

Patient & Consumer Organisations at the European Medicines Agency: Financial disclosure & transparency

Overview

Patient and consumer organisations are increasingly involved as stakeholders and experts in management and scientific committees at the European Medicines Agency (EMA). As with all experts working with the Agency, civil society groups are asked to disclose their sources of income and the corresponding financial contributions relative to the organisation's operating budget. 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.

The survey

HAI Europe surveyed levels of corporate sponsorship between 2006 and 2008 among the patient and consumer organisations eligible to work with the Agency (n=23). The survey looked at how many groups received sponsorship and the levels of sponsorship involved. The study also establishes the organisations' compliance with the EMA's criteria on financial disclosure.

Main findings

Two-thirds of the patient and consumer groups working with the EMA received partial or significant funding from medicines manufacturers and/or industry associations.

Fifteen organisations received between 0.2% and 99% of their annual income from corporate sources, whilst seven organisations were funded entirely from alternative sources. No financial data or revenue sources could be retrieved for one of the 23 organisations.

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 EUR per sponsored organisation in 2006, to 282,090 EUR in 2007, and to 321,230 EUR in 2008. These amounts correspond to 47%, 51% and 57% of the average annual revenue of an organisation, respectively.

Fewer than half of the 23 organisations met the EMA's financial reporting guidelines.

Six organisations identified their income sources by name and included the corresponding financial contributions relative to the organisation's operating budget. An additional nine organisations specified donors by name with their corresponding contribution, but did not express the donation as a percentage of their total income.

Main conclusions

The EMA appears to have failed in the monitoring and enforcement its guidelines on financial transparency.

The Agency introduced transparency guidelines 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. The EMA guidelines do not stipulate a reporting deadline or cycle, and as a result some organisations have not yet met the requirements established in 2005.

There are insufficient public and non-corporate funding sources to support the valuable work of patient and consumer organisations, particularly at the regulatory level.

Aside from corporate sponsorship, some organisations sampled received partial or full funding from member fees, foundation grants, and funding programmes from national governments and European institutions. However, public financing sources are limited, and so this contributes to the prevalence of pharmaceutical industry sponsorship of the patient voice at the EMA.

More research needs to be done to realise complete transparency.

The execution of this 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. In several cases, organisations updated their websites and financial records immediately after receiving our request. The rapid responses to requests for information facilitated the data collection, and contributed greatly to this study.

What can be done?

Recommendations for the European Medicines Agency

- Enforce the precise reporting format outlined in the existing financial transparency criteria.
- Establish a clear definition of “financial contributions” that includes honorariums, travel fees and other forms of sponsorship.
- Fix deadlines for the submission of financial disclosure reports to the EMA (i.e. annually).
- Be responsible to set up monitoring and enforcement mechanisms to ensure that the information is publicly available, potentially on the EMA website.
- Make participation in EMA activities conditional on the fulfilment of all eligibility criteria, with particular regard to financial transparency.

Recommendations for patient and consumer organisations

- Include references to the organisation’s funding policy in financial reports.
- Move towards full disclosure of all financial contributions, including honorariums and travel fees.
- Post regular and easily accessible financial reports on the organisation’s website and other relevant registers, such as the European Commission’s lobby register.