Paris, 15 October 2019

Response to a public consultation

Prescrire's contribution

to the public consultation on the

Inception Impact Assessment on the Revision of the EMA fee system

In the EMA consultation in summer 2018 on the evaluation of its fee system for the approval and monitoring of medicines, *Prescrire* already called on the necessity to strengthen and to guarantee the independence of the European Medicines Agency from the pharmaceutical industry: a prerequisite to ensure trust and to serve EU citizens' interest as a priority.

The independence of the European Medicines Agency is paramount

The Commission Inception Impact Assessment points out that 90.2 % of the Agency's total budget is funded by fees paid by pharmaceutical companies and ca. 9.6% by EU/EEA budget contributions. This confirms that the Agency is very heavily funded by pharmaceutical companies. The European drug regulatory authority has therefore become a service provider for pharmaceutical companies, at the expense of its public health mandate, which is also reflected in the priorities put forward in the Regulatory Science Strategic paper, in confidential pre-submission "scientific advices" to companies, or in accepting weaker evidence or fewer data for marketing authorisations.

We understand that the underlying aim of the announced proposal to revise the EMA fee system is to set up a simpler and more efficient system, to be more flexible and to adapt the system to future developments, including the implementation of the new Veterinary legislation.

EMA's financing has always been based on a fee-for-service model. However, the Regulation 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* in its *article 67 (4)* called on *adequate public funding* for pharmacovigilance activities and market surveillance *commensurate with the tasks conferred*[1]. Unfortunately, the Regulation No 1235/2010 on pharmacovigilance made a step backwards paving the way to charging fees also for these activities at the condition that independence is strictly guaranteed.

[1] Regulation No 726/2004, article 67 (4) : "4. *Activities relating to pharmacovigilance, to the operation of communications networks and to market surveillance shall receive adequate public funding commensurate with the tasks conferred.*" https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R0726&from=EN

For Prescrire, in order to be able to carry out its public health tasks, the EMA needs to be weaned off from a fee-for-service relationship with pharmaceutical companies and funded through public funding from the European Union.

We are concerned that the Commission in its policy options only make suggestions based on a cost-based fee for service system without exploring other options and considering adequate public funding.

Industry fees undermine the independence of drug regulatory agencies

Fees make drug regulatory agencies dependent on funding from the industry that they are supposed to regulate. This is an obvious conflict of interest. Health authorities have a responsibility to act objectively and in the public interest, without being swayed by the business concerns of companies who are seeking product approval or who are "regular clients" within the framework of post-marketing follow-up.

Concrete alternatives to a fee-for-service system

To guarantee EMA's independence, and to make sure that EMA is acting as a regulator protecting public health rather than industry interests, any direct financial relationship between the Agency and industry should be banned. EMA should therefore solely be financed through public funding like the French Health Products Agency (ANSM) for instance.

In line with the original article 67(4) of Regulation No 726/2004, we call on the Commission to guarantee adequate public funding for independent post-marketing studies, realised in-house or by independent organisations. These studies are of particular importance as there is a continuous trend towards faster marketing authorisations with a shift from pre-marketing approval evidence-collection towards post-approval assessment.

Ultimately, the principle of the independence of European Medicines Agency must be safeguarded, to ensure that the business interests of pharmaceutical companies do not override public health interests.

For more information

Prescrire is a non-profit continuing education organisation, committed to better patient care. Prescrire provides independent, reliable information on treatments and therapeutic strategies, in order to support informed decisions. Prescrire is entirely financed by its subscribers, and accepts no advertising or other external financial support. For more information, please visit http://english.prescrire.org

EU Transparency Register: 982539711698-79