EFCNI european foundation for the care of newborn infants

Code of Practice

Between patient organisations and the healthcare industry*[1]

Preamble

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

Patient organisations are targeting to work constructively together with all stakeholders to ensure that their credibility is safeguarded.

For this reason, patient organisations (see list below) have developed the following transparent and robust *Code of Good Practise* 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. This code aims at defining a set of basic principles and recommendations.

We fully appreciate and support that 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, patient organisations play an increasingly important role. Their work is extremely varied depending on local needs, but can generally be divided into two broad categories: firstly, raising awareness and advocacy about diseases and health policy issues and secondly 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 guarantee equality in healthcare and to support the laudable goal of “health for all”.

Demographic change, ageing societies and a growing range of medical high-tech treatments existing, will confront our society with difficult decisions on how finite resources are fairly allocated within European healthcare systems and budgets. Patient 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. Patient organisations have the role to warrant that the patients’ voice is heard at all levels of decision making, monitoring the

[1] The healthcare industry is defined as commercial manufacturers of healthcare products, devices and services, including distributors and wholesalers.

implementation of policies and actions that concern health and healthcare and that the existing system achieves the best outcome for our society. Patient organisations take an interest in interacting and communicating with different stakeholders, including industry representatives, in the interest of their patients. Good communication will embrace trust, integrity, honesty and openness.

Funding support for NGO 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 patient 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 patient groups. This poses an ongoing challenge to patient groups: the need to develop a strategy which will balance corporate funding with a maximum from other sources.

We owe it to our partners, 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 would like to thank the European Cancer Patient Coalition (ECPC), the European Aids Treatment Group (EATG), the European Organisation for Rare Diseases (EURORDIS) and the International Patient Organisation for Primary Immunodificiencies (IPOPI) for the development of this Code.

1. Recommendations

As EFCNI, we adhere to the following recommendations and invite patient organisations to develop their own *Code of Practise* 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. Patient 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's 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. Patient 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

Financial support 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 and findings may not be used or quoted by the funder without the explicit permission of the patient organisation 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.

1.4 Funding of patient organisation events

Patient organisations may accept financial support 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. Financial engagement should not exercise any control over the programme's content or choice of speakers at patient organisations' events.

1.5 Funding of communication activities

Patient organisations should mention the names of the corporate partner supporting their website or electronic materials. Corporate logo size and the space dedicated to the mention of the corporate partner 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.

1.6 Involvement with industry sourced websites, publications or leaflets

Patient organisations should not be funded for activities aimed at promoting the use 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. In this context we refer to the International Codex of Marketing of Breast-Milk Substitutes.

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 (prescription) medicines are not permitted within the current EU legislation and respective industry codes of ethics. Patient organisations must guarantee 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 but is not limited to 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 an 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).
- Participating in an ad hoc meeting supported by a single company to inform patients on their products. (see below 2.4).
- Appearing in promotional materials for a certain product of the company (e.g. 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.

2.2 Industry press releases

- Patient organisations and their representatives must be alert 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.

2.3 Training organised by industry or a group of companies

If corporate partners offer to provide patient organisations with training and capacity building programmes, either about general themes such as "Diseases and the Media", "Management of an 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 funded 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 fund 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 photos 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 funded 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 the

information is more balanced. Information meetings without independent experts present could be considered as an infringement e.g. of the EU Pharmaceutical Advertising Directive or other adequate legislation.

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. 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.

2.7 Disease awareness campaigns by industry

Disease awareness campaigns can be considered as an indirect form of advertising in some EU countries and may therefore be 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 assure 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

- 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.

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Policy
Acceptance/Refusal of Gifts and Donations

The Trustee and Executive Boards of EFCNI take responsibility for decisions relating to whether a donation is accepted or refused. Decisions are made based on the following criteria:

1. it is in the best interests of EFCNI and will assist in the goals of the foundation
2. do not undermine the key areas of EFCNI's activities according to the statutes
3. do not damage the reputation of EFCNI and potential future funding
4. promote any Trustee's or employee's personal moral agenda

EFCNI's Trustee and Executive Boards meet once per year to monitor EFCNI's activities and funding and the Chair Executive regularly with the Chair of the Board of Trustees.

Policy on Acceptance of Gifts

EFCNI will be transparent about gifts accepted in terms of their sources and purposes.

