

Working Together

A guide to relationships between
health consumer organisations
& pharmaceutical companies



MEDICINES
Australia



Letter from key partners:

What is the *Working Together Guide*?

Welcome to the third edition of the *Working Together Guide*, which provides health consumer organisations and pharmaceutical companies with a roadmap that can help to achieve the best outcomes for health consumers, carers and families. The guide was developed by the Consumers Health Forum of Australia and Medicines Australia in 2005 and was first updated in 2008.

While the general consensus among health consumer organisations and pharmaceutical companies is that a print version of the guide remains important, an online version provides a useful additional resource. As a result, this shorter print version of the guide has been produced to present a general overview of the key components involved in a successful collaboration between health consumer organisations and pharmaceutical companies, while the additional materials and toolkits, formerly accessible from the *Working Together Manual* are available online at workingtogetherguide.com.au

The benefit of taking the guide online is that it enables new resources to be made easily available to health consumer organisations, particularly those who have never worked with pharmaceutical companies before. Many of these resources are based on the International Alliance of Patients Organisations excellent *Working with partners and stakeholders toolkit*: www.iapo.org.uk/working-partners-and-stakeholders-toolkits

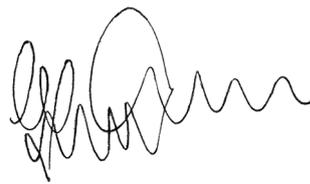
We thank the International Alliance of Patients' Organisations for agreeing to the use of their toolkit.

We are proud of the *Working Together Guide* and website, and believe these resources can help health consumer organisations and pharmaceutical companies negotiate the often complex pathway to developing a productive working relationship.



Tony Lawson

Chairperson
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Martin Cross

Chairperson
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What are the key principles of working together?

A valuable collaboration between a health consumer organisation and a pharmaceutical company requires a strong relationship based on core principles such as independence, trust, fairness, openness, transparency, confidentiality and accountability.

Pharmaceutical companies and health consumer organisations are different types of organisations, so it is sensible to discuss the following key principles in detail before starting a collaboration. These standards should be met every step along the way.

More detail about how these key principles can be applied to relationships between health consumer organisations and pharmaceutical companies can be found in the Medicines Australia Code of Conduct which is available at www.medicinesaustralia.com.au.

Respect for independence

An effective working relationship brings independent parties with different skills together for a common purpose. Each party remains true to its purpose and expresses its views even when the other party doesn't agree. Neither party should compromise the integrity or independence of the other.

While partners should follow the goals of mutual benefit and shared understanding, they should acknowledge that each will have different expectations. It is recommended to get independent legal advice before signing any agreement.

Achieving and maintaining public trust

A collaboration is most successful when healthcare consumers and the community trust that the aim of the relationship is to deliver the best possible health outcomes. It is therefore important that when a health consumer organisation and pharmaceutical company collaborate, they consider how to avoid any perception that one party has unfairly or inappropriately influenced or compromised the other.

As collaborations are often between organisations with different levels of resources, it is important that financial imbalances are dealt with appropriately to avoid any financial or other coercion. This is fundamental to achieving and maintaining public trust. The collaboration should be open and publicly transparent. It should be declared, in forms appropriate to different audiences, while still retaining the privacy entitlements of the parties involved.

Open communication

For a collaboration to be successful, from the outset partners should be direct and honest about what they hope to achieve. They should be clear about their expected roles and responsibilities, and any constraints that might limit their ability to perform them.

Other relationships that may be relevant to or impact the collaboration should be declared in accordance with anti-bribery and corruption legislation as well as Competition and Consumer law.

Each partner in the relationship should always feel free to raise issues and speak openly, and should not feel pressured by the other partner. Fairness is essential during the negotiations to establish the relationship, throughout the relationship, and at the completion of the relationship.

It is important to agree at the start on how each partner will be acknowledged throughout the collaboration. Acknowledgement can take many forms, such as written acknowledgements in educational resources, websites and annual reports. Any pharmaceutical companies that are Medicines Australia members are required to provide information regarding any formal relationships with health consumer organisations for publication on the website under a provision of the Code of Conduct. Participating health consumer organisations should be aware that details of sponsorships will be publically disclosed, including monetary values.

When the goal of a collaboration is to create physical materials, such as educational resources, both partners need to agree beforehand on the ownership of the resources and who will hold intellectual property

(IP). For example, if a patient booklet is developed the health consumer organisation and the pharmaceutical company should agree on the ownership of its ongoing use, future reprints and so on.

In addition, appropriate arrangements to bring the relationship to a close should be part of any agreement to work together.

Confidentiality

The partners in a relationship must respect the confidentiality and privacy of the relationship in accordance with existing legislation and regulation.

