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Open letter

EMA's policy on conflict of interest: improvements needed

Paris, 18 June 2010

Dear Sir,

This open letter is to draw your attention firstly to the need for the European Medicines Agency (EMA) to better implement its own basic rules on conflict of interest at the management board level. Secondly, please find our more general comments on the need for the EMA to strengthen its policy on the conflict of interest of experts working with the Agency.

Firstly, the EMA has failed to implement its basic policy on conflict of interest at the management board level. Civil society representatives can provide valuable input into the European Medicines Agency work and such collaboration should be encouraged.
However, evidence indicates that there is a risk of abuse by groups that receive their core funding from the pharmaceutical industry[1]. This particular scenario demands a commitment from the Agency to proactively monitor representatives to ensure the independence of stakeholders involved in EMA's activities.

It came as a shock to learn from the Corporate Europe Observatory (CEO) report that the EMA had failed to implement its policy on conflict of interest[2].
As we understand it, the EMA has failed to validate the accuracy of experts' statements even at Management Board level, which decides on the political orientations of the Agency.

Most notably, two patient group representatives on the EMA Management Board did not meet basic EMA rules on conflict of interest, by not even declaring the financial ties of their organisations with the pharmaceutical industry.

Corporate Europe Observatory reported that

> "*Mary Baker represents the European Federation of Neurological Associations (EFNA). According to EFNA website, it received roughly 90 % of its 2008 budget from pharmaceutical corporations like GlaxoSmithKline, Novartis and Solvay, making them almost completely*

dependent on corporate funds. While EFNA's website does at least conform to the EMA's financial disclosure standards, Baker denies that EFNA receives funding from any pharmaceutical companies in her conflict of interest statement on the EMA website. Indeed that statement suggests that EFNA is economically independent of corporate cash; that is not the case.
O'Donovan's conflict of interest statement similarly fails to mention the hundreds of thousands of euros that the European Patients Forum (EPF) receives each year from the pharma industry. In fact, the conflict of interest statement wasn't even available to the public before CEO wrote to the EMA and asked for it. It appears the statement was actually only made following CEO's request in January 2010, as it is dated 1/2/10." (**a**)

According to article 63 paragraph 2 of Regulation (EC) N°726/2004, « *Members of the Management Board, members of the committees, rapporteurs and experts shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality* [our emphasis]. *They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests (…).* »

We urge you to address this particular problem without delay. The participation of consumer and patient organisations that are independent of any pharmaceutical or medical device industry support should be actively promoted. Such groups are better equipped to represent the interest of civil society.

Secondly, the EMA's conflict of interest policy in general needs to be strengthened. Much available evidence implies that commercial interests bias regulatory science (i.e. granting of marketing authorisations, withdrawal due to pharmacovigilance concerns, etc.)[3].
Despite that knowledge, EMA's conflict of interest policy is not only insufficiently monitored and hardly implemented (read example above), but also too weak[3].

For example, the EMA does not require the declaration of interest of the experts' households, whereas several National Agencies do. EMA's experts are asked to declare their financial interest in the pharmaceutical industry only if the value exceeds 50,000 euros.
As of April 2008, fewer than half of the 4 528 experts registered in EMA's register had up-to-date declarations of interest[3]. More than 1 in every 4 of the experts registered were classified as having a "high risk level" of conflict of interest, particularly in respect to decisions about specific products. They benefited from a waiver allowing them to continue in EMA's activities in 65% of cases referred to the EMA's declaration of interest assessment group since 2004[3].
The declarations of experts' conflict of interest are not easily publicly available, European citizens being in many cases required to come to the EMA's office (Article 63 – paragraph 2 of Regulation (EC) N°726/2004).

A very first step to improve the situation would be to improve EMA's transparency practices (**b**). EMA also needs to reorient its roadmap to 2015 toward more independence from pharmaceutical companies, including a more active search for non-conflicted experts (**c**).

We look forward to hearing from you about your plans to adequately strengthen, monitor and enforce internal rules, vis-à-vis conflict of interest and stakeholder engagement.

Sincerely,

Medicines in Europe Forum
International Society of Drug Bulletins

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Notes:

a- The findings from Corporate Europe Observatory underline the need to tackle patients organisations' funding through alternative mechanisms (i.e. via a public European fund). Concerns about the independence of patient groups have also been brought up by Commissioner Dalli during his hearing at the European Parliament earlier this year.

b- EMA's unacceptable secrecy is increasingly challenged, notably by the European Ombudsman (ref. 4 to 6).

c- EMA's road map to 2015 contains a number of practices that strengthen structural conflict of interest and increase EMA's financial and intellectual dependence on pharmaceutical companies (ref. 7).

Selected references:

1- Ball DE, Tisocki K, Herxheimer A. "Advertising and disclosure of funding on patient organisation websites: a cross-sectional survey" *BMC Public Health* (2006) 6:201.

2- Corporate Europe Observatory. "Patient Groups Need a Strong Dose of Transparency - how a lax conflict of interest policy allows patient groups to hide pharma-industry funding". www.corporateeurope.org/lobbycracy/content/2010/04/patient-groups-need-dose-transparency accessed 27 April 2010.

3- Lexchin J, O'Donovan O. "Prohibiting or 'managing' conflict of interest? A review of policies and procedures in three European drug regulation agencies [European Medicines Agency, Irish Medicines Board, the UK Medicines and Healthcare products Regulatory Agency]" *Social Science & Medicine* 70 (2010): 643-647.

4- European Ombudsman. "European Medicines Agency should review refusal to release reports on adverse drug reactions" Press release, 10 May 2010. www.ombudsman.europa.eu/press/release.faces/en/4819/html.bookmark

5- European Ombudsman. "European Medicines Agency should disclose clinical reports on anti-obesity drugs" Press release, 7 June 2010. www.ombudsman.europa.eu/press/release.faces/en/4940/html.bookmark

6- HAI Europe, ISDB, Medicines in Europe Forum. "EMA transparency draft policy is just window dressing" Press release, 24 September 2009. www.isdbweb.org/documents/uploads/sept2009 EMEA trasparency.pdf

7- HAI Europe, ISDB, Medicines in Europe Forum. "The European Medicines Agency Road Map to 2015: Independence should be the priority" Joint contribution, 30 April 2010. www.prescrire.org/docus/JointAns_EMAFiveYearPlan2010.pdf

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 the pharmaceutical industry. Currently, ISDB has 79 members in 40 countries around the world. More info: www.isdbweb.org. Contact: president@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 in 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 about European medicines policy. Admittedly, medicines are not 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.