

# Look – no strings!

Patient groups are seeking to redefine their relations with the industry

→ Anna Wagstaff

As patient groups begin to gain access to the corridors of power, the spotlight is falling on their relations with the powerful pharmaceutical industry. In an effort to protect their credibility from a murky sea of rumour and speculation, many patient groups are now trying to negotiate a more transparent and arm's length relationship with their industry sponsors.

**A** Parliamentary Committee in the UK has been hearing damning allegations about relations between pharmaceutical companies and patient organisations, as part of an investigation into the influence of the industry.

Patient groups have been accused of acting as 'stooges' for the pharmaceutical industry, Trojan horses under whose cover the industry has been able to infiltrate policy-making bodies. Criticisms range from Biogen setting up Action for Access to campaign for reimbursement of one of its multiple sclerosis drugs – it was later shut down by the regulators – to the time when the long-established Alzheimer's Society sent out a statement from a drugs company under its own name. Questions have been asked as to why, in the debate over the safety of selective serotonin uptake inhibitors (SSRIs), one mental health group which has kept a distance from the industry was highly critical, while two others, who take industry sponsorship, were silent. The Association of the British Pharmaceutical Industry came under fire for allegedly describing patient groups as 'ground

troops' that they could use to weaken "political, ideological and professional defences" against direct to consumer advertising.

Similar debates are taking place in other countries. The issue has come under the media spotlight in the Netherlands – the only country in Europe to set aside 30 million euros a year for patient groups. It is also a hot topic in Germany, where a number of cancer patient groups have been criticised for taking money from the industry. European umbrella groups, which have mushroomed in order to have an input into the EU consultation processes, have also proved rich targets for rumour and speculation.

Taken together, a few examples of bad practice, a greater number of allegations, and a murky atmosphere of rumour, pose a severe threat to the credibility of patient groups. Many are now trying to erect firewalls against inappropriate influence by renegotiating their relationship with the industry.

## AN UNEQUAL RELATIONSHIP

By law, pharmaceutical companies are not permitted to communicate with patients directly.



Europa Donna put on this breast cancer exhibition during its campaign to get policy passed by the European Parliament. Getting the right facts across to the right people at the right time can't be done on the cheap

## Patient groups have been accused of acting as 'stooges' for the pharmaceutical industry

Building a relationship with a patient group gives them an avenue for getting information to patients about their products and research results, and can be helpful in recruiting to clinical trials. It gives them a chance to get feedback about how patients perceive their products and to identify potential gaps in the market. Support from patients can be very helpful in getting a new drug approved or onto the reimbursement list. A good relationship with patient groups also does wonders for the corporate image, and can be particularly valuable during a public relations crisis.

The relationship works both ways. Patients have an interest in the effectiveness, safety, side-effects and cost of drugs, and want to know about clinical trials they may be eligible

for. Patient groups want to influence research and development and keep up to date with research results.

The industry and patient groups both benefit from a constructive relationship. The problem is that the relationship is unequal: pharmaceutical companies have money, scientific knowledge and expertise in marketing and public relations. Patient groups do not. When patient groups accept money from the industry, questions are asked about inappropriate influence. Is the group driven by the interests of patients or the agenda of sponsors?

Some patient groups refuse money on principle. They are, however, in a small minority. A survey of 45 groups who attended the first conference of the European Cancer Patient

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Coalition in Milan last June elicited 22 responses, covering nine countries: Belgium, Germany, Italy, Netherlands, Poland, Romania, Spain, Sweden and the UK. Results showed that 19 of the 22 (86%) receive industry funding on occasion. Two refuse money on principle. One is forbidden to accept industry sponsorship by its funding body, a national cancer charity.

Few of the 19 who accept industry sponsorship use this money to cover core running costs. The exceptions are in Poland and Romania, where there is little tradition of state or charitable funding for voluntary groups, and what there is, says Simona Ene of the Romanian Association of Cancer Patients, is not made available to cancer patient groups because of the appallingly negative attitude towards cancer in that country.

