Patient and consumer organisations at the European Medicines Agency

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Financial disclosure and transparency

Katrina Perehudoff & Teresa Leonardo Alves

Research Article
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Patient and Consumer Organisations at the European Medicines Agency: Financial disclosure and transparency

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Foreword

The long history of drug regulation, with its considerable achievements, has been marked by the persistence of one seemingly intractable paradox. The nature of the work of regulatory bodies means that they are continually entrusted with data given to them in confidence by pharmaceutical companies to make their assessments. Much of this material is unprotected by patent, so has to remain confidential to prevent leaks to competitors. One consequence of this situation has however often been a marked reluctance to grant other parties full access to regulatory proceedings; while the regulators have frequent close contact with industrial applicants, representatives of the public, in whose interests regulation exists, are commonly excluded from the process. That in turn leads many people, not only cynics, to regard regulation as primarily a process serving the needs and interests of the pharmaceutical industry.

It is to the credit of the regulatory process in the European Union that it has in recent years tried to involve patient and consumer groups in some aspects of drug policy and approval. Experience seems to show that this can be achieved without endangering any other valid interest. But the procedures have to be well defined and respected, and the consumer groups involved must be financially independent and truly impartial. With some years of accumulated experience it is now possible to assess whether that ideal has indeed been achieved. In the study presented here, Health Action International Europe has taken a uniquely close look at experience to date, particularly as regards the independence of the groups concerned; its findings will be important in determining the future pattern of public involvement in drug regulation.

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Abstract

Background

The transparency criteria adopted by the European Medicines Agency require eligible patient and consumer organisations to disclose the names and contributions of their public and private revenue sources. Despite various transparency initiatives, the exact funding sources of, and amounts received by, eligible organisations remain unclear. This article examines how many patient and consumer organisations eligible to work with the Agency (n=23) received corporate sponsorship between 2006 and 2008 and how much. The article also reports how many organisations met the Agency's criteria on financial disclosure.

Methods

Financial data were retrieved from organisations' and pharmaceutical companies' websites in January and February 2010, as well as through direct requests for the information placed in March 2010. A method for estimating sponsorship in the absence of reported contributions was developed and applied uniformly.

Results

Fifteen of the twenty-three eligible organisations received financial sponsorship from corporate sources whilst seven received funding entirely from other sources. We failed to retrieve any financial data or revenue sources for one of the 23 organisations. The annual average corporate contribution per sponsored organisation rose from €185,500 in 2006, to €282,090 in 2007, to €321,230 in 2008. These amounts correspond to 47%, 51% and 57% of organisational average annual revenue, respectively. Fewer than half of the 23 organisations met the Agency's financial reporting guidelines.

Conclusions

This study indicates low compliance with the guidelines which EMA introduced in 2005 to ensure the financial transparency of the organisations working with it. Levels of corporate sponsorship differ greatly between those organisations that receive no financial support and others who rely upon it heavily. The lack of a uniform and detailed reporting system hinders complete public disclosure of the nature, and extent of, corporate sponsorship of these organisations.

This study focuses on the issue of corporate sponsorship of patient and consumer organisations active at the EMA. However, these organisations represent only a selection of non-governmental organisations (NGOs) and other stakeholders active in the area of health and pharmaceutical policy in Europe. Thus, further research is called for on financial transparency, and the nature of corporate sponsorship and conflicts of interests of civil society representatives in European health policy making.

Introduction

Patient organisations have established themselves as a valuable source of information, services and support for those living with a disease and their carers. They can stimulate additional research in their disease area, promote public awareness for their condition and needs, and call for changes on behalf of patients.[i] The broader public is also affected by pharmaceutical policies and so consumer groups act as representatives for all those who on occasion or continuously, need medicinal treatment for a disease or condition.

