



Australian Government
Department of Health
Therapeutic Goods Administration

TGA advisory committee guidelines

Declarations of interests, managing conflicts of interests and confidentiality obligations

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TGA Health Safety
Regulation



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Historical document

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A. Purpose of the guidelines

The purpose of these guidelines is to provide guidance for members, chairs and secretaries of the Therapeutic Goods Administration's (TGA) statutory advisory committees (and their subcommittees and working groups) established under Part 6 of the [Therapeutic Goods Regulations 1990](#) (the Regulations), on:

- declaration of interest requirements
- the management by committees of members'¹ interests in relation to matters coming before the committee
- members' obligations of confidentiality.

B. Significance of the management of 'conflicts of interest'

The committees of the TGA undertake a vital function in providing advice and expertise that is essential to the TGA in carrying out its regulatory functions. Members must have specialist knowledge and expertise in one or more designated areas and are appointed to a committee for the purpose of providing expert advice in relation to matters coming before the committee. It is assumed therefore that members will apply their professional expertise and experience in relation to matters coming before the committee.

This is not what the conflict of interest rules are concerned with. These rules are about ensuring that there can be no perception that, taking into account the nature of the functions of the committee and the expertise of the relevant member, the member will not be able to bring an independent, objective and impartial approach to a particular matter before the committee because of a personal interest. However, because in many cases, the pool of potential members in Australia with the necessary expertise and experience and in a position to contribute to Australian public health outcomes through membership of one of these committees is not large, there is a potential for a conflict of interest to arise from time to time.

Any advice or recommendation of a committee in relation to a specific matter may be open to challenge if any of the members who participated in the development of that advice or recommendation had an actual or perceived 'conflict of interest'. Good management of conflict of interest issues protects the reputation and integrity of committees by helping ensure their impartiality and independence. This in turn helps ensure that the advice and recommendations of committees that inform the TGA's regulatory functions reflect the highest standards of professionalism and independence.

A conflict of interest will arise if a person's personal interests (whether financial/pecuniary or not) conflict with their duties as a committee member such that the person may not be independent, objective and impartial in relation to those duties. An apparent conflict of interest will arise if a conflict of interest may be perceived by a reasonable observer as conflicting, whether or not there is an actual conflict.

¹ A member is defined as a member of a committee or an expert advisor

C. Relevant legislative provisions

The Regulations do not refer to 'conflicts of interest' as such. However, they contain provisions for the disclosure of 'personal' interests by members of the statutory advisory committees (and their subcommittees) established under the Regulations that are designed to ensure that any conflicts of interest that may arise can be managed appropriately by the relevant committee.

Subregulations 42(4) to (7) (refer [Attachment A](#)) require that:

- any member of a committee (or of one of its subcommittees) who is aware that he or she has a direct or indirect material personal interest (whether pecuniary or not) in a matter being considered, or about to be considered at a meeting, discloses, without delay, the nature of the interest at, or before the meeting of the committee
- the disclosure be recorded in the minutes of the meeting
- the member must not, unless the committee otherwise determines, either be present during any deliberation of the committee about the matter or take part in any decision of the committee about that matter
- when a committee is making a determination about a member who has made a disclosure, the member, and any other member who has a direct or indirect pecuniary interest in the matter to which the disclosure relates, must not either be present during any deliberation of the committee nor take part in making the determination

The Minister may, under the Regulations, terminate a member's appointment if the member fails to comply with these disclosure obligations.

D. Declaration of interests

So that any potential conflicts of interest can be more readily managed by the committees, the TGA requires members to declare any interests of the kind that a member may need to disclose under Regulation 42. Members should declare both pecuniary (which may include professional) interests and non-pecuniary interests. Members should take into account the nature of the committee's role, functions and responsibilities when determining whether to declare a particular interest but are advised to err on the side of declaring interests rather than not.

Members declare their interests by means of the following declarations.

- a declaration of interest in support of application/expression of interest in relation to committee membership
- a declaration at the time of appointment as a committee member
- an annual declaration by the member thereafter
- a meeting disclosure of interests declaration or
- the notification of any new/additional interests as soon as practicable after they arise or become apparent, which may be before, or at a meeting, or on an ad-hoc basis.

What kinds of interests must be included in these declarations?

There is no legislative definition of the terms 'personal interest' or 'pecuniary interest' in the [Therapeutic Goods Act 1989](#) (the Act) or in the [Regulations](#). Nor are there definitions of 'direct' and 'indirect' interests.

