



# The patient & consumer voice and pharmaceutical industry sponsorship

S. Katrina Perehudoff & Teresa Leonardo Alves

<sup>1</sup>Health Action International (HAI) Europe

<sup>§</sup>Corresponding author

Email addresses: [Katrina@haieurope.org](mailto:Katrina@haieurope.org)

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S. Katrina Perehudoff<sup>1§</sup> Teresa Leonardo Alves<sup>1</sup>



# Abstract

Given the ever expanding role of civil society groups in advocating for changes in health policy, the aim of this study was to explore whether there exists any association between patient and consumer organisations' financial sponsorship from the pharmaceutical industry and their positions on the European Commission's legislative proposal on *Information to patients*. This research specifically surveyed organisations' opinions on four aspects of this legislative proposal: the type of medicines information that citizens need; the role of the pharmaceutical industry as an information provider; the regulation of information generated by the industry; the channels through which this information should be provided. Policy positions were elicited through a self-administered, structured questionnaire sent to 22 European patient and consumer organisations (response rate 55%, n=12) in 2009 and through an analysis of their policy documents published after 2006 (n=14). Two external research assistants analysed the blinded policy documents using a separate survey tool. Financial data was retrieved for sponsorship received in 2008 from public sources, the websites of sponsoring companies and through direct request. The questionnaire responses demonstrated that most organisations (n=10) agreed that there is a need for better access to independent and comparative information, and that information generated by the pharmaceutical industry should be approved by drug regulatory authorities before publication. An association was observed between receiving sponsorship and support for an expanded role of the pharmaceutical industry as an information provider about its pharmaceuticals. Organisations that received sponsorship also supported new modes of communicating that could be opened up by the *Information to patients* legislative proposal, specifically information provided through brochures and leaflets, over the internet and on CD-ROMs. Findings from the analysis of policy documents mirrored the opinions expressed in the questionnaire about the type of information that citizens need and the role of the industry as an information provider. However, the level of technical detail in the policy documents did not yield sufficient data to draw strong conclusions about organisations' opinions on the regulation of this information and appropriate dissemination channels. This study suggests that corporate sponsorship may be associated with civil society perspectives on specific policy debates. The formation of pharmaceutical policy at the EU level relies on a multi-stakeholder approach where each stakeholder group is given an opportunity to express their unique perspective. These findings suggest that a financial relationship between commercial and civil society groups could jeopardise the uniqueness of the patient and consumer perspective and threaten the integrity of the multi-stakeholder format and the policy formulation process. It is imperative to maintain the distinct view of each stakeholder in order to make balanced decisions about pharmaceutical regulation and health policy.



# Introduction

Patient and consumer organisations are non-profit entities that represent the views and interests of their respective constituents, and/or founding principles. As a result of their role as public interest representatives, these organisations are perceived as a reliable conduit for communicating citizen's needs. They play an important role in directing public attention to social problems,<sup>i</sup> and increasingly, patient and consumer organisations are expanding their roles to include advocating for changes in health policy. This evolution is born out of the shift away from a top-down model of health care towards more patient-centred care, where the end users are involved in decisions that affect their health. This trend of including health service users in health policy decision-making is part of the shift from government to governance.<sup>ii</sup> In response, political and regulatory bodies have established consultation mechanisms to involve citizens in the decision-making process.

As with most civil society organisations, patient and consumer groups are engaged in securing sustainable funding in order to support their work. As such they might naturally seek or be offered funding by pharmaceutical companies, related industries and their trade associations<sup>iii</sup> who have the resources to give supplemental or substantial income to groups that need funds. Under these conditions, a conflict of interest can arise between the public advocate's primary interest, representing the interests of patients and consumers, and a secondary interest, such as securing and maintaining financial sponsorship from companies selling medical products.<sup>iv</sup> Studies have indicated that greater involvement in these types of partnership can result in non-profit groups having difficulties in preserving their primary and original mission while at the same time satisfying the requirements of corporate donors.<sup>v</sup> As a result the credibility of advocacy organisations sponsored by the pharmaceutical industry has been called into question, for example as was the case with Europa Donna.<sup>vi</sup> It has been suggested that the potential influence of these donors could compromise the independence of civil society's role as citizen advocates and public interest guardians.<sup>vii</sup>

In December 2008, the European Commission published three legislative proposals concerning pharmacovigilance, counterfeit medicines and information to patients, which are known together as the Pharmaceutical Package. Current EU legislation prohibits direct-to-consumer advertising of prescription-only medicines. However, the *Information to Patients Directive and Regulation*<sup>viii</sup> could expand the role of the pharmaceutical industry to provide information on prescription medicines directly to patients, beyond the patient information leaflet that is currently distributed with each package. The *Information to Patients Directive and Regulation* therefore raises the contentious debate about the role of the pharmaceutical industry as a provider of information about its products. Throughout this debate, patient and

consumer groups have played a privileged political role as stakeholders entrusted with articulating the needs of EU citizens. Patient and consumer organisations have expressed varied opinions about this proposal. Some seek direct access to information from the pharmaceutical industry, particularly concerning diseases with limited treatment options.<sup>ix</sup> Other groups caution against expanding direct communication between companies and patients, which could open the door to the dissemination of unbalanced information and could lead to the promotion of medicinal products to a wider population of consumers.<sup>x</sup>

Taking the European Commission's legislative proposal on *Information to Patients* as a starting point, this research explores whether there exists any association between patient and consumer organisations' financial sponsorship from the pharmaceutical industry and their positions in this health policy debate, specifically about:

1. The type of medicines information that citizens need;
2. The role of the pharmaceutical industry as an information provider;
3. The regulation of information generated by pharmaceutical companies;
4. The channels through which information generated by the pharmaceutical industry should be provided.

The contrasting opinion of public interest groups combined with the pharmaceutical industry's clear interest in communicating directly with patients, make this a useful topic to explore stakeholder positions on legislative proposals concerning pharmaceuticals. The conclusions of this research could offer policy makers insight into the relationship between corporate funding sources and the political agenda of public advocates.<sup>xi</sup>

# Methods

## Sample

A sample group of 23 patient and consumer organisations (hereafter called *organisations*) were selected for their eligibility to work with the European Medicines Agency (EMA) as of 1 August 2009.<sup>xii</sup> These were identified from the list available at <http://www.ema.europa.eu/Patients/organisations.htm>.<sup>1</sup> Given their mandate as patient and consumer representatives at the EMA, particularly in matters of product information, transparency and the dissemination of information, these organisations were considered to be active advocates holding informed positions on the *Information to Patients Directive and Regulation*. HAI Europe was one of the 23 eligible organisations but has been excluded from the study, leaving a sample of 22 organisations.

