

Fabry Australia Working with Pharmaceutical Companies Policy

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1. INTRODUCTION

1.1 *About Fabry Disease*

Fabry Disease is one of several dozen Lysosomal Storage Disorders that interfere with the body's ability to break down specific fatty substances. It is a rare disease and because the rate of occurrence is less than 1 in 200,000, it is considered as one of the many "Orphan" diseases.

Fabry affected patients are missing or lack sufficient alpha-galactosidase A (alpha-gal A) enzyme which results in sugars and fatty acids (Gb3) accumulating in the cells throughout the body and impairs the function of several major organs including the kidneys and heart.

The diagnosis of Fabry Disease in one family member may lead to the evaluation and diagnosis in other relatives, as Fabry is a defective gene in the X-chromosome.

1.2 *About Fabry Australia*

Fabry Australia is a non-profit, patient lead membership patient organisation founded in 1994. Fabry Australia is a registered charity supported by volunteer donations, educational grants, fundraising and is managed by the patients themselves.

Fabry Australia's Mission Statement is;

Uniting the Australian Fabry community, by working together to improve the lives of those affected by Fabry Disease.

Fabry Australia's Aims

- Improve contacts, information and support among people affected by Fabry disease, and their families, within Australia.
- Bring about more public awareness of Fabry Disease.
- Improve the medical services to Fabry patients in Australia.
- Promote and support research into Fabry Disease.
- Share information on Fabry Disease, ongoing management and care as well as available treatments /therapies, to Fabry patients, their supporting carers and related Fabry stakeholders.
- Build links with families, clinicians, researchers and support groups, to strengthen and support local knowledge about Fabry disease.
- Co-operate and collaborate with other Fabry related groups and individuals interested in rare diseases to promote common interests.
- Help raise money to support with achieving these aims.

1.3 *About Fabry Australia's Working with Pharmaceutical Companies Policy*

Fabry Australia is recognised as the National Patient Organisation, founded in 1994 by patients with support from the Murdoch Research Institute in Victoria. Fabry Australia partnered with Nephrologist Dr Kathy Nicholls of the Royal Melbourne Hospital and helped to set up Australia's first Fabry Clinic for adults raising money to fund a part time research student to do further studies into Fabry Disease. Since this time Fabry Clinics have been set up in New South Wales, Queensland, South Australia and Western Australia for adults and children. Fabry Australia membership worked hard to advocate for the Australian Federal Government to fund two new

therapies being Enzyme Replacement Therapies (Replagal and Fabrazyme) on the Life Saving Drugs Program in 2004. Unlike the United States and other countries where only one treatment is listed and funded, Australia was uniquely placed to accept and fund both treatments.

Fabry Australia believes that the long history of working with Government bodies, Fabry Clinics, experts and pharmaceutical companies brings a broad range of expertise and experience. Fabry Australia has a unique insight into the particular issues faced by the Australian Fabry Disease community. The collective personal experiences add passion to Fabry Australia's commitment to improving the lives of every Australian who lives with Fabry disease.

Fabry Australia attracts attention from the pharmaceutical companies that have an interest in the development of treatments and other services for Fabry Disease patients.

In all its activities, Fabry Australia respects and promotes the fundamental value of transparency and Fabry Australia's agreed values; integrity, collaboration, equity, accessibility, inclusivity, sustainability and innovation.

Fabry Australia believes that it is important to establish transparent rules about financial support from commercial pharmaceutical companies.

2. General Principles

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

Fabry Australia welcomes financial support by commercial companies providing the relationship between Fabry Australia and the company is based on the following principles;

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

Fabry Australia believes it is important to establish and maintain relationships with commercial companies to enhance communication between Fabry Disease patients, whose interests Fabry Australia represents and companies, whose decisions will affect provision of health services or treatments to Fabry disease patients.

2.2 Fabry Australia's Principles in practice

- a) Fabry Australia will independently set its own priorities, policies and plans.
- b) Fabry Australia is committed to total transparency in all dealings with commercial companies.
- c) Fabry Australia will not endorse individual pharmaceutical products or suppliers of health care services.
- d) Fabry Australia will seek to develop relationships with multiple pharmaceutical companies, thus not pertaining to develop a relationship with only one company.
- e) Fabry Australia will engage in dialogue with pharmaceutical companies about Fabry disease treatments for the benefit of Australians living with Fabry Disease and to the betterment of all concerned.

A relationship between Fabry Australia and commercial companies is based on partnership, while preserving Fabry Australia'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 diseases; 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 Fabry Australia represents
- must not entail product advertisement
- cannot influence in any way Fabry Australia's policy, positions or decisions, whether explicitly or implicitly.

3.1 Funding of Fabry Australia projects, events, activities

Fabry Australia may accept financial or in kind commercial companies' support for a specific project. It provides Fabry Australia with a reliable source of income 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 Fabry Australia 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 Fabry Australia. 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) Fabry Australia will only encourage funding for projects that have been identified as priorities in the annual Fabry Australia strategy planning process. Fabry Australia's strategic plan will identify clearly particular activities and project in line with Fabry Australia's Mission, Aims and Objectives.

