



# Patient Organisations & Medicines Policy

Financial engagement with the  
pharmaceutical industry

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# Foreword

Health Action International (HAI) Europe believes that medicines policy should be determined by the needs of patients and consumers, and the overarching considerations of public health and safety. Patients are particularly affected by medicines policy and so their representatives, in the form of patient organisations, can play a valuable role in voicing the patient experience in health-related policymaking. However, consumers are also affected by medicines policy; ‘consumers’ signify all those who, whether at some point or continuously, need to consider pharmaceutical therapy for a disease or condition. As most, if not all, of us fall into this category, consumers and their representatives also have a legitimate interest in ensuring that the treatments are available, safe, effective, and appropriate.

There are a number of stakeholders in medicines policy and a variety of interests and viewpoints that contribute to dynamic debates on medicines policy issues. HAI Europe proactively promotes the independence and transparency of all stakeholders and advocates for commercially ‘interest-free’ pharmaceutical policymaking in Europe.

This paper forms the basis for the Health Action International (Europe) research on patient and consumer organisations and their relationships with the pharmaceutical industry. The goal of the project is to examine the extent to which patient and consumer organisations active in European health policy fora are funded by the pharmaceutical industry, and to ascertain whether or not this support is related to the policy positions of the groups involved. The views expressed in this paper represent those of the author, and not of HAI Europe.

# Introduction

Patient organisations (POs) are typically characterised as not-for-profit, non-governmental entities that represent and support the interests of patients and their lay-carers, whilst also being 'driven' or governed by them to a significant extent (EMEA 2005, IAPO 2009). Within this broad definition, however, lies a huge diversity of organisations in terms of their focus, actions, organisational size, structure and leadership.

The various activities undertaken by POs include: raising awareness about a disease; fighting against social prejudices associated with certain conditions; disseminating information about health problems, their prevention and treatment; or working for improved care of patients by promoting or providing access to better health services, self-help initiatives, or new and improved therapies (Wood 2000: 70; Ball et.al. 2006; Gasparini et.al. 2006: 194-195).

Whilst some POs pursue such goals through small, volunteer-run operations, many 'grass-roots' associations have evolved into organisations of considerable size and income, employing large numbers of paid professionals to manage their activities at the local, national, or international level. Similarly, the *scope* of POs varies considerably, from those focusing on single diseases, to those with interests in a wider range of related conditions around which common concerns emerge for affected patients (Traulsen & Almarsdottir 2005: 274; Van der Zeijden 2000: 8; IAPO 2009). Inevitably, the organisational characteristics and activities of a PO will depend to a large extent on the nature of the condition(s) being addressed by the organisation and the social context within which it operates.

## The role of patients in medicines policy

POs have become increasingly visible and vocal actors in medicines policy in recent years. A gradual shift from 'paternalism' to 'consumerism' in the healthcare sectors of many societies has resulted in wide-spread recognition that patients should no-longer be regarded simply as 'passive recipients' of healthcare, but need to be actively engaged in making decisions about their treatment. Medicines policy-making institutions have therefore sought to increase the legitimacy of their activities by seeking heightened levels of input from representative groups of patients (EMEA 2006: 1; HAI Europe 2005; Traulsen & Almarsdottir 2005: 274).

There have been several instances over the last few decades where POs have dramatically altered the healthcare landscape thereby encouraging prescribers, policy-makers and

industry to take POs more seriously as stakeholders (Wilkinson 2008: 200-201). AIDS activist groups, for example, successfully lobbied the US Food and Drug Administration (FDA) for faster access to new AIDS drugs through expedited review procedures in the 1990s (Barton Hutt 2003; Letore, 2001: 28). The growth in size and popularity of POs has also been fuelled by an increasing number of patients and consumers who are turning to these organisations as a source of 'independent information' on medicines and disease because of dissatisfaction over gaps in publicly produced information, and mounting mistrust of state-sponsored data - related at least in part to concerns about government 'rationing' of healthcare (Wood 2000; Mackay 2001: 4; Law 2006).

## Representing patients- a variety of approaches

Diverse factors influence the nature and extent of POs engagement in medicines policy. In cases where medicines exist to treat a disease, POs often act as a source of information about those therapies, or try to promote patients' interests by encouraging better access to effective drugs by lobbying governments, healthcare providers and industry for more favourable pricing & reimbursement policies. In the UK, for example, patient groups systematically engage with the National Institute for Health and Clinical Excellence (NICE) in relation to its decisions about whether or not new medicines should be made available on the NHS, whilst in the developing world, AIDS activist groups have lobbied the pharmaceutical industry to reduce the prices of anti-retroviral medicines (Mackay 2001: 4-5; Mintzes 2007; Ford et.al. 2004).

