

# WORKING TOGETHER

REVISED EDITION

THE MANUAL

## THE MANUAL

Supporting Materials

### **Working Together:**

A Guide to relationships between  
Health Consumer Organisations  
and Pharmaceutical Companies

# THE MANUAL

## Supporting Materials

This document is designed to be used in conjunction with “*Working Together, The Guide*”, and has been produced to assist those who may need further support and information. The Guide is attached to this Manual in hardcopy or is available through [www.chf.org.au](http://www.chf.org.au) and [www.medicinesaustralia.com.au](http://www.medicinesaustralia.com.au).

### Glossary of terms (as used in the Guide and this resource)

#### Consumers Health Forum of Australia –

The Consumers Health Forum of Australia Inc (CHF) is the national voice for health consumers. It helps shape Australia’s health system by representing and involving consumers in health policy and program development.

CHF, established in 1987, is an independent member-based non-government organisation for health consumers. It receives funding from membership, specially-funded projects, and the Australian Government Department of Health and Ageing.

**Health consumer organisations** – not-for-profit organisations that represent the interests and views of consumers of health care. They may range from small volunteer groups to large organisations, and generally promote views that are independent of government, the pharmaceutical industry and professional health service providers

**Important principles** – high level broad values to guide the relationships between health consumer organisations and pharmaceutical companies.

**Pharmaceutical companies** – companies that discover, develop, manufacture and market medicines. Pharmaceutical companies are represented nationally by Medicines Australia and are bound by its Code of Conduct.

**Medicines Australia** – the peak industry body representing Australian research-based pharmaceutical companies. Medicines Australia seeks to ensure that industry views contribute to national health policy and planning.

**Pharmaceutical Benefits Scheme (PBS)** – Commonwealth government system of subsidising access to approved medicines for Australian consumers.

**Relationships** – relationships between health consumer organisations and pharmaceutical companies that are developed to jointly pursue areas of common interest. The relationships may involve funding, access to information, advice, sponsorship to attend conferences, education and training, access to meeting rooms, assistance with printing, and so forth.

## Some tips on how to measure benefits of working together

### Types of benefits

Health consumer organisations and pharmaceutical companies often work together to improve the health and quality of life of consumers.

These relationships result in many types of benefits. A key benefit is producing positive health outcomes for Australian consumers. This is a shared benefit for the pharmaceutical company, health consumer organisation and the community.

Benefits may be shared or may differ for each party. It is useful for each party to spend some time thinking about what it hopes to achieve from the relationship, but also what the other party hopes to achieve.

### Building organisational capacity

There may be advantages that flow from the relationship and are not immediately obvious, or that only develop beyond the life of the relationship. One of the advantages of working together is the building of each party’s capacity to do its work more effectively. This benefit may not be as tangible as a resource or an event, but it is still a very important outcome.

#### Results that suggest enhanced capacity include:

- learning, understanding and awareness
- new skills
- a greater understanding of the other party’s needs and concerns
- better awareness of consumers’ issues relating to medicines
- increased ability to work collaboratively with other organisations
- extended networks and key contacts.

These outcomes are more likely to be achieved if the parties have thought about building organisational capacity from the beginning of the relationship. Sometimes, small changes to a collaborative project can have big results in boosting capacity, so they are often worth making.

The best relationships acknowledge and support (through funding or other actions) the building of organisational capacity. This means that while the specific initiative to be delivered through the relationship (the project, the resource, the study or other agreed outcome) may require a certain allocation of resources, additional resources to build the capacity of the parties through information exchange or skills development might also be needed.

### Sustainability of the project

Sustainability is a goal of most education or service initiatives; how can the benefits of any project extend beyond the particular period for which it is funded? For example, if a relationship has been forged to produce 500 copies of a resource, what steps can be taken to ensure ongoing access to this valuable resource after the 500 copies have been distributed?

#### Building the sustainability of the project can:

- enable benefits to flow to consumers well after the actual project has concluded
- demonstrate cost-effectiveness of the project
- build support in both sectors for further cooperation.

#### Sustainability may be promoted by:

- building knowledge and skills that endure beyond funding
- building infrastructure that can be used over time (such as computer and information systems or establishing libraries)
- planning for ongoing availability of information and resources produced through the project
- promoting successful projects to identify alternative future funding sources.