The growing trend for corporate financing of patient and/or consumer groups raises questions about their independence and the interests they represent in health and medicines policy fora.[ii] Pharmaceutical, bio-tech and medical device companies sponsor patient organisations in a variety of ways, ranging from direct financing to various forms of in-kind sponsorship.[iii] Despite overlapping objectives on some issues, the goals of groups representing medicines and device manufacturers can conflict with the aims of patients and consumers.[iv] For example, a manufacturer generally strives to obtain and expand market share for its products as quickly as possible to maximise returns. On the other hand, patients may or may not benefit, depending on the product characteristics, its cost, the range of existing treatments, and the new product's relative therapeutic value. For these reasons and others, a donor-recipient relationship forged between pharmaceutical companies and patient organisations could lead to conflicts of interest, or could unduly threaten the groups' independence.[1]

Patient organisations are increasingly involved as political stakeholders at the European Commission and related agencies. The European Medicines Agency (EMA) established a Patients' and Consumers' working group in 2005, which became a Working Party (PWCP) in 2006. The PCWP makes recommendations to the Agency and its Management Board in matters that interest patients and consumers, including product information, transparency and dissemination of information, pharmacovigilance, and how patient organisations interact with the EMA Scientific Committees.[v]

In 2005, the EMA developed clear guidelines (*Criteria to be fulfilled by Patients' and Consumers' Organisations involved in EMEA Activities*[vi]*)* requiring financial transparency from patient and consumer organisations that are eligible to work with the Agency. The Agency specifically asks for financial data to be disclosed in a format that includes the names of income sources and their corresponding financial contributions relative to the organisation's operating budget. The guidelines document does not include a monitoring procedure, concrete timelines for adherence, nor does it state the potential consequences of non-compliance.

Despite various initiatives promoting financial transparency, the exact funding sources and amounts received by some eligible patient and consumer organisations remain unclear. Furthermore, little research has been done on the sources of funding of EMA's patient and consumer experts. This article examines the disclosure practices of eligible organisations. The article quantifies the annual corporate sponsorship that the patient and consumer groups active at the EMA have received in 2006, 2007 and 2008. It addresses the following questions:

1. How many of the patient and consumer organisations that are eligible to work with the EMA have received corporate sponsorship?
2. How much corporate sponsorship has each eligible organisation received?
3. How many eligible organisations disclose corporate sponsorship in line with EMA financial transparency criteria?

Methods

Sample

On 1 August 2009 twenty-three patient and consumer organisations (hereafter called *organisations*) were eligible to work with the EMA.[vii] The organisations are named at http://www.ema.europa.eu/Patients/organisations.htm.

Definitions

Conflict of Interest- A situation in which a person or organisation has a private or personal interest sufficient to appear to influence the objective exercise of his/her/its official duties.[viii]

Declining sponsorship- Organisations were considered to have declined corporate sponsorship when their policy on financial support stated corporate or private company donations were not accepted and their website identified no corporate donors as financial contributors.

Receiving sponsorship- This refers to financial contributions (i.e. restricted or unrestricted contributions for core/operational work, events, projects, education grants or research initiatives) and/or other types of contributions from corporate sources, such as payment of conference attendance and related travel costs for patient organisation representatives or honoraria. [iii]

In-kind contributions to the organisation's annual income from corporate or other sources were excluded from this study.[1]

Sponsorship was identified in two ways:
1) if the patient or consumer group reported revenue from a corporate source;
2) if the company reported having provided a contribution to the patient or consumer group.

Corporate sources were defined to include the following types of businesses and organisations:

- Companies that produce healthcare-related products or services, including pharmaceuticals or medical devices;
- Company-owned foundations, or foundations and associations established by a single company;
- Industry associations representing medical, drug or device companies.

The above enterprises and associations pursue economic objectives that could conflict with the aims of any patient and/or consumer organisation they sponsor, and have, therefore, been included in this study.

We excluded non-profit foundations that received some health-sector corporate revenues if this was only a part of overall revenue. While these foundations are also private entities, their objectives are, in general, not in competition with those of patient and consumer groups. Foundations established by a single pharmaceutical company were included in the survey.

Data sources

Data for the years 2006, 2007, and 2008 were extracted from electronic sources between January 20 and February 7, 2010. Average annual currency exchange rates were calculated from Oanda.com.

