

# CODE OF PRACTICE BETWEEN PATIENTS' ORGANISATIONS<sup>1</sup> AND THE HEALTHCARE INDUSTRY<sup>2</sup>

## PREAMBLE

The valuable and serious work of patients' groups and the service they provide needs to be recognised, valued and supported. However, most groups are struggling to find sufficient, diversified resources, to fulfil their mission and objectives and remain independent, whether funding comes from corporate or public sources.

Patients' organisations are keen to work in a constructive manner together with all stakeholders to ensure that the credibility of patients' groups is safeguarded.

For this reason, patient organisations (see list below) have developed the following transparent and robust Code of Good Practice to guide the relations between patient organisations and the industry (including their representatives and consultants). We encourage all patient organisations to adopt this Code when engaging in a dialogue, working partnership, joint initiative, and/or when accepting support from any funding source. We expect all signatories to adhere to this Code which may be revised over time as circumstances demand. This Code does not intend to cover every possible funding opportunity or relationship, but rather to define a set of basic principles and recommendations.

We fully appreciate and support that our European healthcare systems stand for social equity and solidarity. We maintain that access to limited resources is governed by principles of equality. In a democratic society, patients' organisations play an increasingly important role. Their work is extremely varied depending on local need, but generally can be divided into two broad categories:

- Raising awareness and advocacy about diseases and health policy issues and how to best maintain health
- Providing support for patients, their families and carers, building capacity within their membership, setting up self help/support groups and sensitising society to equitable sharing of healthcare.

Our governments in Europe are committed to protecting the health of their citizens based on social solidarity, irrespective of age, race, gender, domicile and socio-economic status. This is intended to ensure equality in healthcare and to support the laudable goal of "health for all".

Increasingly as our populations age in Europe and more and more high-tech treatment becomes available; society will be faced with difficult decisions on how finite resources are fairly allocated within healthcare systems and budgets. Patients' organisations along with other stakeholders need to be involved in those debates to ensure that policy decisions and actions are fully transparent and adopted in a consensual manner.

Many interests and stakeholders interact in our health systems. Patients' organisations have the role to ensure that the patients' voice is heard at all levels of decision making, implementation and monitoring of policies and actions that concern health and healthcare and that the existing system achieves the

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<sup>1</sup> Patient organisations are defined as not-for profit organisations which are patient focused, and whereby patients and/or carers represent a majority of members in governing bodies.

<sup>2</sup> The healthcare industry is defined as commercial manufacturers of healthcare products, devices and services, including distributors and wholesalers.

best outcome for society. Patients' organisations have an interest in interacting and communicating with these different stakeholders, including industry, in the interest of their patients. Good communication will embrace trust, integrity, honesty and openness.

Funding support for European activities is difficult to obtain. It very much depends on the organisation raising its own financial resources and relying largely on volunteers to carry out the workload.

Credibility, transparency and democracy are the most treasured assets of patients' organisations.

Every group aims to be in a position to carry out its work based on the support of purely altruistic charitable contributions. However, there are hardly any non-commercial sources prepared to fund patients' groups at a European level. This poses an ongoing challenge to European patients' groups: the need to develop a strategy which will balance corporate funding with a maximum from other sources.

We owe it to our members and patients across Europe, who have placed their trust in us, to act in a fully democratic, independent and transparent manner, according to the highest standards of good governance. We derive our legitimacy from our membership, our statutes and our democratically elected boards, many of whom are patients, carers or survivors who volunteer their time and expertise.

## **1. RECOMMENDATIONS**

We invite patient organisations to adhere to the following recommendations and develop their own Code of Practice along these guiding principles:

### ***1.1 Funding of patient organisation activities***

A patient organisation should only accept funds for activities that are consistent with its mission and objectives. Patients organisations that receive funding from any source, including industry or governmental bodies, should at all times remain open, honest and transparent concerning the amounts and sources of such funding. Public documents of patient organisations, e.g. annual reports and websites, should clearly illustrate such information and be fully accessible. For transparency sake, funders should also receive public acknowledgement for their support. Acknowledgement should be attributed to the funding person or organisation itself, but not to a specific product or project. In line with the EMEA criteria<sup>3</sup>, organisations should indicate the percentage of the overall income that each funder (individual person, government organisations, industry, etc) represents.

