



RARE
DISEASES
INTERNATIONAL

Rare Diseases International (RDI) Policy on the Relationship and Financial Support by Commercial Companies

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1. Introduction

1.1. About rare diseases

Rare diseases are diseases that affect a small number of people compared to the general population and that bring specific challenges in relation to the diseases' rarity. Each country or region establishes its own definition of a rare disease. For instance, in Europe a disease is defined as rare when it affects fewer than one in 2,000 citizens, while in Japan, a disease is defined as rare when it affects fewer than 50,000 in the Japanese territory, which corresponds to up to four per 10,000 people.¹

Rare diseases are characterised by a wide diversity of symptoms and signs that vary not only from disease to disease but also from patient to patient. Still, rare disease patients face common challenges derived from the rarity of their conditions and aggravated by the low priority given to rare diseases globally. Rare diseases are often chronic, progressive, degenerative, and life-threatening. Most rare diseases are genetic and affect children. Inability to obtain an accurate diagnosis, lack of treatments and care are difficulties faced by rare disease patients everywhere, and these difficulties are greater in many low- and middle-income nations.

Addressing rare diseases on an international level is critical to reduce health inequalities between populations worldwide and ensure that people living with a rare disease have access to the same resources as any other population.

1.2. About Rare Diseases International (RDI)

RDI is the global alliance of people living with a rare disease across all nationalities and all rare diseases. RDI brings together national and regional rare disease patient organisations from around the world as well as international disease-specific federations to create the global alliance of rare disease patients and families. Objectives are to:

- promote rare diseases as an international public health and research priority through public awareness and policy-making
- represent RDI Members and people living with a rare disease at large in international institutions and forums
- enhance the capacities of RDI Members through information, exchange, networking, mutual support and potentially joint actions

Further details concerning RDI are available at: <https://www.rarediseasesinternational.org>.

¹ Orphanet, *About Rare Diseases* and *About Orphan Drugs*: https://www.orpha.net/consor/cgi-bin/Education_AboutRareDiseases.php?lng=EN and https://www.orpha.net/consor/cgi-bin/Education_AboutOrphanDrugs.php?lng=EN&stapage=ST_EDUCATION_EDUCATION_ABOUTORPHAN_DRUGS_JAP

1.3 About RDI funding

As any other organisation, RDI needs funds to carry out its mission. From its inception in 2009 until its launching as a fully fledged NGO in 2019, RDI was hosted and funded by EURORDIS- Rare Diseases Europe. EURORDIS will continue to support RDI through 2024 with in-kind administrative services, strategic and management support, and advocacy capacities thanks to funding secured for EURORDIS' International Initiatives.

Progressively, RDI is developing its funding base to include member and volunteer contributions, companies in the healthcare sector and beyond, and foundations. Like many other patient organisations, RDI seeks to engage companies for financial support, and to work appropriately with corporate stakeholders to advance RDI's mission. To maintain its independence, RDI has set itself the objective to balance revenues, both monies and in-kind, from multiple sources, working toward the following distribution: one-third from RDI Members including the economic valorisation of volunteer contributions; one-third from a broad range of companies and one-third from non-profit organisations, including foundations, and RDI's own events to raise funds.

1.4 About RDI Policy on the Relationship and Financial Support by Commercial Companies

RDI believes it is essential to establish transparent rules about financial support from commercial companies. This Policy covers issues related to financial support, in-kind support, involvement of RDI in companies' activities, and meetings between companies and RDI's staff or volunteers. It is aimed at ensuring that RDI's Members, the general public and all relevant stakeholders are aware of RDI's policy as validated by the RDI Council. RDI Council Members, staff and volunteers are expected to adhere to this policy.

This policy may be further reviewed when needed.

2. General Principles

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

- interactions with and contributions by companies are driven by patient needs
- full independence of RDI
- mutual respect
- transparency
- traceability
- accountability

RDI believes it is important to establish and maintain relationships with commercial companies in order to enhance communication between patients, whose interests RDI represents, and companies whose decisions affect health services or treatments for rare diseases.

RDI sees corporate donation programmes as a good practice in corporate governance, as one of the ways to support people affected by the companies' products or services, or to redistribute to the rare disease community some of the profits companies make.

RDI does not support any specific product, brand, or service, but rather supports the availability of the widest range of effective medicines, treatments, health services and technologies. RDI encourages active partnership among patients and health professionals as well as discussion of all available options to ensure patients make informed choices.

The relationship between RDI and commercial companies is based on partnership, while preserving RDI's independence and integrity. To ensure a successful partnership, each partner must learn to understand the other's internal culture and external constraints.²

All funding by commercial companies:

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

As long as these principles are respected, RDI does not foresee any potential conflict of interest with commercial companies at large.

