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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council on the fees payable to the European Medicines Agency (EMA) for the conduct of pharmacovigilance activities in respect of medicinal products for human use

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1. INTRODUCTION AND PROBLEM DEFINITION

The EU pharmacovigilance legislation has been subject to a major review and an impact assessment that lead to the adoption of a revised legislation in 2010[1], which strengthens and rationalises the system for monitoring the safety of medicines on the European market. This legislation provides for a number of EU-wide procedures to assess pharmacovigilance data. Some additional adjustments were introduced in 2012[2].

In order to finance these activities, the 2010 Pharmacovigilance legislation provides for fees to be charged to marketing authorisation holders (MAH).

The impact assessment has evaluated the various options for charging fees to MAHs for the pharmacovigilance activities performed at the level of the EU involving the European Medicines Agency (EMA).

The specific problems posed by the absence of fees for pharmacovigilance activities of the EMA can be outlined under the following areas.

1.1. Inexistence of financial instrument to implement the pharmacovigilance legislation and inadequate funding for the related activities

Prior to the amended pharmacovigilance legislation, the EMA was only tasked with pharmacovigilance of products with an EU-wide marketing authorisation. The new legislation has substantially increased the scope of EMA competence in pharmacovigilance, by including also products which are authorised via national procedures. The introduction of assessments to be carried out at EU level in the context of specific pharmacovigilance procedures laid down in the legislation i.e. for the assessment of PSUR[3]s, the assessment of PASS[4]s and assessment in case of pharmacovigilance referrals,[5] leads to a substantial workload with associated costs. Furthermore, the EU-wide assessments require adequate EU-wide information technology tools.

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1 Regulation (EU) No 1235/2010 amending Regulation (EC) No 726/2004 and Directive 2010/84/EU amending Directive 2001/83/EC.

2 Directive 2012/26/EU, OJ L 299 of 27.10.2012, and Regulation (EU) No 1027/2012, OJ L 316 of 14.11.2012.

3 Periodic Safety Update Reports.

4 Post-Authorisation Safety Studies.

5 A pharmacovigilance referral is a procedure in which a safety concern is referred to the EMA and is examined at EU level with respect to all concerned products authorised in the EU.

All the fees currently payable to the EMA are laid down in Council Regulation (EC) No 297/95[6] which at present does not include any provisions on specific fees for the pharmacovigilance activities provided for in the legislation. Therefore, the legal instrument that would enable the EMA to charge fees for these activities is missing. As a consequence, the existing fee structure of EMA does not reflect the requirements set out in the legislation and there is no adequate funding for pharmacovigilance activities at EU level. This has direct consequences as regards rapporteurs from the Member States (MS) who are currently not remunerated for their assessment work within the EU procedures. This situation is unsustainable even in the short term.

1.2. Lack of transparency and clarity in the current situation of pharmacovigilance fees across the EU

In general, the existing fees for pharmacovigilance activities in the EU do not reflect the requirements and parameters set out in the 2010 pharmacovigilance legislation.

At the level of the EMA, as described above, there are no specific fees for the financing of EMA's pharmacovigilance activities laid down in the 2010 pharmacovigilance legislation.

At national level, some MS currently charge fees for pharmacovigilance. For these MS it would be difficult to adapt, if appropriate, their fees to the new pharmacovigilance legislation, unless the fees for pharmacovigilance activities of the EMA are actually introduced. The EU is not competent with respect to national fees and it is therefore reasonable to expect that any adaptation of these fees, if considered necessary by the MS, would only take place after the introduction of pharmacovigilance fees collected by the EMA for EU-wide pharmacovigilance procedures. This would in particular allow MS to ensure that there is no double charging at national level for the activities performed at the level of the EU for which a fee is charged by the EMA.

2. OBJECTIVES

The general objective of this initiative is to ensure a high level of human health protection in the EU as well as to promote the functioning of the internal market.

The specific objective is to ensure the proper implementation of the 2010 pharmacovigilance legislation through defining the structure and the level of the fees charged to MAHs for pharmacovigilance activities performed at the level of the EU. In order to ensure that adequate funding for pharmacovigilance activities of the EMA is available, such fees should allow the EMA to cover its estimated costs, including remuneration of rapporteurs from the MS for the work that they provide. The fee structure should also underpin a transparent, fair, activity-based and cost-based fee system for pharmacovigilance activities of the EMA.

