

# **Rare Voices Australia Working With Industry\* Policy**

**Version 4: July 2021**

\*Includes Research-Based Pharmaceutical Companies, Generic Pharmaceutical Companies, Consumer Medicines (OTC), Complimentary Medicines Companies and Medical Device Companies, Diagnostics Companies, Reproductive Technology Companies, Biopharmaceutical Companies, Biotherapeutics Companies

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## 1. Introduction

### 1.1 What is a Rare Disease?

A disease is rare if it affects less than five in 10,000 people. While estimates may vary between countries and studies, it is prominently cited that there are more than 7,000 different rare diseases. Approximately 80 per cent of rare diseases are of genetic origin.

An estimated eight per cent of Australians live with a rare disease – this equates to around two million Australians.

### 1.2 About Rare Voices Australia

Rare Voices Australia (RVA) is Australia's peak body for Australians living with a rare disease. We provide collaborative leadership for the development and implementation of rare disease policy in Australia. RVA provides a strong, unified voice to advocate for policy as well as health, disability and other systems that work for people living with a rare disease. Our person-centred focus sees us working with all key stakeholders, including people living with a rare disease, governments, key peak bodies, researchers, clinicians, and industry.

RVA led the collaborative development of the National Strategic Action Plan for Rare Diseases (the Action Plan), which is the first nationally coordinated effort to address rare diseases in Australia. The Action Plan was launched in February 2020 by the Minister for Health with bipartisan support.

#### Our Vision

RVA is dedicated to working with all stakeholders to drive the best outcomes for Australians living with a rare disease.

#### Our Mission

RVA provides collaborative leadership for the development and implementation of rare disease policy in Australia.

#### How We Work

- **We are person-centred**  
We want the outcomes that are best for each person as an individual. We will be driven by the needs of each person and by what works best for them. We won't impose our assumptions on people.
- **We will actively build and maintain partnerships**  
We are the voice of the sector, magnifying the voices of all stakeholders that share our goals. We recognise that achieving the transformation we want to see in Australia will require us working in partnership with stakeholders.
- **We aim for a unified voice**  
We recognise that without a unified voice, the rare disease sector cannot be successful in achieving the support for people living with a rare disease that we need. As a result, we will prioritise consultation and conversation within the sector to ensure that our voice to policymakers and the broader community is as unified as possible.
- **We work for equity of access and participation**  
We believe that equity of access and participation is vital for all people living with a rare disease in Australia. In our initiatives, we will ensure that equity is a key factor in our planning and design. And in our advocacy, the principles of equity will be foremost in our messaging.

- **We will equip and empower**  
We aim to equip and empower organisations and people to help them advocate and work for themselves.
- **We are solutions and results oriented**  
We want to see results for people living with a rare disease in Australia. We are not going to be bound to theoretical models. We will adopt what works and will test our initiatives against the results they deliver.
- **We are credible**  
We recognise that our effectiveness is only as good as our credibility and trustworthiness. We will ensure that all of our actions and words build our credibility, rather than erode it. We recognise that trust takes a long time to build but can be quickly lost.
- **We will adopt a systemic focus**  
We are uniquely positioned to engage in systemic advocacy. Effective reform to systems and processes must be prioritised to reduce individuals and groups repeatedly facing common challenges. This is vital to achieving sustainable change at scale.

### 1.3 About the RVA Working with Industry Policy

Industry provides funding through participation in the RVA Round Table of Companies and project sponsorship. The RVA Round Table of Companies is a group of industries that share a common interest in rare diseases and orphan drug development.

Establishing transparent rules regarding financial support from industry is essential. This document has been developed in line with the Australian Ethical Health Alliance's Consensus Framework for Ethical Collaboration in the Healthcare Sector (Australian Ethical Health Alliance, 2019), and Consumers Health Forum of Australia's and Medicines Australia's Working Together Guide (Consumers Health Forum of Australia, 2015).

## 2. General Principles

### 2.1 Principles to be Applied by RVA in its Relationship with Commercial Companies

RVA welcomes financial support from commercial companies as long as the relationship between RVA and the company is based on the following ethical principles:

- RVA maintains full independence
- Safety and harm reduction
- Equity
- Collaborative partnerships that are strengths-based, solutions-focused and relevant to the Action Plan and RVA's priorities
- Strategic and shared understanding
- Person-centred approach for the best outcomes for Australians living with a rare disease
- Effectiveness and efficiency
- Sustainability
- Open and robust communication

- Integrity, reflexivity and responsibility
- Mutual respect
- Mutual benefit
- Accountability and transparency

RVA believes it is important to establish and maintain relationships with industry. This enhances communication between rare disease patients, whose interests RVA represents, and companies whose decisions will affect the provision of health services or treatments to rare disease patients. RVA will ensure that consumer representatives are consulted when new arrangements are being discussed.

