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**A case study in the need for
mandatory financial disclosure**

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Does the European Patients' Forum represent patient or industry interests? A case study in the need for mandatory financial disclosure

The European Commission has quite rightly felt under pressure to involve patients in discussions and decisions about EU health policy and has sought to deal with a single, pan-European organisation, rather than a myriad of different patients' interest groups. The Commission has recently also articulated concerns about the need for disclosure of the sources of non-government organisations' and lobbyists' funding: Commissioner Siim Kallas in his 'European Transparency Initiative', launched in March 2005, establishes transparency as "an essential prerequisite for the integrity and credibility of our political institutions"¹. Yet the European Patients' Forum (EPF), the chief patients' group consulted by, indeed established with the backing of, the Commission, is a model of secrecy and conflict of interest. The EU's reputation depends on applying strong rules about transparency. Its policies stand to benefit from the fuller consultation with civil society that such transparency would enable.

Origins and structure of the EPF

The EPF was formally established in January 2003 and defines itself as "*a response to [then-] recent calls by the European Commission and other EU institutions to have one pan-European patient body to address and be consulted on issues concerning the interests of patients in the European healthcare debate*"². The EPF grew out of a meeting between the Commission and various patients' groups – and also the European Consumers Union and the European Public Health Alliance – on 18 July 2002. What was variously described in the minutes of that meeting as the 'European Patient Platform' or the 'European Patient Forum' was at that stage simply a declaration of intent signed by nine groups indicating their wish to set up a Europe-wide patients' organisation. On the basis of such an extremely limited and informal consultation, the European Patient Platform / Forum was immediately elevated into a position of presumed legitimacy as the representative of European patients. It was as the representative of the European Patient Platform that Rodney Elgie, President of the EPF from its formal inception until June 2005, took up a place on the *High Level Process of Reflection on Patient Mobility and Healthcare Developments in the EU*, the product of a Council decision of June 2002. The Commission's thinking towards the EPF therefore

¹ *The need for a European transparency initiative*, Siim Kallas, Vice-President of the European Commission and Commissioner for Administrative Affairs, Audit and Anti-Fraud, speaking at The European Foundation for Management, Nottingham Business School, 3 March 2005

² European Patients Forum homepage: <http://www.europeanpatientsforum.org/>.

seems from the very start to have been driven by a need to be seen to be consulting with patients regardless of whether the groups concerned are genuinely representative and accountable.

According to its Constitution, the purposes of the EPF include:

- *“To facilitate an open and inclusive Patients Forum enabling ALL pan-European patients' groups to exchange information and points of view in the area of EU Health Policy and all other EU initiatives of interest or concern to patients;*
- *To voice the views of patients, as stakeholders in the European healthcare debate, by means of a broad, truly representative and independent patient group resource;*
- *To become the natural first point of reference for the European Commission and other European institutions when seeking the opinions of patients and/or when seeking to consult patient groups”³.*

Thirteen members are listed on the EPF website. These do not include many major European patient organisations, including for example groups representing patients with heart disease, diabetes, stroke, or most cancer groups.

The EPF’s Constitution also stresses that “[t]he Forum aims to be as transparent, democratic and inclusive as possible” and its internal rules include reference to the need for “[t]ransparency: European patients' organisations should disclose their sources of funding and generally make available their audited financial accounts”⁴. Neither the EPF nor six of the members listed on its website give details of funding. Others give some information about the companies supporting their work, but, with the exception of the European Organisation for Rare Diseases (EURORDIS), do not specify the sums and proportion received from industry. The European Network of (ex-)Users and Survivors of Psychiatry is the only EPF member which states that it does not receive funding from the pharmaceutical industry.

The EPF’s claims to independence are as difficult to support as its claims to be representative and transparent. It did not succeed in securing Commission funding in either 2003 or 2004, apparently failing to heed Commission advice that core funding could not be granted. There are a number of indications that the pharmaceutical industry funds or otherwise supports much of the EPF’s work. The difficulties in uncovering these links are forceful evidence in the case for mandatory transparency rules.

³ article 2, EPF Constitution, www.europeanpatientsforum.org

⁴ article 4, EPF Constitution, www.europeanpatientsforum.org.