Where medical treatments are *unavailable* (or have a poor risk-benefit profile) patients' groups are often interested in encouraging more research into new medicines. As a result, some POs (particularly those dealing with cancer or 'rare' diseases) are heavily involved in fundraising for health research related to the development of potential drug therapies, whilst others have started to engage with policy debates around the efficiency, appropriateness and priority-setting of pharmaceutical research and development (R&D). This kind of engagement by POs suggests that they often view medicines as an essential, or even 'primary', ingredient in the path to better health (Traulsen & Almarsdottir 2005: 273).

There are many POs, however, that are careful to emphasise a more balanced, or even 'cautious' approach to the use of medicines in patient care. Organisations representing patients with preventable chronic illnesses often stress the need for broad health promotion strategies to help people prevent or slow the onset of disease in the first place, rather than rely on medical technologies to treat patients once they have already become unwell. Similarly, some groups work hard to encourage healthcare providers to recognise the need

for non-medicinal or complementary therapies, especially in relation to more ‘contested’ conditions such as mental illness or multiple sclerosis where drug therapies have demonstrated mixed levels of success (Yamey 2000; O’Donovan 2007: 722). Rather than pushing for expedited or increased access to medicines, POs representing patients suffering from iatrogenic (drug-induced) illnesses have instead been associated with demands for more rigorous approaches to drug development, regulation and use.<sup>1</sup>

There are, therefore, a wide range of POs that have legitimate interests in medicines policy, including issues around information, access, availability, pricing, drug research, development and regulation. Yet, there remain considerable variations in the focus and emphasis of their approaches to medicines policy matters.

## **Industry funding of patients organisations**

Pharmaceutical corporations have made considerable donations to POs in the form of restricted or unrestricted financial contributions; sponsorships for research projects, publications, event organisation and attendance; or ‘in-kind’ donations of facilities, expertise, goods and services to POs and their target groups. Whilst few would suggest that industry has made these resource transfers to POs out of genuine ‘altruism’, both the industry and the POs it funds have emphasised the ‘mutual benefits’ arising from their funding relationships. Indeed, both parties have defended the legitimacy of industry’s financial support to POs on the basis that it enables POs to ‘do more’ for the patients and families they represent, and because they are ‘natural’ partners who often share similar objectives in medicines policy, albeit for different reasons (Herxheimer 2003: 1210; Hirst 2003; Lapsley 2003: 344; Gebhardt 2003; Korsia 2000). For instance, whilst industry is motivated by considerations of profit and financial growth, and POs out of a concern to improve patients’ health and wellbeing, both are interested in relaying information to patients and consumers about diseases and their potential for treatment, or in seeing new medicines come to market.

## **The value of patient partners for the pharmaceutical industry**

In tandem with POs’ growing influence on drug development, regulation and use, the pharmaceutical industry has recognised the political and economic gains it can make by helping to fund their activities (Mills 2000; Tuffs 2006). This is especially in view of the fact that, as charitable institutions, POs are generally attributed with high levels of credibility in

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<sup>1</sup>See for example, The Thalidomide Society in the UK (at <http://www.thalidomidesociety.co.uk/>).

the public gaze (Wood 2000: 70). In contrast, industry is often approached with cynicism because of its profit-making imperatives and connections with high-profile medicines disasters. Any 'philanthropic' or collaborative ventures with POs thus have the potential to reflect positively upon the corporate image of the pharmaceutical industry as a 'socially responsible' business (Herxheimer 2003: 1208; Richter 2002).

Beyond this, however, pharmaceutical companies have realised that if they can support POs as 'surrogate pressure groups' in pursuing public policy and regulatory agendas that coincide with their own, the chances of achieving their commercial and strategic goals may be increased by piggy-backing upon the good reputation of POs (Burton 2005; Ball et.al. 2006). In addition, the industry has identified POs as an alternative route to promote its products amongst consumers, given that direct-to-consumer-advertising (DTCA) of prescription products is banned in most countries. By promoting disease-awareness and providing information to patients about medicines, POs' activities also have the potential to assist industry with expanding their markets by encouraging the identification of new patients, or by influencing existing patients to ask their doctors about new drug therapies (Ball et.al. 2006; Kmietowicz 2004).