## 2.2 RVA Principles in Practice

- RVA will independently set its own priorities, policies and plans in alignment with our strategy and the Action Plan
- RVA will develop and drive all industry-funded projects and make final decisions on industry involvement and how this is communicated to stakeholders
- RVA is committed to full transparency and disclosure in all dealings with commercial companies
- RVA will not endorse individual pharmaceutical products or suppliers of health care services
- RVA will seek to develop relationships with multiple industries, thus not pertaining to develop a relationship with only one particular company
- RVA will engage in dialogue with industry about rare disease treatments for the benefit of Australians living with a rare disease and to the betterment of all concerned
- RVA will not engage in or accept funding that will affect RVA's sustainability
- RVA will identify, declare, deliberate and manage all conflicts of interest, whether pecuniary or non-pecuniary
- RVA will publicly declare all relationships with industry

Relationships between RVA and industry are 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. Before engaging in a relationship, upon renewal of membership and before each RTC meeting, RVA expects all companies and individuals to disclose their interests. These will be documented in RVA's Conflicts of Interest Register. This is necessary to ensure that dualities and conflicts of interest are identified and managed ethically.

## 3. Funding Agreement

Financial support resulting from partnerships with industry is dedicated to activities in the areas of rare disease awareness and education, access to diagnosis, treatments and research, patient support, capacity building for the rare disease sector, social and health research, and policy development.

Funding by commercial companies must:

- Be for the benefit of people living with a rare disease

- Relate or be transferable to a range of rare diseases
- Be collaborative and person-centred
- Respond to an unmet need in rare disease or address existing gaps
- Not entail product advertisement
- Not, in any way, influence RVA's policy, positions or decisions, whether explicitly or implicitly

### 3.1 Funding of RVA Projects, Events and Activities

RVA may accept financial or in-kind industry support for a specific project. Industry is invited to participate in the following ongoing core projects of RVA:

- Mentorship and education
- Parliamentary Events
- Biennial National Rare Disease Summit
- Other policy research activities

Industries that provide financial support to a project, event or activity will be appropriately acknowledged publicly by RVA to ensure transparency, recognition and disclosure. Acknowledgments may occur via printed materials, documents, websites and electronic communication.

Industry support does not influence RVA's decision making or the design and conduct of the project, event or activity, its participants or publication, which will be the property of RVA. Industries supporting projects may be regularly consulted through transparent and ad hoc processes as required.

### 3.2 Funding Principles in Practice

- RVA will document all relationships with industry
- RVA will disclose all relationships with industry on written materials related to the activity and/or to the audience of the activity where necessary and appropriate
- RVA will only seek funding for projects that have been identified as priorities in RVA's strategy planning process and in the Action Plan. RVA will ensure that activities clearly align with one or more pillars or priorities in the Action Plan and align with RVA's Vision, Mission and Purpose.

### 3.3 Membership of RVA's Round Table of Companies

RVA's person-centred focus sees us working with all key stakeholders in the rare disease sector. Industry has a key role to play in the systemic advocacy necessary for Action Plan implementation.

RVA's RTC was set up to establish a forum that cultivates effective and transparent working relationships and open communication between RVA and industry. The RTC includes industries with interest in rare disease treatments, drugs, medical devices, food supplements or health services. Members of the RTC recognise the need for a shared responsibility for the best health and wellbeing outcomes for Australians living with a rare disease. These relationships are governed by RVA's Working With Industry Policy and its principles,

Medicines Australia's Code of Conduct and the Australian Ethical Health Alliance's framework principles. All industry nominees must sign RVA's Working with Industry Agreement and declare their interests in writing. New declarations of interests will be sought before each RTC meeting.

The specific aims of RVA's RTC are to:

- Provide a formal vehicle for open and transparent communication in a neutral forum and to share the different perspectives and expertise of rare disease organisations and industry
- Identify barriers, opportunities and incentives for the development of treatments for the rare disease patient community
- Share information and discussions around systemic gaps and issues in health technology assessment (HTA) related to the development of and timely access to treatments and services for Australians living with a rare disease
- Act as a conduit for more effective networking with the rare disease community, rare disease organisations and key stakeholders, such as HTA bodies and decision-makers
- To provide pooled unrestricted support that builds the capacity of RVA to influence policy reform to improve health and wellbeing outcomes for people living with a rare disease. This collaborative work includes raising awareness of rare diseases, improving diagnosis and access to health technologies, progressing integrated care and support, and advocating for growth and improvements in data collection and research. As rare disease policy experts, RVA encourages industry to communicate with us openly about their planning and involvement in projects across the rare disease sector.