## Financial data sources

The organisations' financial data was retrieved from public sources, including their websites, the websites of sponsoring companies and through direct request. The corporate sponsorship received by each organisation in 2008 was employed in this study. The data retrieval and calculation method, as well as the amounts themselves, have been previously described in HAI Europe's research article on financial disclosure and transparency.<sup>xiii</sup>

## Questionnaire

### Questionnaire structure

Policy perspectives on the *Information to Patients Directive and Regulation* were elicited through a self-administered, structured questionnaire based on the three legislative proposals in the Pharmaceutical Package. Only responses to the 10 statements about the *Information to Patients Directive and Regulation* are addressed in this paper (Table 1). The statements reflected the four research questions that represent ideas that have arisen from the political debate surrounding this issue:

1. The type of medicines information that citizens need;
2. The role of the pharmaceutical industry as an information provider;
3. The regulation of information generated by the pharmaceutical industry; and

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<sup>1</sup> Since the time of study, more organisations have become eligible to work with the EMA and they are named on the Agency's website. Not all of these organisations were included in this study.

4. The channels through which this information should be provided.

The purpose of each statement was to ascertain the organisations' positions in relation to these policy proposals. Responses were provided on a five-point Likert Scale (from *strongly support* to *strongly oppose*) with the option to select *don't know* and to provide additional comments to each statement.

Prior to dissemination, the content of the four-page questionnaire was reviewed by a voluntary advisory committee of academics from HAI Europe's membership<sup>2</sup> to ensure its clarity and objectivity, as well as to minimise misinterpretation.

In September 2009, the selected patient and consumer organisations were made aware of this study by e-mail. In addition, organisations were asked to identify the person from their organisation who was best equipped to fill out the questionnaire. In October 2009, the questionnaire was sent by e-mail to the identified contacts in the 22 organisations who were invited to return their completed questionnaire within two weeks. During this period, two reminders were sent and the deadline for responses was subsequently extended by five weeks to enhance participation.<sup>3</sup> Responses were voluntary and confidential. Reference numbers were used to blind the researcher during analysis and to maintain the anonymity of respondents. For that reason, individual respondents have not been identified in the *Results* section.

After receiving the completed questionnaires, the responses were coded on the Likert scale, data was entered into MS Excel and analysed in light of the corporate sponsorship received by each organisation in 2008. Responses to each statement were analysed independently. The data was examined to identify common points of view and associations between opinions on the four research questions and sponsorship. All additional comments made by respondents are provided as illustrative quotes in the *Results* section.

## Policy document analysis

In addition to the above method, two external research assistants were commissioned to analyse policy documents using a separate survey tool created to ascertain the organisations' opinions vis-à-vis the four aspects of the proposal stated earlier.

The survey tool was created using the grounded theory approach. Using two blinded policy documents from organisations outside of the sample, the four research questions in the

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<sup>2</sup> The names and affiliations of this advisory committee are available in the *Acknowledgements* section.

<sup>3</sup> The second period to respond ran from 12 December 2009 until 15 January 2010, which was considered to be three working weeks and two weeks of vacation.

survey tool were refined into clear, relevant statements. The 27 statements in the survey tool were born out of this process (Table 2). The survey tool was reviewed by a voluntary advisory committee of academics from HAI Europe's membership<sup>2</sup> to ensure clarity and completeness.

Data sources included any policy papers on medicines information published on the organisations' websites<sup>xiv</sup> after 2006 and organisations' responses to the DG Enterprise and Industry open consultation on the *Information to Patients* legislative proposal published on the Pharmaceuticals website in 2008.<sup>xv</sup> Only documents self-published by the organisations were included; joint statements co-published with other organisations were excluded. These criteria yielded one document for each of 12 organisations and two documents for each of two organisations.

Relevant phrases were identified and assigned to the most suited statement in the survey. Each research assistant independently recorded one of four possible responses to each statement (*agree, disagree, ambiguous, not stated*). When a phrase expressed an unclear opinion about a statement in the survey, then *ambiguous* was recorded. If the statement was not addressed in the policy document, *not stated* was recorded. The two research assistants then compared their responses to one another and discussed any discrepancies until a mutual response was reached.

# Results

## Questionnaire analysis

The questionnaire response rate was 55% (n=12). One of the respondents was excluded from the analysis due to unavailable financial data. Eighteen percent of the organisations approached (n=4) declined the invitation to participate, stating various reasons recorded in the *Discussion* section. An additional 27% (n=6) of the groups did not respond to the invitation.

Table 3 summarises the responses given to each statement in the questionnaire by the participating organisations.

### **The type of medicines information that citizens need**

All organisations that expressed an opinion (n=10) agreed that there is a need for better access to independent sources of information and to documents that compare medicines in terms of effectiveness, safety and cost. One patient organisation highlighted that “*many countries already have excellent sources of INDEPENDENT information which could be used [respondent emphasis].*”<sup>4</sup> Another organisation identified the need for information to be patient-centred and said: “*Treatment is often 'tailor made'. Patients are not always in a position to compare medicines in their personal situation. What is the best medicine for one person is not the best for another patient.*”<sup>4</sup>

Two respondents<sup>4,5</sup> indicated their interest in having access to information about ongoing clinical trials, such as the information provided in the US register [www.clinicaltrials.gov](http://www.clinicaltrials.gov) which is independent of the pharmaceutical industry.

### **The role of the pharmaceutical industry as an information provider**

All organisations that did not receive sponsorship (n=5) opposed a change to the legislation that currently limits the role of pharmaceutical companies as providers of information about the products they sell. An association was observed between supporting an expanded role of the pharmaceutical industry as an information provider and receiving corporate sponsorship (See Figure 1).

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<sup>4</sup> This organisation did not receive corporate sponsorship.

<sup>5</sup> This organisation did receive corporate sponsorship.

