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Joint Press Release

European Medicines Agency (EMA) softens its conflict of interest policy: Does this further open the door to undue influence instead of closing it?

At the end of November 2014, the European Medicines Agency has announced the adoption of a *“more balanced approach to handling conflicts of interests”* to become effective on 30 January 2015. In reality, this revised EMA COI policy relaxes EMA’s position in relation to the conflicts of interest of experts with pharmaceutical companies. The evaluation of the efficacy and harms of medicines must be free from undue influence and be based on scientific data, so that the Agency’s work can benefit public health. The Agency’s integrity is at stake.

The European Medicines Agency (EMA)'s evaluation system works mainly through a network of external European experts. These experts serve as members of the Agency's scientific committees, working parties or scientific-assessment teams.

The last review of the EMA’s conflicts of interest policies for Experts in 2012 followed strong criticism from the EU Parliament mainly about conflicts of interest (COI) (1,2). An ensuing report by the European Courts of Auditors encouraged a strengthening of EMA’s COI policies (3).

EMA remains in denial of the influence COI can have despite scientific evidence. The EU legislation states that *“members of the Scientific Committees and experts shall not have financial and other interests in the pharmaceutical industry that could affect their impartiality”* (4). Nevertheless, the EMA’s 2014 policy keeps on artificially distinguishing between “direct” and “indirect” interests, though there is no evidence that such a distinction affects the influences exerted on the decision-making process.

Moreover, the EMA’s burdensome COI “rating” system aims at “mitigating” COI, instead of avoiding them. Such a system allows key opinion leaders and patient organisations that are heavily sponsored by pharmaceutical companies to act as “experts”, sometimes in very strategic positions (a). This occurs although COI subjects them to corporate influence, which is often deleterious to public health, and while independent health professional or independent patients’ and consumers’ organisations would be best placed to do the job.

2014 review did not take a turn for the better. On 6 September 2013, the EMA organised a workshop on COI. Among the key points raised, the EMA noted the need to avoid COI rather than to “manage” them: *“prohibiting the use of experts in Agency activities who have, or have had, any financial involvement with the industry, and having all scientific assessments carried out by employees of competent authorities”* (2). Nevertheless, one year later, in November 2014, the EMA published a revised policy that weakens its 2012 policy instead of reinforcing it (4).

Among the most notable changes:

- The notion of *“risk levels”* was replaced by the softer wording *“interest levels”*;
- Even for one of the highest responsibility, that of Scientific Committee Chair, no “cooling-off” period any longer applies when financial interests or funding/sponsorship to an organisation or institution are involved (b); This means that a person can stop acting as opinion leader for a company in exchange for honoraria just

a- For example, receipt of funding or sponsorship from a pharmaceutical company is still considered to be an *“indirect COI”*. This allows the two patient representatives sitting at the EMA management board to represent organisations heavily funded by the pharmaceutical industry (ref. 8). According to the 2014 policy, they just have *“to be replaced for the discussions, final deliberations and voting as appropriate in relation to any medicinal product from the relevant company”* (ref. 4).

b- According to the 2014 policy, *“the declared interest [e.g. holding of shares of a company or receiving “compensation, fees, honoraria, salaries paid directly by a pharmaceutical company to the individual”] is considered over when such interest is no longer present”* (ref. 4).

before coming on an EMA committee, and then take it up again. Isn't that an effective way of exerting influence?

- Transparency requirements are watered down, which is unacceptable since it will hamper public scrutiny (c). A change that might be seen as a progress is that a leading role during previous employment with a pharmaceutical company now results in "lifetime non-involvement":
 - "for any medicinal product for which that pharmaceutical company is the marketing authorisation holder" in case of a leading executive role;
 - "for that specific medicinal product" in case of a leading role in its development.

But being the principal investigator of a clinical trial on a specific medicinal product is not a bar to being an ad hoc scientific advisory chair if the clinical trial is over, with no "cooling-off" period. Moreover, pharmaceutical company employees with no such a leading role can still act as "expert witnesses" and remain entitled to express their opinion during crucial scientific committee meetings (d) (4).

It should be noted that the 2012 policy implementation and impact have not been evaluated independently. Most notably, no written public consultation on the 2014 revision has taken place. Why the hurry to weaken the 2012 policy?

Key recommendations to improve EMA's conflict of interest (COI) policies. Contrary to the EMA's apparent belief, evidence does not show that experts' knowledge or competences are higher if they have conflict of interest with pharmaceutical companies (e). On the contrary, evidence clearly shows that conflict of interest, and even small gifts, do influence the decision-making process (5,6). It has also been shown that doctors with COI use drugs less rationally than doctors who are not conflicted (7).

To be able to act independently and in the public interest, the EMA should firmly commit to avoiding conflicts of interest, starting by:

- Abandoning the artificial distinction between direct and indirect COI, and considering sponsorship and funding by pharmaceutical or medical devices companies to an institution or organisation a serious COI, notably to ensure that patient and healthcare professional representatives on the Scientific Committees and on the Management Board are independent;
- Reinforcing its monitoring actions: checking the accuracy of COI declarations (e.g. by liaising with National Drug Regulatory Authorities and/or checking sunshine registers in Member States that have them (f)), watching over prospective conflicts of interest, avoiding revolving doors;
- Stimulating collective and transparent decision-making procedures, starting with the reinstatement of previous transparency provision on COI during the whole process (including in assessment reports and a specific section in EPARs) and allowing for more public scrutiny on Scientific Advisory Working Party (SAWP) activities (g);
- Waiting until the scientific evidence has been duly reviewed to consult with experts who have conflicts of interest in the few cases where their help could be needed to answer a specific question.