3.3 One off charitable donations

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

3.4 Other in-kind support

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

- Seconded staff or professional services provided with no charge or invoice to Fabry Australia
- Equipment or donations (e.g. computers and other equipment)
- Meeting rooms

- Other non-monetary contributions (e.g. furniture, printing services)

4. Fabry Australia's involvement in activities in the health industry

This section deals with Fabry Australia's involvement in activities related to medicinal products, medical devices or services which are marketed or distributed by pharmaceutical industry or still under development.

4.1 Promotional activities related to approved prescription medicines

All promotional activities related to approved prescription medicines are not permitted within the current Australian legislation and Medicines Australia code of conduct. Fabry Australia does not become involved in activities that can be possibly associated with a pharmaceutical industry's promotional strategy. Fabry Australia always keeps in mind potential conflicts of interest and is guided by its Mission, Aims/Objectives and business strategy which is always with the intent of what is best for Australians living with Fabry Disease.

Types of activities that can be considered promotional under Australian legislation:

- Disseminating unbalanced, non-validated or partial information on products, services or MDs distributed or marketed by a third-party company funded by pharmaceutical money;
- 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 Fabry Australia (Patient Organisation) can be included in a separate section.

4.2 Industry press release

If Fabry Australia feels the need to communicate to media about a product or a product under development, it will issue its own statement independent of industry via Fabry Australia communication channels.

Pharmaceutical companies wishing to publish and communicate to media about a product with a statement from Fabry Australia must do so with prior written agreement from Fabry Australia.

4.3 Participation in conferences or seminars held by industry

If Fabry Australia 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.

- Fabry Australia 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.
- Medical meetings that are instigated and funded by pharmaceutical industry with a focus to educate the medical professionals about Fabry Disease, diagnostics, management and treatment, should reach to the Medical Advisors and Fabry Clinic health professionals to support and attend such meetings. Fabry Australia will refer to its Medical Advisors to discuss the medical side of Fabry Disease including clinical research, management of patients, access to medical services and treatment at such events.

- Where possible, Fabry Australia will approach ALL pharmaceutical industry companies that have an interest in Fabry Disease for support in attending conferences where all pharmaceutical companies will have a presence. For example, WORLD Conference in the United States of America is a conference hosted by the University and all the Fabry Australia pharmaceutical industry have a presence at this meeting. Another example is the HGSA (Human Genetics Society of Australasia) meeting held in Australia.

4.4 Fabry Disease Awareness campaigns and services by industry and third-party companies funded by industry

Fabry Disease awareness campaigns and services and third-party services sponsored and funded by pharmaceutical companies for Fabry Disease patients in Australia can be considered as an indirect form of advertising. Fabry Australia must ensure that any campaign, services or third-party initiatives, funded by pharmaceutical industry, its representatives participate is not only an industry initiative but does respond to a well characterised public health need.

Pharmaceutical Companies wishing to mention the name of Fabry Australia or sharing information about Fabry Australia in any written or public forum, must ask prior written permission.

5 Process

When approaching or being approached by a commercial company, Fabry Australia will request information such as the main business activities of the company. Fabry Australia also conducts background research into the company, including and not limited to, the company's reputation with concerned patient groups and regulators. Fabry Australia will set up a meeting with the pharmaceutical company's representative (ideally the Head of Patient Services and or Head of Government Relations). Fabry Australia provides companies with its Working with Pharmaceutical Companies Policy and Fabry Australia's Governance. All meetings with pharmaceutical companies are diarised at regular agreed times with an agreed agenda and minutes. Attendance to meetings will be managed by Fabry Australia's Managing Director and all companies will be given equal opportunity to meet at regular intervals. Fabry Australia is unable to meet as often or as regularly as a Company may wish however, Fabry Australia will ensure it meets as often as it can manage with its limited resources.

Fabry Australia will invite all the companies to meet as a collective (up to two representatives from each respective company) with the Fabry Australia Committee at its Strategic Planning Day in a separate meeting to update the group on matters concerning strategy and projects and events for the following year.

Fabry Australia requests every commercial company it collaborates with to carefully read and approve this Policy. A copy of this Policy remains with the company.

5.1 Documentation

All projects and events will be reported and documented and shared with sponsor companies.

5.2 Recognition and visibility of the relationship

In accordance with Australian Medicines Code of Conduct, companies who provide Fabry Australia with financial support need to disclose this publicly, ideally on their website. Fabry Australia discloses information about the pharmaceutical companies that provide grants to its projects via the Fabry Australia website and its project information programs i.e. the Fabry Patient Meeting Conference. Information about pharmaceutical companies will be shared in a section on the Fabry Australia website. The pharmaceutical companies will be listed in alphabetical order and have links to the respective company websites.

5.3 Promotion

- Fabry Australia will not endorse any specific drug or treatment.
- Fabry Australia 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>
2. EURORDIS (Rare Diseases Europe) 2009, Policy on financial support by commercial Companies
3. Rare Voices Australia, Working with Pharmaceutical Company Policy, 2012

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