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[6] 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,

3. ANALYSIS OF SUBSIDIARITY

The EMA is a decentralised Agency of the EU[7] and hence decisions on its funding, including through charging fees, are taken at the EU level.

The pharmacovigilance legislation enables the EMA to charge fees for pharmacovigilance. Only the Union can act to introduce new types of fees for the Agency.

4. POLICY OPTIONS

It is proposed to introduce a self-standing legal instrument: Regulation of the European Parliament and of the Council.

Based on estimated annual costs of pharmacovigilance at EU level, several policy options to collect pharmacovigilance fees were considered.

Option 1: No change to the current situation (baseline scenario)

No introduction of specific pharmacovigilance-related fees to be charged by the EMA.

Option 2: One annual flat fee covering all pharmacovigilance activities

An annual flat fee for all pharmacovigilance activities of the EMA would be introduced and would be applicable to all MAHs having medicinal products authorised in the EU.

A decreased annual flat fee for medicinal products for which the MAH is a small or medium-sized enterprise would be set at the level of 60 % of the full annual flat fee. No fee would be charged for medicinal products for which the MAH is a micro-enterprise.

A fee reduction of 20% would be applied to authorised generic, homeopathic and herbal medicinal products and medicinal products authorised on grounds of well-established use.

Option 3: A combination of separate fees for procedure-based activities and an annual flat fee for all other activities

Two types of fees would be charged. (1) Fees for specific pharmacovigilance procedures that are provided for in the legislation, i.e. for the assessment of PSURs, the assessment of PASSs and assessment in case of pharmacovigilance referrals, would be charged to all MAHs having a medicinal product that is subject to the procedure in question. Additionally, (2) an annual flat fee would be charged to all MAHs having medicinal products authorised in the EU. This additional annual flat fee would be based only on the costs of pharmacovigilance activities of the EMA other that those related to the specific procedures.

Small and medium-sized enterprises would pay 60% of the full fee and no fee would be charged for medicinal products for which the MAH is a micro-enterprise.

A fee reduction of 20% in respect of the annual flat fee would be applied to authorised generic, homeopathic and herbal medicinal products and medicinal products authorised on

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[7] The founding Regulation of the EMA is Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004, OJ L 136, 30.4.2004

grounds of well-established medical use. However, where these medicinal products are included in the pharmacovigilance procedures, the normal procedure-based fee would apply.

Option 4: Procedure-based fees only

All costs of EU-level pharmacovigilance activities would be used as a basis to set fees to be charged only to those MAHs having a medicinal product involved in one of the three procedures outlined in option 3.

Small and medium-sized enterprises would pay 60 % of the full fee per procedure and no fee would be charged to MAH which are micro-enterprises.

5. ASSESSMENT OF IMPACTS

In view of the operational objectives, the assessment criteria are:

- Transparency – a clear relationship between the type and level of fee and the corresponding work carried out.
- Fairness – MAHs should contribute to the financing of pharmacovigilance activities on the basis of potential safety concerns of their products and double charging should be avoided.
- Stability – providing for a stable fee system based on the highest possible degree of financial predictability and avoiding variable remuneration of similar scientific services.
- Simplicity – minimum additional administrative burden.

Option 1: No change to the current situation

MAHs would not benefit from the enhanced and rationalised pharmacovigilance system introduced by the legislation. The expected public health benefits would not be achieved. Moreover, stakeholders would lack clarity as regards the sustainability and the funding of pharmacovigilance activities in the EU.

The EMA would not be in a position to implement its new tasks with regard to the 2010 legislation, due to the absence of adequate funding for the costs incurred by the performance of these tasks.

As a consequence, the rapporteurs from the Member States would not be remunerated by the EMA for their work within the EU-wide procedures.

Option 2: One annual flat fee covering all pharmacovigilance activities

Each MAH would be charged once per year for all pharmacovigilance activities performed at EU level, based on the number of its authorised products, as registered by the Agency. All products on the market would be thus considered as potentially subject to safety concerns at the same level and would contribute equally to the financing of the pharmacovigilance activities at EU level.

An annual flat fee is a predictable fee that MAHs would be able to take account of in their financial planning.

In comparison with options 3 and 4, option 2 is less transparent and the MAHs may perceive that they are charged twice for the same work by EMA and by NCAs.

As under options 3 and 4, rapporteurs would be remunerated according to a fixed scale, which is based on estimated average costs per evaluation procedure.