Pharmaceutical company support for the EPF

Two representatives of the EPF – Annette Dumas and Don Marquis – have been conducting a series of interviews in the first half of 2005 with key EU health actors about how the EPF can improve its profile and establish a more secure funding base. This exercise is funded by Baxter Healthcare – a large US-based pharmaceutical corporation – and by a grant from an EPF member, the European Coalition of Positive People⁵. Ms Dumas, formerly an employee of the pharmaceutical company Merck, Sharp and Dohme, is the EPF's official lobbyist to the European Parliament⁶. There is no mention of Ms Dumas on the website of the EPF; she is neither a patient nor a representative of any of the EPF's member organisations.

EPF activities carried out with funds from the pharmaceutical industry

- On 22 - 23 June 2005, the EPF held a conference in Brussels on the theme of *Health Education and Compliance*. Travel and lodging expenses were apparently paid by Pfizer. The website of the European Coalition of Positive People, an EPF member, made clear that '[p]articipation is by invitation only'⁷.
- On 1 February 2005, the EPF organised a workshop on biosimilar medicinal products. "Financial support for this meeting has been provided by way of an unrestricted educational grant from [biotechnology company] Amgen". Invitations to the meeting were sent out by Julie Cooper, who is the Director, Public Health Unit, Interel Public Relations & Public Affairs⁸.
- The conference *Strengthening Patient Groups in the EU: Exchange of best practice between patient groups* held on 26-27 November 2004 in Brussels was '[o]rganised by the European Patients' Forum in co-operation with the European Federation of Pharmaceutical Industries and Associations'⁹.
- On 3-5 November 2004 the EPF, together with EPF-member, the European Federation of Neurological Associations (EFNA), the Genetic Interest Group and the European Institute of Women's Health, organised *Enabling Good Health for All:*

⁵ Ms Dumas, personal communication, March 2005 (meeting with the European Public Health Alliance).

⁶ The list of accredited lobbyists to the European Parliament is available at:

<http://www2.europarl.eu.int/lobby/lobby.jsp?lng=en&sort=byorg&index=E>

⁷ <http://www.ecpp.co.uk/upcomingconf.htm>, as of 30 June

⁸ The original invitation from Ms Cooper was forwarded to HAI Europe. The website for Interel's Brussels office does not list its clients. That of its subsidiary in Bratislava indicates that clients include GlaxoSmithKline, Merck Sharp & Dohme, Abbot and Serono.

⁹ http://www.efpia.org/7_patient/Programmewkshop1104.pdf, as of 30 June

A Shared Responsibility, A Training Workshop for Patient Groups. The workshop aimed to ‘*explore how patient groups can contribute to the processes related to healthcare in regards to the European Parliament and European Commission*’. According to another EPF member, the European Organisation for Rare Diseases (EURORDIS), there is “[n]o registration fee. Accommodation and standard class travel is covered by an educational grant from the pharmaceutical company, Novartis”¹⁰. The contact for information about the event is given as Catherine Matheijs whose e-mail indicates that she works for GPC International / GPC Public Affairs, which numbers Novartis among its clients¹¹ and suggests that the company may have been more closely involved in the event than simply paying costs¹².

The EPF is receiving public relations and other services from Weber Shandwick, a PR company which runs a ‘European healthcare practice’ offering “a strategic, integrated approach to healthcare public relations in Europe” for “companies of all sizes - from global multinationals to innovative biotechs”¹³. The EPF’s General Assembly Meeting on 24 June 2005 was held in the Brussels offices of Weber Shandwick. In December 2004, Weber Shandwick organised the launch of the European Parliament Interest Group on Patients. Invitations to the event were sent out by Gráinne Crowley, Weber Shandwick’s Principal Consultant for Pharmaceuticals and Healthcare, “on behalf of the President of the EPF”. The Interest Group, whose secretariat is provided by the EPF “aims to act as a forum informed for debate and initiating policy action for MEPs on the views of patients regarding health issues and European policy developments”¹⁴. Linking up patient groups and pharmaceutical companies seems to be standard practice in Weber Shandwick’s approach to public relations and lobbying¹⁵.

¹⁰ http://www.eurordis.org/article.php3?id_article=479, as of 30 June

¹¹ see http://www.sourcewatch.org/index.php?title=GPC_Market_Access

¹² GPC International or GPC Public Affairs, in its own terms ‘the premier Public Affairs & Communications consultancy group in Europe’ has also co-organised events with the CHES, for example a roundtable on Patient Mobility in Europe on 27 February 2004, see:

<http://www.madariaga.coleurop.be/ches/documents/040227pr.pdf>

¹³ <http://www.euhealth.webershandwick.com/about.html>

¹⁴ The original invitation sent by Weber Shandwick was forwarded to HAI Europe.