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And contrary to the approach taken by several Member States and by the United States of America that implemented "sunshine acts" to expose payments to health professionals by pharmaceutical companies in order to raise awareness on the influence of such "advantages", the EMA 2014 policy now excludes the "reimbursement of reasonable expenses (i.e. accommodation or travel costs) directly related to a conference/seminar attendance" from the financial conflict of interest experts have to declare! (ref. 4).

c- According to the 2014 policy, only the "publication (...) of the minutes of the scientific committees' meetings, including – where relevant – restricted involvement of the chairs, members and experts" will be made available (ref. 4). By contrast, the 2012 policy insisted on the "introduction of transparency on declared conflicts of interests throughout the whole scientific review process, starting with the (Co)-Rapporteur assessment reports (...) to the minutes of the various fora up to a specific section in EPARs (or equivalent public documents) on all conflicts of interests declared throughout the scientific review" (ref. 1).

d- According to the policy, "current financial interests are compatible with such concept [that of Expert witness]" (ref. 4).

e- See for example this statement added to the paragraph on the objective of the COI policy: "It is, therefore, of utmost importance to strive for the optimal balance between the cooling-off periods for the declared interests versus maintaining the experts' knowledge" (ref. 4).

f- Sunshine acts require that medical products companies collect and make public financial relationships with physicians and other health professionals via publicly accessible online databases in order to highlight potential conflicts of interest.

g- The Scientific Advisory Working Party (SAWP) has an increasingly important and early role in preparing decisions on marketing authorisations. However the process is opaque and the COI policy applying to working parties is not stringent (refs. 4,9).

References:

- 1- ["European Medicines Agency policy on the handling of conflicts of interests of scientific committee members and experts \(EMA/513078/2010\)"](#) 3 April 2012: 9 pages.
- 2- HAI Europe, ISDB, Medicines in Europe Forum "EU Parliament says no and no again to EMA: Independent groups echo decision" Joint press release May 2012. Accessed on 14 February 2014 at: <http://www.isdbweb.org/documents/uploads/press/EMA.pdf>
- 3 - European Court of Auditors. "Selected EU agencies did not adequately manage conflict of interest situations" - EU Auditors (ECA/12/39) ; Luxembourg, 11 October 2012. Website <http://eca.europa.eu> consulted on 22 November 2013: 2 pages.
- 4 - European Medicines Agency "European Medicines Agency policy on the handling of declarations of interests of scientific committees' members and experts" 10 October 2014. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/11/WC500177253.pdf
- 5- Prescrire Editorial Staff "[The proven, often unconscious, influence of small gifts](#)" *Prescrire Int* 2011; 20 (122): 303-305.
- 6- Prescrire Editorial Staff "[Key opinion leaders: used as a marketing tool by drug companies](#)" *Prescrire Int* 2012; 21 (128): 163-165.
- 7- Gøtzsche PC "Deadly medicines and organised crime: How big pharma has corrupted health care" London: Radcliffe Publications, 2013.
- 8- See: http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/MB/people_listing_000052.jsp&mid=WC0b01ac0580028c30
- 9- AIM, HAI Europe, ISDB and MiEF "[Providing "scientific advice" to pharma industry undermines the independence of regulatory authorities](#)" Joint consultation response, 15 July 2014 : 7 pages.

Endorsing Organisations

AIM. The Association Internationale de la Mutualité (AIM) is a grouping of autonomous health insurance and social protection bodies operating according to the principles of solidarity and non-profit-making orientation. Currently, AIM's membership consists of 41 national federations representing 29 countries. In Europe, they provide social coverage against sickness and other risks to more than 150 million people. AIM strives via its network to make an active contribution to the preservation and improvement of access to health care for everyone. More info: www.aim-mutual.org. Contact: corinna.hartrampf@aim-mutual.org.

ISDB. The International Society of Drug Bulletins (ISDB), founded in 1986, is a worldwide Network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of pharmaceutical industry. Currently ISDB has around 80 members in 41 countries around the world. More info: www.isdbweb.org; Contact: press@isdbweb.org

MiEF. The Medicines in Europe Forum (MiEF) was launched in March 2002 and reaches 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. It is a unique group and a testament of the importance of European medicines policy. Admittedly, medicines are no mere consumer goods, and the Union represents an opportunity for European citizens to seek further guarantees of efficacy, safety and pricing. Contact: pierrechirac@aol.com

NCC. The Nordic Cochrane Centre is part of the Cochrane Collaboration, an international not-for-profit international network of more than 30,000 dedicated people from over 100 countries preparing, maintaining and promoting the accessibility of systematic reviews of the effects of health care. More information: www.cochrane.org. Contact: pccg@cochrane.dk