Step 1: All financial data were first extracted from organisations' financial reports, annual reports, websites and other publications. When relevant documents could not be found, a Google search term was used: {patient or consumer organisation name} + annual report OR financial report OR finances OR sponsors OR donations + {year}. Only the first 20 results

[1] Although it is important to declare in-kind contributions as they can constitute corporate sponsorship, such contributions were excluded from this comparative study. In-kind contributions are assigned a self-determined value that can bias objective comparisons between organisational revenues. This includes, for example, corporate-sponsored administrative support or the economic value assigned to volunteer hours worked.

were investigated for efficiency, and in order to apply a systematic approach regardless of how many Google 'hits' appeared per organisation.

Step 2: The European Federation of Pharmaceutical Industry Associations (EFPIA) adopted a Code of Practice on Relationships between Pharmaceutical Industry and Patients Organisations in 2008.[ix] Under this self-regulatory code, all EFPIA member companies are requested to publish the names of the patient organisations they support.[x] EFPIA hosts a list of their 31 members that voluntarily declare patient group sponsorship and provides links to their websites at http://www.efpia.eu/content/default.asp?PageID=603.

The 31 EFPIA members' websites were searched for financial data to supplement the information found on patient and consumer organisations' websites. If data could not be found on company websites, we used the Google search term: {company name} + {patient organisation name} OR patient organisation OR patient group + {year}

The first 20 results were investigated. When a company's reported donation exceeded the contribution specified by the organisation, the difference was added to the amount reported by the organisation.

Step 3: Finally, if sponsorship for at least one of the three years could not be accurately calculated from the data collected in the previous two steps, financial data in the EMA format was requested directly from organisations by e-mail during March 2010. This final step served as a validation tool for sponsorship estimates.

Methods used to estimate sponsorship

On occasion companies referred to their position or level on a donor hierarchy. For example, a company might be described as a *Platinum Sponsor* of the organisation. The term *Platinum Sponsor* was usually defined by the organisation as corresponding to a specific contribution, for example, €40000 in one case.

In another case, the amount of the donation was known for only one of the *Corporate Partners*. An average *Corporate Partner* contribution was calculated based on the previous two years, both of which had a similar number of *Corporate Partners* and a comparable value of their total donations. The average *Corporate Partner* contribution was attributed to the remaining *Corporate Partners* for the year in question.

If the information reported by patient groups did not distinguish between public and corporate donations, we used an estimation method. We investigated funding for projects that had corporate sponsorship, identified by company logos or acknowledgements published on project materials. It was assumed that each company donated an equal amount towards the

total, unless otherwise specified on the company website. Corporate sponsorship was calculated by aggregating the estimated company contributions for each project.

Sometimes patient groups' annual financial reports did not identify project-specific income, but project-related expenses were clearly marked. In these cases, project expenses were assumed to be equal to the funds raised to execute the work. This allowed us to estimate the project-specific corporate sponsorship by assuming that each company donated an equal amount towards the total raised (see above).

In all cases when detailed data on donations were not provided for at least one of the three years, we first asked the organisations to provide the data, and only used the estimation procedures described above when the data were not available.

Methods used to estimate income

The annual revenue was extracted from organisations' financial reports. In some cases, revenue was not reported.

In the absence of reported revenue, we checked if the organisation was sponsored by a pharmaceutical company that specified its contribution in currency and as a percentage of the organisation's annual revenue.

The following formula was used to estimate the organisational revenue:

$$\frac{\text{[Company X contribution in euros (or converted to euros) * 100]}}{\text{Company X contribution as a percentage of Organisation Y's annual revenue}}$$

Results

Fifteen of the twenty-three eligible organisations received financial sponsorship from corporate sources whilst seven received funding entirely from other sources. We failed to retrieve any financial data or revenue sources for one of the 23 organisations.

