation arrangements, in order to identify the strengths and weaknesses of the current system.
A key objective is to examine whether fees are established on a sound economic basis for all actors involved, whether they are fair and proportionate and whether the system is not overly complex in order to avoid unnecessary administrative burden.

The Fee Regulation and the Pharmacovigilance Fee Regulation provide that any review of fees is to be based on an evaluation of the underlying costs. Therefore, it is important to base the

[9] http://ec.europa.eu/health/files/pharmacos/news/emea_final_report_vfrev2.pdf

[10] See for instance the ECA 'Report on the annual accounts of the European Medicines Agency for the financial year 2011': *'16. As in previous reports, the Court has noted the need to introduce a system of remuneration for services provided by Member State authorities based on their real costs.'*
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2012.388.01.0116.01.ENG

[11] SWD(2013) 234 final, SWD(2013) 235 final.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52013SC0234
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52013SC0235

evaluation on costing models. It will be important in this respect to obtain information about those costs, both from the EMA and from the NCAs who contribute to the EMA activities.

Thus, the evaluation will assess the existing information and gather information about the costs of the activities concerned by the evaluation. More particularly, it will focus on the following elements:

Work Package 1 – Mapping of EMA activities and data gathering

- Produce a **detailed fee grid of EMA activities** in a user-friendly format (e.g. under Excel) including all possible amounts charged by EMA and all possible amounts for remuneration of NCAs where such remuneration is paid.. The fee grid should make reference to the applicable legislative and non-legislative texts on which the fees and the remuneration are based. The contractor will endeavour to gain a deep understanding of the fee and remuneration system currently in place through thorough analysis of the applicable texts, in close collaboration with EMA who has the expertise in operating the current system in practice, and consulting the NCAs regarding their remuneration, as appropriate.

- Gather from the NCAs and from the EMA data and information on the costs associated with EMA work and the extent to which the current fees contribute to the financing of costs of the activities concerned (see targeted consultation).

- Analyse and validate the time data produced by the Data Gathering Steering Group set up by the Management Board of the EMA, and in particular:

    - Review and verify the time data provided by the NCAs and the EMA which has been fed into the Data Gathering exercise. A methodology for validation will be proposed for agreement by the Commission inter-services steering group (validation of the consistency and the reliability of the data produced).

    - Consult the NCAs and the EMA in order to collect data on their respective costs of assessment activities at EMA level included in the data gathering exercise (targeted consultation).The views of the pharmaceutical industry should also be sought in this consultation. The consultation strategy of this targeted consultation shall be agreed with the Commission interservices steering group.

Work Package 2 – Analysis and Evaluation

- Produce a costing methodology taking into account all the information gathered and apply it to the available time data from the data gathering in order to obtain, where possible, theoretical levels of fees and remuneration of the NCAs which are to be compared with the actual levels. If fees are legally or operationally not possible, as per the analysis of the contractor, the contractor shall propose how to deal with the respective cost.This proposal and the proposal for fees and remuneration shall be based on the analysis of the contractor of the data gathering outcome, the outcome of the targeted consultation, the legislation and other applicable texts, the acquired knowledge of the contractor of the EMA activities and any other relevant information acquired by the contractor The methodology will be produced as a stand-alone document.

- On the basis of the above, assess, *inter alia*, the extent to which the current fee and remuneration levels correspond to the relevant costs of EMA and the NCA's contribution to EMA activities. This evaluation also includes assessing the pharmacovigilance fees, as well as all activities included in the data gathering outcome, including those which are currently not subect to a fee and / or a remuneration of the NCAs paid by EMA. In case the revised veterinary medicines legislation is finalised before the final report is prepared, its implications for the fee system should be factored into the analysis. In particular, the new activities stemming from the revised veterinary medicines legislation and their respective costs should be included in the analysis and determination of costs for the EMA and for the NCAs for the work they carry out. In case of lack of data for these new activities, the consultant shall provide the best estimates based on the information available and, where possible, on extrapolations.

- Based on the above and taking into account the applicable legislation, develop a financial model for EMA including fees allowing a fair and balanced contribution of different types of fees (including an analysis of the annual fees charged by EMA) to the overall financing of the EMA fee system which includes a fair and cost-based remuneration of NCAs. This model is a separate deliverable of the assignment, so to ensure that it can also be used as a basis for discusson for possible future revisions of the EMA fee system, independent of the current cost structure. Different options, including grouping of fees or flat/annual fees for certain activities should be proposed. A summary of the model will be presented based on the format of the detailed fee grid under Work package 1. Currently non-remunerated activities, such as but not limited to certain orphan medicines-related and paediatric medicines-related will be included. For activities where there is currently no fee / no remuneration to NCAs, fees / remuneration may be included in this model, provided that the underlying legislation allows it., An analysis will be provided by the contractor on whether a fee / a remuneration to NCAs could be set up, taking into account the operational point of view and a first analysis of the legislation; the contractor will consult the Commission in respect of the legal aspects. The contractor will consult EMA and the NCAs and will thoroughly analyse the input provided in the light of the applicable legislation in performing this task.

  The contractor will present a gap analysis between this theoretical financial model and the current model and will take this gap analysis into account in its evaluation of the current EMA fee system.