## Sustainability of health consumer organisations

Most relationships between health consumer organisations and pharmaceutical companies only last for a certain time. Parties to relationships should consider how a withdrawal of resources will be managed when they are setting up the relationship. Building capacity and sustainability throughout the relationship may allow the health consumer organisation to address longer term sustainability or continue activities after the relationship has concluded.

Parties to the relationship should at least consider how a withdrawal or reduction of funds might be managed in order to have the least negative impact on the organisation's sustainability. 'Exit strategies' that determine how relationships might be terminated, including unexpectedly, should be developed from the outset

### Maintaining the relationship

Maintaining a longer-term collaborative relationship will be promoted by each party communicating with the other on how the relationship is going. Each party's needs and expectations will evolve over time, and regular consideration of these factors will help ensure the relationship evolves appropriately.

### Measures of sustainability

#### Including:

- likelihood that the project will sustain itself beyond the term of the collaboration
- chances of the project being picked up and pursued by others
- increases in community understanding and knowledge
- infrastructure established
- support from the community, government, or other agencies.

## Some tips for implementing principles – best practice approaches, common pitfalls and how to avoid them

### Respect for independence

#### Separate purposes or missions

All relationships require give and take, including collaborations between health consumer organisations and pharmaceutical companies. Parties may need to adapt their practices and modify their positions to cooperate effectively, but each party will also need to stay true to its fundamental beliefs. These are usually set out in a vision or mission statement, or in a statement of core values.

Parties need to be clear about the other's purpose and objectives. Respecting independence involves respecting the fact that each party will stick to its core values.

#### Media or public commentary

Health consumer organisations and pharmaceutical companies may agree to jointly advocate for a common objective. At other times, there may be strong differences of opinion.

Effective relationships may influence the way in which public criticisms of partners may be made.

It is an act of courtesy to advise the other party of a particular position that will be taken publicly, but the parties should still enjoy the right to free expression of views.

Parties should agree about the way in which differences of opinion will be handled in the media.

### Achieving and maintaining public trust

Sometimes the relationships between health consumer organisations and pharmaceutical companies may appear to compromise the independence of the parties. While the reality is that both parties have strengths and weaknesses, in practice it is more likely that the health consumer organisation will appear to have lost its independence. Integrity is key to any organisation's ability to inform or educate the community. Any perceived loss of integrity would reduce the value of the collaboration, damage the reputations of the individual parties and their respective sectors.

#### Inappropriate funding arrangements

This is a complex and difficult area; therefore, the essential principles referred to in the Guide should be considered and reflected in relationships involving funding, regardless of the activities being funded. Any funding arrangements the community may see as inappropriate may affect the level of public trust in the relationship.

One strategy for building and maintaining public trust is to keep the financial aspects of the relationship separate from the governance and high-level decision-making activities of the health consumer organisation. For example, some health consumer organisations might choose to keep industry funding separate from its decision and policy-making functions (for example, its Executive or Board meetings, its Annual General Meetings, its Executive Director or its policy staff). Another example is sponsorship of a medicines publication, where it might be more appropriate that funds are provided for printing and distribution, rather than the editor's salary.

Due to the diversity of health consumer organisations and their relationships with pharmaceutical companies, there will always be a range of opinions in relation to the appropriateness of accepting core funding. It is up to each party to determine the appropriateness of any funding relationship before an agreement is entered into.

### Multi-party relationships

To combat perceptions that a health consumer organisation has been influenced, it may be appropriate to seek relationships that involve more than one pharmaceutical company. Such relationships are common and bring a range of advantages in addition to reducing perceptions of bias: multi-party relationships share risk across several companies and reduce the impact on health consumer organisations of the withdrawal of one company. Such relationships also offer opportunities for industry collaboration.

### Specific endorsements

Health consumer organisations that endorse specific medicines, thereby promoting specific companies, may risk a perception of lost independence.