Table 1 - Corporate sponsorship of organisations eligible to work with the EMA

	2006		2007		2008	
Group Name	**Amount € thousands**	**Percent of annual budget**	**Amount € thousands**	**Percent of annual budget**	**Amount € thousands**	**Percent of annual budget**
European AIDS Treatment Group (EATG)	€ 86,78 ⊥	9% ⊥	€ 650,39	90%	€ 642,20	83%
International Alliance of Patients' Organisations (IAPO)	€ 388,29 ⊥	78% ⊥	€ 558,13	96%	€ 565,12 ⊥	89% ⊥
European Organisation for Rare Diseases (EURORDIS)	€ 347,00	25%	€ 451,00	20%	€ 492,00	25%
European Patients' Forum (EPF)	€ 342,50	99%	€ 495,00 ^	105% ^	€ 458,50	78%
European Parkinson's Disease Association (EPDA)	€ 154,02	35%	€ 218,27	37%	€ 330,23	34%
International Diabetes Federation Europe (IDF)	€ 432,40	66%	€ 380,00	41%	€ 289,17 ⊥	36% ⊥
European Federation of Neurological Associations (EFNA)	€ 122,35	72%	€ 88,88	45%	€ 281,95	91%
Alzheimer Europe (AE)	€ 183,18	24%	€ 221,41	25%	€ 248,69	26%
European Multiple Sclerosis Platforms (EMSP)	€ 213,30	48%	€ 216,12	33%	€ 242,34	32%
International Patient Organisation for Primary Immunodeficiencies (IPOPI)	€ 122,09	51%	€ 164,80	66%	€ 215,38	88%
European Cancer Patient Coalition (ECPC)	€ 47,27 ⊥	15% ⊥	€ 31,30 ⊥	9% ⊥	€ 203,31 ⊥	46% ⊥
Myeloma Euronet (ME)	€ 133,60	99%	€ 190,94	94%	€ 170,17	79%
European Genetic Alliances' Network (EGAN)	€ 23,38	34%	€ 1,00	4%	€ 37,00	32%
European Heart Network (EHN)	€ 0,79	0%	€ 0,00	0%	€ 0,00	0%
AVERAGE	€ 185,50 #	47% #	€ 282,09 *	51% *	€ 321,23 *	57% *

⊥ This is an estimate based on relevant but incomplete information from the organisation's website and donor company websites.

^ This calculation is based on self-reported values; however, the amounts in the *Acknowledgement of financial support* section of the organisation's annual report are not clearly reflected in the *Profit and loss account* section. Thus, the support reported from corporate sponsors exceeded the total income.

Average was calculated based on reported sponsorship values for the year indicated (n=14)

* Average was calculated based on reported sponsorship values for the year indicated (n=13)

Table 2 - Organisations eligible to work with the EMA that did not receive sponsorship or where limited financial information was retrievable

Did not receive corporate sponsorship in 2006, 2007 and 2008
European Consumers' Organisation (BEUC)
European Myeloma Platform (EMP)
European Older People's Platform (AGE)
European Public Health Alliance (EPHA)
Health Action International Europe (HAI-E)
Insulin Dependent Diabetes Trust (IDDT)
International Confederation of Childhood Cancer Parents Organisations (ICCCPO)
No financial information available for the years 2006, 2007 and 2008
Rett Syndrome Europe (RSE)
Received unspecified corporate sponsorship during 2006, 2007 or 2008
European Heart Network (EHN)[2]
Thalassaemia International Federation (TIF)

Organisations that received sponsorship

Table 1 and Table 2 identify the 15 corporate-funded organisations. Of those sponsored, the level of corporate sponsorship ranged from 0.2% to 99.0% of their annual income.

The annual average corporate contribution per sponsored organisation rose from €185,500 in 2006, to €282,090 in 2007, to €321,230 in 2008. These amounts correspond to 47%, 51% and 57% of organisational average annual revenue, respectively.

One organisation self-reported that it was funded exclusively by their members, who were identified as other patient- and disease-related organisations, and/or the European Commission, and therefore, (it was interpreted) that they did not accept sponsorship. However, a pharmaceutical company reported contributing honorariums to this patient group.

Organisations that received no sponsorship

Seven of the 23 eligible organisations received no corporate sponsorship, with four of the seven explicitly stating that they declined commercial funding. Table 2 lists the organisations that did not receive sponsorship and those where limited information was retrievable.