This task includes:

- Analysis of the relevant legislation
- Collection and analysis of data with a view to assess the framework for fees
- Including models for financing of EMA that incorporates a fair remuneration of the NCAs
- Establish list of criteria to be used for differentiating the fee structure, special attention should be given to SME and to variation fees, in close collaboration with

EMA. Attention will be given to any standardised activities which may justify fee reductions.

- Consult with EMA and NCAs to gather, analyse and use the input.

- Assess the sustainability of the current model and the model proposed by the contractor (see evaluation question on sustainability)

- Based on information collected from Member States and from EMA, assess whether there are instances where a risk of overlap with national fees exists. This tasks is limited to the possible existence of overlap areas, to the strict exclusion of any analysis or evaluation of the national fee and funding systems. This task will require the contractor to get deeply acquainted with the lifecyle of a product, depending on the route of authorisation, and the different assessments through which the product goes at different stages of this lifecycle and possible interferences. The EMA will be consulted, *inter alia*, to provide the contractor with expertise on these aspects. Possible overlaps identified will be taken into account in the abovementioned theoretical financial model.

- Analyse and assess the funding model of all fee incentives applicable, including those applied to SMEs, in close collaboration with EMA. The outcome of this analysis will be taken into account in the abovementioned financial model.

A useful benchmark for part of the evaluation could be the estimations that were made in 2013 as part of the impact assessment accompanying the Commission's proposal for pharmacovigilance fee legislation as this impact assessment provided volume and workload estimations which were expected to correspond to a reasonable degree to the real activity. [12]

2.2 Scope of the evaluation

This evaluation will cover the entire fee system of the EMA and the way in which it funds the activities carried out at the level of the Agency which includes contributions from NCAs. Both human and veterinary medicines activities of EMA are included.

The scope of the evaluation will also include the remuneration paid by the Agency to the NCAs[13].

The geographical coverage includes all EU Member States and EEA states.

The evaluation should use recent data reflecting the current situation and historical data, subject to availability, where relevant for the analysis. The evaluation shall include data gathered from the NCAs, the EMA, pharmaceutical companies including SMEs and other stakeholders, such as patient organisations and academia.

[12] SWD(2013) 234 final, SWD(2013) 235 final.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52013SC0234
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52013SC0235

[13] Rapporteurs and, where relevant, co-rapporteurs from NCAs carry out the scientific assessments in relation to the Union-wide pre-authorisation, authorisation and post-authorisation procedures and activities of the Agency.

It should be noted that the EMA has been assigned new tasks since the last revision of the general fee regulation in 2005 which, with the exception of pharmacovigilance tasks, are not fully reflected in the fee structure of the Agency. Therefore, activities which currently are not subject to a fee will also be included in the scope of the evaluation. In addition, it should take account of new activities resulting from the current review of the veterinary medicines legislation.

2.3 Tasks to be performed by the contractor

The support study by the contractor includes the tasks and deliverables outlined below.

All tasks performed under this contract shall comply with the Better Regulation Guidelines[14]. Any data used in the analysis by the contractor shall be provided in an electronic format.

- The contractor should get acquainted in detail with the Fee Regulation and the Pharmacovigilance Fee Regulation, the implementing rules of the Fee Regulation and all other legislative and non legislative texts shaping the EMA fee system including the remuneration to NCAs.

- Detailed description of the currently applicable EMA fee system (detailed spreadsheets with a fee grid of all possible combinations of fees and remuneration, including all possible reductions; detailed description of amounts of fee revenue and remuneration). The spreadsheets will be presented in a user-friendly format. Explanatory text will be provided where necessary in order to facilitate the understanding. This work will be underpinned notably by detailed fee grids.
- Analysis of the various forms of collaboration between EMA and the NCAs (based on texts such as the cooperation agreement, data gathering outcome and proceedings as well as consultations with EMA and NCAs).
- In-depth methodological and statistical analysis of the robustness and the absence of significant bias of the outcome and assurance of the validity of the data gathered through the data gathering project, based on the totality of raw data, reports and proceeding of that project. An auditing methodology will be developed, validated with the Commission interservice steering group and used for that purpose, e.g. including interviews, questionnaires, on-site visits, consistency checks, etc.
    - The outcome of the data gathering project, together with proceedings thereof, will be provided to the contractor who will examine the data in detail and will extensively use them for the evaluation of the current fee model/system. The data gathering project is expected to report by end 2016.

- Any other relevant evidence and data provided by the EMA, the Commission or the Member States in the framework of the consultations will also be duly taken into account in the analysis of the contractor.
- The contractor will verify the quality of the data provided, and should request where necessary further clarifications.