For this reason, many relationships include safeguards such as the following:

- health consumer organisations distribute information about use of medicines generally (how to use them effectively, including when not to use them) rather than focussing on use of particular medicines
- health consumer organisations may distribute information on availability of medicines, but do not endorse or recommend them
- health consumer organisations may refer to or provide information about classes of medicines rather than specific brands
- health consumer organisations may prefer to mention all medicines in a class rather than a single medicine
- health consumer organisations may wish to clarify that reference to a medicine or a class of medicines is not to be taken as endorsement.

If a health consumer organisation considers that it has a responsibility to promote a specific medicine, it may take steps to protect its reputation for independence in these circumstances. It may be advisable for the health consumer organisation to base its endorsement on independent medical/scientific evidence (including from overseas) rather than rely upon the company's own data.

### Being public about the relationship

When thinking about ways to build community trust, the parties should consider the way the relationship is presented to the outside world. It is important that both parties agree at the outset of the relationship what information will be private and what will be public and how this information may be made available. While health consumer organisations and pharmaceutical companies may wish to keep some aspects of their relationships private, it is good practice to be open about a relationship's objectives or its intended outcomes.

### Fairness

Each party has specific strengths. These strengths may be in areas such as media influence, political influence, financial resources, scientific expertise, marketing, access to doctors and other health practitioners, or relationships with consumers.

Understanding a potential partner's strengths and vulnerabilities can help to ensure partners are treated fairly. An awareness of these factors, and care to avoid exploiting such pressures, will contribute to free and equitable negotiations.

### Openness and transparency

Openness involves an expectation that the parties be clear and honest with each other. Relationships are best based on a clear understanding of what the parties hope to gain from the relationship. This may require, in addition to discussions about cooperation and understanding, frank discussions about such things as funding and access to consumers..

### Developing agreed objectives

Openness around objectives should be matched by clarity in roles and responsibilities. Depending on the relationship and the sort of project being conducted, it may be appropriate to be quite detailed about who is going to do what. This also involves being open about the constraints under which each party is operating. It is easier to avoid problems if the parties are clear about the pressures they are experiencing.

### Negotiating the relationship

Openness between the parties requires truthfulness about other relationships or negotiations that may be relevant to this relationship (for example, approaches by the pharmaceutical company to other health consumer organisations, or by the health consumer organisation to other companies or other parts of the same company).

Where a pharmaceutical company thinks it is negotiating with a specific health consumer organisation as representative of a sector and the health consumer organisation knows it does not hold such status, openness requires disclosure of the full facts. This can be a real problem in cases where national bodies are (sometimes wrongly) considered as peaks for state groups, or where health consumer groups have, unbeknown to the pharmaceutical company, become factionalised.

### Ownership and acknowledgement

Parties need to be clear about who owns what from the relationship. This should be determined at the outset of the relationship.

Acknowledgement is also relevant to the aim of building and maintaining public trust; public acknowledgement of collaboration demonstrates openness and avoids any suggestion of secrecy. It is desirable that parties acknowledge the relationship on their websites or through a media release at the beginning or conclusion of the relationship, or acknowledgement in material produced. For example if a pharmaceutical company has provided funds for a health consumer organisation to undertake a specific project, it may be appropriate to include a statement such as: "This project was funded by an unrestricted grant from company x and company y. These companies had no part in the direction, analysis or findings contained in this report".

## Commercial-in-confidence information

One of the challenges for health consumer organisation and pharmaceutical company relationships is how to identify and handle commercial-in-confidence information – notably information considered to have great commercial value and therefore not to be disclosed to competitors. There may be times when, for commercial reasons, a pharmaceutical company wishes to keep information out of the public domain, but a health consumer organisation thinks the information should be shared with consumers. Each case will be different so there is no easy solution, but relationships should acknowledge:

- parties will have different core missions and values, so may have different approaches to sharing information
- confidentiality may be critically important to ensuring a fair return on investment in research
- health consumer organisations may occasionally feel some tension between their roles as collaborative partner and consumer advocate
- agreements should deal with questions of when information may be shared, under what conditions information may be shared, and protocols for observing confidentiality.

## Accountability

It is useful for the parties to talk about what forms of accountability they want. In a general sense, each party will want to know how the resources it has contributed have been used by the other. Beyond this, parties should consider how this information is to be provided, for example, through informal conversations, written reports or financial statements. Keeping each other informed contributes to a sense of goodwill, and having this information helps the individuals involved demonstrate the effectiveness of the relationship to others within their own organisation.

