



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Sponsoring of Patients' Organisations by pharmaceutical industry – proposed actions

Management Board meeting 7 October 2010

Background note

On 13 August 2010, an article by Kevin Grogan, titled *Pharma putting in the cash for 'patient voice' at EMA* was published by PharmaTimes Online (a copy of the article is attached to this cover note; a link to the website is herewith <http://www.pharmatimes.com/WorldNews/article.aspx?id=18363>).

Subsequently, an enquiry was received from a Member of the Board regarding the Agency's awareness of the article and the response.

Matters for consideration

The aforementioned article refers to the publication of a report by Health Action International (HAI), which concluded that the Agency's financial transparency criteria for Patients' and Consumers' Organisations working with the Agency are not being fulfilled.

The Agency disagrees with these conclusions as all financial interests of Patients' and Consumers' Organisations are disclosed to the Agency as required by the transparency criteria.

As part of the evaluation by the Agency of the eligibility to work with the EMA, the EMA requests each Organisation to provide financial statements, including details on the specific donors and their contributions. Each Organisation is re-evaluated (including financial aspects) every 2 years.

EMA makes participation of Patients' and Consumers' Organisations conditional to the fulfilment of the EMA criteria, which includes an analysis of their funding source in order to rule out any possible conflict of interest.

The conclusions of HAI were based only on information found on the internet. Although the Agency encourages Organisations to publish as much information as possible on their websites, it cannot oblige Organisations to do so. Therefore, the findings are only accurate as regards the publication or failure to publish details by patient groups on their own websites.



In view of the above and in order to increase transparency of the process the EMA operates to involve Patients' and Consumers' Organisations, the following actions are proposed:

- Prepare and publish by 4Q 2010 an Standard Operation Procedure (SOP) describing the procedure that EMA has in place to evaluate and further monitor that all Organisations fulfil the EMA criteria (including the processing of financial information).
- Revise EMA criteria, in particular the section on transparency, in order to make clearer which are the EMA requirements in terms of funding source and in terms of activities (both for the information the Agency evaluates before involving them and for the information the Agency expects the Organisations to make public).

The Agency will further discuss this issue in the context of the Patients' and Consumers' Organisations Working Party (PCWP) and will come with revised "criteria for involvement" as part of the Framework of Interaction between the Agency and Patients' and Consumers' Organisations (currently being revised).

For ease of reference the current Agency's criteria that Patients' and/or Consumers' Organisations should fulfil in order to be involved in the Agency's activities, as adopted by the Board during their September 2005 meeting, are also attached.

Pharma putting in the cash for 'patient voice' at EMA

WORLD NEWS | AUGUST 13, 2010

KEVIN GROGAN

Eyebrows are sure to be raised following the publication of a report which shows that two-thirds of the patient and consumer organisations working with the European Medicines Agency received “partial or significant funding from pharmaceutical manufacturers and/or industry associations”.

A research article from the independent Netherlands-based Health Action International Europe notes that patient and consumer organisations are “increasingly involved as stakeholders and experts in the management and scientific committees at the EMA”. They are all asked to disclose their sources of income and the corresponding financial contributions relative to their operating budget.

HAI Europe says that “complete disclosure is important because it provides a qualitative and quantitative evidence base from which to assess potential conflicts of interest”. Any “competing interest could influence the decision-making process around medicines regulation and as a result, have an impact on public health”.

Given this scenario, HAI Europe surveyed levels of “corporate sponsorship” between 2006 and 2008 among the 23 patient and consumer organisations eligible to work with the EMA. It found that 15 organisations received between 0.2%-99% of their annual income from corporate sources, whilst seven were funded entirely from alternative sources. No financial data could be retrieved for one of the 23.

The report goes on to note that the average corporate contribution per sponsored organisation “continued to rise over the period studied at a rate greater than inflation”. The average donation rose from 185,500 euros in 2006, to 282,090 euros in 2007, and to 321,230 euros in 2008 - 47%, 51% and 57% of the average annual revenue of an organisation, respectively.

Worryingly, fewer than half of the 23 organisations met the EMA's financial reporting guidelines, HAI Europe found. Nine of them specified donors by name with their corresponding contribution, but did not express the donation as a percentage of total income.

EMA fails to enforce transparency guidelines

The report says that “the EMA appears to have failed in the monitoring and enforcement of its guidelines on financial transparency”. These were introduced in 2005, but by March 2010, 20 of the 23 eligible groups had not yet reported their 2006 income online. “Despite the lack of compliance, all organisations were invited to participate in the EMA annual meeting in December 2009”.