[14] http://ec.europa.eu/smart-regulation/guidelines/toc_guide_en.htm

- If the data gathering has not provided time data (or has not provided data which is robust enough) by end of 2016 on all the fee earning and non-fee earning activities that were included in the scope of the data gathering, both from EMA and from Member States, propose and apply a methodology to fill in the data gaps. The Pharmacovigilance Fee Regulation provides for specific monitoring and reporting obligations relating to components that may have a bearing on the costs such as the number of hours spent on pharmacovigilance procedures. Data from this reporting will also be used.
- Detailed consultations with EMA and with NCAs in order to gather sufficient and robust documented evidence on their respective costs of the activities included in the data gathering exercise which gathers data on time. Where necessary, the contractor will also have to collect additional data and evidence from both the NCAs and the EMA on their respective costs in order to propose costing models for the evaluation of the current fee and remuneration system of the EMA.
- Consider available economic/statistical analyses and market studies about the present situation regarding determination of costs for the EMA and for the NCAs for the work they carry out at EU level (e.g. under the centralised procedure and for relevant pharmacovigilance work referred to in the Pharmacovigilance Fee Regulation).
- Analyse and research the parameters to be considered for determining costs for the Agency and for the NCAs.
- Propose costing models regarding the time data stemming from the data gathering exercise, knowing that NCAs and EMA have each different cost bases. These costing models will use data on cost of labour and overheads which are to be gathered from both the EMA and the NCAs (see above).
- Using standard methods and techniques from analytical accounting and analyse available data from other comparable EU decentralised fee-earning Agencies, as appropriate. Data from comparable organisations in other regions of the world may be considered in the reflection, as appropriate.
- Collection and analysis of fees charged by comparable public bodies for comparable activities (in and outside the EU).
- Research, analysis and recommendation for the calculation of fees to be paid by industry and take those recommendations into account in the financial model described in the work packages.
- Research, analysis and recommendation concerning the framework model for the financing of EMA and the fair remuneration of the NCAs and use those for the financial model porposed.
- Analysis of the need for a dispute settlement procedure in relation to the payment of fees. The need for including such a procedure in the legislation will be assessed based on the experience and feedback of stakeholders.
- All tasks related to the stakeholders consultations, described in section 2.5.1.
- All tasks described in the work packages.
- The contractor will acquire knowledge of the pilot project 2008-2009 of the costing group of the EMA Management Board (information to be provided by EMA and DG SANTE), will analyse its outcome which will be included in the reflection and the analysis of the contractor, as background information.

- The contractor will acquire knowledge of the final report of the external evaluation of EMA in 2009 and will take it into account in the analysis of the contractor, as background information.
- The contractor will take into account the calls of the European Court of Auditors and of the European Parliament for a cost-based approach .

- The contractor will propose refined evaluation questions and will propose an evaluation matrix (see section on evaluation questions).

2.4 Evaluation questions

The proposed offer is expected to evaluate the legislation on on EMA fees according to the evaluation criteria listed below. In this respect the contractor may refine the specific evaluation questions provided below in agreement with the Commission inter-services steering group.

2.4.1 Relevance

Evaluation question: To which degree does the current fee system fulfill the need to fund the relevant legislative tasks of EMA, including the remuneration of NCAs?

2.4.2 European Added Value

It is only possible to set up fees of the EMA, as a decentralised EU Agency, at EU level, therefore evaluating this aspect has no particular relevance, as the tasks assigned to EMA by the legislation, which have to be financed, are not the subject of this evaluation.

2.4.3 Effectiveness and efficiency

Evaluation question: With a view to assessing the effectiveness and the efficiency of the fee system, to which degree the current financial model of the fees charged by EMA to industry at large, including the remuneration paid by EMA to rapporteurs and experts from NCAs, is sustainable and fair?

Fairness corresponds broadly to the level of correlation between the cost of delivering the service and the structure and the amount of fees. This includes reductions and waivers as part of special supporting activities such as those of the EMA SME office. It will also be examined if the legislation is effective in setting out a clear, transparent and simple system.

The efficiency of the fee system is also related to the current structure of fees and it will be evaluated whether such structure is optimal to achieve the general and the specific objectives of the initiative. Potential for simplification and burden reduction will be explored.

2.4.4 Coherence

Evaluation question: To wich degree the current EMA fee system is coherent, both internally and externally?

The internal coherence relates for example to the coherence of the structure of the fees, the coherence of the remuneration levels, etc.
In addition, the overall external coherence of the EU-level and national-level fee systems should be taken into account, i.e. identifing, on the basis of information obtained from the Member States or other stakeholders, instances where EMA fees may overlap with national fees, in terms of possible areas / activities financed by fees and to the exclusion of any analaysis of the national fee and funding system, the Union being only competent for Union-level fees for tasks assigned to EMA by the Union legislation (see Work package 2).

2.4.5 Sustainability

Evaluation question: to which degree the current fee system of EMA is sustainable?

Sustainability is understood mainly as to what extent the system is based on a cost-related model. The evaluation will focus on costs / fees per type of procedure. In addition, some fees, notably annual fees, which cover some cross-cutting activities of the Agency, such as IT activities, will also fall under the scope of the evaluation.

The sustainability of the EMA fee model will be also assessed based on data to be gathered mainly from the EMA on the trends that were observed during the evaluation period as well as on projections of future developments. The sustainability of the system includes a fair remuneration of the services provided by the NCAs.

Sustainability also reflects the ability of the EMA and the NCAs to continue to invest in their staff and activities to ensure that they can provide high quality scientific assessment and advice.

The contractor will summarise its strategy how to answer these questions in an evaluation matrix. This is an example of an evaluation matrix. The contractor may structure it in a different way.

evaluation questions	judgement criteria/evaluation indicators	data sources/lines of evidence	data collection method	analytical methods to process the data
Relevance				
Q1				
Q2				
Q3				
……				
Effectiveness				
Q1				
Q2				
Q3				
……				
efficiency				
Q1				
Q2				
Q3				

.....				
Coherence				
Q1				
Q2				
Q3				
.....				
Sustainability				
Q1				
Q2				
Q3				
.....				
European Added Value				
Q1				
Q2				
Q3				
.....				