¹⁵ See for instance “The Rise of PR in German Healthcare” by Christian Deutsch, Director, Healthcare Practice for Weber Shandwick in Germany

(www.webershandwick.co.uk/outcomes/issue4/story1_print.html) or the references to the speech by Gráinne Crowley at www.patient-view.com/projects4.htm. Weber Shandwick’s EU website does not list its pharmaceutical clients, but the group’s UK branch indicates that Pfizer, Lilly, Serono, Schering, *inter alia*, are clients, as well as groups such as the International Osteoporosis Foundation and the UK Blood Pressure Association.

Weber Shandwick was involved in promoting the first of two reports on *The Informed Patient* coming out of the Centre for Advancing Health Information, set up by pharmaceutical giant Johnson & Johnson¹⁶. The contact for an event in the European Parliament to promote the first report was Christine Marking, who held the post of Director, Health & Pharmaceuticals for Weber Shandwick¹⁷. Ms Marking has since taken on the role of coordinator of the Centre for Health, Ethics and Society (CHES), which was also founded and continues to be funded by Johnson & Johnson¹⁸. Ms Marking is said to have provided 'invaluable support' to the authors of the *Informed Patient* reports, which in turn advocates that the EPF should have a central role in the provision of health information for the public¹⁹. The risk is that the Commission places too much reliance on this core of mutually-endorsing industry-funded stakeholders.

The European Commission gives the EPF a central role

The EPF has succeeded in securing for itself a prominent position in key EU fora. It was a member of the organising committee of the conference *Patient Safety - Making it happen - The European perspective*, held under the auspices of the Luxembourg EU Presidency and the European Commission, 4-5 April 2005. A member of the EPF Executive Committee, Jean Georges, who also represents the European Federation of Neurological Associations (EFNA), is the first-ranked of four patients' representatives proposed by the Commission to take two places on the Management Board of the European Medicines Agency (EMA)²⁰. The EMA coordinates the evaluation and supervision of medicinal products throughout the European Union. The second-ranked proposed representative is François Houyez of the EURORDIS. The EPF, the EFNA and the EURORDIS are also among the eight groups represented on the CHMP/EMA Working Group with Patients' and Consumers' Representatives. Other members include the 99% pharmaceutical industry-funded International Alliance of Patients Organisations.

¹⁶The first *Informed Patient* report was published in May 2003. The second – *An EU Framework for Action* – came out in August 2004. The reports can be accessed on the website of the Judge Institute for Management (www.jims.cam.ac.uk). Johnson & Johnson also funds Patient Talk, the International Council of Nurses 'Informed Patient Project' (www.patienttalk.info)

¹⁷ <http://www.amicus-cphva.org/publichealth/phephanlefeb03.pdf>

¹⁸ see <http://madariaga.coleurop.be/ches/>. For some CHES Roundtable events, Christine Marking is given in the participants' list as a representative of Johnson & Johnson.

¹⁹ p15, *The Informed Patient: an EU Framework for Action*. At the European Health Forum Gastein, October 2004, Johnson & Johnson sponsored and Scott Ratzan, Vice President, Johnson & Johnson chaired a lunch workshop titled 'Towards a health competent consumer: EU policy action for improved health information'. The three speakers were Peter Singleton, one of the authors of *The Informed Patient*, Christine Marking and Rodney Elgie.

²⁰ Allowing representatives of patients, doctors and veterinarians onto the EMA Management Board is an element of the pharmaceuticals' legislation passed in 2004 (article 65, Regulation (EC) No 726/2004).

Transparency criteria exist on paper only

The EPF is in theory meant to meet a number of obligations about transparency. The EMEA has developed criteria to be fulfilled by patients' and consumers' organisations involved in EMEA activities, specifically those that are members of the Working Group, but also those occasionally consulted as experts. Technically, the criteria would only come into force when finally approved by the Management Board, though they have been agreed by the EMEA's scientific committees and by the Working Group itself. These criteria include reference to:

“Transparency – the organisation should disclose its sources of funding both public and private by providing the name of the public and/or private bodies and their individual financial contribution in terms of percentage of the organisation budget. Any relationship with corporate sponsorship should be clear and transparent. Any conflict of interest should be disclosed to EMEA. In case of umbrella organisations, the list of member associations should be publicly available. The reference to private bodies does not include private individuals unless this presents a potential conflict of interest as referred to above”²¹.

The EPF does not publish: its sources of funding, the proportion that each funder contributes, its relationships with corporate sponsors, nor its full list of members.