A significant benefit of collaboration is that pharmaceutical companies and health consumer organisations can share scientific data and other information that is not publicly available. Some of this material may be 'commercial in confidence'. Before entering into a relationship, all partners should agree on which information is to be shared, the terms under which it will be shared, and how security and privacy will be protected.

Accountability

Because accountability is critical to a successful collaboration, a health consumer organisation and a pharmaceutical company should demonstrate that the resources they contributed have been used appropriately and that agreed outcomes have been achieved.

In a relationship between a health consumer organisation and a pharmaceutical company there are many stakeholders – that is, individuals and groups who have an interest in the outcome. These include: the partners themselves, governments, current and potential users of medicines, shareholders in the pharmaceutical company and, indirectly, all Australian health consumers. A health consumer organisation and a pharmaceutical company may consider appropriate methods for reporting the results of their relationship to the key stakeholders and the wider Australian community.

As per the Medicines Australia Code of Conduct, pharmaceutical companies that are members of Medicines Australia are required to adhere to the obligations included.

Accountability requires effort, so some time should be spent carefully considering the actions each partner will take to remain accountable.

Successful collaborations focus on the health consumer and their carers

Successful collaborations improve the health and quality of life of consumers and their carers.

Collaborations can develop and make available information and educational resources. They can raise awareness of health conditions and related issues, and health consumer organisations and pharmaceutical companies can share skills with each other. In addition, collaboration can increase a pharmaceutical company's understanding of consumers' needs and a health consumer organisation's awareness of the health and treatment options available.

Collaboration is usually more successful when each partner is clear about what it wants to achieve by working together, and when each partner works hard at understanding how the other operates.

Creating a meaningful collaboration can be a complex and challenging process, so we encourage you to visit workingtogethertoguide.com.au which contains useful information and resources to support the start of a collaboration, and the building and maintenance of a productive relationship.



Case Study:

Tuberous Sclerosis Australia and Novartis

Tuberous Sclerosis Complex (TSC) is a rare multi-system genetic disorder in which tumours can grow in any organ of the body but most commonly the brain, skin, heart, lungs and kidneys. TSC can also cause epilepsy, developmental delay, kidney disease and other health complications.

Tuberous Sclerosis Australia (TSA), founded in 1981, is the only not-for-profit organisation supporting families living with TSC in Australia and New Zealand. It is a small consumer health organisation supported by volunteers.

The Working Together Guide in action

In 2010, Novartis Oncology was in the process of developing the first medicine for TSC when it approached TSA, which had never collaborated with a medicines company.

From the first meeting, the *Working Together Guide* was used to create the framework supporting the partnership between TSA and Novartis.

A successful collaboration

TSA has held several educational events for families living with TSC. These were partially supported by grants from Novartis. Another grant from Novartis helped fund a large project that vastly improved the technology capabilities of TSA.

TSA has reviewed information produced by Novartis for clinicians to better reflect the patient experience. TSA and Novartis have held regular meetings to share knowledge about developments in TSC. TSA has also presented an independent submission to the Pharmaceutical Benefits Advisory Committee (PBAC), which supported the listing of a medicine for TSC sponsored by Novartis.

Addressing key issues and challenges

The TSA volunteer committee created a policy document for working with medicines companies. This process helped TSA identify the key issues and challenges in collaborating with a pharmaceutical company.

For example, a major consideration for a small organisation such as TSA is sustainability: how to ensure that the organisation does not become reliant on funding that may not be available in the future. To address this, TSA decided not to accept funding from the pharmaceutical company for ongoing expenses such as regular publications or patient support staff, but to accept grants from Novartis for capability improvements such as implementation of new technologies that will enable future growth of the organisation.

Respect for independence

As a small organisation with limited capacity, TSA wanted to ensure that a grant from Novartis didn't shift its priorities. TSA made the decision to seek financial assistance from Novartis only for projects nominated as priorities in its strategic plan.

Additional benefits

As a consequence of regular meetings between TSA volunteers and Novartis staff, each partner has an increased understanding of the other. Novartis has more appreciation of the challenges of living with TSC, including symptoms not previously targeted by its medicine. TSA volunteers are now much more familiar with the Therapeutic Goods Administration (TGA) and Pharmaceutical Benefits Scheme (PBS) processes, and are able to update families on the availability of new medicines for TSC.

Areas for improvement

The collaboration began with a Novartis research project conducted by a third party, which needed to contact TSA for help identifying potential participants in the project.

The third party refused to disclose that it had been commissioned by Novartis, an unfortunate oversight. As TSA volunteers knew that Novartis was the only company trialling a medicine for TSC, the secrecy was unwarranted. It could have been avoided with standard confidentiality practices.

