EUROPEAN COMMISSION
Impact Assessment Board

Brussels,
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Opinion

Title **DG SANCO - Proposal for a Regulation of the Council and European Parliament on the fees payable to the European Medicines Agency (EMA) for the conduct of pharmacovigilance activities**

(draft version of 13 March 2013)*

(A) Context

The 2010 Pharmacovigilance legislation became applicable in July 2012. It reviews existing provisions and significantly widens the tasks of the European Medicines Agency (EMA), providing it with pharmacovigilance competences for nationally and centrally authorised medicines which were previously carried out and financed at the national level. To finance these activities, the legislation allows fees to be charged at the EU level to marketing authorisation holders (MAH). These fees would not cover the pharmacovigilance activities of the National competent authorities (NCA) except remuneration of rapporteurs for scientific evaluations within the framework of the EU procedures. Member States may therefore continue to charge national fees for pharmacovigilance activities. This impact assessment report evaluates various options for charging fees to MAHs for pharmacovigilance activities performed at the EU level.

(B) Overall opinion: POSITIVE

The report should be improved in a number of respects. Firstly, it should more clearly describe what lies behind the inadequate funding of pharmacovigilance at the EU level. Secondly, it should better describe the content of each option and explain why a revision of the Fees Regulation is not considered a feasible option. Thirdly, it should better assess the impacts, in particular with respect to the risk of double-charging at the EU and between the EU and national level. Finally, it should better explain how the main concerns of stakeholders have been addressed.

In their written communication with the Board DG SANCO accepted to amend the report along the lines of these recommendations.

(C) Main recommendations for improvements

(1) Clarify the problem definition and the baseline scenario. The report should better distinguish the issues that the introduction of fees for pharmacovigilance activities at the EU level would address, particularly with respect to the causes of the inadequate funding of EMA pharmacovigilance activities. In order to do so, the report should first briefly

* Note that this opinion concerns a draft impact assessment report which may differ from the one adopted

describe the basic characteristics of the sector in the main text (number of MAHs, market authorisations and EV-codes, number and types of products and active substances, type and frequency of pharmacovigilance procedures). It should then explain what pharmacovigilance activities are funded through the current annual EMA fee. Finally, it should identify what new activities the 2010 legislation entrusted to EMA and clarify whether they were previously performed and financed by NCAs. Against this background, the report should develop a more complete baseline scenario by describing how the EMA procedures, workload, costs and EU budget contribution would evolve in the absence of additional fees. Underlying assumptions should be clearly presented.

(2) Better present the options. The main text of the report should better describe the content of each option, indicating who will be charged, on what basis (MAH, MA, EV-code), for what activities, how much and when. It should also better justify the level of the fee discounts offered to micro-enterprises, SMEs and generics (100%, 40% and 20% respectively). It should also explain how correction coefficients to reflect the national cost of NCAs will be defined and whether benchmarks at EU level would be established. Finally, the report should explain why the option of a general revision of the Fees Regulation is ruled out and only options envisaging a separate legal instrument establishing specific pharmacovigilance fees are considered. Given this choice, the report should also consider any measures that could minimise the risk of overlap with existing fees and discuss any timing issue raised by the expected future revision of the Fees directive.

(3) Better assess and compare options. The report should assess the risk of double-charging, and the way it would be managed, under the various options. This refers to possible overlaps between the new pharmacovigilance fees and (i) the current annual EMA fee for centrally authorised products and/or (ii) fees charged by NCAs. The report should also discuss if, and how, introducing pharmacovigilance fees could affect (i) the consumers of medicinal products; (ii) competition among pharmaceutical companies (operating in market segments which might be affected differently); and (iii) industry's competitiveness. In addition, the report should clarify whether, and under what conditions, the different options would have a (positive) impact on the EU budget. The report should compare options in terms of their effectiveness, efficiency and coherence after having better justified the criteria chosen to define alternative fee structures.

(4) Improve the presentation of stakeholder views. The report should better reflect throughout how the stakeholder concerns (e.g. impracticability of grouping, possible double-charging by EMA and NCAs) have been addressed. It should also explain the low number of replies, especially from individuals and NCAs.

Some more technical comments have been transmitted directly to the author DG and are expected to be incorporated in the final version of the impact assessment report.

(D) Procedure and presentation

The report should present all essential information for the decision making in the main text. It should also better integrate the annexes into the main text by consistently referring to them throughout the report. The report should present more clearly the problems to be addressed by this initiative. It should explain technical terms to make the text more accessible for non-expert reader. The two-page executive summary sheet should be integrated within the main text.

(E) IAB scrutiny process	
Reference number	2012/SANCO/003
External expertise used	No
Date of IAB meeting	10 April 2013 (Written Procedure)