



Health Action International (HAI) is an independent, global network, working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy.

## HAI Europe Statement

### EMA talks the ‘conflicts of interest’ talk, but will it walk the walk?

18 October 2010 – The European Medicines Agency (EMA) has taken a step in the right direction by adopting an improved policy to handle potential conflicts of interest among its scientific committee members and experts. Independence in scientific and expert advice is crucial to balanced decision making. Conflicts of interest (CoI) can bias regulatory affairs, and compromised decisions could result in the market approval of medicines of questionable efficacy or unproven safety, which would ultimately put citizens at risk.

According to the new policy, any declared interest will now be classified into a risk level based on: the nature of the interest (i.e. employment, financial interest); the time elapsed since the interest occurred; and the capacity in which the person would be acting at the Agency. Individuals with the highest risk levels will be restricted from engaging in some aspects of the Agency’s work. Similar requirements will be put into place for chairperson and rapporteur positions within the Scientific Committees. Most notably, the EMA has defined experts who play strategic advisory roles to pharmaceutical companies as having direct interests with the industry, which would, therefore, warrant a higher risk level. This is a very positive development, as the undue influence posed by strategic advisory roles often goes unnoticed or underestimated.

The Agency has re-iterated its commitment to transparency by pledging to publish all committee members’ and experts’ declarations of interest online. The EMA will also ‘pro-actively’ screen all declarations of interest prior to the individual’s formal nomination by the competent authorities. These standards can only be effective if the Agency takes the responsibility for their enforcement and compliance. HAI Europe encourages the EMA not only to pro-actively screen the declarations, but also to verify their accuracy. Experts’ participation in EMA activities should be conditional on the complete and public disclosure of any potential conflicts of interest.

Furthermore, the new policy still raises some unanswered questions:

- Given the number of exemptions made for ‘expert witnesses’, how can the impartiality of this advisory position be ensured?
- Deadlines for interest disclosure and implications for failing to uphold or adhere to this policy were curiously absent from the Agency’s statement. The policy could easily flounder if the EMA does not commit to continuous monitoring of its application and to establishing clear consequences for non-compliance.
- As this improved policy to handle conflicts of interest has been said to apply only to the scientific committees, will the Agency also be revisiting and issuing a CoI policy vis-à-vis the Management Board?

- Participation in the Patient and Consumers' Working Party (PCWP) and in the Healthcare Professionals' Organisations Working Group is governed by different criteria. Will the agency be reassessing criteria soon, based on recent reports on Col and corporate sponsorship at PCWP level?

HAI Europe maintains that the Agency's financial and intellectual independence from the pharmaceutical industry remains an essential component of sound regulatory decision making. The EMA's improved policy on conflicts of interests could strengthen independent scientific and expert advice, provided that the policy is properly implemented and monitored. It's a case of wait and see.

### **Health Action International (Europe)**

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STATEMENT