Being accountable takes not only a philosophical commitment, but may also take time and effort. It is useful to think about this when allocating resources to support a relationship.

Parties should also consider all the people who have a stake in the success of the relationship, and then consider how they can be accountable to these stakeholders.

## Developing a clear agreement

The level of formality and detail in the relationship needs to be reflected in the agreement. One-off projects may require only a simple agreement whereas longer-term collaborations might require a more formal written agreement.

It may be desirable to develop a statement of agreement, a memorandum of understanding or a contract. A contract might be appropriate, but contracts are often drafted in anticipation of dispute and consequently try to cover every possible contingency in ways that protect the parties through use of restrictive language. A statement of agreement or memorandum of understanding is simpler and accepts that not every matter is covered. Rather than anticipating dispute, a statement of agreement focuses on shared vision and commitment to joint ventures, accepting that the relationship will evolve over time. While not being overly prescriptive, agreements should address:

- vision for/purpose of the joint venture
- roles and responsibilities of the parties
- process and timetable for transfer of goods or funds
- ownership of finished products
- dispute resolution
- termination of the relationship

If there is a written agreement about the relationship, it may be appropriate for it to be signed by someone at a senior level. This indicates institutional support for the collaboration.

In addition to the formalised agreement, it is important to provide the opportunity for open dialogue as issues arise, and assist in building and maintaining the relationship.

An example of a statement of agreement follows.

## Example Statement of Agreement

This is an example of an agreement to a specific project. An agreement has to be tailored to meet the needs of the particular relationship – there is no ‘one size fits all’.

**THE FOLLOWING IS AN EXAMPLE ONLY.  
YOU SHOULD TAKE LEGAL ADVICE PRIOR  
TO ENTERING INTO ANY AGREEMENT.**

### Statement of Agreement

1. This agreement is made between (party 1) and (party 2). It confirms the parties’ support and respective contributions for the “XYZ” project (the Project).
  2. The term of this agreement commences on (date) and expires on (date).
  3. The parties have the following shared objectives for the Project:
    - collaborate in the production of three medicines seminars for (party 1)’s members.
    - production of a report of the seminars for dissemination to (party 1)’s members by hard copy and via the (party 1) website (the Project Report).
    - creation of opportunities for (party 1) and its members to learn more about medicines and health management options.
    - creation of opportunities for (party 2) to learn more about the health needs of (party 1)’s members.
    - the construction of an effective working relationship between the parties that may be the basis for future relationships.
  4. (party 1) will make the following contributions to the Project as its own cost:
    - participate in a Steering Committee for the Project
    - promotion of medicines seminars among its membership through member newsletters
    - provide party 2 with opportunities to attend the medicines seminars
    - drafting of the Project Report for approval by the Steering Committee
    - once the Project Report is approved, distribution of the Project Report to its members by post and by inclusion on its website.
  5. (party 2) will make the following contributions to the Project at its own cost:
    - participate in the Steering Committee
    - coordination of the three medicines seminars
    - design and printing of the Project Report
    - provision of technical experts to speak at medicines seminars
    - ensure that relevant (party 2) representatives support and attend the medicines seminars
  6. (party 1) and (party 2) agree to form a committee (the Steering Committee) to coordinate the proposed medicines seminars and to approve the Project Report. The Steering Committee will be composed on one representative from (party 1) and one representative from (party 2) and such other members as jointly agreed to by the parties.
  7. The initial representative of (party 1) on the Steering Committee is (NAME).
  8. The initial representative of (party 2) on the Steering Committee is (NAME).
  9. The Steering Committee will meet at least monthly for the first three months of this agreement and as required thereafter.
  10. Any disputes that arise between the parties in the course of this joint project will be dealt with initially by the representatives of the parties. If no agreement can be reached by the representatives, then the dispute shall be referred to the Chief Executive Officers of the parties or his or her delegate. Should this fail to resolve any dispute, then this agreement may be terminated by either party by written notice to the other party.
  11. Should a party wish to withdraw from the Project prior to the expiry date set out in clause 2 above, then the withdrawing party agrees that it (a) will meet any of its outstanding obligations under this agreement to the other party prior to the date of any withdrawal; and (b) that all intellectual property rights in any Project material developed by the parties will be owned by (party 1).
  12. Under this agreement:
    - Each party may publicise the Project after consultation with the other party.
    - (party 1) will publish the Project’s objectives, its intended outcomes and the participation of the other party in any annual report published by (party1) during the term of this agreement.
    - Both parties must keep information designated as confidential by the other party, confidential and secure.
    - Both parties agree that copyright and other intellectual property rights in the materials contributed to the Project remains the property of the contributing party.
    - The copyright and intellectual property right in the Project Report and any other Project materials developed by the parties will be owned by (party 1).
    - (party 2) hereby assigns all intellectual property rights that it may have now or in the future in the Project Report or any other Project materials to (party 1).
  13. The parties agree that the relationship between them is not one of partnership.
  14. At the conclusion of this Project, the parties expect the following outcomes to have been achieved:
    - Three informative seminars will have been conducted for (party 1)’s members.
    - A Project Report will have been produced and disseminated to (party 1)’s members.
- Signed as an agreement by (party 1) and (party 2)