2.5 Other tasks under the assignment

2.5.1

Stakeholder consultations

The contractor shall manage two types of stakeholder consultations, first a targeted consultation and second, an open public consultation. This entails producing stakeholder mapping, using a stakeholder consultation strategy and stakeholder questionnaires for the public and for the targeted stakeholders. When carrying out this work, the contractor shall use the EC templates and forms, where applicable, e.g. personal data protection (disclaimer) or the mapping of the consultation strategy. The Commission/DG SANTE will provide a description of the range of stakeholders. On this basis, the contractor should carry out the following tasks:

- Map the stakeholders by defining the following four broad categories: stakeholders with 1. big influence and big interest in the topic; 2. big influence and small interest in the topic (maybe the media); 3. small influence and big interest in the topic (always a challenge to identify and reach)**;** 4. small influence, small interest in the topic.

- Develop the stakeholder consultation strategy based on the roadmap[15] of the evaluation that will include a bundle of methods to reach the stakeholders. The strategy must include the 3 month-internet-based open public consultation. Other methods include workshops and surveys among targeted stakeholders. The presented strategy should illustrate how the contractor intends to reach all stakeholder groups as described above. Taking into account the the description of the evaluation indicators for each of the 5 mandatory evaluation

[15] http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_sante_683_evaluation_ema_fees_en.pdf

criteria stated in section 2.4 of this document, the contractor shall develop stakeholder questionnaires, in a way that the input collected will contribute to meeting the five mandatory evaluation criteria.

- Prepare the questionnaire for the consultations. The contractor shall at all times comply with Regulation (EC) 45/2001 on personal data protection. For all consultations the contractor must observe the Commission's rules on personal data protection and use the disclaimer on personal data protection, approved by the Commission. See Annex VI. A question to the stakeholders if they are registered in the Transparency Register must be present in the questionnaires. The questionnaires will be approved by the Commission inter-services steering group before they are used.

- After each round of consultations (internet, targeted), prepare a statistical summary report on the number of respondents and how they answered. These reports are purely factual and include no analysis and conclusions just state the facts.

- Upon analysis of the stakeholders' input, prepare in an annex or in a dedicated section of the contractor's report about the outcome the stakeholder consultations and how these are used in the evaluation: what the respondents answered, perform an analysis of the answers and draw conclusions. The contractor will produce a synopsis report covering all consultations launched as foreseen by the better regulation toolbox:

http://ec.europa.eu/smart-regulation/guidelines/toc_tool_en.htm

Targeted stakeholder consultations will be conducted in study month 3 in order to gather further evidence notably about the cost structures and to complement/fill gaps from the data gathering exercise. The main stakeholders concerned are the EMA, the NCAs and the industry. The costs elements gathered and the costing methodology will be provided in a specific deliverable. The consultation items have to be approved by the Commission, before being executed. The contractor will endeavour to duly inform the consulted parties that commercially confidential information should not be submitted to the contractor.

The open public consultation will be carried out based on the preliminary conclusions following the initial evaluation with a duration of 3 months. The questionnaire has to be agreed with the Commission.

3. METHODOLOGY

The contractor will have a free choice as to the methods used to gather and analyse information and for making the assessment, but must take account of the following:

- The evaluation must be based on recognised evaluation techniques and triangulation methods (incl. data triangulation) are required. The validation methodology of the data gathering exercise, the gap analysis of the outcome of that exercise and the methodology of filling such gaps, the methodology of the data collection on costs (targeted consultation of EMA and NCAs) and the costing methodology (applying the cost data obtained to time data from the data gathering of the EMA Management Board in order to obtain a theoretical fee model for the evaluation) are some of the important methodological aspects.

- The choice and a detailed description of the methodology must form part of the offer submitted. Advantages, limitations and risks involved in using the proposed tools and techniques should be explained. There should be a clear link between the evaluation questions addressed and the corresponding methodology proposed. The evaluation questions can be further elaborated, e.g. by providing operational sub-questions under each question, to be agreed by the Commission inter-services steering group.

- Considerable emphasis should be placed on the analysis phase of the evaluation. In addressing the evaluation questions, quantitative indicators should be sought and used as far as possible. The contractor must support findings and recommendations by explaining the degree to which these are based on opinion, analysis and objectively verifiable evidence. Where opinion is the main source, the degree of consensus and the steps taken to test the opinion should be given.

- The approach proposed by the contractor must be clearly set out in the bid. It should clearly identify

    a. data to be collected

    b. consultation strategy

    c. Analysis to be conducted and what will be the basis for such analysis.

- Evaluation matrix: success criteria, indicators, data sources, methods, limits.

4. REPORTING AND DELIVERABLES

4.1 General reporting requirements

The study must be completed within **15 months** after the signature of the contract.

The present assignment includes the submission of a series of deliverables: reports and presentations. The contractor will deliver the following reports at key stages of the evaluation process: **inception report**, **interim report** and **final report**. Each report should be written in English, and critically assessed as it provides the basis for tracking the quality of the work done by the evaluator. These reports will be submitted by DG SANTE to the established Commission inter-services steering group, which may ask for complementary information or propose adjustments in order to redirect the work as necessary. Reports must be approved by the Commission. With work progressing and in the light of new findings, revisions of reports already approved may be necessary.