One organisation stated: *“In our opinion, information about medicines should be provided by a neutral organisation such as EMA (previously EMEA) in order to avoid a promotional aspect in the information process. Some individual patients can be quite vulnerable and easily influenced because of their disease. Any information should be disconnected from commercial aspects.”*<sup>4</sup> A second organisation commented that, *“Patients require unbiased and independent information to inform their choices. It is naive to believe that information from pharmaceutical companies can or will provide unbiased and independent information.”*<sup>4</sup>

### **The regulation of information generated by pharmaceutical companies**

Ten organisations supported the approval of information from the pharmaceutical industry by drug regulatory authorities (DRA) prior to publication and one organisation had no opinion. One patient organisation suggested that the production and public dissemination of brochures, leaflets and CD-ROMS by the pharmaceutical industry would be permissible *“only if the information was to be reviewed by a neutral body.”*<sup>4</sup>

Respondents raised concerns about if DRA would be appropriate information gatekeepers, questioning the DRA’s independence from the pharmaceutical industry, their efficiency and timeliness in reviewing and approving information, and their resource capacity to take on this additional role. To illustrate these concerns, one patient organisation said: *“There must be approval by a body that is independent of the pharmaceutical industry. This may or may not be drug regulatory authorities but if this is the only option for regulation, it is better than self-regulation of the industry.”*<sup>4</sup> In contrast, another patient organisation stated that *“Self-regulatory mechanisms based on a clear and transparent ruleset [sic], and clear transparency on the source with sanctions for bad practice might be equally effective but less bureaucratic and expensive. Approval by authorities might unduly delay information, e.g. about clinical trials (if we are not talking only about prescription medicines here, but also experimental therapies in trials).”*<sup>5</sup>

### **The channels through which information generated by the pharmaceutical industry should be provided**

Organisations that did not receive sponsorship from the pharmaceutical industry in 2008 tended to oppose all channels of information dissemination by the pharmaceutical industry proposed in the questionnaire. One organisation stated that all of these modes of communication represent *“advertising under the guise of information.”*<sup>4</sup> An association was observed between receiving sponsorship and support for dissemination channels that could be opened up by the *Information to Patients Directive and Regulation*, including information provided by brochures and leaflets, over the internet and on CD-ROMs (See Figures 2, 3 and 4). There was no association between receiving sponsorship and organisations’ support for

information disseminated through broadcast media and newspapers, or for disease awareness campaigns in which prescription medicines are mentioned directly or indirectly.

Information provided through broadcast media, including the radio, television and print publications, such as newspaper supplements, is generally referred to as “push” information that is unsolicited by consumers and audiences. One organisation noted that the dissemination of medicines information via broadcast media “*amounts to advertising and is unlikely to give sufficient time to provide information about adverse effects and what to do about them.*”<sup>4</sup> On the other hand, information provided by brochures and leaflets, over the internet and on CD-ROMs is all sought voluntarily by consumers, and are generally known as “pull” information. A second organisation stated “*The company website should be open also for patients - but avoiding contacting patients directly.*”<sup>5,6</sup> Another organisation in favour of “pull” information on the internet clarified that companies should provide “*information on request on websites, but NOT push information (e.g. SMS, unsolicited e-mail without prior request)* [respondent emphasis].”<sup>5</sup>

Five organisations were in favour of companies communicating information about their products via CD-ROM. One organisation supported the use of CD-ROMs on the condition that “*it is basic information and not promoting only one drug*”<sup>5</sup> while a second organisation noted that CD-ROMs play a minor role in communication and will soon become marginalised, however, “*if written information is allowed, more visual/video-based information should be treated equally.*”<sup>5</sup> In relation to information on CD-ROMs, another organisation identified that “*the pharmaceutical industry has an insurmountable conflict of interest when providing any information about their products to the general public.*”<sup>4</sup>

The role of patient and consumer organisations as information providers was raised in the open comments section of the questionnaire. One organisation stated “*It would be better if patient organisations would develop and produce leaflets/brochures with clear and honest information together with physicians.*”<sup>5</sup> The respondent added that this would result in scientifically based but easy to understand information. The same organisation supported the idea of pharmaceutical companies producing and disseminating CD-ROMs because “*patient organisations can't afford the costs to produce them [on] their own.*” Another respondent group stated that information should not be provided directly over the internet to patients. Instead, information could be provided to “*patient support organisations (discussed with a medical advisory board).*”<sup>5</sup>

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<sup>6</sup> Statement refers to certain pages of company websites that are only accessible to healthcare professionals.

One organisation considered disease awareness campaigns to be “push” information and clarified that *“products should not be mentioned”* in these campaigns.<sup>5</sup> On the other hand, another organisation felt that products should be directly referred to in disease awareness campaigns *“only if this is done in an objective way and all available medicines are also mentioned, including those of competitors.”*<sup>4</sup>

## **Policy document analysis**

Policy documents from 14 organisations were included in the analysis. The number of organisations whose policy documents were in favour of, spoke out against, expressed an ambiguous opinion on or refrained from commenting on each survey statement is identified in Tables 4, 5, 6 and 7.

### **The type of medicines information that citizens need**

This portion of the study revealed that most organisations agreed that people need objective, comparative and non-promotional information about medicines (See Table 4). One third of the organisations (n=5) agreed that people need to have access to information on prescription medicines from a variety of sources, including the pharmaceutical industry, while another third (n=4) disagreed. The policy documents of the remaining organisations gave ambiguous opinions (n=3) or their opinions were absent (n=2).

### **The role of the pharmaceutical industry as an information provider**

On statements regarding the appropriateness of companies as information sources, the majority of opinionated organisations were opposed to the pharmaceutical industry as a suitable provider of objective (n=6) or comparative (n=5) information (See Table 5). Three organisations agreed that pharmaceutical companies are appropriate providers of non-promotional information on prescription medicines. Five groups disagreed with this statement and the remainder (n=6) did not address this issue in their policy document.

Most organisations (n=12) agreed that the EU ban on advertising prescription medicines directly to the public should be maintained. Two organisations refrained from commenting on this subject. Moreover, five organisations receiving sponsorship agreed that EU legislation should be changed so that pharmaceutical companies can provide “pull” or solicited information about prescription medicines directly to the public; one organisation disagreed and the remainder did not state their opinion (n=3). Most organisations not receiving sponsorship (n=3) opposed loosening the legislative controls to allow “pull” information and the remainder expressed ambiguous opinions (n=2).

## **The regulation of information generated by pharmaceutical companies**

No clear trends were identified on the issue of regulating information generated by the pharmaceutical industry (See Table 6). Three organisations agreed that a distinction can be made between information and advertising, two organisations disagreed and the remainder expressed ambiguous opinions (n=2) or refrained from commenting (n=7). Four organisations felt that the *Information to patients* legislative proposal does not make an adequate distinction between information and advertising. The remaining groups expressed ambiguous opinions (n=6) or refrained from commenting (n=4). All opinionated organisations (n=5) agreed that information should be approved by a government regulatory body. Moreover, nearly half of the organisations (n=6) did not support information approval by industry through a self-regulatory code or a co-regulatory body. Four organisations felt that the content of any additional information provided by the industry should be approved before publication, while the remaining groups expressed ambiguous opinions (n=5) or refrained from comment (n=5). Similarly, one organisation favoured post-publication approval, three organisations disagreed with this method of regulation and the remaining groups expressed ambiguous opinions (n=5) or refrained from commenting (n=5).

