POLICY

RARE DISORDERS NEW ZEALAND

WORKING WITH

PHARMACEUTICAL COMPANIES

POLICY

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Version 1.0

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1. INTRODUCTION

1.1 About rare disorders

It is estimated that there are between 5000 to 8000 distinct rare disorders collectively affecting between a total of 1.2-2 million New Zealanders. Most rare disorders are chronic, progressive, disabling, life limiting and life-threatening. They affect children and adults at any time in their life. There is no treatment or cure for most rare disorders.

1.2 About Rare Disorders New Zealand

Rare Disorders New Zealand is a non-government non-profit, patient-driven national rare disorder alliance of patient organisations and individuals active in the area of rare disorders. Rare Disorders New Zealand is dedicated to improving quality of life for all New Zealanders living with a rare disorder.

Rare Disorders New Zealand Mission Statement is:

To amplify the collective voices and improve healthcare/wellbeing for people and their whanau living with a rare disorder.

Rare Disorders New Zealand's goals (to be formerly ratified by RDNZ Board)

1. Connecting all those in the rare disorder community to ensure improved outcomes, including mental health and wellbeing;

2. Developing a proposed framework and action plan for positive policy change in NZ;

3. Raising awareness and understanding of rare disorders and strengthen our presence as the collective voice on rare disorders in NZ;

4. Ensuring RDNZ is financially viable and sustainable long-term.

1.3 About Rare Disorders New Zealand Working with Pharmaceutical Companies Policy

In New Zealand at a political level, Rare Disorders New Zealand is widely credited and referenced

officially in the Hansard as being the voice of people living with a rare disorder. The New Zealand Organisation for Rare Disorders was established in September 2000 and changed its name to Rare Disorders NZ in June 2019.

RDNZ believes that the broad range of expertise and experience it holds gives unique insight into the particular issues faced by the New Zealand rare disorder community. In addition, the collective stories of personal experience detail the combined challenges, and point to solutions which RDNZ is committed to enabling in order to improving the lives of every New Zealander who lives with a rare disorder.

These links to leaders of rare disease support groups and individuals attracts attention from the pharmaceutical companies that have a particular interest in the development of treatments and other services for rare disorder patients.

In all its activities, Rare Disorders New Zealand respects and promotes the fundamental value of transparency and RDNZ's agreed values; Manaakitanga (Respect), Ngakau Pono (Integrity) and Whakatairanga (Upliftment).

Rare Disorders New Zealand believes that it is important to establish transparent rules about financial support from commercial pharmaceutical companies hence the adoption of this policy and clarification of our purpose, intention and independent support for people living with a rare disease in New Zealand.

2. General Principles

2.1 Principles to be applied by Rare Disorders New Zealand in its relationship with Commercial Companies

Rare Disorders New Zealand welcomes financial support by commercial companies as long as the relationship between RDNZ and the company is based on the following principles:

- relevance of a public health objective driven by patient needs
- full independence of Rare Disorders New Zealand
- mutual respect
- mutual benefit
- accountability and transparency

Rare Disorders New Zealand believes it is important to establish and maintain relationships with commercial companies in order to enhance communication between rare disorder patients, whose interests RDNZ represents and companies, whose decisions will affect provision of health services or treatments to rare disorder patients.

2.2 RDNZ Principles in practice

a) RDNZ will independently set its own priorities, policies and plans.

b) RDNZ is committed to total transparency in all dealings with commercial companies.

c) RDNZ will not endorse individual pharmaceutical products or suppliers of health care services.

d) RDNZ will seek to develop relationships with multiple pharmaceutical companies, thus not pertaining to develop a relationship with only one particular company.

e) RDNZ will engage in dialogue with pharmaceutical companies about rare disorder treatments for the benefit of New Zealanders living with a rare disorder and to the betterment of all concerned.

A relationship between Rare Disorders New Zealand and commercial companies is based on partnership, while preserving RDNZ's independence and integrity.

To ensure a successful partnership, each partner should learn to understand each other's internal culture and external constraints.

3. Funding Agreement

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

Funding by commercial companies:

- must be for the benefit of the patients Rare Disorders New Zealand represents
- must not entail product advertisement
- cannot influence in any way Rare Disorders New Zealand’s policy, positions or decisions, whether explicitly or implicitly.

3.1 Funding of Rare Disorders New Zealand projects, events, activities

Rare Disorders New Zealand may accept financial or in-kind commercial companies’ support for a specific project. It provides Rare Disorders New Zealand with a reliable source of income over a number of years to cover direct costs such as personnel, equipment, consultants or suppliers and travel expenses as well as indirect costs (telephone, administration and other incidental associated costs to the project).

Companies that provide financial support to a project or an event or an activity will be publicly acknowledged by Rare Disorders New Zealand throughout printed materials, documents, website, electronic communication to ensure transparency and recognition.

The companies’ support has no influence on the design and conduct of the project, event or activity, its participants or publication, which will be the property of Rare Disorders New Zealand. Companies supporting projects may be regularly consulted through transparent and ad hoc processes as required.

3.2 Funding Principles in Practice:

a) All relationships with pharmaceutical companies will be documented in signed memoranda of understanding (MOU). This MOU will have agreed roles and responsibilities clearly defined for all parties.

b) RDNZ will only encourage funding for projects that have been identified as priorities in the annual RDNZ strategy planning process. RDNZ’s strategic plan will identify clearly particular activities and project in line with RDNZ’s Vision, Mission and Objectives.