It is essential that all the reports be clear, concise, unambiguous and comprehensive. They should also be understandable for non-specialists. The presentation of the texts, tables and graphs has to be clear and complete and correspond to commonly recognised standards for studies to be published. A structured and precise elaboration of add-ons based on previous deliverables at every stage of the process is requested (for example, this could be done via colour-coding parts of the report developed at the offer, inception, interim and draft final stage). An indicative size of each report to be provided is (excluding annexes):

- inception report: up to 40 pages

- interim report: up to 80 pages
- final report: up to 160 pages

The reports should be provided to the Commission in both MS-Word and Adobe Acrobat (PDF) format with the data and charts in Excel (other formats may be added). They should be accompanied, where requested, by appropriate annexes and delivered in accordance with the deadlines and requirements set out in the Terms of Reference and agreed with the Commission inter-services steering group.

Every two weeks, the contractor may be asked to submit a **short progress note** to the Commission reporting on the state of execution of the tasks. Furthermore, the following reports and presentations shall be delivered:

Kick-off meeting report

After signature of the contract, the contractor will participate in a kick-off meeting with the Commission inter-services steering group. The purpose of this meeting is to verify:

- The contractor's understanding of the Terms of Reference
- The proposed general approach to the work (methodology, planning, structure of deliverables etc.)
- The composition and eligibility of the contractor's team.

The stakeholder mapping will be discussed during that meeting.

Inception report – within 1.5 month after the kick off meeting

This phase should demonstrate the understanding of the contractor of the tasks assigned, once he was able to round up sufficiently preliminary work, the methodology should be described in detail and the resources planning finalised, GANTT charts are welcome. The evaluation matrix shall be part of the inception report. If ready, the stakeholder questionnaires should be provided. If work on questionnaires has not been completed, a timetable for completion will be provided for agreement by the Commission inter-services steering group.

The inception report completes the structuring phase of the evaluation. It should give a concise and comprehensive description of the overall approach, the methodology applied, the work plan and the organisation of the work. It should set out in detail how the methodology for data and evidence gathering, for analysis and reaching the conclusions. It should describe how the methodology will be implemented, and in particular lay out clearly in tabular form how the method allows each evaluation question to be answered via establishment of judgement criteria and within these, of evaluation indicators (see above). In addition the table should have a further column indicating the evaluation tools chosen. Alternative proposals on the strategy to answer the evaluation questions may be put forward by the contractor for the agreement of the Commisison inter-services steering group. The inception report should be a stand-alone document of maximum 40 pages (without annexes) and include enough detail for the Commission inter-services steering group to gain a good understanding of the evaluation tools and related methodological steps proposed.

The report may supplement with detailed evaluation sub-questions as considered necessary to answer the evaluation questions (for agreement by the Commission inter-services steering group). As such, this document will provide an opportunity to make a final check on the

feasibility of the method proposed and the extent to which it corresponds with the task specifications.

The known sources of information, use of tracers, case studies, contact persons in Member States, as well as the way the contractor will interact with Member State representatives will be fully clarified at this stage.

The inception report will be submitted to the Commission inter-services steering group which will discuss on this basis with the contractor and may request changes and improvements. The contractor is expected to present the inception report in a summarized way at the occasion of the meeting. The final versions of evaluation questions suggested by the contractor and the evaluation indicators to be used will be validated by the Commission inter-services steering group at this stage. After the meeting the contractor will submit a final version of the inception report.

Interim report – within 10 months of the signature of the contract

This initial interim report will provide information on the initial analysis of data collected. It will describe the progress made and provide information on the analysis of data of the data gathering of time data, possible gaps filled in, the cost data collected by the contractor, the costing methodology and a draft theoretical fee grid resulting from all this elements against which the existing fee grid should be assessed (including activities for which there is currently no fee and / or no remuneration of Member States) . The evaluator should already be in a position to provide: a) **aggregated data**, and b) **preliminary findings and conclusions**.

It should contain a suggestion for the structure of the final report and not exceed the size of 80 pages (without annexes).

The report will provide DG SANTE with an opportunity to check whether the evaluation is on track and whether it has focused on the specified needs.

The contractor will submit a final interim report with the necessary updates after discussion with the Commission inter-services steering group in a specific meeting. At this meeting, the contractor will define in agreement with the DG SANTE and the Commission inter-services steering group the table of contents and structure of the draft final report. A document outlining the latter must be submitted by the contractor at least ten working days in advance of the meeting. It will serve as a basis for the discussion. The contractor is expected to present the interim report in a summarized way at the occasion of the meeting.

Draft final report – within 13 months of the signature of the contract.

The draft final report will provide the draft final conclusions of the contractor with respect to the tasks set in the present assignment. . It will also provide the preliminary conclusions of the evaluator in respect of the evaluation questions. These will be based on evidence generated through the evaluation. Remarks provided by the Commission inter-services steering group will be addressed.

Any judgements provided should be clear and explicit. The draft final report should also contain substantiated recommendations/options for change made on the basis of the conclusions reached by the evaluator. It will also provide a technical overview of the evaluation process, highlighting limitations and possible bias therein.

The draft final report should be structured along the lines of Commission Evaluation Standards. It will not exceed the length of 160 pages (without annexes) and it will include an

executive summary of not more than 10 pages (factual data concerning the implementation of the Programme and summary of analyses and conclusions) in EN and FR, the main report (presenting the results of the analyses in full, conclusions and recommendations) and technical annexes (including these Task Specifications and the synopsis report of the consultations) and a draft one-page summary on the Key Messages (conclusions and recommendations in bullet form) of the evaluation.

