



PRESS RELEASE  
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## EUROPEAN MEDICINES AGENCY & PHARMACOVIGILANCE: NO TO A FEE-FOR-SERVICE SYSTEM

***The European Commission's proposed pharmacovigilance fee structure turns the European Medicines Agency (EMA) into a mere provider of services to the pharmaceutical industry<sup>1</sup>. Other funding strategies need to be considered to safeguard the Agency's independence<sup>2</sup>.***

Since 2004, the European Union's (EU) regulatory framework for medicines has ensured that medicines safety surveillance, referred to as pharmacovigilance, is publicly funded. However, legislation adopted in 2010 allows for the EMA to fund its pharmacovigilance activities through fees charged to the pharmaceutical industry.

**Industry fees undermine the independence of regulatory agencies.** The Commission's proposed draft enables the EMA to charge fees to the pharmaceutical industry in exchange for specific post-marketing surveillance activities of medicines. This structure could have perverse effects as regulatory agencies would become dependent on funding from the very industry that they are supposed to regulate. Experience at the EMA and at the US Food and Drug Administration (FDA) has demonstrated that such a system creates a conflict of interest.

**Institutionalising biased decision-making.** The new pharmacovigilance legislation foresees a stronger role for the pharmaceutical industry in the collection and analysis of adverse drug reactions, literally letting the fox guard the hen house. In practice, regulatory agencies are required to base their pharmacovigilance decisions on information provided and interpreted by pharmaceutical companies, thereby providing ample opportunities for withholding and manipulating of data.

**Concrete alternatives to a fee-for-service system.** A strong and independent pharmacovigilance system not only leads to less human suffering; it also leads to substantial financial savings (prompt regulatory action would lead to fewer people experiencing adverse drug reactions, so to fewer medical consultations and hospitalisations). Public funding of pharmacovigilance is a societal investment that yields social benefits.

**If there is insufficient political will to dedicate public financing for pharmacovigilance activities, several alternatives are possible to support a global pharmacovigilance fund:**

- Pharmaceutical companies can be required to pay a **percentage of their sales (global turnover) or of their promotional budgets**; or
- **A tax** (i.e. very small amount of money for each box of a medicine) could be **charged to all actors in a medicine's distribution chain** (marketing authorisation holders, prescribers, wholesalers, and pharmacists).

Ultimately, the principle of the independence of European and national medicines agencies must be safeguarded, to ensure that the business interests of pharmaceutical companies do not override public interests.

**International Society of Drug Bulletins  
(ISDB)**

**Medicines in Europe Forum  
(MiEF)**

**Health Action International  
(HAI) Europe**

**ISDB.** The International Society of Drug Bulletins, founded in 1986, is a worldwide Network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of pharmaceutical industry. Currently ISDB has around 80 members in 41 countries around the world. More info: [www.isdbweb.org](http://www.isdbweb.org). Contact: [press@isdbweb.org](mailto:press@isdbweb.org)

**MiEF.** The Medicines in Europe Forum (MiEF) was launched in March 2002 and reaches 12 European Member States. It includes more than 70 member organizations representing the four key players on the health field, i.e. patients groups, family and consumer bodies, social security systems, and health professionals. It is a unique group and a testament of the importance of European medicines policy. Contact: [pierrechirac@aol.com](mailto:pierrechirac@aol.com)

**HAI Europe.** Health Action International (HAI) is an independent global network of health, consumer and development organisations working to increase access to essential medicines and improve their rational use. More info: [www.haieurope.org](http://www.haieurope.org). Contact: [katrina@haieurope.org](mailto:katrina@haieurope.org)

<sup>1</sup>- Outlined in the draft paper submitted for public consultation during the summer of 2012 on the "Introduction of fees to be charged by the European Medicines Agency (EMA) for pharmacovigilance" link: [http://ec.europa.eu/health/files/pharmacovigilance/2012-06\\_concept\\_paper\\_en.pdf](http://ec.europa.eu/health/files/pharmacovigilance/2012-06_concept_paper_en.pdf)

<sup>2</sup>- The joint response of MiEF and ISDB to the open consultation is available here: [http://english.prescrire.org/Docu/DOCSEUROPE/2012\\_09\\_AnswerConsult\\_Fees\\_Pharmacovig\\_MiEF\\_ISDB\\_HAI.pdf](http://english.prescrire.org/Docu/DOCSEUROPE/2012_09_AnswerConsult_Fees_Pharmacovig_MiEF_ISDB_HAI.pdf)