[2] Honorarium of unspecified amount in 2008

One organisation stated that its only two funding sources were an EU operating grant and member contributions. Two of the other organisations clearly state that they do not accept "*funding from commercial entities*" or "*any financial assistance or sponsorship from pharmaceutical companies*". Although the fourth group's funding declaration is less specific, the secretariat clarified that their organisation "*does not accept support, whether direct or indirect, from economic actors*".

One organisation maintains a restricted funding policy, in which project- or event-related costs can be sponsored while operating costs cannot be financed by companies. However, their annual financial reports showed clearly that the organisation received no corporate sponsorship for a project, event or other restricted activity between 2006 and 2008.

The Articles of Confederation of another organisation identify "*national and international private entities*" as viable income sources. A Sanofi-Aventis-sponsored project benefiting members was acknowledged in their annual report. However, in the context this research, this group was deemed not to receive sponsorship because their financial records do not identify any private donors and the direct recipients of Sanofi-Aventis support are unclear.

One organisation lacks an identifiable funding policy, although its annual reports indicate that "*most of our expenses in the year [year] were directly financed by our partner organisations, [...] members organisations or by individual members*." Its formal policy on corporate funding was unclear.

Compliance with EMA transparency criteria

Six organisations presented their financial data in the EMA format, for at least one of the three years studied. In some cases, the EMA format was adopted after we asked the organisation to direct us to these data, or provide us with them (methods step 3).[3]

Nine additional organisations specified donors by name and their corresponding contribution, but did not express the donation as a percent of their total income. The financial records for two of these organisations were hosted on the UK Charity Commission website.[xi]

[3] Research steps 1 and 2 showed that HAI had not reported its revenue as a percentage of annual organisational income. The missing information was requested from HAI's Financial Director and HAI's public records have since been updated to comply with the EMA criteria. All other organisations contacted in research step 3 have had the same opportunity to update their financial data.

Discussion

This research has found that 65% (n=15) of the 23 organisations working with the Agency received corporate sponsorship between 2006 to 2008, whilst 35% (n=7) did not. Only six of the 23 eligible organisations were found to meet the EMA's financial transparency criteria for at least one of the years examined. No financial data was located for one of the 23 organisations.

These results illustrate the lack of patient and consumer group compliance with the EMA criteria as well as the limited application of the guidelines. In addition, there is no indication that the EMA enforces or upholds the 'public availability' requirement. The guidelines were introduced in 2005, but by March 2010, we were still unable to locate the income sources for 20 of the 23 eligible groups reported online. Despite persistent non-reporting, all the organisations were invited to participate in the EMA annual meeting with eligible groups in December 2009.[xii]

The importance of disclosure

European patient and consumer organisations can voluntarily disclose their sources of revenue on their websites, but no common definition or format has been unanimously adopted. Disclosure of all sponsorship sources, its intended purpose, its value and the proportion of organisational revenue that it represents, is important because it provides a qualitative and quantitative evidence base from which to assess potential conflicts of interest. In general, patient groups' websites give insufficient information about corporate donors to assess whether their interests might conflict with those of their pharmaceutical and other corporate funders. [iii] Although the European Commission introduced the voluntary '*Register of Interest Representatives*' in June 2008,[xiii] only five of the 22 organisations eligible to work with the Agency had registered by September 2009.[xiv] A significant majority of these groups conduct advocacy campaigns aimed at the EU Institutions on behalf of the patients and individuals they represent.[4]

Unclear EMA financial reporting guidelines

The EMA guidelines do not clearly define *financial contribution,* and therefore various differing definitions have been used in financial reporting. As a result, in some cases "other" donation types, such as honoraria and travel costs, were not reported as *financial*

[4] Nineteen of the 23 organisations sampled state that their mission includes the goal to raise awareness among and/or to influence EU Institutions and Agencies. Source: EMA *Working with Patients and Consumers – Eligible Organisations* Accessed at: http://www.ema.europa.eu/Patients/organisations.htm on 31 March 2010.

contributions. Without clear definitions, discrepancies can arise and comparisons between organisations are difficult. These omissions also hinder assessment of possible conflicts of interest.