## **The channels through which information generated by the pharmaceutical industry should be provided**

Most organisations disagreed with allowing pharmaceutical companies to communicate information through television, radio and written media (See Table 7). Four organisations agreed that pharmaceutical companies should be allowed to disseminate information about prescription medicines to patient organisations while three organisations had ambiguous opinions and seven organisations refrained from commenting on this issue. Additionally, four organisations agreed that pharmaceutical companies should be allowed to provide information over the internet, while another four organisations disagreed and the remainder expressed ambiguous opinions (n=1) or refrained from commenting (n=5). Most organisations were ambivalent about, or refrained from comment on brochures, leaflets, CD-ROMs and disease awareness campaigns that directly or indirectly mention prescription medicines.

# Discussion

All patient and consumer organisations included in this sample agree that there is a need for better access to independent and comparative information. An association was observed between receiving corporate sponsorship and supporting an expanded role for the pharmaceutical industry as an information provider about its pharmaceuticals as proposed in the *Information to Patients Directive & Regulation*. Most organisations supported the pre-release approval of information generated by the pharmaceutical industry. An association was observed between the receipt of corporate sponsorship and support for dissemination channels that could be opened up by this legislative proposal, specifically information provided by brochures and leaflets, over the internet and on CD-ROMs.

The policy document analysis revealed that most organisations agree that people need objective, comparative and non-promotional information. The majority supported the EU ban on advertising prescription medicines and objected to changing the legislation to allow unsolicited or “push” information. Organisations receiving sponsorship supported a legislative change to permit solicited or “pull” information, however, those not receiving sponsorship opposed this change. The level of technical detail in the sample documents did not yield sufficient data to draw strong conclusions about organisations’ opinions on the regulation of information generated by the pharmaceutical industry and appropriate dissemination channels. Instead, these documents reflected general opinions on the issue of medicines information rather than specific considerations on the content of the legislative proposal.

Previous studies have concluded that the transparency surrounding funding relationships could be enhanced, however, no investigation has related this financial support to organisations’ policy perspectives and advocacy activities in the field of pharmaceuticals.<sup>xvi,xvii</sup> Building on existing knowledge, the present study has generated empirical evidence that suggests there is an association between receiving corporate sponsorship and an organisation’s support for an expanded role for the pharmaceutical industry as a provider of information about its products. This suggests that corporate sponsorship may be associated with those organisations’ perspectives on specific policy debates.

## Can industry sponsorship lead to corporate capture?

Patient organisations represent their constituents through a variety of approaches. Groups mobilised around conditions that lack adequate medical treatments are often heavily involved in policy debates around the efficiency, appropriateness and priorities of research & development (R&D), as well as in consultation with medicines manufacturers to inform the development of potential therapies that can fulfil their unmet medical needs. Organisations representing patients with preventable chronic illnesses tend to emphasize the need for broad health promotion rather than rely solely on medical technologies once they are unwell. For these reasons, patient organisations have a wide range of legitimate interests in health and social policies that impact on members whose interests they represent. Select patient group interests may overlap with those of the pharmaceutical industry, albeit for different underlying reasons.<sup>xviii</sup>

Patients or their representatives often manifest an interest in or initiate a campaign around a particular treatment with the potential to improve their health. Subsequently, pharmaceutical companies may offer these patients support or sponsorship in situations where their interests in the promise of a new treatment mirror industry motivations to increase its market share, as seen in the case of patients with breast cancer seeking the reimbursement of Herceptin in the UK.<sup>xix</sup> Alternatively, the industry may have a relationship with a patient organisation from the outset and play an integral role in the initial foundation of an advocacy organisation, such as the recent establishment of several prominent patient federations by one or more pharmaceutical companies.<sup>xx</sup> As with all founders, there is the potential for their influence over the organisations' missions and activities. Numerous cases have fuelled speculation about whether corporate sponsorship causes patient organisations to purport pro-industry messages or to advocate for industry-friendly policies.<sup>xxi,xxii</sup> However, no empirical evidence has demonstrated the existence of a causal relationship between receiving sponsorship and advocacy groups' public messages or political objectives.

The research presented here demonstrates a link between sponsorship of patient organisations by the pharmaceutical industry and their position a legislative proposal on which some argue will favour the interests of the pharmaceutical industry over the interest of public health.<sup>7xxiii</sup> It is not clear if those groups whose message is coincidental with that of the pharmaceutical industry do so as a result of receiving funding or whether those who receive sponsorship had a pre-existing perspective coinciding with that of their donor.

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<sup>7</sup> In her presentation at the European Parliament in 2009, Dr. Mintzes presented evidence that corroborates the pharmaceutical industry's vested interest in communicating directly with patients about its products. She demonstrates, however, that there is no evidence that direct or disguised advertising improves health or quality of care, based on data from countries where the pharmaceutical industry is legally entitled to generate information or engage in direct-to-consumer advertising.

## The citizen voice in the EU's multi-stakeholder platforms

The European Commission, the executive body of the European Union, adopts a multi-stakeholder approach<sup>xxiv</sup> in which interested parties, each representing a unique perspective, are consulted on legislative proposals. The formation of pharmaceutical policy<sup>8</sup> at the EU level also relies on the multi-stakeholder approach that includes diverse scientific, social and political actors. Pharmaceutical companies develop, manufacture and supply medicines. Regulators control for medicine safety, quality and efficacy and determine what is and is not authorised for use by patients and available on the market. Be they governments or insurers, those who pay for medicines play a role in medicines availability and affordability. Health care professionals bring their expertise and experience in the oversight of medicines use by the wider population. Patients and consumers are pivotal players, wielding knowledge and understanding about themselves, their conditions and the medicines they take.

This format is adopted to ensure that each stakeholder group is given an opportunity to express their perspective. Given the Commission's size, finite expertise and limited resources, stakeholder involvement is deemed to be essential to formulating technically sound and practicable policy proposals.<sup>xxv</sup> This research has, however, demonstrated that receiving corporate sponsorship could be associated with patient and consumer organisations' perspectives on specific policy debates. A financial relationship between commercial and civil society groups could jeopardize the uniqueness of the patient and consumer perspective and threaten the integrity of the multi-stakeholder format and the policy formulation process.