Sponsorship from four or five different companies is common. One group reported support from 20 different companies; none reported funding from a sole sponsor. The money tends to finance particular projects: public awareness campaigns, information leaflets, newsletters, organising conferences and travel costs.

The proportion of income derived from industry varied from marginal to well over 50%. It tended to be lower among groups with a focus on supporting and informing patients, and higher among groups geared heavily to promoting public awareness and advocacy, and among European umbrella groups, where travel and translation costs can be heavy.

The majority of groups have some form of policy on sponsorship, but it is rarely written down, almost never publicly available, and usually amounts to a vague commitment not to take funding from companies with a poor ethical reputation or accept funding with strings. Sponsors are often acknowledged on the back

of publications or on a group's website, but very few patient groups have a policy on declaring sources of funding.

A recent survey of its affiliates by Europa Donna Italy revealed that just under one-third of the 67 groups that responded received sponsorship from the pharmaceutical industry, but only two had a policy document on transparency.

Few groups are aware of laws or regulations governing sponsorship. Deutsche Leukaemie- und Lymphom-Hilfe say they were obliged to sign a statement of good intent in order to accept sponsorship from the pharmaceutical industry without jeopardising grants from Germany's health insurance companies.

The overall picture shows that, in general, pharmaceutical companies choose what activities they wish to sponsor, but details of the size of the sponsorship, what it is used for, and what they can expect in return are rarely disclosed in full.

### RENEGOTIATING TERMS

Lack of clarity and transparency does not mean that inappropriate relationships are being deliberately concealed. In fact, cancer patient groups tend to be strongly driven by patients' priorities, as one might expect of groups run largely by people who know what it means to have cancer.

But bad practice does exist, and a number of cancer patient groups are now taking steps to ensure they don't get tarred with the same brush. Central to this has been a move to define relations with industry sponsors in quasi-legal detail. The European Cancer Patient Coalition defines four types of funding – 'sustaining partnerships' (unrestricted grants of at least 20,000 euros as one among a group of sponsors), project funding, sponsorship, and smaller unrestricted grants. It spells out what input sponsors get into a project, the nature of acknowledge-

ments and what sponsors can expect in return. As well as guiding principles, it sets guidelines for commercial companies governing the use companies can make of ECPC's name and logo and the avenue of communication between the companies and ECPC, down to the terms on which ECPC will deal with companies' public relations agencies.

The ECPC policy borrowed ideas from similar documents drawn up by other patient groups such as the European Organisation for Patients with Rare Diseases (EURORDIS). Other patient groups, including Europa Donna (the European Breast Cancer Coalition) and the Global Lung Cancer Coalition, have used the ECPC guidelines to beef up their own policies. New European groups will be able to draw on these policies. In this way a new and more transparent relationship with the industry is being forged.

The concept of a 'sustaining partnership' or 'founding partner' is becoming increasingly popular as a way of receiving funding that can be spent entirely as the patient group sees fit. The traditional model of sponsorship for particular projects opens patient groups to allegations that their activities are skewed towards issues of commercial interest. Conferences, newsletters, information leaflets and websites are of interest to the industry because they all help spread awareness about the latest treatments. Campaigns to cut waiting lists for radiotherapy or to ensure that cancer surgeons treat a minimum number of patients per year are of less interest, and therefore less likely to receive funding. Using the sustaining partnership model enables patient groups to follow their own agenda.

Efforts are also being made to avoid being tied too closely to a single sponsor – something for which the Global Lung Cancer Coalition was criticised in the Australian press. The Coalition had been set up from a meeting

organised by AstraZeneca, who also initially provided the secretariat. Jesme Baird, a founding member, said "We all knew it didn't look transparent from the outside to have just one company supporting us, and we felt the coalition should be more independent." The secretariat has now been taken over by the UK Roy Castle Lung Foundation, and more companies have come on board to finance activities through a sustaining partnership agreement. Baird argues, however, that the Coalition has been a huge boost for lung cancer patient groups, who struggle with a unique set of difficult problems. She insists that without AstraZeneca taking the initiative, it could never have got off the ground.