As a proposed member of the EMEA Management Board – patients' representatives are expected to first take up their positions at the Board meeting of 28-29 September 2005 – the EPF is also subject to Article 63 of Regulation 726/2004, which states that members of the Management Board *“shall declare, at each meeting, any specific interests which could be considered to be prejudicial to their independence with respect to the items of the agenda. These declarations shall be made available to the public”*. In its letter to the President of the European Parliament endorsing the Commission's nominations for patients' representatives on the Management Board, the Parliament's Environment, Public Health and Consumer Policy Committee noted that:

“the Commission did not provide any information on the patient organisations concerned and how they are structured and financed, including their potential financial links to the pharmaceutical industry. It was thus not possible, for the committee to take this aspect into full account in

²¹ Draft criteria to be fulfilled by patients' and consumers' organisations involved in EMEA activities, ref: EMEA/101572/2005, 15 March 2005

its overall assessment of the candidates. The committee expects, therefore, as a condition to their nomination, on a reaffirmation by the candidates that, if appointed, they will act in complete independence when taking their decisions on the Management Board. They should also be asked to disclose any relevant financial interests, notably any links that their organisation might have with the pharmaceutical industry”²².

Both the EMEA and the European Commission therefore appear to have put themselves in the difficult situation of accepting the EPF into a position of influence while it does not meet the standards of transparency and independence to which they aspire.

For the Commission, this is a consequence of its original wish to have a single patients’ group to deal with. In a 2003 Communication, the Commission identified a pivotal role for the EPF in “provid[ing] a mechanism to consider patient’s needs in relation to information and how these can be best met”²³. In a further recommendation, the Commission advocated “providing core funding for European patient groups to enable them to participate independently in the debate and decision making on health matters in the EU”²⁴. It is clear from the implementing actions to that recommendation that ‘European patient groups’ was to be taken to mean the EPF.

Since the rules on core funding were not changed, the Commission has had to try again in its latest proposed Health and Consumer Protection Strategy: “[c]urrently, patient groups and non-governmental organisations in the health field can find it difficult to develop initiatives at EU level and to stabilise their organisations because they have inadequate resources...The Commission is therefore proposing operational grants as well as project grants to provide core funding to certain NGOs, including patient groups, in order to help them develop their organisational capacity and put themselves on a sound basis”²⁵. In the context of its previous desire to fund the organisation, this

²² Letter from Karl-Heinz Florenz MEP, chair of the Environment, Public Health and Food Safety Committee, to Josep Borrell Fontelles MEP, President of the European Parliament, April 2005

²³ Implementing Action 10.5 to Recommendation 10: Enhanced Information, *Communication From The Commission To The Council, The European Parliament, The Economic And Social Committee And The Committee Of The Regions: A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient – A Call for Action*.

²⁴ Recommendation 13, as per footnote 22

²⁵ pp53-54, *Communication From The Commission To The European Parliament, The Council, The European Economic And Social Committee And The Committee Of The Regions: Healthier, safer, more confident citizens: a Health and Consumer protection Strategy; Proposal for a Decision Of The European Parliament And Of The Council establishing a Programme of Community action in the field of Health and Consumer protection 2007-2013*.

reference appears to amount to an intent to adapt funding rules to the specific benefit of the EPF.

Tackling secrecy and conflict of interest

Commissioner Kallas has described the aim of establishing transparency as being “to promote the long term success of sound, time-tested policies by acquiring general public support.”²⁶ The sense of disillusionment and distance that the European public seems to feel towards EU institutions, typified in the recent ‘no’ votes in France and The Netherlands, has added to the momentum behind efforts to rebuild public trust by tackling the culture of secrecy that characterises EU consultation and decision-making processes. The example of the European Patients Forum demonstrates the need for the European Transparency Initiative to be founded on clear and enforceable rules about disclosure of who is really behind the activities of ‘patient’ groups, public affairs companies and lobbyists.

The Commission and the EMEA also need to think again about how they consult with patients. The EPF’s non-disclosure of links to the pharmaceutical industry is a serious problem that needs to be remedied. Fundamentally, however, there is a conflict of interest inherent in receiving funds from companies seeking to sell products to the people an organisation represents. The interests of patients and those of the industry are not the same. If the Commission and the EMEA truly wish to consult with patients, they must seek groups that are independent of pharmaceutical industry financing.

²⁶ *The need for a European transparency initiative*, Siim Kallas, Vice-President of the European Commission and Commissioner for Administrative Affairs, Audit and Anti-Fraud, speaking at The European Foundation for Management, Nottingham Business School, 3 March 2005