### Limitations

This particular study on the *Information to Patients Directive and Regulation* required respondent organisations operating at the European level with knowledge and expertise in pharmaceutical policy. In order to meet these needs, patient and consumer organisations working with the EMA were selected as the study group. The relatively few respondents, coupled with the specificity of this study, limit the generalisation of the results to other policy areas.

A selection bias was observed in the 55% questionnaire response rate. The four organisations that declined the invitation to participate received between 36-89% of their

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<sup>8</sup> Recently transferred from the competence of the Directorate General for Enterprise and Industry to the DG for Health and Consumer Protection (SANCO)

annual income from the pharmaceutical industry.<sup>xxvi</sup> Their reasons for not participating were voluntarily communicated and they included:<sup>9</sup>

- Concerns about HAI Europe’s position as coordinator of this research and member of the Patients’ and Consumers’ Working Party at the European Medicines Agency
- Concerns about HAI Europe’s “single” funding source [an operating grant in 2009 from Executive Agency for Health & Consumers that implements the EU health programme]
- Concerns about HAI Europe’s previously stated position on civil society organisations financed by the pharmaceutical industry
- Belief that the research would not be able to draw meaningful conclusions from the self-administered questionnaire
- Limited staff time to complete the questionnaire

One invited respondent noted that “*the questions raised are interesting and legitimate as such*” while a second indicated “*I have discussed this proposal with the [name of organisation] executive, and they would like to suggest that such a survey be undertaken by a neutral body, such as the EMEA itself*”. Though declining to participate, the responses of these two organisations suggest that they deemed this exploratory study to be of value to the wider debate about corporate sponsorship of patient and consumer organisations.

### **I. Limitations of the financial assessment**

In the absence of a uniform way of organisations reporting their funding sources and disseminating this information, we developed a methodological tool<sup>10</sup> to generate the sponsorship amounts for two organisations in this study. As a result, the data may not represent the exact levels of sponsorship for two organisations in this study. In general, estimations based on information from organisations and company websites were below the actual value of contributions when compared to the financial data that individual organisations provided on request.

### **II. Limitations of the questionnaire approach**

In this study, a questionnaire was used as one method of ascertaining an organisation’s policy position. Each respondent organisation was responsible for deciding how the questionnaire would be answered. Some organisations direct these types of policy enquiries to the internal EU policy expert, while others formulate their responses to the questionnaire in

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<sup>9</sup> Summarised by author in order to maintain the anonymity of the sources.

<sup>10</sup> Described and executed in HAI Europe’s research article “Patient & consumer organisations at the European Medicines Agency: Financial disclosure & transparency” (2010) Available to download at [www.haieurope.org](http://www.haieurope.org)

consultation with their board of directors and/or their members. Because internal response mechanisms differ between organisations, it is likely that all self-administered questionnaires were not completed using the same strategies. In order to minimise this variation, the authors informed each organisation about the nature of the questionnaire and asked that it be directed to the most appropriate person in the organisation.

### **III. Limitations of policy document analysis**

Policy documents express organisations' broad opinions about a political issue. Although every effort was made to include the relevant policy documents, not all survey statements were addressed in each document. Due to this lack of technical detail, valid conclusions could not be drawn for the three research questions concerning the pharmaceutical industry's role in information provision, the regulation of such information and the appropriate dissemination channels.

## **Future research**

The results of the study suggest that in the case of the *Information to Patients Directive & Regulation*, the policy perspectives of organisations that operate independently of corporate sponsorship are generally opposed to the pharmaceutical industry providing information about its products directly to patients. The authors call for additional studies to further explore this association between the receipt of corporate sponsorship and organisations' perspectives on other health policies, and to ascertain if these results can be extrapolated to a wider population of patient and consumer organisations.

Other variables may inform organisations' policy positions, such as the type of condition the organisation represents. Patients with diseases for which few treatments exist have different needs than patients with more common chronic conditions. Therefore, it would not be surprising if organisations representing these two distinct groups of patients might have differing perspectives on certain policy proposals. The authors recommend that a larger study is executed which considers if there is a relationship between organisations' perspectives on certain policies and the kind of condition or health issue around which they are mobilised.

# Conclusion

A relationship was found between the receipt of corporate sponsorship from the pharmaceutical industry and support given by sponsored patient and consumer groups for an expanded role for the industry as an information provider. This suggests that such sponsorship could be associated with greater difficulty in impartially representing the views of patients, consumers or citizens. Overall, a financial relationship between commercial and civil society groups could threaten the uniqueness of the citizen perspective in the policy process. It is imperative to maintain the distinct view of each stakeholder in order to make balanced decisions about medicines regulation.

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## Declaration of interests

HAI Europe has been a member of the European Public Health Alliance (EPHA) since 2002. The Insulin Dependent Diabetes Trust (IDDT) has been a member of HAI Europe since September 2005. Both EPHA and IDDT 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, regional organisations, 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, which partially supported the execution of this research. A complete list of donors and their contributions is publicly available at <http://www.haiweb.org/donors/donors.pdf>.

**Table 1 – Questionnaire statements about the Information to Patients Directive & Regulation**

<b>Information to Patients Directive and Regulation</b>
<p><b>The type of medicines information that citizens need</b></p> <ol style="list-style-type: none"> <li>1. There is a need to facilitate better consumer access to independent sources of information about medicines in the European Union (i.e. sources with no connection to the pharmaceutical or medical device industry).</li> <li>2. Within the European Union, there is a need for better access to information that compares medicines with one another in terms of effectiveness, safety and cost.</li> </ol>
<p><b>The role of the pharmaceutical industry as an information provider</b></p> <ol style="list-style-type: none"> <li>3. European legislation should be changed so that pharmaceutical companies can provide information about prescription medicines directly to patients.</li> </ol>
<p><b>The regulation of information generated by the pharmaceutical industry</b></p> <ol style="list-style-type: none"> <li>4. If pharmaceutical companies are legally entitled to provide additional public information to patients beyond what is currently legally required, then the information should be approved by drug regulatory authorities before its publication.</li> </ol>
<p><b>The channels through which this information should be provided</b></p> <ol style="list-style-type: none"> <li>5. Pharmaceutical companies should be allowed to pay for information about prescription medicines to be disseminated through broadcast media (i.e. television, radio).</li> <li>6. Pharmaceutical companies should be allowed to inform patients about their prescription medicines through newspaper supplements.</li> <li>7. Pharmaceutical companies should be allowed to produce and publicly disseminate brochures and leaflets about their prescription medicines, in addition to those accompanying prescription medicines at the point of distribution.</li> <li>8. Pharmaceutical companies should be allowed to provide information on prescription medicines to patients or the public over the internet or other new technologies (e.g. SMS).</li> <li>9. Pharmaceutical companies should be allowed to provide the public with information about diseases and their treatments on CD-ROMs.</li> <li>10. Pharmaceutical companies should be allowed to mention prescription medicines directly (i.e. by referring to a specific brand) or indirectly (i.e. by announcing “if you have this disease, there is a product available to help you”) in disease awareness campaigns.</li> </ol>