Such a fee would mean a relatively stable, predictable income for the Agency. As the collection of the entire fee revenue for pharmacovigilance would be disconnected time-wise from the actual pharmacovigilance procedures, the EMA would have to ensure financial management of the total pharmacovigilance fee income throughout the year.

Option 3: A combination of fees for procedure-based activities and an annual flat fee for all other activities

In this scenario, MAHs would be charged as follows:

- MAHs having at least one product involved in a pharmacovigilance procedure would be charged a procedure-based fee. The fee would be divided between MAH based on the proportion of products held by each MAH involved.

- all MAHs in the EU[8] (with the exception of micro enterprises) would be charged an annual flat fee for their authorised products.

MAHs that are not involved in any EU procedure would only pay the annual flat fee.

As for options 2 and 4, rapporteurs from NCAs would be remunerated with regards to pharmacovigilance procedures according to a fixed scale per procedure, based on estimated average costs.

In comparison with option 2, the exact overall fee revenue is not entirely predictable given that the number of procedures is more difficult to predict (except for PSURs).

The procedure-based fees are proportionate to the average workload. With regards to the annual flat fee component, it would only cover non-procedure-related costs of the Agency which would substantially lower its amount as compared to option 2.

Option 4: Only procedure-based fees and no annual flat fee

Under this option, only MAHs whose products are involved in a pharmacovigilance procedure would be charged a fee in connection with the procedure. The fee levels per procedure would be higher than those in option 3, where the total cost is covered by a combination of procedure-based fees and an annual flat fee.

The non-procedure-related EMA costs would be distributed only amongst those MAHs that are included in a procedure. MAHs that are not subject to any EU procedure would not contribute to the financing of the system whilst potentially and indirectly benefiting from it. In

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[8] as per information recorded by the EMA from the database set up by Art 57(1)(l) of Regulation (EC) No 726/2004

this respect, option 4 is likely to be less transparent, and less fair and proportionate than option 3.

As under options 2 and 3, rapporteurs from NCAs would be remunerated according to the same fixed scale per procedure based on average estimated costs.

As opposed to option 2 and option 3, the EMA would only have to charge a fee in relation to an EU procedure.

6. COMPARISON OF THE OPTIONS

The criteria for evaluating the options follow the principles of effectiveness, efficiency and coherence. The specific criteria against which the options are compared include (1) transparency of the fee levels and structure, (2) stability and financial predictability, (3) simplicity of the fee structure and (4) fairness and proportionality of fees.

Based on the analysis, the individual options were assigned scores of how well each option meets the criteria as compared to the baseline scenario (option 1).

Further, each criterion was assigned a relative weight, to formalise its relative importance. The overall relative hierarchy among the criteria suggests that 45 % of the objective weight is on fairness and proportionality, 32 % on transparency, 14 % on stability and predictability and 9 % on simplicity. These values were subsequently used in making the decision on the preferred option.

The relative importance (weighting) of the four criteria and its application to the analysis of individual options is summarised in Table 1 below. The absolute score obtained determines the ranking of the options in terms of achieving the objectives of this initiative.

Table 1: Final comparison of options

Options / Objectives	transparency	stability / predictability	simplicity	fairness / proportionality	**Total Score**
Option 1	0	0	0	0	**0**
Option 2	3	4	3	5	**15**
Option 3	10	3	1	14	**27**
Option 4	6	1	2	9	**19**

Based on this analysis, it follows that option 3, i.e. the combination of procedure-based fees and an annual flat fee, is the preferred option. This option has been considered to be the most transparent, cost-based, activity-based, fair and proportionate way of setting the new fees, in order to cover the EMA's costs, including remuneration of rapporteurs from MS. In this way, the products being part of a pharmacovigilance procedure at EU level would contribute to the financing of the cost of the procedure. At the same time, the cost of general pharmacovigilance activities of the EMA, and only that part of the overall cost, would be used as a basis for the annual flat fee, charged to MAHs with respect to their authorised products.

7. MONITORING AND EVALUATION

The necessary monitoring information will be provided by the EMA and would be linked to the implementation of its annual budget. The annual activity report on the performance of the EMA would need to be adapted to provide reliable performance information and key indicators related to the activity.

Based on this information, the Commission will consider, if appropriate, whether there is a need to revise the level of fees for pharmacovigilance.