The draft final report will be discussed with the Commission inter-services steering group and the contractor in a meeting. The contractor is expected to present the draft final report in a summarized way at the occasion of the meeting.

Final report – within 15 months of the signature of the contract

This document will provide the **final conclusions** of the contractor with respect to the tasks set in the present assignment. Any judgements provided should be clear and explicit. It will also provide a technical overview of the study process highlighting limitations and possible bias therein. Remarks provided by the Commission inter-services steering group will be addressed.

The final report shall take into account the outcome of the public consultation. It shall include an final **executive summary** of not more than 10 pages (synthesis of analyses and conclusions), the main report (structure to be confirmed by the Commission services but planned to reflect the content of the assignment), technical annexes (inter alia the Task Specifications and a compilation of all requested country-based and EMA information where applicable, as well as the consultations synopsis report. The latter should precede. This executive summary report has to be in English and French.

The final report will present the deliverables in English. It must be a self-contained document that can be read in isolation from the preceding interim report. More detailed/technical elements related to specific tasks will be included as annexes. An electronic version and six hard copies of the final report must be provided after the report has been accepted by the Commission.

The final report will provide the conclusions of the contractor drawn from the work, duly substantiated by the facts and based on the evidence generated and the analysis performed, as well as a technical overview of the project highlighting limitations and possible biases therein and a justification why such limitations and / or biases were not overcome. Any judgments made should be clear, explicit and based on relevant data and / or analysis.

It will take account of the results of the comments and discussions with the Commission inter-services steering group regarding the draft final report and during the meeting devoted to the final report, insofar as they do not interfere with the autonomy of the contractor in respect to the conclusions. The executive summary (including the Key Messages section preceding it) should be provided.

The copyright of the reports remains with the European Commission.

Each report (except the final version of the Final Report) should have an **cover page** providing an overview and orientation of the report. It should describe what parts of the document, on the one hand, have been carried over from previous reports or been recycled from other documents, and on the other hand, represent progress of the evaluation work with reference to the work plan.

Moreover each report should consist of the following sections:

- Executive summary (max 10 pages)
- Introduction (describing the topic of the report)
- Background and context
- Methodology (justifying its adoption)
- Findings (showing quantitative figures in narratives and few selected tables, making as much use as possible of graphs and tables to illustrate numbers, the majority of tables will be annexed)
- Conclusions (clear, concise)
- References and annexes (e.g. tables with data, stakeholder feedback etc.)
- List of data sources used
- List of all contributing authors, their organisational affiliation as well as their respective concrete contribution to the analysis and report

All reports must be drafted in English (except the Executive Summary of the final report which must be in English and French) and submitted according to the timetable below to the responsible body. All reports should have numbered paragraphs and pages and a clear identification, containing:

- The contract number (not the call number)
- The acronym
- The version (draft, revision or final) and
- The date.

Other deliverables

The contractor should also provide a PowerPoint presentation of final key aspects and findings of the evaluation, together with speaking notes. At the request of the Commission, the contractor should provide presentations to the EMA management and the Commission. The contractor, in these cases, will be requested to be physically present at those meetings/events with one or maximum two members of their team. These may be organised in Brussels or in London. The Commission will hold the copyright of the reports, annexes and presentations.

Deliverables regarding the stakeholder consultations

- Mapping of stakeholders in electronic format (including their names, e-mail and internet addresses).

- The analysis of the contributions received through the public consultation, and suggestions for reply to the stakeholders (the size of this document depends on the number of contributions to be received). To note that although the questionnaire for this public consultation will be only in English some replies may be received possibly in all 24 EU languages. All replies must be taken into account.

- Statistical summary reports on the number of responses received and categorised by the type of stakeholders for each type of stakeholder consultations – open internet-based and targeted consultations. A synopsis report presenting the main comments/contributions and how these shall be integrated in the evaluation work. (The requirements for the content of this report will be discussed further with the Commission inter-services steering group, while the contractor will take into account and use the better regulation toolbox http://ec.europa.eu/smart-regulation/guidelines/toc_tool_en.htm) The synopsis report of the stakeholder consultation must be a stand-alone document, which may be annexed to the main report.

Requirements applicable to all above-mentioned deliverables

The offer shall provide an indicative table with deadlines of all deliverables and estimations of ressources used per deliverable. The final version of such table will be agreed at the kick-off meeting.

It is essential that all the reports are clear, unambiguous and comprehensive. They should also be understandable for non-specialists. The reports should be provided to the European Commission in Word format and the raw data and charts in Excel. They should be accompanied, where requested, by relevant annexes. All reports and presentations are to be submitted in electronic format in accordance with the deadlines set in the specified time-schedule.

Data protection rules have to be respected. If personal data is collected and processed, the processing has to comply with the Regulation (EC) 45/2001 on the protection of personal data. Regarding the consultation, it will be clearly stated that contributions are going to be published on the dedicated website, unless respondents provide a substantial justification for their opposition to the publication of their contribution.

Through the Transparency Register, organisations that wish to submit comments will be asked to provide the Commission and the public at large, with information about their interests they represent and how inclusive their representation is. Submissions from organisations that choose not to register will be treated as "individual contributions" unless they are recognised as representative stakeholders via relevant Treaty provisions.

4.2. Quality Assessment

The contractor will establish robust means to ensure the reliability, validity and comparability of the information collected as well as of its analysis and of its reporting.

