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Parliament’s stand against conflicts of interest: Is it enough to ensure medicines safety?

Health Action International (HAI) Europe, Medicines in Europe Forum (MiEF) and the International Society of Drug Bulletins (ISDB) congratulate the European Parliament on calling for the European Court of Auditors to evaluate the performance of the European Medicines Agency (EMA). The EMA’s handling of conflicts of interest between its scientific experts, its in-house personnel and its former employees, and the pharmaceutical industry will go under the microscope from now until the end of June. However, will this audit be enough to prevent competing interests from influencing medicines regulators?

The mandate of European medicines regulators is to guard the safety, efficacy and quality of medicines sold in Europe. Decisions about medicines should be made by impartial experts and based on the most objective evidence. Nonetheless, regulators’ close ties with drug makers calls into question the independence of their decisions.

Pharmaceutical companies pay a fee to the Agency to have their medicine evaluated in order to obtain marketing approval. As these payments constitute the majority of the EMA’s budget (81.3%), the European medicines regulatory agency finds itself dependent on industry financing. An ever-increasing share of the EMA’s budget comes from services and scientific advice provided to industry applicants, thereby questioning the Agency’s objectivity.

“The Agency needs to be weaned off the fee-for-service relationship that it currently has with pharmaceutical companies,” said Katrina Perehudoff, Project Officer at HAI Europe.

To guarantee the EMA’s independence, any direct financial relationship between the Agency and the pharmaceutical industry should be avoided. This could be achieved by channeling application fees to the European Commission and by financing the Agency exclusively through the EU budget.

“It is unacceptable that the very agency evaluating medicines safety and efficacy is dependent on funding from the manufacturers it controls. Only when regulators, such as the European Medicines Agency, are intellectually and financially independent from the pharmaceutical industry can we be assured they are acting in the public interest,” said Jorg Schaabber, President of ISDB.

The EMA provides a public service as the guardian of medicines safety, and it is, first and foremost, accountable to European citizens. HAI Europe, MiEF and ISDB call on
the Agency to strengthen its transparency policy and demonstrate its political will to put citizens first, and to protect public health.

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

**Medicines in Europe Forum (MIEF)**, launched in March 2002, covers 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. Such a grouping is unique in the history of the EU, and it certainly reflects the important stakes and expectations regarding European medicines policy. Admittedly, medicines are no simple consumer goods, and the Union represents an opportunity for European citizens when it comes to guarantees of efficacy, safety and pricing. Contact: pierrechirac@aol.com.

**International Society of Drug Bulletins (ISDB)**, founded in 1986, is a world wide Network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of pharmaceutical industry. Currently, ISDB has 79 members in 40 countries around the world. More info: www.isdbweb.org. Contact: press@isdbweb.org.