**Table 2 – Survey statements about the Information to Patients Directive & Regulation**

<b>Information to Patients Directive and Regulation</b>
<p><b>The type of medicines information that citizens need</b></p> <p>People need...</p> <ul style="list-style-type: none"> <li>... objective information on prescription medicines.</li> <li>... comparative information on prescription medicines.</li> <li>... non-promotional information on prescription medicines.</li> <li>... information on prescription medicines from a variety of sources, including the pharmaceutical industry.</li> </ul>
<p><b>The role of the pharmaceutical industry as an information provider</b></p> <p>Pharmaceutical companies are appropriate providers of...</p> <ul style="list-style-type: none"> <li>... objective information on prescription medicines.</li> <li>... comparative information on prescription medicines.</li> <li>... non-promotional information on prescription medicines.</li> </ul> <p>The EU ban on advertising prescription medicines directly to the public (called direct-to-consumer advertising or DTCA) should be maintained.</p> <p>European legislation should be changed so that pharmaceutical companies can provide unsolicited or pro-active information (i.e. “push” information) about prescription medicines directly to the public.</p> <p>European legislation should be changed so that pharmaceutical companies can provide “pull” information about prescription medicines directly to the public.</p>
<p><b>The regulation of information generated by the pharmaceutical industry</b></p> <p>If pharmaceutical companies are legally entitled to provide additional information to the public, the content should be...</p> <ul style="list-style-type: none"> <li>... approved by a government regulatory body.</li> <li>... governed by a self-regulatory code body.</li> <li>... governed by a co-regulatory body, including government and industry.</li> <li>... approved before publication.</li> <li>... approved after publication.</li> </ul>
<p><b>The channels through which this information should be provided</b></p> <p>Pharmaceutical companies should be allowed...</p>

... to disseminate information about prescription medicines through television.

... to disseminate information about prescription medicines through radio.

... to disseminate information about prescription medicines through written media.

... to disseminate brochures and leaflets about prescription medicines, other than the Package Leaflet that accompanies prescription medicines.

... to provide information about prescription medicines to patient organisations.

... to provide information about prescription medicines over the internet.

... to provide the public with information about prescription medicines on CD-ROMs.

... to mention prescription medicines directly in disease awareness campaigns (i.e. by referring to a specific brand).

... to mention prescription medicines indirectly in disease awareness campaigns (i.e. by announcing "if you have this disease, there is a product available to help you") [no brand mentioned].

**Table 3 – Questionnaire responses [ n=number of organisations (%) ]**

Abbreviated statement		Support	No opinion	Oppose	Don't know	Missing
The type of medicines information that citizens need						
There is a need for independent sources	Received funding	5 (83)				1 (17)
	Did not receive funding	5 (100)				
There is a need for comparative information	Received funding	6 (100)				
	Did not receive funding	4 (80)	1 (20)			
The role of the pharmaceutical industry as an information provider						
Change current legislation	Received funding	6 (100)				
	Did not receive funding			5 (100)		
The regulation of information generated by the pharmaceutical industry						
Pre-release approval	Received funding	5 (83)	1 (17)			
	Did not receive funding	5 (100)				
The channels through which this information should be provided						
Dissemination via broadcast media	Received funding	1 (17)	1 (17)	4 (67)		
	Did not receive funding	1 (20)		4 (80)		
Dissemination via newspaper supplements	Received funding	3 (50)	1 (17)	2 (33)		
	Did not receive funding			5 (100)		
Dissemination via brochures and leaflets	Received funding	4 (67)	1 (17)			1 (17)
	Did not receive funding			5 (100)		
Dissemination via new technologies including SMS and the internet	Received funding	5 (83)			1 (17)	
	Did not receive funding			5 (100)		
Dissemination via CD-ROM	Received funding	4 (67)	1 (17)		1 (17)	
	Did not receive funding	1 (20)		4 (80)		
Dissemination via disease	Received funding	2 (33)	1 (17)	3 (50)		

awareness campaigns	Did not receive funding	1 (20)		4 (80)		
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\*The percentages are rounded to the nearest whole number. As a result, responses to some statements may not total 100%.

Note: The statements are an abbreviated version of those that appeared in the questionnaire.

**Table 4 – Results of policy document analysis showing organisations’ perspectives on citizens’ needs in terms of medicines information \* [ n=number of organisations (%) ]**

Question		Agree	Disagree	Ambiguous**	Not stated
People need objective information on prescription medicines.	Received funding	8 (89)		1 (11)	
	Did not receive funding	5 (100)			
People need comparative information on prescription medicines.	Received funding	6 (67)			3 (33)
	Did not receive funding	4 (80)			1 (20)
People need non-promotional information on prescription medicines.	Received funding	9 (100)			
	Did not receive funding	5 (100)			
People need information on prescription medicines from a variety of sources, including the pharmaceutical industry.	Received funding	4 (44)		3 (33)	2 (22)
	Did not receive funding	1 (20)	4 (80)		

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\* The percentages are rounded to the nearest whole number. Responses to some statements may not total 100% in order to maintain an accurate distribution.

