



PRESS RELEASE

EU Parliament says no and no again to EMA: Independent groups echo decision

Brussels, 15 May 2012 - Health Action International (HAI) Europe, the International Society of Drug Bulletins (ISDB) and the Medicines in Europe Forum (MiEF) welcome and support the European Parliament's decision to postpone the discharge of the European Medicines Agency's (EMA) accounts (2012). For the second year in a row, the Parliament has postponed this decision due to concerns, among others, about the management of conflict of interest risks at the Agency.

Greater independence is needed to ensure the reliability of EMA's advice. The EMA relies on scientific experts to evaluate the safety and efficacy of medicines that could enter the European market. However, findings of inconsistencies and omissions in experts' interest declarations have motivated the European Parliament to call for an overhaul of the system that is now "primarily based on trust rather than on verification" (European Parliament, 2012). We echo the Parliament's call on the EMA to check, systematically and at random, declarations of interest and to verify their contents in order to avoid conflicts of interest that could harm public health (European Parliament, 2012).

Katrina Perehudoff of HAI Europe, states: "*The EMA is ultimately responsible for the quality and independence of scientific advice provided by its experts, therefore it is essential for the EMA to be not only accountable for experts' complete and accurate declarations of interest, but also for their thorough scrutiny.*"

Improved policies to remove the risk of conflicts of interest are still needed at EMA.

Disappointingly, in 2012, the EMA's policy on handling the declared interests of its staff members still does not guarantee that medicines files will at all times be handled by independent regulatory staff (EMA, 2012). We call not only for the adoption of stronger staffing rules to ensure public trust in the regulatory process, but also for their rigorous enforcement.

The European Parliament has already asked for further information about how EMA's policy on handling the declared interests of its staff members is being implemented (European Parliament, 2012). Last week, the European Parliament also reflected concerns raised by civil society about the EMA's application of the Staff Regulation. Citing the example of the Agency's former Executive Director and his post-service employment by a consultancy that advises, among others, pharmaceutical companies, the European Parliament described the EMA's management of the case as "clear proof that the Agency did initially not apply the Staff Regulations properly, which in turn raises serious questions about their application of the rules in general" (European Parliament, 2012).

Jörg Schaaber of ISDB, states: “Improperly handled risks of conflicts of interest notably arising from managing staff who join the EMA after working for the industry, or who leave the Agency to work for pharmaceutical companies, casts a shadow on the independence of the EMA and on its capacity to independently evaluate medicines.”

The EU Parliament has a crucial role to play in eliminating conflicts of interest at EMA.

Last week’s vote is a step in the right direction. As part of its role in holding Agencies accountable to European citizens, we urge the European Parliament to commit to the elimination of conflicts of interest at the EMA. It is particularly important that conflicted experts do not participate in EMA’s Committees. Among others, two concrete and short term actions could be:

- ensuring that the future patient and healthcare professional representatives belonging to the Management Board (EMA, online) and/or to the Scientific Committees, for example as proposed Commission appointees, do not represent organisations sponsored by the drug and medical device industry, and are free of conflicts of interest (MIEF and ISDB, 2010).
- requiring that the European Court of Auditor’s Special Report on conflicts of interest management is made publicly available, and requiring the Agency to explain any shortcomings identified and the measures taken or intended to take to rectify shortcomings and prevent any further shortcomings.

ENDS

References:

European Medicines Agency, 2012. </Titre>Decision on rules relating to Articles 11a and 13 of the Staff Regulations concerning the handling of declared interests of employees of the European Medicines Agency [online]. Article 4.3. Available at :
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500122908.pdf

European Medicines Agency. Management Board [online]. Available at:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000098.jsp&mid=WC0b01ac0580028c2f Accessed on 15 May 2012.

European Parliament, 2012. Decision of 10 May 2012 on the closure of the accounts of the European Medicines Agency for the financial year 2010 [online]. Point 1. Available at:
<http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2012-175> Accessed 15 May 2012.

European Parliament, 2012. Resolution of 10 May 2012 with observations forming an integral part of its Decision on discharge in respect of the implementation of the budget of the European Medicines Agency for the financial year 2010 [online]. Points 25, 27, 29, 31, 33 and 34. Available at:
<http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2012-175> Accessed 15 May 2012.

Medicines in Europe Forum and International Society of Drug Bulletins, 2010. EMA’s policy on conflict of interest: improvements needed [online]. Available at:
http://www.isdbweb.org/documents/uploads/press/EMA_COI_Final.pdf

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. Contact Katrina@haieurope.org

ISDB. 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 nearly 80 members in more than 40 countries around the world. More info: www.isdbweb.org. Contact: press@isdbweb.org

MiEF. 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