EVALUATION ROADMAP			
TITLE OF THE EVALUATION	Evaluation of the fee system of the European Medicines Agency		
LEAD DG – RESPONSIBLE UNIT	SANTE-D5 (SANTE-D6 associated on the veterinary part)	**DATE OF THIS ROADMAP**	12 / 2015
TYPE OF EVALUATION	Evaluation Ex-post Mixed	**PLANNED START DATE** **PLANNED COMPLETION DATE**	Q3 / 2016 Q4 / 2017
		PLANNING CALENDAR	http://ec.europa.eu/smart-regulation/evaluation/index_en.htm
This indicative roadmap is provided for information purposes only and is subject to change.			

A. Purpose

(A.1) Purpose

The purpose of this evaluation is to examine in a comprehensive way the functioning of the fee system of the European Medicines Agency (EMA, also referred to as the Agency), as laid down in the relevant body of legislation and related implementation arrangements, in order to identify the strengths and weaknesses of the system that is currently in place.

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

(A.2) Justification

This evaluation answers to the legal obligation set out in Article 12 of the **general fee regulation of EMA**[1] to provide by 24 November 2010, a report on the regulation's implementation. This article also stipulates that any review of the fees must 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.

Such a report has not been presented to date, due to adoption of the **pharmacovigilance fee regulation of EMA**[2], which set up new fees specifically for the pharmacovigilance[3] activities of EMA, as laid down in the new Union legislation from 2010[4] and 2012[5].

The pharmacovigilance fee regulation of EMA[2] recognises that an overall legislative revision of the fees system in the medicinal products sector is to be expected and stipulates 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 national competent authorities.

[1] Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products (OJ L 35, 15.2.1995, p. 1).
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01995R0297-20150401&rid=1

[2] Regulation (EU) No 658/2014 of the European Parliament and of the Council of 15 May 2014 on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use (OJ L 189, 27.6.2014, p. 112).
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0658&rid=1

[3] Pharmacovigilance is the safety monitoring of medicines in the EU.

B. Content and subject of the evaluation

(B.1) Subject area

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 EMA related to medicinal products for human and veterinary use. The main area of responsibility of the Agency is the coordination of the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products.

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 committees of the Agency 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 role of the EMA, through its scientific committees, is to provide scientific opinion in case of disagreement between Member States. EMA also provides technical and administrative support to a coordination group composed of the Member States' authorities.

Under **national** procedures, the authorisation is granted by the authority of the Member State and is valid only on its territory. The EMA may have a role in assessing, through its committees, issues related to the post-authorisation safety monitoring of medicines (pharmacovigilance).

The scientific assessment of the EMA committees is performed by experts from the Member States ('rapporteurs') which are represented in those committees. The Secretariat of the Agency provides technical, scientific and administrative support for all the committees and working parties and ensures appropriate coordination between them. The Agency has also other technical, scientific and administrative tasks defined in its **founding regulation**[6].

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

[4] Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products (OJ L 348, 31.12.2010, p. 1).
http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1448380946559&uri=CELEX:32010R1235

[5] Regulation (EU) No 1027/2012 of the European Parliament and of the Council of 25 October 2012 amending Regulation (EC) No 726/2004 as regards pharmacovigilance (OJ L 316, 14.11.2012, p. 38).
http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1448381114339&uri=CELEX:32012R1027

[6] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).
http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1448381200617&uri=CELEX:02004R0726-20130605

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 for the scientific assessment work of 'rapporteurs' appointed by the EMA scientific committees.

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

- the founding regulation of EMA[6];

- the general fee regulation of EMA[1];

- the pharmacovigilance fee regulation of EMA[2] and

- the SME regulation[7].

A number of other sectorial legislative acts (such as, but not limited to, the legislation on orphan medicinal products[8] or on advanced therapy medicinal products[9]) and further texts have an impact on the fee system of the Agency, providing notably for specific fee reductions.

It should also be noted that the outcome of the ongoing legislative process following the 2014 legislative proposals[10] to revise the veterinary medicines legislation[11] may have an impact on the future setup of the fees for veterinary medicinal products. However, the impact on the fee system may only be known once the co-legislators (the European Parliament and the Council) finalise the current legislative process.

(B.2) Original objectives of the intervention

General objective

The main objective of the intervention was to establish a fee-based system in order to address the need to secure 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.

Specific objectives

The specific objectives 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 must correspond to the service actually provided;

[7] 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 (OJ L 329, 16.12.2005, p. 4) http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1448378234454&uri=CELEX:32005R2049

[8] Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1).
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32000R0141&rid=1

[9] 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 (OJ L 324, 10.12.2007, p. 121).
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32007R1394&rid=1

[10] 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

[11] 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, p. 1).