### ***1.2 Core funding***

Funds for core activities should always be received on an unconditional basis. To avoid undue reliance on any particular company, such funds should be balanced and diversified as much as possible to avoid conflicts of interest and guarantee independence.

### ***1.3 Project funding***

Funds or sponsorships for projects can only be accepted without any conditions imposed on the design and conduct of the project, guaranteeing full independence of the patient organisation. Any ensuing publication will be the property of the patient organisation(s) and findings may not be used or quoted by the funder without the explicit permission of the patient organisation(s) involved. No information in relation to the project should ever be used to promote the use of any specific product or business of the funder.

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<sup>3</sup> <http://www.emea.europa.eu/pdfs/human/pcwp/1461004en.pdf>

### ***1.4 Funding of patient organisation events***

Patients' organisations may accept funds, sponsorship or assistance in kind for their own specific events. Funding should ideally come from more than one source, though it is recognised that this will not always be possible.

Sponsors should not exercise any control over the programme content or choice of speakers at patient organisations' events.

### ***1.5 Funding of communication activities***

Patient organisations should mention the names of the sponsors supporting their website or electronic materials. Sponsor logo size and the space dedicated to the mention of the company on the website should be modest in size to avoid being perceived as an advertisement. If logos need to be displayed, their size should be restricted and fully implement national/European legislation<sup>4</sup> into consideration.

### ***1.6 Involvement with industry sourced websites, publications or leaflets.***

Patient organisations should not be funded for activities aimed at promoting the use<sup>5</sup> of any specific product and/or service. They may contribute to the production of material that relates to the management of a specific condition but should make all best efforts to ensure that no specific product or other treatment can be perceived to be recommended by the patient organisation.

## **2. PATIENTS ORGANISATIONS' INVOLVEMENT IN ACTIVITIES OF THE INDUSTRY OR OTHER FUNDERS**

Regarding activities relating to a healthcare product, device or service, marketed or distributed by the healthcare industry /or still under development, the following measures are highly recommended:

### ***2.1 Promotional activities related to approved prescription medicines***

All promotional activities related to approved Rx (prescription) medicines are not permitted within the current EU legislation and respective industry codes of ethics. Patient organisations must ensure that none of their activities can possibly be associated with promotional activities. Genuine interaction/cooperation (e.g. satellite symposiums) is encouraged, provided this is in no way promotional. Patient organisations should be mindful of potential conflicts and unintended consequences and ensure that they strictly adhere to their own independent patient-centred agenda.

Patient organisations should develop a list of the types of activities that can be considered promotional and therefore might cause a conflict of interest and be against the law. The list should include the following:

- Disseminating unbalanced, non-validated or partial information about a product/service which is produced, marketed or provided by a company, whether it funds your organisation or not.
- Being quoted in the company's corporate communication in favour of, or against a product.
- Participating as speaker/ participant in a company event for the launch of a pharmaceutical product (see below §2.4).

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<sup>4</sup> European Advertising Directive, [http://ec.europa.eu/consumers/cons\\_int/safe\\_shop/mis\\_adv/index\\_en.htm](http://ec.europa.eu/consumers/cons_int/safe_shop/mis_adv/index_en.htm)

<sup>5</sup> Any use, including compassionate use of the product, not formally marketed.

- Participating in an ad hoc meeting sponsored by a single company to inform patients on their products. (See below §2.4).
- Agreeing that a company displays/disseminates a patient organisation's own materials on the company's exhibition stand at any commercial or trade exhibition or scientific conference.
- Appearing in promotional materials for a certain product of the company (eg. booklets about a specific medicine) or to testify as a "consumer" of that medicine. Contact information to patient organisations can be included in a separate section.

Patient organisations should develop a full list of the types of activities that could be considered promotional under their national legislation.

## **2.2 *Industry press releases***

- Patient organisations and their representatives must be vigilant and refuse to be quoted in industry press releases that relate to a marketed product or a product under development.
- If a patient organisation feels the need to communicate to the media about a product, it should issue its own press release which is clearly independent of industry.
- If a company quotes a patient organisation's opinion or refers to the organisation's own communication materials (magazines, publications, web site etc.) without the organisation's written permission, it is important to object to the company by registered letter with a copy to the company's national industry association<sup>6</sup>.