3. Exclusion factors

RDI's primary means of interacting with companies is through the RDI Alliance of Companies for Patient-Centered Action (RDI Alliance of Companies). Inclusion and exclusion decisions are made by RDI. Exclusion can be decided by RDI on grounds such as a breach of the RDI Alliance of Companies Code of Conduct, or of this Policy.

² Acceptance of companies' support should not be interpreted as an endorsement by RDI, which cannot be aware of all aspects of its corporate donors.

4. Types of Financial Support by Commercial Companies

4.1 Membership of the RDI Alliance of Companies for Patient-Centered Action (RDI Alliance of Companies)

The RDI Alliance of Companies is being created in 2019 to establish a long-term educational relationship between RDI and companies with products or services that have an impact on people living with a rare disease. This relationship is driven by the principles stated in the RDI Alliance of Companies Code of Conduct, signed by all companies joining the group.

The RDI Alliance of Companies is RDI's platform for companies to support the rare disease cause and to increase mutual understanding of issues important for rare disease patients and the companies. Engagement is driven by the principles stated in this Policy and in RDI Alliance of Companies Code of Conduct.

The alliance aims to:

- A. Build an international, cross-industry network of companies working in areas that affect rare disease patients.
- B. Exchange perspectives on issues vital to the industries and to rare disease patients, as reflected in RDI's advocacy agenda.
- C. Stimulate companies across many industries to address patient needs.
- D. Provide RDI with pooled financial support for unrestricted funding to advance RDI's mission.

Members of RDI Alliance of Companies make an annual contribution to be used at the discretion of RDI. Members are expected to send up to two delegates to participate in:

- The RDI Annual Meeting (with exception of the Annual General Assembly)
- One - two annual virtual meetings or webinars to gain input from corporate stakeholders of the rare disease cause
- RDI Policy events as they arise and as the Company is able

To ensure transparency, companies in the alliance are recognised on the RDI website and Annual Activity and Financial Reports.

4.2. Funding of RDI Fellowship Programme

RDI may accept financial support from commercial companies for the RDI Fellowship Program. Corporate funding assists RDI to cover costs including travel, subsistence and in some cases event fees or other charges associated with an educational activity, as well as costs to administer the programme.

Contributions are combined in a common pool of funding to assist rare disease patients and their representatives to participate in mentoring programs and events such as: the RDI Annual Meeting, conferences co-organized by RDI, and United Nations events relevant to rare diseases.

Companies providing support do not exercise any control over fellowship allocation or choice of fellowship recipients. Companies providing support are publically acknowledged to ensure transparency of funding (RDI website, printed and electronic materials). The companies' logo size should be modest to avoid being perceived as an advertisement. The mention is company-related and not product-related.

4.3. Funding of RDI Conference Programme

RDI may accept financial or in-kind support from companies for conferences, workshops and other events it organises or supports. Support from commercial companies provides RDI with a reliable source of income to cover direct costs such as personnel, equipment, consultants or suppliers, mission and travel expenses, as well as indirect costs.

Funding should come from more than one source.

Companies providing support for an event are publicly acknowledged by RDI to ensure transparency and recognition.

Companies providing support do not exercise any control over events' programme, choice of speakers or selection of attendees.

4.4. Funding of RDI projects

RDI may accept financial or in-kind commercial companies' support for a specific project. It provides RDI 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 indirect costs.

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

Companies' funding has no influence on the design and the conduct of the project, its participants or publication, which will be the property of RDI. Companies supporting a project

may be regularly consulted through transparent ad hoc processes such as a donors' committee.

4.5. One-off charitable donations

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

4.6. Other In-kind support

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

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

5. RDI involvement in activities of the health industry

5.1 Promotional activities related to products

RDI does not get involved in activities that could be associated with companies' promotional strategies. RDI always keeps in mind potential conflicts of interest or competing interests and is guided by RDI's own agenda and professional ethics, led by the interests of rare diseases patients.

Types of activities that can be considered promotional include:

- Disseminating unbalanced, non-validated or partial information on products or services provided or marketed by a company
- Being quoted in the company's communication in favour – or against – a product or service
- Participating as speaker's/participant in a company event launching a product or service
- Participating in an ad hoc meeting sponsored by a single company to inform patients about their products or services

- Agreeing that a company displays or disseminates a patient organisation's own material on the company's exhibition stand at any commercial or trade exhibition or scientific conference
- Appearing in promotional materials for a certain product or to testifying as a "consumer" of a medicine or service

5.2 Industry press releases

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

5.3 Training organised by industry or a group of companies

It is highly preferable for trainings organised by industry to be funded by several companies. If an RDI representative participates in the training, it is preferable for RDI or another patient organisation to be involved in the preparatory phase of the training programme.