- the amount of fees must be justified by the corresponding work and expenditure;

- the amount of the fees should not be a determining factor for the applicant for an authorisation where there is a choice between a centralized procedure and a national procedure;

- a 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, 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 estimations of the workload involved;

- fees should be levied on all marketing authorisation applicants and marketing authorisation holders on a fair basis;

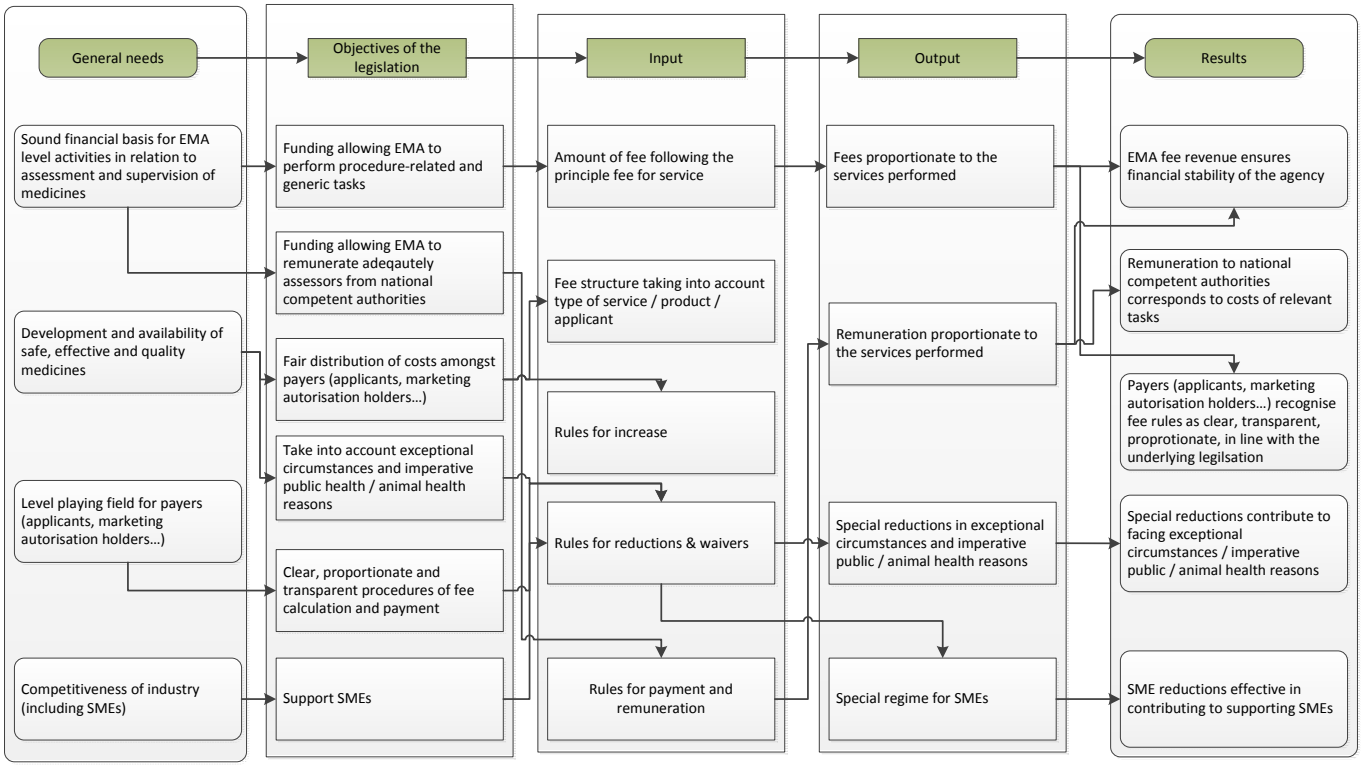
- micro-, small and medium-sized enterprises should be supported.

(B.3) How the objectives were to be achieved

In order to achieve the abovementioned objectives, the fee legislation was expected to provide EMA with the corresponding financing stemming from fee revenue, part of which is currently used to remunerate the national competent authorities for the assessments they carry out.

The amount of the fees per type of procedure and the amount of remuneration of rapporteurs and experts pertaining to those procedures were expected to cover the estimated cost of carrying out the corresponding assessments and running the procedures. The reductions for SMEs and other reductions, as per the applicable legislation and implementing rules, were expected to provide incentives and facilitation for small and medium-sized businesses and for some specific types of products. The structure and the fee amounts of the EMA fee system were expected to match the typology of procedures, to be transparent and easy to apply for the marketing authorisation applicants and marketing authorisation holders.

In the case of fees for pharmacovigilance, the impact assessment[12] accompanying the Commission proposal[13] provided volume and workload estimations which were expected to correspond to a reasonable degree to the real activity.



C. Scope of the evaluation

(C.1) Topics covered

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. Both human and veterinary medicines activities of EMA are included in the scope of the evaluation.

The scope of the evaluation will also include the remuneration paid by the Agency to rapporteurs and experts[14].

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

In view of the enlargement of the EU in 2004-2007 and of the date of the last revision of the general fee

[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] COM(2013) 472 final.
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2013:0472:FIN

regulation of EMA[1] in 2005, the evaluation should consider the time period starting with the 2004 enlargement of the EU until the present day, with a focus on more recent data reflecting the current situation. Historical data will be used, subject to availability, where relevant for the analysis.

