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Copy to:  
**Nils Behrndt**, Deputy Head of Mr Dalli's Cabinet  
**Jo Leinen**, President of the ENVI Committee  
of the European Parliament  
**Thomas Lönngren**, EMA's Executive Director  
**P. Nikiforos Diamandouros**, European Ombudsman

## Open letter

### Action is needed to enforce the European Medicine Agency's policy on conflicts of interest

Brussels, 9 July 2010

Dear Commissioner Dalli,

On June 18<sup>th</sup> of 2010, following the release of a report by Corporate Europe Observatory (CEO), which revealed that the EMA had failed to implement its policy on conflicts of interest at the management board level<sup>1</sup>, the *International Society of Drug Bulletins* and the *Medicines in Europe Forum* issued an open letter to the EMA's Executive Director<sup>2</sup>.

In that letter, we highlighted how important and necessary it is for the EMA to implement its internal rules on conflicts of interest, and to strengthen them.

In fact, the two representatives of patient groups that sit on the EMA Management Board are members of organisations that are heavily funded by pharmaceutical companies, namely the European Federation of Neurological Associations (EFNA) and the European Patients Forum (EPF).

The need to ensure the independence of patient groups is an issue that you addressed during your first hearing at the European Parliament, earlier this year. The growing trend for increased financing of patient and/or consumer groups by commercial interests raises questions about the groups' independence and the interests being represented when dealing with health policy and medicines regulation<sup>3</sup>.

Answering the press, the EMA's spokesperson mentioned that the Agency is looking into how to adapt the declaration form to improve the disclosure conflicts of interest, but "*that the two representatives still sit on the board and could be removed only by the European Commission, which appointed them*"<sup>4</sup> (a).

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1- 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](http://www.corporateeurope.org/lobbycracy/content/2010/04/patient-groups-need-dose-transparency) accessed 27 April 2010.

2- ISDB and MiEF "EMA's conflict of interest: improvements needed" Joint open letter ; 18 June 2010. [www.isdbweb.org/documents/uploads/campagne/EMA\\_COI\\_Final.pdf](http://www.isdbweb.org/documents/uploads/campagne/EMA_COI_Final.pdf) : 3 pages.

3- Jones K. (2008) 'In Whose Interest? Relationships between health consumer groups and the pharmaceutical industry in the UK' *Sociology of Health & Illness*, Vol. 30, No. 6.

4- Wilson P "European drug regulator is criticised over patient representatives' conflicts of interest" *BMJ* 2010; 340:c3349.

In line with the 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**. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests (...).* »

There is ample evidence that commercial interests bias regulatory science, as well as its procedures and decisions<sup>5</sup>.

**We call upon you to encourage the EMA to address this problem effectively.** Consumer and patient organisations that are independent of any pharmaceutical or medical device industry support are better equipped to represent the interest of civil society.

**Thank you for bearing in mind the concerns of our organisations, which are relevant to ensure the accountability of the EMA and to maintain citizens' trust in European institutions.**

Sincerely,

**Medicines in Europe Forum  
International Society of Drug Bulletins**

<b>Contacts:</b> ISDB: <a href="mailto:president@isdbweb.org">president@isdbweb.org</a> MiEF: <a href="mailto:pierrechirac@aol.com">pierrechirac@aol.com</a>
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<p><b>ISDB.</b> 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, their members include 79 members in 40 countries around the world. More info: <a href="http://www.isdbweb.org">www.isdbweb.org</a>. Contact: <a href="mailto:president@isdbweb.org">president@isdbweb.org</a>.</p>
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<p><b>MiEF.</b> 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: <a href="mailto:pierrechirac@aol.com">pierrechirac@aol.com</a>.</p>
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**Note :**

a- According to article 65 paragraph 1 of Regulation (EC) N°726/2004, in addition to the other management board members, « *two representatives of patients' organisations, one representative of doctors' organisations and one representative of veterinarians' organisations shall be appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission which includes appreciably more names than there are posts to be filled. The list drawn up by the Commission shall be forwarded to the European Parliament, together with the relevant background documents. As quickly as possible, and within three months of notification, the European Parliament may submit its views for consideration to the Council, which shall then appoint the Management Board.* »

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5- 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.