



EURORDIS
Rare Diseases Europe

P O L I C Y

EURORDIS POLICY ON FINANCIAL SUPPORT BY COMMERCIAL COMPANIES

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1 INTRODUCTION

1.1 About rare diseases

There are about 6,000 to 8,000 rare diseases affecting an estimated 30 million people throughout Europe. Most rare diseases are chronic, progressive, disabling, severe to very severe and most often life-threatening. While they mainly affect children, they can occur at any time in life. There is no treatment and no cure for most rare diseases.

1.2 About EURORDIS

The European Organisation for Rare Diseases, EURORDIS (Rare Diseases Europe) *is a non-governmental patient-driven alliance of patient organisations and individuals active in the field of rare diseases, dedicated to improving the quality of life of all people living with rare diseases in Europe.*

EURORDIS represents more than 400 rare disease organisations in over 40 different countries, covering more than 1,000 rare diseases. It is therefore the voice of 30 million patients affected by rare diseases throughout Europe.

It is supported by its members, the French Muscular Dystrophy Association (AFM), the European Commission, and corporate foundations and the health industry. EURORDIS was founded in 1997.

Further details concerning EURORDIS and rare diseases are available at: <http://www.EURORDIS.org>

EURORDIS' mission is to build a strong pan-European community of patient organisations and people living with rare diseases, to be their voice at the European level, and - directly or indirectly - to fight against the impact of rare diseases on their lives.

To this end, EURORDIS undertakes activities on behalf of its members, notably in favour of:

- Empowering rare disease patient groups
- Advocating rare diseases as a public health issue
- Raising public rare disease awareness, and also that of national and international institutions
- Improving access to information, treatment, care, and support for people living with rare diseases
- Encouraging good practices in relation to these
- Promoting scientific and clinical rare disease research
- Developing rare disease treatments and orphan drugs
- Improving quality of life through patient support, social, welfare and educational services.

Amongst its major achievements, EURORDIS played a fundamental role in the adoption of the EU Regulation on Orphan Medicinal Products, the EU Regulation on Paediatric Use of Medicines, the EU Regulation on Advanced Therapies, as well as of the Commission Communication on "Rare Diseases: Europe's challenges" and the Council Recommendations on an action in the field of Rare Diseases. EURORDIS is taking an active role in the implementation of these regulatory and policy documents and will follow up closely on concrete achievements. This track record has been made possible thanks to EURORDIS legitimacy, credibility, strength of its network, as well as to its independence.

1.3 About EURORDIS funding

As any other organisation, EURORDIS needs funds to carry out its mission. When it was first established, EURORDIS was funded 100% by its members, in particular by AFM-Telethon, a major patient group. EURORDIS has gradually diversified its sources of funding from the European Commission and private sources. The European Commission supports EURORDIS activities through grants such as Research or Public Health grants. Private sources of funding include private foundations and commercial companies from the health and non-health sector.

Like many other patient organisations, EURORDIS is increasingly expanding the financial support it receives from commercial companies for a significant proportion of its activities and projects.

To maintain its independence, EURORDIS has set itself the objective to balance revenues, both monies and in-kind, from these 3 different sources in its Strategy 2010-2015. The ideal goal is to reach the following distribution: 1/3 from Patient Organisations including membership fees to EURORDIS, AFM-Telethon and the economic valorisation of volunteers contribution, 1/3 from the public sector including the European Commission (EC) and national authorities and 1/3 from the private sector including not-for-profit organisations and commercial companies, both from the health and non health sectors.

In its annual budget, EURORDIS limits the total financial support it receives from commercial companies in the health sector to the total amount of funding provided by Patient Organisations including its membership fees, the AFM-Téléthon and volunteers.

To avoid the risks inherent in an economic relationship with a single company, or a limited number of companies, from the health sector, EURORDIS diversifies the types of financial support it receives from commercial companies and gradually increases the number and profile of its corporate donors.

To avoid the risks inherent in a relationship between an NGO and commercial companies, and to avoid potential conflicts of interest, the following activities of EURORDIS are never funded by commercial companies of the health sector:

- All activities related to governance, mainly the Board meetings and the General Assembly;
- The salaries of the staff dedicated to advocacy work (mainly the CEO and the European Public Affairs Director and Advisor);
- All activities related to EURORDIS representation in different fora, such as the EMEA Committees or the EU Committee of Experts on Rare Diseases.