Organisations used up to six different reporting formats in their reports. Reporting organised as combined contributions from unspecified donors was the most difficult to deconstruct. Financial links to corporate sponsors are obscured when public and private incomes are reported together as one contribution. In these circumstances, it is almost impossible to calculate or estimate the real value of sponsorship from the organisations' records alone. Full disclosure cannot be achieved without a uniform definition and format for financial reporting.

The guidelines do not stipulate a reporting deadline or cycle, and some organisations have, as a result, not yet met the requirements established in 2005. Without a clear reporting timeline, an enforced monitoring procedure, and tangible consequences for non-compliance, the EMA guidelines for patient and consumer groups cannot secure the transparency of stakeholders.

Alternative funding sources

The EMA transparency guidelines apply to both public and private sources of funding. While this study only focuses on disclosure practices of corporate sources, financial support from public sources should also be disclosed.

Besides corporate sponsorship, organisations sampled in this study relied partially or entirely on fees from member associations, foundation grant schemes, and funding programmes from national governments and European institutions. Some of these funding bodies have eligibility criteria that include a threshold on corporate co-financing. The Executive Agency for Health and Consumers (EAHC), which awarded 2009 or 2010 operating grants to six of the organisations sampled, considers applicant organisations receiving more than 20% of their funding from the private sector or other conflicting interest for their functioning to be ineligible to receive financial assistance.[xv]

Absence of a uniform reporting system

Despite the involvement of patients and consumers in pharmaceutical policy under both DG SANCO and DG Industry, there is neither a cohesive financial disclosure system nor detailed criteria for the participation of civil society organisations for pharmaceutical policy.

The EAHC, under the competence of DG SANCO, employs a 20% threshold for corporate funding, determined following the submission of annual financial disclosure reports. This

threshold is enforced and organisations receiving more than 20% are ineligible to receive operating grants from EAHC.

The European Union Health Policy Forum (EU HPF) is a multi-stakeholder platform hosted by DG SANCO that aims to contribute to and advise on the development, implementation and evaluation of EU health-related policies and actions.[xvi] The EU HPF adopted a series of *Guiding Principles with regard to Transparency* in 2007. The principles explicitly state that information about member organisations' finances, revenue sources and amounts, in sum and as a percentage of the organisational budget, shall be made public at least six months after review by the organisations' General Assemblies. The names of public and private funders are to be also be disclosed, as well as the purpose of the contribution. According to these principles, compliance will be monitored by the European Commission at least every two years and outstanding information will be noted in the Forum.[xvii] However, some EMA-eligible organisations surveyed in this research article also participate in the EU HPF. Therefore, it is reasonable to assume that the EU HPF's financial disclosure guidelines are not yet instituted by all members.

The Pharmaceutical Forum was a high-level political platform, administered by DG Enterprise and Industry from 2007 to 2008, to host discussions on EU pharmaceutical policy, including the issue of the provision of information to patients. The Forum did not establish clear financial disclosure criteria nor did it have a procedure for members to declare potential competing interests. Patient and consumer representatives were hand-picked by DG Enterprise & Industry without clear participation criteria and with no objective assessment of their representivity or potential conflicts of interest. [xviii]

The EMA was moved under the oversight of DG SANCO in 2010 but was previously under the competence of DG Enterprise & Industry. Financial transparency guidelines applied to patient and consumer groups eligible to work with the EMA remain unchanged since their adoption in 2005.

Increased transparency through research

The performance of this project has led 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.

The data collection process has illustrated how few data on corporate contributions are available. For example, one organisation's corporate income was estimated, through

methods step 1 and 2, to be between 10% and 16% of their annual income in 2006 and 2007, respectively.[5] After requesting and receiving the organisation's complete annual financial reports in methods step 3, the corporate sponsorship level was in fact between 25% and 56% higher than the available information originally suggested.