\*\* Ambiguous opinion includes those documents that mentioned the issue or referred to the importance of the question at hand without expressing a clear opinion in favour of or against that aspect of the proposal

**Table 5 – Results of policy document analysis showing organisations’ perspectives on the role of the pharmaceutical industry as an information provider \* [ n=number of organisations (%) ]**

Question		Agree	Disagree	Ambiguous**	Not stated
Pharmaceutical companies are appropriate providers of objective information on prescription medicines.	Received funding	1 (11)	2 (22)	1 (11)	5 (56)
	Did not receive funding		4 (80)		1 (20)
Pharmaceutical companies are appropriate providers of comparative information on prescription medicines.	Received funding		1 (11)	1 (11)	7 (78)
	Did not receive funding		4 (80)		1 (20)
Pharmaceutical companies are appropriate providers of non-promotional information on prescription medicines.	Received funding	2 (22)	1 (11)		6 (67)
	Did not receive funding	1 (20)	4 (80)		
The EU ban on advertising prescription medicines directly to the public (called direct-to-consumer advertising or DTCA) should be maintained.	Received funding	7 (78)			2 (22)
	Did not receive funding	5 (100)			
European legislation should be changed so that pharmaceutical companies can provide unsolicited or pro-active information (i.e. “push” information) about prescription medicines directly to the public.	Received funding		5 (56)	1 (11)	3 (33)
	Did not receive funding		5 (100)		
European legislation should be changed so that pharmaceutical companies can provide “pull” information about prescription medicines directly to the public.	Received funding	5 (56)	1 (11)		3 (33)
	Did not receive funding		3 (60)	2 (40)	

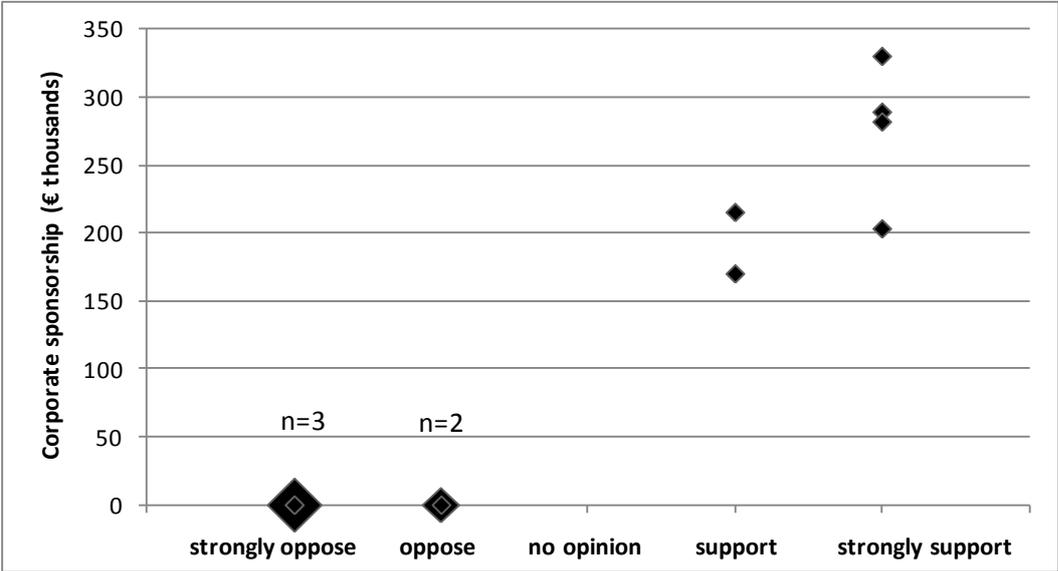
**Table 6 – Results of policy document analysis showing organisations’ perspectives on the regulation of information generated by the pharmaceutical industry \* [ n=number of organisations (%) ]**

Question		Agree	Disagree	Ambiguous **	Not stated
A distinction can be made between information and advertising.	Received funding	2 (22)		1 (11)	6 (67)
	Did not receive funding	1 (20)	2 (40)	1 (20)	1 (20)
The Information to patients proposal makes an adequate distinction between information and advertising.	Received funding		4 (44)	1 (11)	4 (44)
	Did not receive funding			5 (100)	
If pharmaceutical companies are legally entitled to provide additional information to the public, the content should be...					
... approved by a government regulatory body.	Received funding	3 (33)			6 (67)
	Did not receive funding	2 (40)		2 (40)	1 (20)
... governed by a self-regulatory code.	Received funding		2 (22)		7 (78)
	Did not receive funding		4 (80)		1 (20)
... governed by a co-regulatory body, including government and industry.	Received funding	1 (11)	2 (22)		6 (67)
	Did not receive funding		4 (80)		1 (20)
... approved before publication.	Received funding	1 (11)		3 (33)	5 (56)
	Did not receive funding	3 (60)		2 (40)	
... approved after publication.	Received funding		1 (11)	3 (33)	5 (56)
	Did not receive funding	1 (20)	2 (40)	2 (40)	

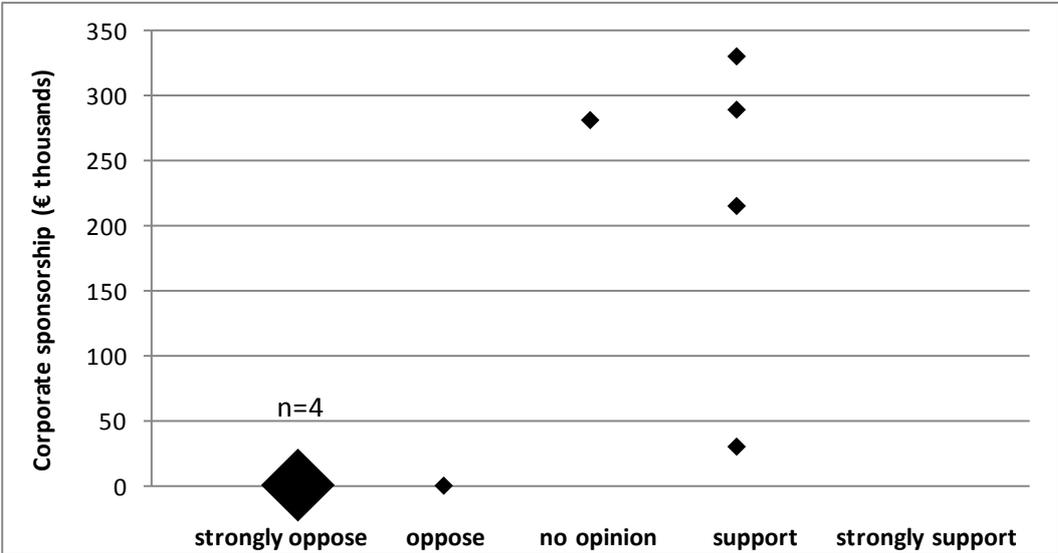
**Table 7 – Results of policy document analysis showing organisations’ perspectives on the channels through which information generated by the pharmaceutical industry should be provided \* [ n=number of organisations (%) ]**