EFCNI will not accept gifts in cases where to do so would, on the balance of risks:

- Create unacceptable conflicts of interest
- Cause material damage to EFCNI's reputation (including deterring significant numbers of beneficiaries or other donors)
- Cause financial loss or any other damage to EFCNI
- The source of the donation is unknown
- Be directly inimical to EFCNI's mission and objectives according to the statutes
- EFCNI will take all reasonable steps, having regard to the size and nature of the donation in question, to ensure that it is aware of the ultimate source of funding for each gift and to satisfy itself that the funds do not derive, directly or indirectly, from activity that was or is illegal or which runs counter to the provisions of this policy. Where necessary EFCNI will look behind charitable trusts and foundations in order to satisfy itself about their ultimate source of funding
- **EFCNI reserves the right to refuse any donation that it believes is not in the best interests of the Foundation**
- **A gift agreement is required for all gifts of 50 € and above**

Policy regarding Donations of Specific Industries

Alcohol Industry

EFCNI will not accept financial donations of any size from an alcohol manufacturer because of the direct link between the use of alcohol and problems in pregnancy and in the newborn.

However, if an employee of an alcohol manufacturer, due to personal circumstances wishes to support and donate to EFCNI from personal efforts, this is acceptable to the Trustees. It is felt by the Trustees that many people who have experienced the heartache of losing a baby often would like to support a charity in memory of their baby and to prevent others from having a similar experience. Not accepting their donations on the basis on who they work for would be unacceptable discrimination.

This policy does not apply companies such as supermarkets where many products are stocked and are not reliant on just alcohol.

Tobacco Industry

We will not accept donations of any size directly from any tobacco company. This decision is made because tobacco plays a key role in problems in pregnancy and undermines our aim to ensure every baby is given the best start in life.

However, if an employee of a tobacco company, due to personal circumstances, wishes to support and donate to EFCNI from personal efforts, this is acceptable to the Trustees. It is felt by the Trustees that many people who have experienced the heartache of losing a baby often would like to support a charity in memory of their baby and to prevent others from having a similar experience. Not accepting their donations on the basis on who they work for would be unacceptable discrimination.

Arms and military industry

The Parties will not accept funding or donations of any size directly from any company involved in the production of or trade with arms or with military. This decision is made because this field of industry hampers neutrality and undermines our aim to ensure every baby is given the best start in life.

However, if an employee of a company active in the above mentioned industry or trade, due to personal circumstances, wishes to support and donate to the organisation from personal efforts, this is acceptable to the Parties. Many people who have experienced the heartache of losing a baby often would like to support a charity in memory of their baby and to prevent others from having a similar experience. Not accepting their donations on the basis on who they work for would be unacceptable discrimination.

Baby Milk Industry

The Trustees strongly support that breastfeeding is necessary for the healthy development of babies, that it is crucial for saving preterm and newborn babies lives and influences a child's development far into the future. Every baby should have access to breast milk. It should be the first choice and should be regarded as best practice.

The Trustees also recognize that, in the case of preterm and newborn babies it is not always possible to follow this best practice and help is required in the form of expressed breast milk

from the mother or from a donor, the use of fortifiers or the use of specially formulated preterm infant formula which needs to be research save and of high-quality.

It is research proven that for very small preterm babies; the milk of their mothers needs fortifiers to ensure a healthy brain development of the baby. Consequently, even existing breast milk from mothers of very preterm babies needs to be supplemented with, what we feel is very important, a research and high-quality proven fortifier.

EFCNI is aware of the WHO's code in relation to marketing of infant formulas and will not enter into initiatives which contravene these. EFCNI accepts financial donations from milk manufacturers. EFCNI will not provide direct endorsement of infant milk products e.g. logo on packaging or promotions which promote infant formula instead of breastfeeding.

No infant feeding products or product information will be passed onto any beneficiary of our training grants nor will personal data be passed onto a milk manufacturer.

The Trustees do not believe this industry contravenes with the cause, vision and mission of EFCNI as stated in the statutes.

Pharmaceutical industry

EFCNI accept financial donations from pharmaceutical companies. We will not be aligned to any one company and seek collaborations with all pharmaceutical companies who can play a major role aim at improving maternal and newborn health. No pharmaceutical company will have influence over our decisions.

For all financial donations, EFCNI adheres to the Code of Conduct signed by the Trustee and Executive Board and also available on our website.

Munich, 9 December 2022

Trustee Board of EFCNI