International umbrella groups in the process of formation, such as Myeloma Euronet, are learning from that experience. Even if they are set up with the support of one particular pharmaceutical company, there does appear to be a recognition that it is important to bring in other industry partners at a very early stage.

### IT TAKES TWO...

Renegotiating a relationship does, of course, require the agreement of the other side. This may be less difficult than expected, as the industry is aware of the need to polish its image. Relations with an increasingly confident and critically minded set of patient groups will also suffer if pharmaceutical companies are perceived to be acting in a cynical and manipulative manner.

Six years ago, the European Federation of Pharmaceutical Industries (EFPIA) drew up a Memorandum of Understanding with Europe-wide patient groups. In 2003, the Swedish Federation drew up its own ethical guidelines, which rule out, for example, core funding. The British Federation is currently reviewing its

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Do you know your risk? Mamazone used shock tactics to get Germany talking about breast cancer

Code of Practice. The current version makes no explicit reference to relations with patient groups, but the Federation expects the revised version at the end of this year to cover this.

This change of approach seems to be reflected among big companies, at least at the European level.

Catherine Steele, International Head of Public Policy at Roche, says the company is moving away from a purely commercial relationship with patient groups to a more carefully structured and transparent ongoing relationship. Steele confirms an industry-wide change

away from funding individual projects towards a greater use of unrestricted grants. Companies are increasingly playing a sustaining role, she says, because many of the international organisations would otherwise not survive.

AstraZeneca recently hammered out a formal policy on its approach to patient groups. Head of public affairs in oncology, Lynn Grant, says that this aims to achieve “long-term and mutually beneficial relationships ... based on transparency and trust.”

Smaller patient organisations may, however, be less able to negotiate unrestricted grants. For example, Romanian pharmaceutical companies recently rejected an approach from the Romanian Cancer Society for a 10,000 euro partnership agreement.

### IS IT ENOUGH?

Some argue that any cooperation between patient groups and the industry necessarily shifts the patient group towards the industry agenda. Anita Hardon of the University of Amsterdam says that the influence is inevitable and often subconscious. Writing in a Dutch newspaper, she says that patient groups tend to focus on medical rather than non-medical treatments, and tend to take the same line as drug companies.

Jenny Hirst of the UK Insulin-Dependent Diabetes Trust, giving evidence to the UK parliamentary enquiry, put it this way: “You cannot criticise the pharmaceutical industry and specific drug companies and take their money at the same time.”

Ulla Ohlms, of the German breast cancer advocacy group Mamazone, rejects what she calls ‘fundamentalist’ arguments, and says that Mamazone does criticise companies it receives money from, for instance, about the excessive price of drugs. Jesme Baird, of the UK Roy Castle Lung Cancer Foundation, says that if

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## The EC needs the existence of umbrella groups to consult with, but gives them no financial support

you are professional and remember that you are there for patients, you have no compunction about criticising a company when appropriate. Both point out that patients have pressing reasons for wanting access to certain drugs, and should not be denied the right to speak out just because a sponsoring company could benefit.

Consumer watchdog Andrew Herxheimer, writing in the *British Medical Journal* (31 May 2003), argues that the key is to be transparent, take money from a variety of sponsors, and keep the industry contribution down to no more than 20% of total income.

Few argue against transparency or multiple sources, although there can be practical difficulties with declaring all small donations, while 'rare disease' organisations can find it difficult to attract multiple sponsors.

There is less consensus, however, over the 20% limit.

For the bigger national and European patient advocacy groups, which make the patient voice felt in the policy arena, the 20% formula doesn't seem to work in the absence of other funding. These groups equip cancer patients with the information and skills they need to argue in a variety of arenas, for more and more appropriate research and better prevention, screening, treatment and palliative care. To do this, they need to be up to date with research, knowledgeable about healthcare systems and policy, familiar with political processes and able to communicate effectively with their members, policy makers, healthcare professionals and the public. None of that comes cheap, while working at a European level entails travel and translation costs.