Study limitations

There are several limitations to this study. First, in the absence of sufficient financial data, some corporate donations had to be estimated, and so, the data may not represent the exact levels of sponsorship. The results in this article are based on an estimation method developed to yield a conservative estimate of the true value of sponsorship. As illustrated above, estimates based on information from organisations and company websites were below the actual value of contributions when compared with the financial data individual organisations provided on request.

Second, this research was carried out by the HAI Europe office, which is also a consumer group eligible to work with the Agency and, since February 2010, an active member of the Patients' and Consumers' Working Party. HAI Europe's ongoing relationship with the Agency and inclusion as a research subject is clearly stated in order to make the research methods, results and objectivity of the analysis as transparent as possible for the reader. Opportunities for undue influence in this study are limited as the data retrieved are largely self-reported evidence, in the public domain, and verifiable by third parties. Three information sources were used to triangulate data collection and maximise data reliability. As with all other organisations, HAI's financial data reported in this study were retrieved from publicly available information on HAI's website.

Conclusions

This study indicates a low level of compliance with EMA guidelines, which were introduced in 2005 to ensure the financial transparency of the organisations working with the Agency. Levels of corporate sponsorship differ greatly between those organisations that receive no financial support and others who rely upon it heavily. Specifically, this study has identified the confusion surrounding the term "financial contribution".

There is an absence of a uniform and detailed financial reporting system applied to civil society groups active in European pharmaceutical policy making. A stronger drive towards the harmonisation of financial disclosure criteria not only at the EMA, but also within the European Commission and across EU agencies is needed. A clear definition and uniform

[5] This estimate is based on relevant but incomplete financial information from the organisation's home website and donor company websites.

reporting format are essential to achieve complete disclosure and to support conflict of interest assessment.

The focus of this study is the issue of corporate sponsorship in relation to patient and consumer organisations active at the EMA. However, these organisations represent only a selection of non-governmental organisations (NGOs) and other stakeholders active in the area of health and pharmaceutical policy in Europe. Thus, further research is called for on financial transparency, and the nature of corporate sponsorship and conflicts of interests of civil society representatives in European health policy making.

Recommendations

Several recommendations for concerned stakeholders arise from the conclusions of this study.

Recommendations for the European Medicines Agency

- Enforce the precise reporting format outlined in the existing financial transparency criteria.
- Strengthen the financial transparency criteria by establishing a clear definition of “financial contributions” that includes honorariums, travel fees and other forms of sponsorship to support full disclosure and complete reporting.
- Establish fixed deadlines for the submission of financial disclosure reports to the EMA (i.e. annually).
- Be responsible to set up and execute 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 criteria, with particular regard to financial transparency.

Recommendations for patient and consumer organisations

- Include references to the organisation’s funding policy in financial reports, to enable third parties to clarify quickly and easily whether organisations accept corporate contributions or not, and if so for what purposes.
- Move towards full disclosure of all financial contributions, including honorariums and travel fees, in order to prevent discrepancies between the organisation’s annual reports and the sponsor’s declarations.

- Post regular and easily accessible financial reports on the organisation's website and other relevant registers, such as the European Commission's lobby register, particularly for groups involved as a stakeholder in European health platforms.

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Dr. Andrew Herxheimer from the Cochrane Collaboration and Dr. Graham Dukes from the University of Oslo peer reviewed and endorsed the final article.

Declaration of interests

HAI Europe has been a member of the European Public Health Alliance since 2002. The Insulin Dependent Diabetes Trust has been a member of HAI Europe since September 2005. Both organisations were included the sample studied in this article.

HAI Europe has a strict organisational policy not to accept funds or support from the pharmaceutical industry or any other commercial interest that could impact on HAI's work.

HAI Europe is funded through fees from its members and the HAI Global Secretariat, which receives grants from national governments and non-governmental international organisations. Apart from membership fees and HAI Global's contributions, HAI Europe received an operating grant from the Executive Agency for Health and Consumers in 2009. A complete list of donors and their contributions is publicly available at http://www.haiweb.org/donors/donors.pdf.

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