



rare voices
A U S T R A L I A

P O L I C Y

RARE VOICES AUSTRALIA

WORKING WITH

PHARMACEUTICAL COMPANIES

P O L I C Y

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With Compliments

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The unified voice for all Australians living with a rare disease

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1. INTRODUCTION

1.1 About rare diseases

It is estimated that there are between 5000 to 8000 distinct rare diseases collectively affecting between a total of 1.2-2 million Australians. Most rare diseases 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 diseases.

1.2 About Rare Voices Australia

Rare Voices Australia is a non-government non-profit, patient-driven national rare disease alliance of patient organisations and individuals active in the area of rare disease. Rare Voices Australia is dedicated to improving quality of life for all Australians living with a rare disease.

Rare Voices Australia Mission Statement is;

Rare Voices Australia, the national alliance of people living with a rare disease, will provide a unified voice to improve the lives of all Australians affected by rare diseases.

Rare Voices Australia's Aims

1. To bring together all Australians connected through the experience of living with rare diseases by consulting and acting upon the needs of the membership.
2. To influence public policy in order to achieve the best outcomes for people affected by rare disease.
3. Promote optimal care outcomes for people living with rare diseases and lobby decision makers in developing these standards across Australia. We will lobby for equality of care for all.
4. To raise awareness of rare diseases in Australia and their impact in the broader community.
 - RVA will work to facilitate access to information on rare diseases.
 - RVA will work to counter discrimination associated with rare diseases.
 - RVA will work to ensure people affected by rare diseases are informed about their conditions and rights.
5. To work collaboratively with our member organisations, key stakeholders, healthcare professionals, national and local Government and others to improve the overall care. Liaise with international organisations, bodies and associations aligned to the RVA Aims and Objectives.

- RVA will promote excellence in the training of healthcare staff in the diagnosis and management of rare diseases
- RVA will encourage appropriate research into rare diseases and its prevalence in Australia

1.3 About Rare Voices Australia Working with Pharmaceutical Companies Policy

In Australia at a Federal political level, Rare Voices Australia is widely credited and referenced officially in the Hansard as being the voice of people living with a rare disease. Rare Voices Australia launched officially at a Parliamentary event held in Canberra 2013. In 2014, Rare Voices Australia received bi-partisan support to establish a rare disease registry.

RVA believes that the broad range of expertise and experience gives unique insight into the particular issues faced by the Australian rare disease community. In addition this collective personal experiences adds passion to RVA's commitment to improving the lives of every Australian who lives with a rare disease.

Therefore Rare Voices Australia attracts attention from the pharmaceutical companies that have a particular interest in the development of treatments and other services for rare disease patients.

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

Rare Voices 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 Rare Voices Australia in its relationship with Commercial Companies

Rare Voices Australia welcomes financial support by commercial companies as long as the relationship between RVA and the company is based on the following principles;

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

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

2.2 RVA Principles in practice

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

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

3.1 Funding of Rare Voices Australia projects, events, activities

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

3.3 Membership of RVA's Round Table of Companies

Rare Voices Australia was set up to establish a forum whereby a long term relationship between RVA and those companies operating within the health sector that have an interest in rare disease treatments, drugs, medical devices, food supplements or health services. This relationship is governed by this policy and its principles. The policy adopts the Medicines Australia Code of Conduct and each member of the round table of companies signs their agreement upon joining the Rare Voices Australia Round Table of Companies.

Specific aims of the Rare Voices Australia Round table of Companies are;

- To provide Rare Voices Australia 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 disease across Australia;
 - 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 networking, information, education and training);
 - Improving identification and increasing knowledge of rare disease patient groups at the Australian level; facilitating networking and reaching out to them.
- To facilitate forums concerning the common goal of 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 (TGA) 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 disease patient community.

3.4 One off charitable donations

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

3.5 Other in-kind support

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

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

4. Rare Voices Australia's involvement in activities in the health industry

This section deals with Rare Voices Australia'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 Australian legislation and Medicines Australia code of conduct. Rare Voices Australia does not get involved in activities that can be possibly associated with promotional strategy. RVA 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 Australians living with a rare 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 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

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

- If RVA feels the need to communicate to media about a product, it will issue its own press release, independently of industry;
- If a company quotes RVA's opinion or refers to RVAs' own communication materials without RVA's permission, RVA 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 RVA 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.

- RVA 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 Disease Awareness campaigns by industry

Disease awareness campaigns can be considered as an indirect form of advertising. RVA must ensure that any campaign its representatives participate in is not only an industry initiative but does respond to a well characterised public health need.

Companies wishing to mention the name of Rare Voices Australia must ask prior written permission.

5 Process

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

RVA provides companies with its Working with Pharmaceutical Companies Policy and RVA's Governance.

RVA 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 Australian Medicines Code of Conduct, companies who provide Rare Voices Australia with financial support need to disclose this publicly, ideally on their website.

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

5.4 Promotion

- RVA will not endorse any specific drug or treatment.
- RVA 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

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