It should be noted that EMA has been assigned new tasks since the last revision of the general fee regulation in 2005 which, with the exception of pharmacovigilance tasks, have not been reflected in the fee structure of the Agency. Therefore, activities which currently do not attract a fee will also be included in the scope of the evaluation.

(C.2) Issues to be examined

1. Effectiveness and efficiency

The **effectiveness** and the **efficiency** of the system will be examined notably with respect to the ***sustainability*** and the ***fairness*** of the financial model of the fees charged by EMA to industry at large, including the remuneration paid by EMA to rapporteurs and experts from national competent authorities.

Sustainability is understood mainly as to what extent the system is based on a cost-related model. The evaluation will focus on unitary 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.

Fairness corresponds broadly to the level of correlation between the assessment effort required by the relevant procedure and products 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 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. Coherence

The overall **coherence** of the EU-level and national-level fee systems needs to be taken into account. The evaluation should therefore examine the internal consistency between EMA fees but also the external consistency between national fees and EMA fees, taking into acount that the Union is only competent for Union-level fees for tasks assigned to EMA by the Union legislation.

3. Relevance

The **relevance** of the fee system will be evaluated in terms of how well it fulfills the need to fund the relevant tasks of EMA assigned by Union legislation.

3. EU added value

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.

(C.3) Other tasks

A specific task of the evaluation will be to analyse and validate the data as well as to close possible data gaps of the outcome of the EMA Management Board data gathering initiative (see below D.1 'Evidence from monitoring'). This ongoing initiative is aimed at assembling evidence on workload and resources, including a reflection on time spent and by whom on EU level procedures at EMA and the national competent authorities. This task will be performed based on a methodological approach to be described and justified.

[14] Rapporteurs from national competent authorities carry out the scientific assessments in relation to the Union-wide pre-authorisation, authorisation and post-authorisation procedures and activities of the Agency.

In addition, costing models will be proposed, discussed and applied to the time data stemming from the EMA Management Board data gathering initiative. These costing models will use data on cost of labour and overheads which are to be gathered from both the EMA and the national competent authorities (see below 'further evidence to be gathered').

This task within the evaluation will answer notably to the provision in recital 7 of the pharmacovigilance fee regulation of EMA[2] 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 national competent authorities. An assessment of the costing models / options presented will be performed and the most suitable will be recommended.

The evaluation will also include an 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.

D. Evidence base

(D.1) Evidence from monitoring

A key input for the evaluation will be provided by the EMA Management Board data gathering initiative aimed at assembling evidence on workload and resources, including time spent and by whom on EU level activities at EMA and the national competent authorities.

In addition, the pharmacovigilance fee regulation of EMA[2] provides for specific monitoring and reporting obligations related to components that may have a bearing on the costs such as the number of working hours spent on pharmacovigilance procedures[15]. Data from this reporting will also be used.

Relevant information provided in annual reports and budgets of EMA will also be used.

(D.2) Previous evaluations and other reports

- European Commission - Evaluation of the European Medicines Agency January 2010, Final report[16];
- 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[17];
- Annual reports and work programmes of EMA[18];
- The European Court of Auditors (ECA) has repeatedly recommended[19] that remuneration for services provided by Member State authorities should be based on costs.

(D.3) Evidence from assessing the implementation and application of legislation (complaints, infringement

[15] Article 15 and Part V of the Annex of of Regulation (EU) No 658/2014 (pharmacovigilance fee regulation of EMA) http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1448380018073&uri=CELEX:32014R0658

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

[17] http://www.hma.eu/fileadmin/dateien/HMA_joint/04_HMA_Induction/07_HMA_Position__on_Rev_fees_2010_12.pdf

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

[19] 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

procedures)
There have been no complaints about alleged infringements or infringement procedures.
(D.4) Consultation
An open public consultation will be carried out based on the preliminary conclusions following the initial evaluation. The main stakeholder categories expected to provide feedback on those conclusions are: - pharmaceutical industry associations, including SMEs and other potential payers; - organisations representing patients and healthcare providers; - Member States through the Pharmaceutical Committee and the national competent authorities; and - the EMA. This consultation will take place in the second half of 2017. Targeted stakeholder consultations will be conducted in the first quarter of 2017 in order to gather further evidence notably on the cost structures. The main stakeholders concerned are EMA and national competent authorities.
(D.5) Further evidence to be gathered
Evidence on cost of the scientific and supporting activities which provide the input to the regulatory activities carried out at EU level will be gathered both at the level of EMA and at the level of Member States (national competent authorities). This will include cost of activities covered by the Management Board data gathering initiative. The objective will be to use this data on cost as an input to costing models which will be applied to the data on time stemming from the EMA Management Board data gathering initiative (see section D1).

E. Other relevant information/ remarks
The results of the evaluation will feed into the report required by Article 12 of the general fee regulation of EMA[1].