## **2.3 *Training organised by industry or a group of companies***

If commercial sponsors offer to provide patient organisations with training and capacity building programmes, either about general themes such as "Diseases and the Media", "Management of a NGO", or on more product related themes such as "Drug Regulatory Process", "Cost/effectiveness studies for pricing and reimbursement", or "How to lobby", patient organisations must be aware that not all themes are neutral. Some programmes may influence the patient organisation's or its representatives' way of thinking. The following check points can help to decide whether to participate in such training programmes:

- The programme is sponsored by several companies, instead of a single one.
- Patient organisations/representatives have been involved in the preparatory phase of the training programme.

At all times it is preferable to find an equivalent programme run by other NGOs or academic institutions and ask the company to sponsor the patient organisation's participation.

## **2.4 *Participation in conferences or seminars held by industry***

- If a patient organisation/representative participates in an industry launch/promotion of a product, no photo must be taken or released without prior authorisation from the person/s involved. For clarity and to avoid future complications, it is recommended to make arrangements in writing before the event.
- If a patient organisation/representative participates in an ad hoc meeting sponsored by a single company to inform patients about their products, the former should insist that multiple sources of information from independent third parties are involved to ensure that

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<sup>6</sup> <http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=3484>

the information is more balanced. Information meetings without independent experts present could be considered as an infringement of the Pharmaceutical Advertising Directive<sup>7</sup>.

## **2.5 Guidance for individual compensation**

There are several situations where industry may propose honoraria to a patient organisation's volunteers or staff members:

- Participation in a meeting or conference organised by the company itself.
- Participation in a meeting or conference organised by a third party.
- Reviewing industry materials, leaflets, protocols etc.
- Consultancy on industry policy, advisory committees etc.

This is current practice for health care professionals. Patient organisations should be considered on an equal basis, and therefore can also receive honoraria for similar circumstances. Patient organisations' internal policies and agreements should be fully transparent.

## **2.6 Involvement in industry-source web sites or other material (DVDs, printed material, etc)**

Patient organisations should refrain from contributing to industry web sites.<sup>8</sup>

## **2.7 Disease awareness campaigns by industry**

Disease awareness campaigns can be considered as an indirect form of advertising in some EU countries and therefore against the legislation. Although such campaigns may benefit some patients or the general public, it is unwise of patient organisations to be associated unless the campaign has the backing of the public health authority.

Patient organisations must ensure that any such campaign is not only an industry initiative, but responds to a well characterised public health need, that is agreed and supported by the national and/or European public health authorities.

### **2.7.1 Disease awareness campaigns by patient organisations**

When conducting their own disease awareness campaigns, patient organisations must ensure that any information regarding a commercial product mentioned by them must be based on the Summary of Product Characteristics (SmPC) or another commercially independent and validated source. This information can be made available by the patient organisation, provided the following conditions are observed:

- Clear statement of how the information was arrived at
- Mention of the validated source of information
- Mention of health professionals / independent experts who have been consulted

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<sup>7</sup> Link to Pharmaceutical Advertising Directive

<sup>8</sup> However, any health-related information that a patient organisation provides on its own website or in its printed materials should be free from any commercial advertising. This should also be stated in the information. The accuracy of the information should be checked by an advisory board that is independent from the commercial interests of the company.

- Identification of the Editorial Board who has control, responsibility and oversight
- The patient organisation has a Transparency Policy in place, disclosing funders,

### ***2.7.2 Within industry's editorial responsibility***

Commercial organisations wishing to mention the name of a patient organisation should seek prior written authorisation from the latter.

### ***Conclusion***

This document is intended as guidance to help and encourage patient organisations to develop their Code of Practice. It is a dynamic document and will be updated as necessary. Other areas of collaboration between patient organisations and industry need to be addressed (e.g. clinical trials) for which guidance will be developed in a separate document.

Date: 1 June 2009

### **Patient organisations endorsing this Code:**

European Cancer Patient Coalition (ECPC)\*

European Aids Treatment Group (EATG) \*

GAT - Portugal

RETT Syndrome

Myeloma Euronet

European Organisation for Rare Diseases (EURORDIS) \*

Alzheimer Europe (AE)

European Patient Forum (EPF) \*

International Diabetes Federation - European Region (IDF)

International Patient Organisation for Primary Immunodeficiencies (IPOPI) \*

Lupus Europe

European Men's Health Forum (EMHF)

\*Patient organisations involved in developing the Code