Paris, 31 July 2018

Response to a public consultation

Prescrire's contribution

to the public consultation on the

Evaluation of EMA fee system for the approval and monitoring of medicines

Rather than responding to all consultation items, Prescrire's contribution to this public consultation focuses on the principle of the essential independence of the European Medicines Agency (EMA) 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

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.

In order to understand how EMA's priorities and functioning have evolved, one should be aware that the Agency is very heavily funded by pharmaceutical companies. Industry funding has progressively increased since 1995 when the EMA was established. In 2017, the collection of pharmaceutical companies' fees amounted to more than 87% of the Agency's overall budget. Only 9% of EMA revenues came from the European Union budget and 3% came from external assigned revenues[i]. The European drug regulatory authority has therefore become a service provider for pharmaceutical companies, at the expense of its public health mandate as reflected in the poor quality of its marketing authorisations.

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 be regulating. This is an insurmountable 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" in the framework of post-marketing follow-up.

Concrete alternatives to a fee-for-service system

To guarantee the EMA's independence, and to make sure that EMA is acting as a regulator with the aim of protecting public health rather than protecting 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.

The European Medicines Agency should no longer be a mere provider of services to the pharmaceutical industry. Other strategies should be considered for funding EMA activities that would help the EU drug regulator to be independent of the regulated companies.

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.

References:

[i] EMA Annual activity report 2017 ; 7 June 2018
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2018/07/WC500251641.pdf

For more information

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