The fact that the interests of POs and industry converge, however, should not obscure the reality that the best interests of patients and medicines producers can be in conflict. Turning again to the example of information provision, the best interests of patients lies in receiving fair, balanced and accurate information about their disease and the benefits and risks of all the various treatments available to them (including non-medicinal forms of treatment) (BUKO Pharma-Kampagne 2008: 3-4). In contrast, a company that sells products targeted at those patients wants to maximise its markets and may seek out opportunities to promote its medicines to patients and consumers by ensuring that any information relating to them is presented as positively as possible; perhaps by over-playing the benefits, or underplaying the risks, particularly in relation to other therapies. By using the inherently unequal nature of their funding relationships with POs, companies thus have an opportunity to exert pressure on those organisations' activities, which, in the case of information provision could result in a PO being used for 'disguised DTCA' by inappropriately promoting companies' products against the best evidence available, or failing to report negatively on product performance. Such pressure does not necessarily need to be 'coercive' (i.e. where funding is 'conditional' upon the PO doing what the company wants it to do) in order to have an impact. More insidious, or 'psychological mechanisms' whereby the PO develops a sense of obligation or sympathy with the funding company could be enough to have an improper influence on the PO's behaviour (Klemperer 2009; Gasparini et.al 2006: 198).

## Can industry sponsorship lead to bias?

There are numerous cases over the last 10 years where the acceptance of funding or other in-kind donations from pharmaceutical companies appears to have resulted in the development of commercial bias such as this in POs' informational and lobbying activities (Wood 2000: 83-84). In the UK for example, the charity Cancerbakup was recently associated with providing unbalanced press-releases about the drug trastuzumab (Herceptin) after receiving sponsorship from the medicine's producer. In particular, it highlighted the 'impressive' results of clinical trials and failed to discuss concerns about the medicine's efficacy, adverse drug reactions and cost-effectiveness that were highlighted in a NICE draft approval for trastuzumab (Anon 2006). Similarly, whilst receiving funding from the manufacturers of COX-2 inhibitors, a range of Arthritis charities in the UK, the US and Canada have been linked to the promotion of those medicines (some of which were subsequently withdrawn because of safety concerns) by providing unbalanced information about their risks and benefits (Hirst 2003; Mintzes 2007).

Funding relationships with pharma have also been linked to the unwillingness amongst certain POs to challenge companies about dubious decisions affecting patient care. In its work on age-related macular degeneration (AMD), for example, the global organisation 'AMD Alliance International' which receives funding from the company Genentech, challenged NICE's decision in the UK to limit access to Genentech's high-cost ranibizumab on the basis of limited cost-effectiveness. Meanwhile, Genentech's decision *not* to develop another drug that it owned for AMD, (bevacizumab) - despite strong evidence from off-label use which suggested it could be a relatively cheap and effective alternative to ranibizumab - received no attention from the AMD Alliance. It has been suggested that Genentech's decision not to seek a licence for bevacizumab's use in AMD was probably due to the fact that it was not in the company's financial interests to market a cheaper drug than ranibizumab for the same indication. Meanwhile, by choosing to focus its advocacy for better access on NICE whilst failing to question Genentech about its actions, the AMD Alliance has been identified as failing to 'explore all possibilities for people with AMD' because of its financial connections with interested medicines producers (Anon 2007; AMD Alliance International 2009).

At a broader policy-level, some POs in Europe who receive significant levels of funding from pharmaceutical companies and industry associations have been associated with pursuing an industrial agenda through advocacy for a relaxation of EU legislation restricting DTCA (Law 2006: 179; Herxheimer 2003; HAI Europe 2005). Although any connection between their funding and policy preferences has been denied by the organisations concerned (Van der Zeijden 2003), any weakening of the laws regulating prescription medicines advertising is



likely to be contrary to the best interests of patients. Numerous examples of unethical practice in the pharmaceutical industry's DTCA activities in countries where this is allowed, and industry's use of unbalanced, poor-quality disease awareness campaigns (DACs) suggest that if industry were given greater scope to communicate directly with patients, they would be unlikely to provide reliable, accurate, unbiased information (Mintzes 1998; Mintzes 2006).