1.4 About EURORDIS Policy on Financial Support by Commercial Companies

On the European political scene, EURORDIS is widely credited with being the voice of people living with rare diseases. EURORDIS has played a major role in creating a favourable framework for research development and access to treatments for people living with rare diseases (PLWRD). It is therefore bound to attract the attention of companies that have a particular interest in the development of treatments and other services for rare diseases patients.

EURORDIS therefore felt the compelling need to establish clear rules to regulate its relationships with commercial companies.

Since 2000, EURORDIS has been at the forefront of the promotion of both good practices in the field of NGOs' Transparency and the regulation of relations between patient groups and commercial companies. This twofold goal has been mainly pursued at three levels:

1. *The adoption in 2005 of the EURORDIS Position on NGOs Transparency* (http://www.eurordis.org/IMG/pdf/Eurordis_position_transparency_oct05.pdf): Eurordis believes that transparency cannot be restricted to the narrow issue of transparency on funding - a necessary but not sufficient condition of transparency. Any policy on transparency should provide clear answers to the following questions: Who does the NGO represent? What is its representativeness? How is the NGO funded and which public or private interests does it represent? Does the NGO have a track record of credible work? Does the NGO really contribute to the debate? Does it have clear written public statements on its positions?

EURORDIS believes that the transparency of an NGO lies primarily in: its mission and values; the legitimacy of its membership base; its governance practices; and its internal and public policy practices. Consequently, the transparency of an NGO also lies in the transparency of its financial information; the internal and external financial control by independent audits; the transparency of its financial relationships with funding sources, both public and private; the transparency of its financial relationships with commercial companies; the prevention of potential conflicts of interest, both public and private.

In all of its activities EURORDIS respects and promotes the fundamental value of transparency, by following the principles of legitimacy, credibility, responsibility, independence and accountability.

2. *The elaboration of the current EURORDIS Policy on Financial Support by Commercial Companies*: this policy was initially adopted in 2001, and successively reviewed in 2003, 2007 and 2009; it does not set out to provide a definition of every possible funding opportunity or relationship, but rather to define a set of principles.

3. *The contribution to the elaboration, in 2008-2009, of a Code of Practice between Patients' Organisations and the Healthcare Industry* (http://www.eurordis.org/IMG/pdf/round_table_code_conduct.pdf).

EURORDIS believes it is essential to establish transparent rules about financial support from commercial companies, and in particular about what companies may - or may not - expect from EURORDIS in return.

The present Policy Paper covers issues related to financial support, in-kind support and involvement of EURORDIS in companies' activities. It is aimed at ensuring that EURORDIS' members, the general public and all relevant stakeholders are aware of the EURORDIS policy as validated by our Directors. EURORDIS directors, staff and volunteers are expected to adhere to this policy and to perform their duties accordingly.

This policy may be further reviewed when needed.

2 GENERAL PRINCIPLES

2.1 Principles to be applied by EURORDIS in its relationship with Commercial Companies

EURORDIS welcomes financial support by commercial companies as long as the relationship between EURORDIS and these companies is based on the following principles:

- relevance of a public health objective driven by patient needs
- full independence of EURORDIS
- mutual respect
- mutual benefit
- accountability and transparency

EURORDIS believes it is important to establish and maintain relationships with commercial companies in order to enhance communication between patients, whose interests we represent, and companies, whose decisions will affect the provision of health services or treatments to patients.

EURORDIS sees corporate donation programmes as a good practice in corporate governance and one of the ways commercial companies can support people affected by the rare diseases they are working on, or redistribute to the European rare disease community some of the profits they are making.

EURORDIS supports the availability of the widest range of orphan medicinal products, other medicines, treatments and health services; it does not endorse individual medicinal products or treatments; it encourages active partnership between patients and health professionals as well as discussion of all available options to ensure patients make informed choices.

The relationship between EURORDIS and commercial companies is based on partnership, while preserving EURORDIS independence and integrity. To ensure a successful partnership, each partner should learn to understand each other's internal culture and external constraints.