Question		Agree	Disagree	Ambiguous**	Not stated
Pharmaceutical companies should be allowed...					
... to disseminate information about prescription medicines through television.	Received funding	1 (11)	4 (44)	1 (11)	3 (33)
	Did not receive funding		4 (80)		1 (20)
... to disseminate information about prescription medicines through radio.	Received funding	1 (11)	4 (44)	1 (11)	3 (33)
	Did not receive funding		3 (60)		2 (40)
... to disseminate information about prescription medicines through written media.	Received funding	1 (11)	2 (22)	1 (11)	5 (56)
	Did not receive funding		2 (40)		3 (60)
... to disseminate brochures and leaflets about prescription medicines, other than the Package Leaflet that accompanies prescription medicines.	Received funding		1 (11)		8 (89)
	Did not receive funding		2 (40)		3 (60)
... to provide information about prescription medicines to patient organisations.	Received funding	3 (33)		1 (11)	5 (56)
	Did not receive funding	1 (20)		2 (40)	2 (40)
... to provide information about prescription medicines over the internet.	Received funding	3 (33)	1 (11)	1 (11)	4 (44)
	Did not receive funding	1 (20)	3 (60)		1 (20)
... to provide the public with information about prescription medicines on CD-ROMs.	Received funding	1 (11)	1 (11)		7 (78)
	Did not receive funding		1 (20)		4 (80)
... to mention prescription medicines directly in disease awareness campaigns (i.e. by referring to a specific brand).	Received funding		2 (22)		7 (78)
	Did not receive funding		1 (20)		4 (80)
... to mention prescription medicines indirectly in disease awareness campaigns (i.e. by announcing “if you have this disease, there is a product available to help you”) [no brand mentioned].	Received funding		2 (22)		7 (78)
	Did not receive funding		1 (20)	1 (20)	3 (60)

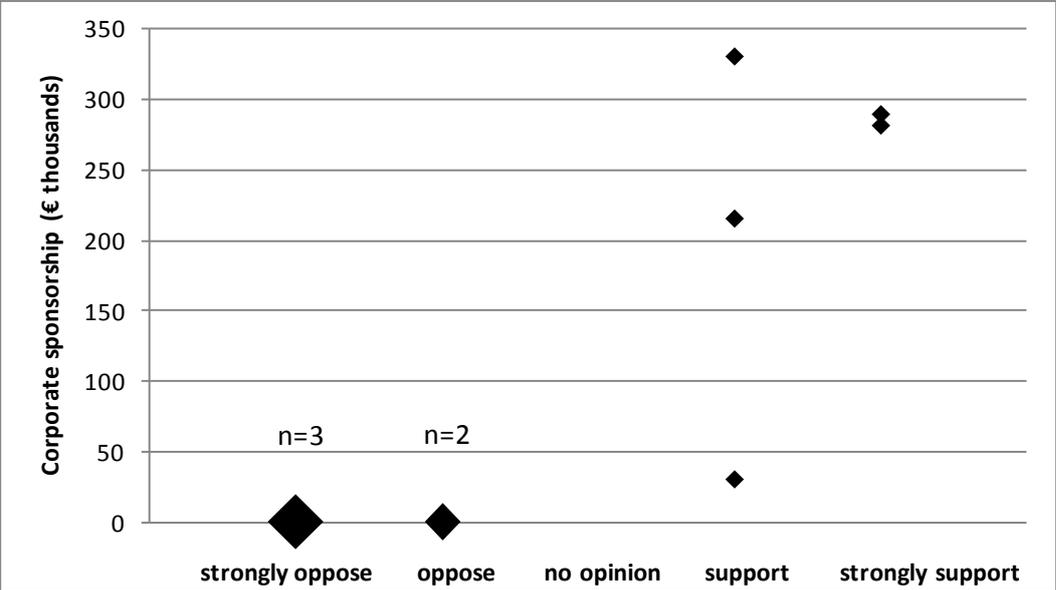
**Figure 1 – Scatter plot of organisations’ level of support for a change in European legislation so that pharmaceutical companies can provide information about prescription medicines directly to patients in relation to the amount of corporate sponsorship received in 2008**



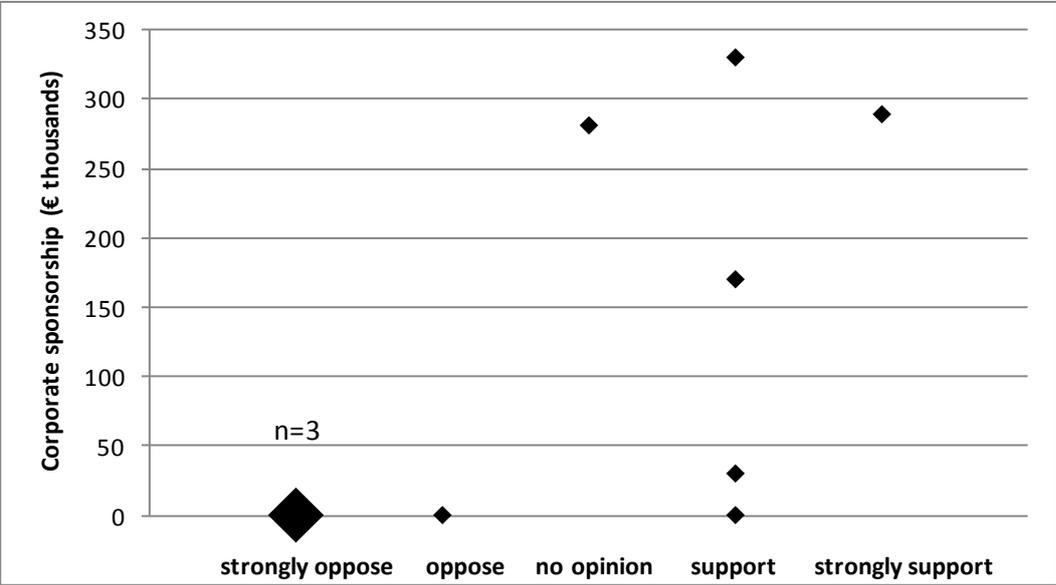
**Figure 2 – Scatter plot of organisations’ support for information dissemination through brochures and leaflets in relation to the amount of corporate sponsorship received in 2008**



**Figure 3 – Scatter plot of organisations’ support for information dissemination through new technologies including SMS and the internet in relation to the amount of corporate sponsorship received in 2008**



**Figure 4 – Scatter plot of organisations’ support for information dissemination on CD-ROMs in relation to the amount of corporate sponsorship received in 2008**



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- <sup>iv</sup> See Eikenberry AM, Kluver JD.
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- <sup>xii</sup> European Medicines Agency 'Working with patients and consumers' webpage, Accessed on 25 June 2010 at <http://www.ema.europa.eu/Patients/organisations.htm>
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- <sup>xiv</sup> List of home websites retrieved at: <http://www.ema.europa.eu/Patients/organisations.htm>
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