## **Next steps: Strengthening the legitimacy of the patient perspective with empirical evidence**

Whilst there are many examples, which suggest that POs' behaviour may have been compromised by the support they receive from pharmaceutical companies, much of the evidence produced to-date about industrial influence over POs has been 'anecdotal' in nature, focusing on the activity of individual POs that have a financial relationship with pharmaceutical companies. Unfortunately, more systematic, comparative analyses of POs' activities and policy outputs in relation to the *extent* to which they are supported by the pharmaceutical industry are lacking. In effect, there is little evidence to show that those POs which *do* accept pharma funding are more likely to demonstrate an industrial bias than those POs which *don't* accept pharma funding (or indeed that those POs who accept *fewer* resources from industry demonstrate a stronger alignment with public health interests than those POs who accept higher levels of support from pharma). Research identifying the correlation, or not, of industry funding with an industrial bias amongst POs could be important for the policymakers that engage with such organisations, who might be concerned about their representational legitimacy as 'the patient's voice'.

# References

- AMD Alliance International (2009)** *Support the Alliance: Partners*, available at <http://www.amdalliance.org/about/howcanyouhelp/supportalliance.php> (accessed 29/05/09).
- Anon (2006)** 'Funding of patients' groups' *The Lancet*, Vo. 368, 1 July 2006, p2.
- Anon (2007)** 'Macular degeneration, patients' groups and pharma' *The Lancet*, Vol.370, 21 July 2007, p 194.
- Ball, D., Tisocki, K., & Herheimer, A. (2006)** 'Advertising and disclosure of funding on patient organisation websites: a cross-sectional survey' *BMC Public Health*, 6:201, available at <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1557495>, (accessed 08/01/09) (Open Access article)
- Barton Hutt, P. (2003)** 'The regulation of drug products by the United States Food and Drug Administration' in J.P. Griffin & J. O'Grady (eds.), *The Regulation of Medical Products*, BMJ Books, London.
- BUKO Pharma-Kampagne (2008)** 'Relevant Health Information for Empowered Consumers' *Pharma-Brief Special*, No. 1 2008, BUKO, Bielfeld, Germany
- Burton, B. (2005)** 'Drug companies told that sponsoring patients' groups might help win approval for their products' in *The British Medical Journal*, Vol. 331, 10 December 2005, p1359.
- European Medicines Agency (EMA) (2005)** *Criteria to be fulfilled by Patients' and Consumers' Organisations involved in EMA Activities*, London, 7 February 2005, Doc. Ref. EMA/14610/04/Final, available at <http://www.emea.europa.eu/pdfs/human/pcwp/1461004en.pdf> (accessed 18/05/2009).
- European Medicines Agency (EMA) (2006)** *Framework on the interaction between the EMA and Patients' and Consumers' Organisations*, London, 14 February 2006, Doc. Ref. EMA/354515/2005-Final, available at <http://www.emea.europa.eu/pdfs/human/pcwp/35451505en.pdf> (accessed 18/05/2009).
- Ford, N., Wilson, D., Bunjumong, O., & Von Schoen Angerer, T. (2004)** 'Viewpoint: The role of civil society in protecting public health over commercial interests: lessons from Thailand', in *The Lancet*, Vol. 363, No. 9408, 14<sup>th</sup> February 2004, pp 560-563.
- Gasparani, M., Bonito, V. Leonardi, M. Tarquini, D. Colombi, L. Congedo, M., Marcello, N., Causarano, R., Gasperini, M., Rizzo, M., Porter, C., Borghi, L., Primavera, A., Defanti, C.A., (2006)** 'Neurologists and patients' associations: alliances and conflicts' *Neurological Science*, Vol. 27, pp194-204.
- Gebhardt D. (2003)** 'The 'benevolence' of the pharmaceutical industry towards patient organisations' Rapid response to Herxheimer, A. (2003) 'Relationships between the pharmaceutical industry and patients' organisations' in *The British Medical Journal*, Vol. 326, 31<sup>st</sup> May 2003, pp 1208-1210.
- Health Action International Europe (HAI Europe) (2005)** *Does the European Patient's Forum represent patient or industry interests? A case study in the need for mandatory financial disclosure*, 14<sup>th</sup> July 2005, HAI, Amsterdam, available at [http://www.haiweb.org/conflict\\_of\\_interest.htm](http://www.haiweb.org/conflict_of_interest.htm) , (accessed 28/04/09).

**Herxheimer, A. (2003)** 'Relationships between the pharmaceutical industry and patients' organisations' in *The British Medical Journal*, Vol. 326, 31<sup>st</sup> May 2003, pp 1208-1210.

**Hirst, J. (2003)** 'Charities and patient groups should declare interests' in *The British Medical Journal*, Vol. 326, 31 May 2003, p1211.