Financial support resulting from partnerships with companies is dedicated to activities in the areas of rare diseases; treatments; public awareness; patient support; capacity-building; and social, health and educational services.

In any case, funding by commercial companies:

- must be for the benefit of the patients EURORDIS represents,
- must not entail product advertisement,
- cannot influence in any way EURORDIS policy, positions or decisions, whether explicitly or implicitly.

As long as these principles are respected, EURORDIS does not foresee any potential conflict of interest with commercial companies at large, with the important exception of commercial companies in the health sector.

2.2 Exclusion factors

EURORDIS does not support any specific medicinal product, brand, or health service. It must not be – or appear to be - associated with any specific commercial company.

EURORDIS refuses financial support from companies generating a public health risk, making unsubstantiated or misleading claims about their products, or not taking into consideration the specific needs of rare diseases patients. EURORDIS is particularly cautious of situations that are brought to its attention by its members or other rare diseases patients in Europe.

Should a company's strategy evolve over time and potentially conflict with EURORDIS' positions and need to maintain its independence, financial support from this company would not be accepted or would be discontinued.

Inclusion and exclusion decisions about membership to the EURORDIS Round Table of Companies are made by EURORDIS. Exclusion can be decided by EURORDIS on grounds such as a breach of the EURORDIS Round Table Code of Conduct or of the EURORDIS Policy on Financial Support by Commercial Companies.

3 Types of Financial Support by Commercial Companies to activities promoted by EURORDIS

3.1 Funding of EURORDIS projects

EURORDIS may accept financial or in-kind commercial companies' support for a specific project. It provides EURORDIS with a reliable source of income over a number of years to cover direct costs such as personnel, equipment, consultants or suppliers, mission and travel expenses, as well as related indirect costs (telephone, administrative follow-up of project...).

Companies providing support for a project are publicly acknowledged by EURORDIS (printed documents, website, and electronic communications) to ensure transparency and recognition.

The companies' support has no influence on the design and the conduct of the project, its participants or publication, which will be the property of EURORDIS. Companies supporting a project may be regularly consulted through transparent ad hoc processes such as a donors' committee.

3.2 Funding of EURORDIS events

EURORDIS may accept financial or in-kind contribution by commercial companies for its conferences, workshops, training, capacity-building sessions and other specific events it organises. It provides EURORDIS with a reliable source of income to cover direct costs such as personnel, equipment, consultants or suppliers, mission and travel expenses, as well as related indirect costs.

Funding should come from more than one source.

Companies providing support for an event are publicly acknowledged by EURORDIS (printed documents, website, electronic communications and onsite display) to ensure transparency and recognition.

Sponsors do not exercise any control over the programme, the choice of speakers and the selection of attendees.

3.3 Funding of EURORDIS communication activities

EURORDIS may accept financial or in-kind commercial companies' support for its communication activities, including awareness campaigns and communication tools, such as newsletter, leaflets, reports, and website. It provides EURORDIS with a reliable source of income to cover direct costs such as personnel, equipment, consultants or suppliers, mission and travel expenses, as well as related indirect costs.

Companies providing support will be mentioned in paper and electronic materials. The companies' logo size will be modest to avoid being perceived as an advertisement. Furthermore, the companies' mention is corporate-related and not product-related.

3.4 Membership of the EURORDIS Round Table of Companies

The EURORDIS Round Table of Companies was created to establish a long-term educational relationship between EURORDIS and those companies operating in the health sector that have an interest in orphan drugs, treatments, medical devices, food supplements and health services for people living with rare diseases. This relationship is driven by the principles stated in the Round Table's Code of Conduct, signed by every company becoming a member of the Round Table of Companies.