HAI Europe believes that “there are insufficient public and non-corporate funding sources to support the valuable work of patient and consumer organisations, particularly at the regulatory level”. Therefore, “this contributes to the prevalence of pharmaceutical industry sponsorship of the patient voice at the EMA”.

The authors of the report acknowledge that its study “has already contributed to greater disclosure by the eligible groups, particularly as a result of requests to individual organisations for financial data in the EMA format”. They add that in several cases, “organisations updated their websites and financial records immediately after receiving our request”, which “facilitated the data collection and contributed greatly to this study”.

However, HAI Europe insists that more needs to be done and has made a number of recommendations for the EMA. These include establishing a clear definition of “financial contributions” that includes honorariums, travel fees and other forms of sponsorship, ensuring that the information is publicly available, “potentially on the EMA website,” and making participation in EMA activities “conditional on the fulfilment of all eligibility criteria, with particular regard to financial transparency”.

For HAI Europe's full article, which details the amounts received by the 23 organisations, follow the link below.

<http://www.haieurope.org/>



Criteria to be fulfilled by Patients' and Consumers' Organisations involved in EMEA Activities

I. Introduction

This paper has been developed to define the criteria patients' and/or consumers' organisations should fulfil in order to be involved in EMEA activities, such as the COMP or the CHMP/EMEA working group with patients and consumers' organisations.

These criteria do not apply to the procedure for external consultation on documents, since such external consultation is open to all external parties.

II. Definition of Patients'/Consumers' Organisations

Patients' organisations are defined as not-for profit organisations which are patient focused, and whereby patients and/or carers (the latter when patients are unable to represent themselves) represent a majority of members in governing bodies.

These could be:

- either general umbrella organisations (e.g. representing either European specific disease organisations and/or national umbrella organisations)
- or European disease specific organisations (i.e. representing national organisations or individual patients on acute and/or chronic diseases).

Consumers' Organisations are defined as not-for profit organisations which defend and promote the general interests of European consumers - citizens as purchasers or users of goods and services.

III. Criteria to be fulfilled

The organisations should be established at European Union (EU) level, and should fulfil the following criteria:

- **Legitimacy:** the organisation should have statutes registered in one of the Member States of the EU. If it is an international organisation not registered in a EU Member State, additional information needs to be provided demonstrating EU focus and activities.
- **Mission/Objectives:** the organisation should have its mission/objectives clearly defined and should agree to have it/them published on the EMEA website.
- **Activities:** the organisation should have, as part of its activities, a specific interest in medicinal products which should be documented (e.g. through a report published on the organisation website).
- **Representativity:** the organisation should be representative of patients or consumers throughout the EU. Organisations already registered at Community level, e.g. in the EU Health Forum, the Council of

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Europe, are considered to adequately represent patients or consumers for involvement in EMEA activities.

- Structure: the organisation should have governing bodies which are elected by their members, who shall be patients, their carers, or their elected representatives.
- Accountability and Consultation Modalities: statements and opinions of the organisation should reflect the views and opinions of its members and adequate consultation procedures with those members should be in place. In particular, the organisation should ensure that the appropriate flow of information is in place to allow dialogue both ways: from and towards its members.
- Transparency: as a general rule, the organisation should be as transparent as possible, e.g. by regularly publishing, on its website, a report on the activities undertaken.
The organisation should also disclose its sources of funding both public and private by providing the name of the public and/or private bodies and their individual financial contribution in terms of percentage of the organisation budget. Any relationship with corporate sponsorship should be clear and transparent. Any conflict of interest should be disclosed to the EMEA. In case of umbrella organisations the list of member associations should be publicly available.
The reference to private bodies does not include private individuals unless this presents a potential conflict of interest as referred to above.

In addition, Patients' and Consumers' Organisations shall be committed to take active part in the interaction with the EMEA. To facilitate communication, a contact person shall be identified.

In case of lack of European associations for a specific disease or treatment areas, the involvement of national organisations may be considered even though preference will be given to European wide-associations. These associations will need to fulfil the same criteria apart from representativity which will be at national level.

In case of several associations existing in different Member States, a choice will be considered on a case-by case basis.

In order to further increase the transparency in this field, the EMEA will create a public registry of those patients' and/or consumers' organisations with whom it will interact, as a consequence of the fulfilment of the above criteria.