**International Alliance of Patients' Organisations (IAPO) (2008)** *Annual Financial Report 2007*, IAPO, London, available at <http://www.patientsorganizations.org/attach.pl/19/628/IAPO%20Annual%20Financial%20Report%202007.pdf> , (accessed 17/05/09).

**Klemperer, D. (2009)** 'Self-help groups conflicts of interest through sponsoring by the pharmaceutical industry' *Bundesgesundheitsbl- Gesundheitsforsch- Gesundheitsschutz*, Vol 52, pp 71-76.

**Kmietowicz, Z. (2004)** 'Tighter controls are needed to root out bogus patient groups' *British Medical Journal*, Vol. 329, 4 December 2004, p1307.

**Korsia, S. (2000)** 'Partnerships between the pharmaceutical industry and patient groups: The patients' view' *Drug Information Journal*, Vol. 34, No. 1, Jan-March 2000 pp 79-81.

**Lapsley, P. (2003)** 'Industry funding of patient support groups' Rapid response to Herxheimer, A. (2003) 'Relationships between the pharmaceutical industry and patients' organisations' in *The British Medical Journal*, Vol. 326, 31<sup>st</sup> May 2003, pp 1208-1210.

**Law, J. (2006)** 'The European Patient' (Chapter 10) in Law, J. *Big Pharma: Exposing the Global Healthcare Agenda*, Perseus Publishing, February 2006, pp178-195

**Letore, D. (2001)** 'Patients' groups: Time to drop the 'them and us' approach?' *Scrip Magazine*, January 2001, pp28-29.

**Mackay, C. (2001)** 'Sustaining Access to Medicines in Europe: Examining consumers' priorities and concerns – The UK experience' in *HAI-Lights*, Vol. 6, No. 3, December 2001, HAI, Amsterdam, available at [www.haiweb.org/pubs/hailights/dec2001/HAILightsDec2001.doc](http://www.haiweb.org/pubs/hailights/dec2001/HAILightsDec2001.doc) , (accessed 28/04/09).

**Mills, F. (2000)** *Patient groups and the global pharmaceutical industry: the growing importance of working directly with the consumer*, London, Informa Pharmaceuticals.

**Mintzes, B. (1998)** *Blurring the Boundaries*, HAI Europe, Amsterdam, available at <http://www.haiweb.org/pubs/blurring/blurring.intro.html> , (accessed 30/10/2008).

**Mintzes, B. (2006)** Disease Mongering in Drug Promotion; Do governments have a regulatory role? *PLoS Medicine*, April 2006, Vol, 3. Issue 4, pp 198.

**Mintzes, B. (2007)** 'Should patient groups accept money from drug companies? No' in *The British Medical Journal*, Vol. 334, 5 May 2007, p935.

**O'Donovan, O. (2007)** 'Corporate colonization of health activism? Irish health advocacy organisations' modes of engagement with pharmaceutical corporations' *International Journal of Health Services*, Vol. 37, No. 4, pp711-733.

**Richter, J. (2002)** 'Codes in context: TNC regulation in an era of dialogues and partnerships' *The Corner House*, Briefing 26, February 2002, available at <http://www.thecornerhouse.org.uk/pdf/briefing/26codes.pdf> (accessed 22/05/09)

**Traulsen, J.M. & Almarsdottir, A.B. (2005)** 'Pharmaceutical policy and the lay public' in *Pharmaceutical World & Science*, Vol. 27, 2005, pp273-277.

**Tuffs, A. (2006)** 'Sponsorship of patients' groups by drug companies should be made transparent' in *The British Medical Journal*, Vol. 333, 16 December 2006, p1238.

**Van der Zeijden (2000)** 'The Patient Rights Movement in Europe' in *Pharmacoeconomics*, Vol. 18, Suppl. 1, pp7-13.

**Van der Zeijden, A. (2003)** 'Correction: International Alliance of Patients Organisations' Rapid response to Herxheimer, A. (2003) 'Relationships between the pharmaceutical industry and patients' organisations' in *The British Medical Journal*, Vol. 326, 31<sup>st</sup> May 2003, pp 1208-1210.

**Wilkinson, E. (2008)** 'Patient organisations aim for greater collaboration' in *Molecular Oncology*, Vol. 2, No. 3 (2008) pp 200-202.

**Wood, B. (2000)** *Patient Power? The politics of patients' associations in Britain and America*, Buckingham, Open University Press

**Yamey, G. (2000)** 'Drug companies seek MS patients to lobby for new products' in *The British Medical Journal*, Vol. 320, 22 January 2000, p207.