The specific aims of the EURORDIS Round Table of Companies are:

- To provide EURORDIS with pooled financial support for unrestricted funding with no strings attached, in favour of activities of common interest and benefit, such as:
 - Improving access to information, treatment, care, services and support for people living with rare disease across Europe;
 - Raising public awareness on orphan drugs, rare diseases, and on the need for more research;
 - Empowering rare disease patient groups and improve their advocacy capacity (through information, training and networking);
 - Improving identification and increasing knowledge of rare disease patient groups at the European level; facilitating networking and reaching out to them.
- To educate concerned companies on the common goal of facilitating rapid development and availability of treatments and services for people affected by rare diseases.
- To network with leaders of the rare disease community, patient groups, voluntary health organisations, regulatory agencies and policy makers, and promote open and frank sharing of information, in a neutral forum, on the process, obstacles and incentives for development of treatments.
- To stimulate orphan drug companies to address patient needs and to encourage other companies not yet involved in this field to develop treatments for rare diseases.

- To offer a venue to educate companies on working with patient groups and help them build partnerships with the patient community and academics.
- To facilitate the exchange of views between patient and industry representatives, in order to understand why, when, and how to work with patients.

3.5 One-off charitable donations

One-off charitable donations are not linked to a specific project or activity. They do not create any obligation by EURORDIS to publicly acknowledge the financial support it receives. However, this information may be shared at times such as the EURORDIS Annual Financial Report and Membership Meeting.

3.6 Other In-kind support

Commercial companies may also make non-monetary contributions to EURORDIS, such as:

- Seconded staff or professional services provided without charge
- Equipment donations (e.g. computers and other equipment)
- Meeting rooms
- Other non-monetary contributions (e.g. furniture, printing services)

4 EURORDIS involvement in activities of the health industry

This section deals with EURORDIS involvement in activities related to medicinal products, medical devices or services which are marketed or distributed by industry or still under development. This new additional section in the 4th revision of the 'EURORDIS Policy on Financial Support from Commercial Companies' derives from the 'Code of Practice between Patient Organisations and the Healthcare Industry' developed in 2008-2009 by a group of patient organisations including EURORDIS.

4.1 Promotional activities related to approved prescription medicines

All promotional activities related to approved medicines are not permitted within the current EU legislation and industry codes of ethics. EURORDIS does not get involved in activities that can be possibly associated with a promotional strategy. EURORDIS always keeps in mind potential conflicts of interest and is guided by its own agenda, lead by the interests of rare diseases patients.

Types of activities that can be considered promotional under European and national legislation:

- Disseminating unbalanced, non-validated or partial information on products, services or MDs distributed or marketed by a company;
- Being quoted in the company's communication in favour – or against – a product;
- Participating as a speaker/attendee in a company's product launch event ;
- Participating in an ad hoc meeting sponsored by an individual company to inform patients on their products;
- Agreeing that a company displays or disseminates a patient organisation's own material on the company's exhibition stand at any trade exhibition or scientific conference;
- Appearing in promotional materials for a certain product or to testify as a "consumer" of that medicine. Contact information to patient organisations can be included in a separate section.

4.2 Industry press releases

- EURORDIS refuses to be quoted in industry press releases that relate to a marketed product or a product under development;
- If EURORDIS feels the need to communicate to media about a product, it will issue its own press release, independently of industry;
- If a company quotes EURORDIS' opinion or refers to EURORDIS' own communication materials without EURORDIS' permission, EURORDIS will object to the company by registered letter (copy to the national industry association of the company).

4.3 Training organised by industry or a group of companies

EURORDIS is aware that not all themes for a potential training provided by a commercial sponsor are neutral, either about general themes or on more product related themes. Some programmes may have an influence on EURORDIS representatives' way of thinking.

In this context, it is important that the programme is sponsored by several companies, rather than a single one, and that EURORDIS' representatives have been involved in the preparatory phase of the training programme.

Generally speaking, it is preferable to find an equivalent programme run by a Patient Group and advisable to ask commercial companies to sponsor EURORDIS participation in the training.

4.4 Participation in conferences or seminars held by industry

- If EURORDIS representatives participate in an industry launch or promotion of a product, no photo must be taken or released without prior authorisation of the person involved. To this end, arrangements in writing prior to the event are recommended.
- EURORDIS representatives will insist that multiple sources of information are involved in an ad hoc meeting sponsored by a single company, aimed at informing patients about their products. Information meetings without the presence of independent experts could be considered as an infringement of the Pharmaceutical Advertising Directive.