Some, such as the Swedish breast cancer group BRO and the NFK (Dutch Federation of Cancer Patient Associations) receive substantial unrestricted national funding from the state or national charities. But they are the exceptions.

German health insurance funds are meant to set aside half a euro per member to fund patient groups. However, Ohlms of Mamazone believes that the grants are out of step with the needs of today's cancer patient groups; Mamazone has never been able to access such support or even to verify whether health insurance funds really distribute what they should. UK groups can apply for potentially generous grants for specific activities from the Department of Health. But like commercial companies, governments only fund projects that match their own priorities.

The European Commission's consultation processes require the existence of European umbrella groups, but the EC gives them no financial support. Most umbrella groups are therefore dependent on the industry.

It appears that the European Medicines Agency (EMA), which is currently developing its own policy document on relations with patient groups, recognises this reality. EMA is expected to reject setting an upper limit to the proportion of income from pharmaceutical funding, focusing instead on issues of transparency, disclosure of direct and indirect funding, and on ensuring no single company has a dominant position.

There has been talk in the UK about establishing an independent body to 'kite mark' patient organisations on the basis of transparency, sources of funding, membership size, internal democracy and so on. However, the National Institute for Clinical Excellence (NICE), which draws up guidelines for treatment and takes decisions over which drugs should be reimbursed, has not seen such a bureaucracy to be necessary.

Marcia Kelson, Director of the NICE Patient Involvement Unit, says the industry cannot unduly influence NICE through patient representatives, "because whatever submission they make we will use to go and

## Some patient groups resent people who are free from cancer staking out the moral high-ground

look at the evidence to see whether it supports what they said.” She says that NICE is perfectly capable of differentiating between a methodologically sound randomised survey undertaken by an established patient group and a letter-writing campaign put together by an organisation established to lobby for a particular drug or treatment.

### HONEST DEBATE

This issue is not new, but the stakes have been raised as decision-making structures at a national and European level open themselves to greater patient involvement, and patient groups become more assertive and effective. Between the highly pragmatic attitude of NICE and the arguments of the ‘fundamentalists’ are many shades of opinion and ideas on how to move forward, and new policies and contract-based funding models are being developed even as the issue is debated by politicians and discussed in the media. However, industry influence is not the only issue here.

Some patient groups resent what they see as people who are free from cancer staking out the moral high-ground with little regard for the adverse impact they may have on patients. Nor do the accusations over ‘tainted money’ seem to value the thousands of hours of voluntary labour provided by the members of these groups, which in most cases are worth many times the value of industry sponsorship. Many groups rely on volunteers to provide counselling, support and information to other patients, staff a phonenumber, run a website or newsletter, write and produce informa-

tion leaflets, travel to conferences and sit on committees.

Nor are critics of these groups always motivated entirely by ethics. Ohlms talks of the time Germany’s health minister Ulla Schmidt attacked Mamazone for “sticking together with industry” after the advocacy group had voiced criticisms of the Government’s forthcoming disease management programme. Ohlms feels this comment was a cheap alternative to responding to the issues.

If this debate is to be honest and constructive, then those who contribute need to be respectful of the people with cancer and what they have at stake. For every alleged ‘stooge’ organisation there are a hundred groups kept going by patients of tremendous bravery, selflessness and dedication.

They have brought hope and comfort to hundreds of thousands of patients, and have been a driving force towards patient-centred research and care.

All groups need funding, from Europa Donna, which successfully lobbied for a European Parliament policy on quality breast cancer care, to cash-strapped patient groups in Romania who are trying to secure chemotherapy pumps, drugs and safe blood products within a system that considers cancer an automatic death sentence.

Simply attacking an important source of funding in the name of ethics and independence will not help them. Supporting them in their attempts to secure their independence through negotiating new terms with industry and finding alternative sources of unrestricted funding will.

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