## CASE STUDIES - General

This section details case study examples of collaboration between consumer health organisations and pharmaceutical companies. The examples include one-off projects and longer-term collaborations.

### Using the Guide to develop a charter

The National Heart Foundation established the Heart Foundation Pharmaceutical Roundtable that brings together pharmaceutical companies with a strong cardiovascular interest. The Roundtable agrees to fund research and projects that the members agree are priorities. Collaborative projects include those on the Quality Use of Medicines (QUM) in Cardiovascular Health and a project on improving adherence to treatment. Other projects funded through the research program include scholarships, fellowships, grants-in-aid and a Chair in Cardiac Nursing. The funds contributed by the companies are acknowledged in the materials produced. Funding contributed by Roundtable members is typically for one to three years.

Early in the life of the Roundtable its members were interested in developing a charter outlining how they could work together and developed a draft charter. Members of the Roundtable were aware that the Working Together Guide was being developed at the same time and agreed to wait until the Guide was launched before they progressed their charter. The Heart Foundation Pharmaceutical Roundtable Charter is informed by the Guide. The Charter has a framework that outlines how the Roundtable should operate and the contributions expected from all parties. The Charter's principles of respect for independence, achieving and maintaining public trust, fairness, openness and transparency and accountability are directly in line with those in the Guide. For example, the principle of respect for independence specifies that pharmaceutical company members of the Roundtable may not contribute to or influence the Heart Foundation's independent research

peer review system or evidence-based guideline development process. The Charter also specifies that the Heart Foundation needs to agree to ownership of any intellectual property generated in association with the Roundtable. Members of the Roundtable acknowledge the usefulness of the Guide in the development of their Charter.

Benefits for members of the collaboration include an opportunity to support relevant research in cardiovascular disease (CVD); maintain and increase government support for the prevention and management of CVD; promote the Quality Use of Cardiovascular Medicines; identify opportunities to advocate for change that will lead to improved health outcomes that utilise Quality Use of Medicines (QUM) principles, for example, timely access to medicines; and recognise and utilise the role of the pharmaceutical industry in promoting better cardiovascular health outcomes.

### Using the Guide in public discussion about collaborative relationships

The Mental Health Council of Australia (MHCA) has a collaborative arrangement with a group of pharmaceutical companies (called the Pharmaceutical Collaboration) with whom they develop an annual work plan to decide on project priorities. Although the funding is important, it is not core funding, as the MHCA is not able to depend on it due to company priorities changing.

The main source of funding to the MHCA is through the Community Sector Support Scheme – Australian Government Department of Health and Ageing (part of their agreement with the Commonwealth is that the MHCA will seek to expand their sources of funding).

Although the MHCA's collaboration with pharmaceutical companies predated the launch of the Guide, it has been a useful document for the Council in a number of ways. The Guide has been important for the MHCA in public discourse, where it has helped to validate the collaborative arrangements between the MHCA and the pharmaceutical companies with which it collaborates. They have

been able to show the Guide to journalists as evidence of the collaboration between CHF and Medicines Australia and the thinking that has gone into reaching agreement about how these partnerships should operate.