4.5 Individual compensation

There are several situations where industry may propose honoraria to EURORDIS representatives:

- Participation in meetings or Conferences organised by the company;
- Participation in meetings or Conferences organised by a third party;
- Reviewing industry materials, leaflets, protocols, etc.
- Consultancy on industry policy, advisory committees and Boards, etc.

EURORDIS representatives are as much entitled as healthcare professionals to receive honoraria for similar circumstances/services?

Nevertheless, EURORDIS internal policies and agreements guarantee full transparency:.

- For volunteers: Before receiving any individual compensation, all EURORDIS volunteers will ask clearance approval to the CEO and who will inform the Board of Officers of his decisions.
- For staff: All EURORDIS staff members may not directly receive individual compensation, this compensation will be received by EURORDIS, after the CEO's explicit clearance approval.

4.6 Involvement in industry-source websites or other material

EURORDIS does not contribute to industry websites.

4.7 Diseases awareness campaigns by industry

Disease awareness campaigns can be considered as an indirect form of advertising in some Member States. It is unwise that EURORDIS be associated unless these campaigns have the backing of the public health authority. EURORDIS must ensure that any campaign its representatives participate to is not only an industry initiative but does respond to a well characterised public health need. Any product information disseminated by the industry during these campaigns must be based on the Summary of Products Characteristics (SmPC).

Companies wishing to mention the name of EURORDIS must ask prior written permission.

5 Process

5.1 Documentation

When approaching or being approached by a commercial company, EURORDIS usually requests information such as the main business activities of the company. EURORDIS also does background research such as the company's reputation with concerned patient groups and regulators.

EURORDIS provides companies with its activity and financial reports, and its Policy on Financial Support by Commercial Companies. EURORDIS requests every commercial company it collaborates with to carefully read and approve this Policy. A copy of this Policy remains with the company.

5.2 Accountability

Commercial companies supporting EURORDIS receive the annual activity report and the annual financial report covering the period of the donation, after these documents have been approved at the Annual Membership Meeting.

The company receives interim and final reports concerning the project. When financial support is provided in the context of a special initiative, the company receives a copy of relevant documents.

5.3 Recognition and visibility of the relationship

Companies may wish to be publicly acknowledged for their financial support. Prior agreement will be reached on communication matters and detailed in the contract. As part of its transparency policy and for 'fair' partnership reasons, EURORDIS may provide adequate recognition to a commercial company for its financial support and commitment.

The level of visibility given to the company, including the logotype used and the wording in the communication material, require prior agreement from both parties.

When a commercial company does mention the financial support it gives to EURORDIS, the wording used and/or EURORDIS' name and logotype cannot be used without prior approval by EURORDIS. Any public information should be jointly agreed between the President or the Chief Executive Officer of EURORDIS and the commercial company.

5.4 Transparency policy

By adopting and publishing a transparency policy on relationships with commercial companies, EURORDIS acknowledges that the financial support it receives will never compromise its independence and future policy decisions.

The Annual Financial Report of EURORDIS reflects the level of financial support it receives from corporate donors and provides fair and reliable information to members and the public. The Annual Financial Report is published on the EURORDIS website.

Financial support is acknowledged in projects and initiatives' reports and documents, as well as in public presentations, other relevant documents, and on EURORDIS' website. The EURORDIS website has a section where financial information is provided; it includes a list of all donors to EURORDIS.

5.5 Derogation

In case of *force majeure* or situation not foreseen in this EURORDIS' Policy on financial support by commercial companies, a derogation is possible. Any derogation to this policy, and in particular to the transparency rules applied for commercial companies in the health sector, has to be officially and transparently discussed, duly motivated, and adopted by the Board of EURORDIS. If such decision was to be significant, it would be mentioned in the Annual Report and the members would be informed through the reports at the Annual General Assembly.

6 Final remarks

The scope of this EURORDIS Policy is its relationships with commercial companies and responds to the need felt by EURORDIS to establish clear rules on financial support it may receive from commercial companies, in particular from commercial companies in the health sector.

While being a EURORDIS Policy Paper, any other patient organisation, whether a member of EURORDIS or not, may feel inspired and encouraged by this Policy when elaborating its own rules in this field.