3.3 Membership of RDNZ’s Round Table of Companies

Rare Disorders New Zealand was set up to establish a forum whereby a long-term relationship between RDNZ and those companies operating within the health sector that have an interest in rare disorder treatments, drugs, medical devices, food supplements or health services. This relationship is governed by this policy and its principles.

The policy adopts the Medicines New Zealand Code of Conduct and each member of the round table of companies signs their agreement upon joining the Rare Disorders New Zealand Round Table of Companies. Special note is section 5 of the Medicines New Zealand Code of Conduct which indicates how companies should engage with Rare Disorders NZ as a patient advocacy group, and any patients who take part in these meetings also (see reference section for a link to this document).

Specific aims of the Rare Disorders New Zealand Round table of Companies are:

1) To create a forum to support a long-term relationship between Rare Disorders NZ (formerly NZORD) and those companies operating within the health sector with an interest in rare disease treatments, medical devices and services;
2) To collaborate on a proposed Rare Disorder National Framework and Action Plan for New Zealand;
3) Empowering rare disorder patient groups and improve their advocacy capacity (through networking, information, education and training);
4) To network with leaders of the rare disorder community, patient groups, voluntary health organisations, regulatory and policy makers and promote open transparent communication of information in a neutral forum on the process, identifying the barriers, opportunities and incentives for development of treatments and timely access to them for the rare disorder patient community. International affiliations include APARDO, Rare Diseases International and GARD.
5) To provide Rare Disorders New Zealand with a pooled financial support for unrestricted funding in favour of activities of common interest and benefit such as:

   - Improving access to information, treatment, care, services and support for people living with a rare disorder across New Zealand;

   - Raising public awareness on orphan drugs, rare disorders and on the need for more research;

   - Improving identification and increasing knowledge of rare disorder patient groups at the New Zealand level; facilitating networking and reaching out to them.

6) To facilitate forums concerning the common goal of development and availability of treatments and services for people affected by rare disorders.

3.4 One off charitable donations

One off charitable donations are not linked to a specific project or activity and will be for the sustained infrastructure required to enable RDNZ to meet its goals and objectives. They do not create any obligation by Rare Disorders New Zealand to publicly acknowledge the financial support it receives.

However, this information may be shared at times such as the RDNZ Annual Report.

3.5 Other in-kind support

Commercial companies may also make a non-monetary contribution to RDNZ, such as;

- Seconded staff or professional services provided with no charge or invoice to RDNZ
- Equipment or donations (e.g. computers and other equipment)
- Meeting rooms
- Other non-monetary contributions (e.g. furniture, printing services)

4. Rare Disorders New Zealand’s involvement in activities in the health industry

This section deals with Rare Disorders New Zealand’s involvement in activities related to medicinal products, medical devices or services which are marketed or distributed by industry or still under development.

4.1 Promotional activities related to approved prescription medicines

All promotional activities related to medicines approved are not permitted within the current legislation and Medicines New Zealand code of conduct. Rare Disorders New Zealand does not get involved in activities that can be possibly associated with promotional strategy. RDNZ always keeps in mind potential conflicts of interest and is guided by its Mission, Vision and business strategy which is always with the intent of what is best for New Zealanders living with a rare disorder.

Types of activities that can be considered promotional under New Zealand 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 release

RDNZ refuses to be quoted in industry press releases that relate to a marketed product or a product under development:

- If RDNZ feels the need to communicate to media about a product, it will issue its own press release, independently of industry;

- If a company quotes RDNZ’s opinion or refers to RDNZs’ own communication materials without RDNZ’s permission, RDNZ will object to the company by registered letter (copy to the national industry association of the company).

4.3 Participation in conferences or seminars held by industry

If RDNZ 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.

- RDNZ 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.

4.4 Disorder Awareness campaigns by industry

Disorder awareness campaigns can be considered as an indirect form of advertising. RDNZ must ensure that any campaign its representatives participate in is not only an industry initiative but responds to a well characterised public health need. Companies wishing to mention the name of Rare Disorders New Zealand must ask prior written permission.

5 Process

When approaching or being approached by a commercial company, RDNZ usually requests information such as the main business activities of the company. RDNZ also does background research such as the company's reputation with concerned patient groups and regulators. RDNZ provides companies with its Working with Pharmaceutical Companies Policy and RDNZ's Governance.

RDNZ 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 Documentation

All projects and events will be reported and documented to companies.

5.3 Recognition and visibility of the relationship

In accordance with New Zealand Medicines Code of Conduct, companies who provide Rare Disorders New Zealand with financial support need to disclose this publicly, ideally on their website.

Logos that are featured on the RDNZ website are high resolution and of equal proportion to each company and contributor to the RDNZ Round Table of Companies. The logos appear in alphabetical order and not necessarily in an order of preference or status of contribution made to RDNZ.

5.4 Promotion

- RDNZ will not endorse any specific drug or treatment.

- RDNZ will not accept or distribute promotional products provided by pharmaceutical companies.

References

1. Consumers' Health Forum & Medicines Australia 2005, Working together. A guide to relationships between health consumer organisations and pharmaceutical companies, Consultation, https://www.chf.org.au/pdfs/fac/fac-Working-together-guide-2008.pdf

3. Medicines New Zealand Code of Practice Edition 17 https://www.medicinesnz.co.nz/fileadmin/user_upload/Code_of_Practice_Edition_17_published_April_2019_effective_September_2019.pdf

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