### **3.4 One-off Charitable Donations**

When one-off charitable donations are not linked to a specific project or activity, RVA is not under any obligation to publicly acknowledge these donations. However, information about charitable donations may be shared, with prior permission from the donor, in RVA's Annual Reports, on the RVA website, and/or on social media platforms, including Twitter, Facebook, LinkedIn and Instagram.

### **3.5 Other In-kind Support**

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

- 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. RVA's Involvement in Activities in the Health Industry**

This section relates to RVA's involvement in activities regarding industry products, devices or services that are marketed or distributed by industry or are still under development.

#### 4.1 Promotional Activities Related to Approved Prescription Medicines

All promotional activities related to approved medicines are not permitted within the current Australian legislation and Medicines Australia's Code of Conduct. RVA does not get involved in activities that can potentially be associated with any promotional strategy. RVA always considers potential conflicts of interest and is guided by its Mission, Vision and Strategy, which focuses on what is best for Australians living with a rare disease.

Types of activities that can be considered promotional under Australian legislation (Therapeutic Goods Administration, 2020) include:

- Disseminating unbalanced, non-validated or partial information on products, services or medical devices distributed or marketed by a company (i.e. information that focuses on the positive qualities of a therapeutic good only and omits negative qualities such as side effects or limitations of use)
- Disseminating information that describes a therapeutic good using superlatives, such as 'the best' or 'works fastest'
- Disseminating information that describes a therapeutic good using descriptive adjectives or statements that are emotive, such as 'brilliant' or 'changed my life'
- Disseminating information on behalf of manufacturers, sponsors, retailers, and any other party with a financial interest in the sale of therapeutic goods
- 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 particular product or testifying as a 'consumer' of that medicine. (RVA asks that contact information to patient organisations be included in a separate section.)

#### 4.2 Industry Press Releases

- RVA will not be quoted in industry press releases that relate to a marketed product or a product under development
- RVA, as the peak body for Australians living with a rare disease, can be quoted as an expert opinion
- RVA will only provide quotes aligned with the Action Plan and RVA's strategic priorities. Please seek permission before quoting RVA to ensure that messaging is aligned with our Mission, Vision, Philosophy and the Action Plan

#### 4.3 Participation in Conferences or Seminars Held by Industry

If RVA representatives participate in an industry launch or the promotion of a product, no photo is to be taken or released without prior authorisation of the person involved. To this end, arrangements in writing before the event are recommended.



RVA representatives will insist that multiple sources of information are involved in any ad hoc conference or seminar sponsored by a single company, aimed at informing patients about their products.

#### **4.4 Disease Awareness Campaigns Funded or Led by Industry**

Disease awareness campaigns can be considered an indirect form of advertising. RVA will ensure that any campaign that includes RVA is not only an industry initiative, but also responds to a well-characterised public health need.

Companies wishing to provide a link to RVA in their awareness campaign must seek prior written permission.

### **5. Process**

When approaching or being approached by a commercial company, RVA will request information about the company's main business activities. RVA also completes background research into the company's reputation with relevant patient groups and regulators.

RVA provides companies that wish to become members of the RTC or engage with RVA in other ways, with RVA's Working With Industry Policy and other governance documents.

RVA expects every commercial company it collaborates with to carefully read and provide signed approval of this Working With Industry Policy. We also recommend that companies keep a current copy of this Policy on hand. The Policy can be accessed on RVA's website under Partnerships – Round Table of Companies.

#### **5.1 Documentation**

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

All potential, actual or perceived conflicts of interests will be declared in writing, stored in RVA's Conflicts of Interest Register, and evaluated and managed appropriately.

#### **5.2 Recognition and Visibility of the Relationship**

In accordance with Medicines Australia's Code of Conduct, companies that provide RVA with financial support need to disclose this publicly — ideally on their website.

Logos featured on RVA's 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 are not in order of preference or status of contribution made to RVA.

#### **5.3 Promotion**

RVA will not:

- Endorse any specific drug or treatment
- Accept or distribute promotional products provided by industry
- Advertise the products or services of any industry

## **6. Expectations**

Any company wishing to engage with RVA in any capacity must agree to all expectations set out in this Policy. If a breach is suspected, it will be dealt with accordingly at the discretion of the Chief Executive Officer (CEO).

If any individual suspects a conflict exists or witnesses a breach or misconduct, it is their responsibility to make the CEO aware.

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