It is generally preferable to find an equivalent programme run by a patient group. Commercial companies may support RDI's participation in trainings but have no control over RDI's input or participation during such events.

5.4 Participation in conferences or seminars held by industry

If RDI representatives do participate in a conference or seminar held by a company or group of companies, no photo must be taken or released without prior authorisation of the person involved. Arrangements in writing prior the event are recommended.

5.5 Bilateral meetings with health sector companies and participation in health sector companies' internal meetings

RDI recognises that patients' organisations have the role to ensure that the patient voice is heard at all levels of decision-making. To this end, patient organisations have an interest in interacting and communicating with different stakeholders, including industry. This can include bilateral meetings with companies and participation at companies' internal meetings. RDI adheres to the following guidelines:

- Bilateral meetings have a clear agenda, including names and titles of people attending, location and time of meeting and topics of discussion. A brief summary of the meeting is kept in RDI's records. In rare cases when a confidentiality agreement has been signed, a copy of the letter is kept both electronically and in a hard file.
- RDI staff and volunteers serving on a committee, working party, or other official group that concerns the healthcare industry inform RDI of their participation and follow the protocol set by the relevant committees.

5.6 Participation in standing committees of commercial companies

It is not advisable for RDI staff or RDI Council members to participate in any standing or ongoing board or committee of a commercial company in the healthcare sector. Staff or volunteers serving in an ongoing capacity, paid or unpaid, for commercial companies or organisations representing the interests of commercial companies, must declare these activities as potential competing interests with RDI.

5.7 Individual compensation

There are several situations where industry may propose honoraria to RDI representatives, including:

- 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.

RDI representatives are as much entitled as healthcare professionals to receive honoraria for similar work. To ensure transparency surrounding honoraria:

- RDI volunteers will ask explicit approval from the RDI Director before receiving any individual compensation.
- RDI staff persons may not directly receive individual compensation. This compensation will be received by RDI, after the Director's explicit approval.
- Consultants working with the health care industry and RDI will inform RDI of meetings with health sector companies. Consultants will comply with any confidentiality agreements they have entered into with RDI and / or companies.

5.8 Involvement in industry-source websites or other material

RDI does not contribute to industry web sites. Companies may list RDI as a recipient of their funding and / or list as a resource for rare disease patient organisations. Companies must receive permission from RDI before use of the RDI logo or listing of RDI's name.

5.9 Diseases awareness campaigns by industry

Disease awareness campaigns may be considered an indirect form of advertising in some countries. It is unwise for RDI to be associated unless these campaigns have the backing of the public health authority. RDI must ensure that any campaign its representatives participate in responds to a well characterised public health need.

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

6. Transparency

6.1 Accountability

RDI provides companies with the RDI Policy on the Relationship and Financial Support by Commercial Companies. RDI requests every commercial company supporting RDI to carefully read and agree to follow this Policy. A copy of this Policy remains with the company.

RDI makes available the annual activity report and the annual financial report, after these documents have been approved at the Annual General Assembly. Companies may also receive interim and final reports concerning the project they have supported.

RDI issues a Letter of Agreement for contributions received from commercial companies, or in some cases signs an agreement provided by the contributing company. Agreements include:

- Amount of and purpose of the contribution
- Acknowledgement of how the contribution will be acknowledged or disclosed

- Acknowledgment of any attendance or participation included or expected in association with the contribution

6.2 Recognition and visibility

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

As part of its transparency policy and for fair partnership reasons, RDI may provide adequate recognition to a commercial company for its financial support and commitment. Donor recognition is agreed in advance of RDI receiving contributions from commercial companies and detailed in the letter of agreement.

7. Process and documentation

Requests for financial or in-kind support for RDI can be made by RDI staff, volunteers or consultants who have explicit remit to seek support for RDI, or who have received explicit permission from the RDI Director.

RDI maintains a record of proposals submitted on RDI's behalf, of funds received and of associated letters of agreement.

8. Derogation

In case of *cas de force majeure* or situation not foreseen in this policy, a derogation is possible. Any derogation to this policy, and in particular to the transparency rules applied for commercial companies in the health sector, will be duly discussed and adopted by the RDI Council. If such decision was significant, it will be mentioned in the Annual Report and the RDI Members will be informed through the reports at the Annual General Assembly.

9. Adoption and revision process

Revisions of this policy are to be adopted by the RDI Council and presented to RDI Members, which will be invited to comment on any revisions made.