The following general quality assessment criteria will be applied to the work and the deliverables of the contractor:

Output criteria:
Relevance of the content - Relevant Scope and Coverage, as defined in the ToR
Adequacy of the methodology - defensible design and methods
Reliability of the data - data sources are verifiable and sufficient. Balanced proportion between the primary and secondary data used.
Robustness of the analysis – Analysis is based on all available data. Triangulation is made where possible. Assumptions made are clearly explained and justified. Analytical methodology is well explained.
Credibility of the results - results relate to analysis and data
Validity of the conclusions - impartial and unbiased conclusions, which demosntrate sound judgement. Clear and relevant conclusions, stemming from the available data and from the analysis performed by the contractor and presented in the documents.
Utility of the recommendations - recommendations related to the objective of the evaluation and the conclusions made
Clarity - clear writing style, the reports are to be proved by a native English speaker. The report should include short stand alone executive summary. The body of the report to include major conclusions and recommendations. Supprortive data is to be presented in annexes
Process criteria:
effective dialogue and feedback throughout the evaluation process
professional qualifications and good management by the evaluation team
effective and encompassing involvement of stakehoders in the evaluation process
scoring system
Three grades will be used: Fulfilled; Not fulfilled; N/A

5. ORGANISATION, TIMETABLE AND BUDGET

5.1 Organisation

The contract will be managed by Unit B5 with the support of Unit A1 of the European Commission Directorate-General for Health and Food Safety (DG SANTE). Unit E5 of DG SANTE is associated on the veterinary aspects.

A Commission inter-services steering group will be involved in the management of the evaluation. The responsibilities of the Commission inter-services steering group will include:

- establishement of the Terms of Reference;
- providing the external evaluator with access to information, as far as the information is held by the Commission services; the contractor will endeavour to collect all the relevant

information required for the evaluation from EMA, from Member States and from industry;
- consultation on all deliverables submitted by the contractor
- providing where possible support and monitoring the work of the external evaluator;
- assessing the quality of the reports submitted by the contractor while ensuring that the Contractor's independence is not compromised.

5.2 Meetings

It is requested that the contractor participate in at least 4 meetings in Brussels with the Commission, as explained under heading 5.4. budget and 1 additional meeting of the Pharmaceutical committee. The contractor is requested to produce records/minutes of his meetings with the Commission inter-services steering group and to submit them to the Commission for approval the week following the meeting. All comments of the Commission will be taken into account by the contractor in producing the final version of the minutes.

The contractor will in addition budget the necessary meetings or phone calls with the EMA and with the Member States, notably for the collection of cost data (targeted consultation).

5.3 Timetable

The following outline work plan and indicative timetable are envisaged:

The specific contract period is expected to run from November 2016 for a duration that will not exceed 15 months. More details are given in the table below.

While most of the work will be carried out in the contractor’s premises, one kick-off meeting and two meetings (interim report and draft final report presentation to DG SANTE) will be held in the SANTE premises in Brussels.

Time	**Milestone**	**Comments**
Month 1	Kick-off meeting	Discussion of the work plan and the contractor’s proposal with the Commission inter-services steering group (meeting in Brussels).
Month 1-2	Inception report	Feedback and suggestions received at the kick-off meeting must be reflected.

Time	**Milestone**	**Comments**
Month 5	Targeted Consultation	The contractor shall furnish the Commission with a summary report on the results of the consultation including an analysis of the robustness of the data obtained and how it will be used in the costing model.
Month 9-10	Interim report	Desk and field research completed, see above. Meeting in Brussels. Presentation of targeted consultation outcome.
Month 10	Open public consultation	The contractor shall furnish the Commission with a summary report on the results of the consultation. The results should also be taken into account in the final report.
Around Month 12 (depending on time schedule of the Commission)	Attendance by the contractor of a physical meeting of the Pharmaceutical committee in Brussels, with the presence of an observer appointed by EMA and an observer appointed by the EMA Management Board.	The contractor shall present to the Committee the project of the draft final report and the main findings of the evaluation.
tbc	Attendance by the contractor of a physical meeting of the EMA Management Board in London.	The contractor shall present to the EMA Management Board the project of the draft final report and the main findings of the evaluation.
Month 13	Draft final report	Contractor provides SANTE with the draft final report. The Draft final report shall include in an annex a synopsis report on the results from stakeholder consultations and how these have been used in the evaluation process. Meeting to be organised in Brussels. Discuss draft final report. Feedback of DG SANTE and of the Commission inter-services steering group to be taken into account.

Time	Milestone	Comments
Month 15	Final report	Taking account of the Commission inter-services steering group 's comments, the contractor sends the final report and executive summary to DG SANTE and the Commission inter-services steering group. Meeting in Brussels. It is obligatory to include an annex the synosis of the stakeholder consultations.

5.4 Budget

The price band for this contract ranges from EUR 200.000 up to a maximum of EUR 250.000.

The Commission will organise (joint) meetings with the contractor when necessary. The meetings that are already planned are listed in point "5.3.*.Timetable"* of this Annex.

The contractor should foresee travel and subsistence costs for at least 4 half-day meetings with the Commission in Brussels, at least 1 half-day meeting of the Pharmaceutical committee in Brussels and at least 2 half-day meetings in London, one of which to present the interim report to the EMA Management Board. Additionally, possible meetings if necessary at the EMA (London) and in Member States (including audio meetings) should be factored in, both at the stage of the validation of the data gathering outcome and at the stage of the data gathering on cost performed by the contractor. In accordance with the framework contract the travel and subsistence expenses for the meetings in Brussels will not be reimbursed by the Commission. These must be included in the general cost of the study.