The MHCA has also used the Guide in developing Memorandum of Understanding (MoU) with the partner companies.

Three important reports were funded by the members of the Pharmaceutical Collaboration. *Not for Service (2005)*, a seminal report that documented the mental health service in each state/territory measured against the national mental health standards; *Let's get to Work: a National Mental Health Employment Strategy for Australia (2007)* that documented the barriers around employment for people with mental illness and suggested strategies to improve outcomes; and *Weaving the Net: promoting mental health and wellness through resilient communities (2006)* that documented communities capacity to function when the systems response is poor. These reports provided evidence that MHCA has been able to use to lobby for improvements to mental health services.

Another important project the collaboration has supported is a national survey of over 900 pharmacists in conjunction with the Pharmaceutical Society of Australia and the Pharmacy Guild of Australia. The aim of the survey was to assess the attitudes of community pharmacy to mental illness and consider how best to promote the quality use of medicines to these key stakeholders. The results of the survey will be used to determine future activities to promote the quality use of medicines for people with a mental illness.

### Concluding the relationship

Council on the Ageing (COTA) NSW became aware of the need for information for its members and the wider community to improve health and quality of life of seniors by education of medication management and the reduction of inappropriate use of prescription and over the counter medicines. COTA NSW entered into negotiations with five pharmaceutical companies in 2002 with a proposal to collaborate on a project that became known as Medication Management.

Presentations were run as a free service for seniors by Peer educators, who were volunteers trained and available to community groups and organisations, wherever a guest speaker was required. The Peer Educator's aim was to encourage people to ask their pharmacist or doctor questions about managing their medicines effectively and obtain vital information.

A train the trainer and volunteers manual was developed and information materials sourced for distribution within the groups. The project was coordinated and promoted through COTA NSW.

After several years the funding was reduced and then the following year was then withdrawn. Quarterly reports with statistical data were produced with meetings held to oversee the project and offer guidance.

The Medication Management project still operates with the trained Peer Educators giving community presentations and receiving funding from a health related organisation. Both COTA NSW and industry partners agree it was a productive relationship.

## CASE STUDIES – One off projects

### Funding a planning conference

In 2000, Alzheimer's Australia approached Pfizer and Janssen Cilag to fund a conference that brought together forty key people from around Australia involved with Alzheimer's. The aim of the conference was to develop a strategic plan to take the organisation forward. The conference was held at an important time for Alzheimer's Australia and provided the organisation with a clear future focus and a plan for achieving their goals. The pharmaceutical companies contributed \$40,000 towards the conference, funding that could not have been easily found elsewhere.

### Funding research

Among Alzheimer's Australia's policy and research priorities was a proposal for an analysis into the economic and social impact of dementia in Australia. In 2003, Janssen Cilag and Pfizer provided unrestricted grant funding for research by Access Economics that produced the report *Dementia Epidemic: Economic Epidemic and Positive Solutions for Australia*. The CEO of Alzheimer's Australia indicated that this research provided the organisation with evidence base that assisted them to advocate for dementia to be made a national health priority – and objective that was achieved in the 2005 Budget.

## CASE STUDIES – Other examples

### Partnership to develop resources

A two-year partnership was forged when Wyeth Australia approached Arthritis New South Wales regarding patient information to assist them when commencing new medicines. At the same time, Arthritis New South Wales wanted information about new medicines available for people with specific types of arthritis. The two organisations worked together on a series of three information resources to inform users on best practice in the use of the medicines in arthritis. The design and wording of the resources were agreed to by both organisations and had high-level sign off. The process of working together developed over time and was assisted by each partner being clear about what they wanted to achieve from the relationship.

### Partnership training

The Schizophrenia Fellowship of NSW has a number of long standing relationships with pharmaceutical companies. Their philosophy is that both parties in a partnership must benefit, each contributing and each receiving. Two examples illustrate their working relationship: when a new medicine is about to come on the market that is of potential benefit to their members, the Fellowship is able to assemble a reference group of consumers to review the product information and provide feedback to the pharmaceutical company as to whether the information is clear and accessible; the Fellowship also provides training to pharmaceutical company representatives to ensure that they understand the impact mental illness and that of their products on consumers.