The establishment of a patient registry for TSC was also challenging, with TSA raising concerns that it had not been involved in the project's planning or governance. There were two reasons for this. The project was driven by the Novartis global team, so it required some adaptation to suit the local circumstances. Meanwhile, Novartis' Australian medical team, which was involved in the project, underwent several staff changes, and new staff took time to get up to speed with the company's relationship with TSA.

For its part, TSA struggled to follow one of its policy rulings: to seek funding from sources other than medicines companies also. TSA revised its plans and delayed some projects, allowing other funding sources to be explored.



What is the purpose of this guide?

For many years, health consumer organisations and pharmaceutical companies have been forming relationships so they can work together for mutual benefit. These relationships are complex, therefore pharmaceutical companies and health consumer organisations have increasingly sought advice about how they can work together successfully.

The Working Together Guide, developed by the Consumers Health Forum of Australia and Medicines Australia, provides the basic principles and suggestions that can be used as a starting point when a relationship is first being established – and as it advances. Organisations can adapt the information in this guide to their own needs and it is a useful resource that can assist with building and maintaining a valuable collaboration.

Collaboration is not suitable for every organisation or project. However, handled carefully, collaboration can deliver meaningful results for health consumers and their families, health consumer organisations and pharmaceutical companies.

Who is working together?

What are health consumer organisations?

Health consumer organisations, also known as patient groups or patient advocacy groups, are not-for-profit organisations representing the interests and views of health consumers, their families and carers.

Health consumer organisations range in size and scope from small volunteer groups to large organisations. They generally promote views that are independent of government, the pharmaceutical industry and health care professionals.

What are medicines companies?

Medicines companies are businesses that make and sell medicines. This brings with it enormous responsibility and an operating environment

where the industry is subjected to constant public and professional scrutiny.

Research-based pharmaceutical companies are a type of medicines company. Other types include generic pharmaceutical companies, consumer medicines companies, complementary medicines companies and medical device companies.

Pharmaceutical companies are committed to improving and maintaining the health of all Australians. They can vary in size and scope. Some of the larger pharmaceutical companies employ thousands of people in a range of departments including research and development, sales, marketing, corporate affairs, manufacturing, legal, compliance, IT, recruitment and accounting. Companies with limited staff and departments may only manufacture and bring to market a select range of medicines.

The pharmaceutical industry is closely regulated by Australian legislation. In addition, the research-based pharmaceutical industry peak body, Medicines Australia, established the Code of Conduct, to which all Medicines Australia members must adhere. It is also common for individual pharmaceutical companies to have their own internal compliance processes.

The compliance process can take additional time to complete, however, it is necessary to safeguard the integrity of sponsorships both for the protection of the health consumer organisation and the pharmaceutical company.

Would you like more information about health consumer organisations and pharmaceutical companies?
Visit workingtogethertguide.com.au

The terms medicines companies and pharmaceutical companies are often used interchangeably. There are important distinctions, however; for example research-based pharmaceutical companies undertake additional activities including the initial research, discovery and clinical trials to create brand new medicines. *The Working Together Guide* and corresponding website uses the term medicine to include any type of product designed for the treatment and prevention of disease or health problem.



Types of relationships and ways of working together

Relationships between health consumer organisations and pharmaceutical companies include one-off projects and longer-term relationships. In some cases, a collaboration may involve more than one health consumer organisation or pharmaceutical company, which may increase the level of complexity.

One-off projects

Partners participating in a one-off project usually limit their contributions to meeting only the needs of that project, for a fixed period of time. A one-off project typically involves a donation, sponsorship or educational grant by a medicines company to a health consumer organisation, to undertake specific activities. In some cases, this support can involve no further return to the medicines company beyond an agreed acknowledgement process – for example a reference in the health consumer organisation's annual report.

Longer-term relationships

A longer-term relationship usually takes the form of a collaboration in which a medicines company and a health consumer organisation work together on areas of common interest. Each partner makes contributions to the relationship, such as funding, the sharing of information, education, training and support. The partners benefit from working together bringing different strengths to achieve goals that might be beyond their reach if they worked on their own.

Would you like more information
about the types of relationships?
Visit workingtogethertoguide.com.au
to find out more.

Consumers Health Forum of Australia

The Consumers Health Forum of Australia is the national peak body representing the interests of Australian healthcare consumers with a network of members covering key conditions and issues across the health system. We advocate for a consumer-centred, high quality and affordable health system. Our diverse membership allows CHF to ensure that government and decision makers hear and understand the consumer voice.

Medicines Australia

Medicines Australia represents the research-based pharmaceutical industry in Australia. Our member companies supply most of the medicines that are available to Australian patients through the Pharmaceutical Benefits Scheme as well as providing a range of other medicines and vaccines to the Australian community. Those medicines keep Australians out of hospitals, prevent and treat disease and play a pivotal role in ensuring a productive and healthy community.

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