The contractor is advised that the working languages for such meetings will be English unless a prior alternative arrangement has been made with the Commission. The contractor is advised that the Commission will not accept any deliverable where the quality of English has not been checked to ensure a sufficient good working language level.

Prices must be quoted in Euro using, if necessary, the conversion rates published in the C series of the Official Journal of the European Union on the day when the contract notice was published (if no notice was published, on the day when the invitation to tender was sent out).

Prices must be fixed amounts in Euro.

Estimated travel and subsistence expenses must be indicated separately.

- Prices should be quoted free of all duties, taxes and other charges, excluding VAT, as the Communities are exempt from such charges under Articles 3 and 4 of the Protocol on the privileges and immunities of the European Communities. If applicable, the amount of VAT should be shown separately.

- Prices are firm and not subject to revision.

A a blank form of model budgetary offer is presented in Annex III.

6. REFERENCES

6.1 Basic documents

- Regulation (EC) No 726/2014 (the founding regulation of EMA), OJ L 136, 30.4.2004, p.1
- Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, OJ L 311, 28.11.2001, p. 67
- Council Regulation (EC) No 297/95 on fees payable to the EMA (the General fees Regulation), OJ L 35, 15.2.1995
- Implementing rules of the Fees Regulation published on EMA's Website: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/03/WC500203708.pdf
- Regulation (EU) No 658/2014 of the European Parliament and of the Council on fees payable to the EMA for pharmacovigilance activities in respect of medicinal products for human use (Pharmacovigilance Fee Regulation), OJ L 189, 15.5.2014, p. 112
- Commission Regulation (EC) No 2049/2005 of 15 December 2005 laying down, pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council, rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises (SME Regulation), OJ L 329, 16.12.2005
- Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (Orphan Regulation), OJ L 18, 22.1.2000, p. 1
- Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use, OJ L 378, 27.12.2006, p.1.
- Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (ATMP Regulation), OJ L 324, 10.12.2007
- Commission Regulation (EC) 1234/2008 of 28 November 2008 concerning the examination of variations to the terms of marketing authorisation for medicinal products for human use and veterinary medicinal products, OJ L 334, 12.12.2008, p. 7
- The Commission guidelines on variations (2013/C 223/01): http://ec.europa.eu/health/files/eudralex/vol-1/c_2013_223/c_2013_2804_en.pdf
- Commisison Proposal for a Regulation on veterinary medicinal products http://ec.europa.eu/health/files/veterinary/vet_2014-09/regulation/reg_part1_en.pdf

6.2 Other existing documents/data and how to access them

- European Commission – Evaluation of the EMA, January 2010, final report:

  http://ec.europa.eu/health/files/pharmacos/news/emea_final_report_vfrev2.pdf

- Heads of Medicines Agencies - Role of the European Regulatory Medicines Network and its relation to a revision of the fees regulation, HMA, December 15, 2010:
  http://www.hma.eu/fileadmin/dateien/HMA_joint/04_HMA_Induction/07_HMA_Position__on_Rev_fees_2010_12.pdf

- Example of a report on the annual accounts of the EMA for the financial year 2011 from the European Court of Auditors (ECA) regarding the need for the remuneration for services provided by Member State authorities to be based on costs; http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2012.388.01.0116.01.ENG

- Legal proposal for the pharmacovigilance Fee Regulation: COM(2013) 472 final. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2013:0472:FIN

- Impact Assessment of the legal proposal for a Pharmacovigilance Fee Regulation:
  SWD(2013) 234 final, SWD(2013) 235 final
  http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52013SC0234
  http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52013SC0235

- Roadmap on the evaluation of EMA Fees of December 2015:
  http://ec.europa.eu/smart-regulation/roadmaps/index_en.htm

- Annual reports and work programmes of EMA: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000208.jsp&mid=WC0b01ac058002933a

6.3 Useful web-links

- EMA's website relating to fees:
  http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000327.jsp&mid=WC0b01ac0580024596

7. REQUIREMENTS

7.1 Resources

The contractor will propose an appropriate team to perform the specific services.

The team will include a team leader with a university degree and at least eight years of experience in the area of evaluation of public policies with a focus on costing of activities in public bodies and auditing of data.

One team member will have a proven experience of minimum 5 years in the area of cost modelling of public bodies and fees charged by the public sector.

One team member will have a proven experience of minimum 5 years in the area of regulatory work in the pharmaceutical sector.

The team will comprise a member with (or will have access to) statistical expertise for the statistical assessment of the robustness of data.

A relevant expertise in expert consultation methods (Delphi panels, survey data gathering, open public consultation etc.) is also expected to be mobilized.

The Contractor shall ensure that experts are adequately supported and equipped. In particular, sufficient administrative, secretarial and interpreting resources, as well as junior experts, must be available to enable senior experts to concentrate on their core evaluation tasks.

The contractor shall present a cost model of the human resources used.

7.2 Absence of conflict of interests

The Contractor shall ensure that both their organization and the individual experts proposed for this evaluation are not in a situation of conflict of interest regarding this specific assignment, and shall include a Declaration of absence of conflict of interest as part of their offer.