In general, pecuniary interests are monetary or financial interests that have the potential for material gain or profit but can be anything that is capable of being measured in terms of money (including loss). Indirect pecuniary interests may include what might otherwise be described as 'professional interests', such as involvement in sponsored research or provision of support by a company to a student or patient. See **Box 1** for examples.

Box 1: Examples of direct and indirect pecuniary interests*

| | |
|--|--|
| <ul style="list-style-type: none"> • Shares • Consultancies • Contracts • Commissioned fee-paid work • Sponsorships • Grants • Directorships • Board memberships • Partnerships, trusts • Other investments • Ownership of a patent • Paid speaker • Paid expert adviser <p>Having a financial involvement with products, services or other matters having any connection with therapeutic goods or any type of paid work</p> | <ul style="list-style-type: none"> • Paid conference expenses • Grants for research or other educational benefits • Holding a paid role to provide professional advice • Hospitality from a company involved in the therapeutic goods industry • Participation as a researcher or unpaid expert adviser • Involvement in any company or organisation involved in the development, manufacture or marketing and distribution of therapeutic goods, including: <ul style="list-style-type: none"> – membership of an advisory board in relation to the company or organisation – accepting sponsorship of an event, or for a professional organisation from such a company or organisation – provision by such a company or organisation of ad hoc support for a patient or student – participation in a clinical trial <p>involvement as a researcher, expert adviser or investigator.</p> |
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* This is not an exhaustive list. If in doubt about whether an interest should be declared, members should declare the interest.

1. Interests of members of the immediate family

Interests of members of the family of a person may well be an indirect pecuniary interest if it affects or could affect the person financially (for instance, the fact that the spouse of a person is an employee of a pharmaceutical company might be regarded as an indirect pecuniary interest of the person).

In the annual declaration form members are asked to list relevant interests of members of their 'immediate family'. Just who is a member of the 'immediate family' for this purpose will depend on the member's particular situation. A spouse/partner will normally be included and children may be, depending on the circumstances (dependent children will for instance, normally be included).

Consideration should be given to whether the nature of the relationship with the particular family member is such that their interests could be perceived by a reasonable observer as impacting on the capacity of the member to be independent, objective and impartial in relation to their duties as a committee member.

2. Personal interests

Personal interests may extend to the holding of strong personal, philosophical or religious beliefs or convictions, or a person's personal circumstances or family, social relationships (for instance where a close friend has extensive involvement in the pharmaceutical medicines industry or has substantial financial interest in particular therapeutic goods).

It may be that the member, a member of their family or a close friend has a specific or uncommon condition, the treatment of which could be affected by a therapeutic good or other matter that could be considered by the committee or a member may have some other personal interest or ethical position in relation to a particular treatment.

Such interests will only be relevant if they are of such a nature that they could give rise to an obligation on the member to disclose the interest under subregulation 42(4) to (7) in relation to a matter to be considered by the committee. That will depend on the nature of the committee's role, functions and responsibilities and the nature of the matters that are likely to be considered by the committee from time to time.

Whether or not a member declares such an interest in an annual declaration form, it will have to be disclosed if it is 'material' to a matter to be considered by the committee. The fact that someone is being treated for common conditions such as hypertension or high cholesterol would not normally be considered as 'material'. If the nature of an interest that involves a medical condition or personal beliefs is particularly sensitive, the member may volunteer not to participate in the committee's consideration of the matter without needing to provide details.

Membership of sporting clubs or societies would not normally be required to be included in a declaration, though membership of a professional organisation should be included.

Process for members to declare interests

Members are responsible for informing the TGA of any interest that could give rise to an obligation to disclose in relation to a matter before the committee.

1. Declaration at time of application/expression of interest

Members of TGA's committees are appointed by the Minister for Health. For the purposes of considering whether a person is suitable for appointment to a committee, the TGA requests information about the range and nature of material interests a potential appointee has currently,

material interests the potential appointee has had over the previous five years, or material interests that are, or may be, forthcoming. An assessment can then be made whether those interests would affect the person's ability to perform effectively his or her role on the committee if the person were to be appointed.

The TGA therefore requires a declaration of interests be provided with an application, or expression of interest, in relation to committee membership. The potential appointee is asked not only to provide information about existing pecuniary and non-pecuniary interests but also about likely future interests.

The TGA has to exercise caution with recommending appointees who already have interests and are likely to acquire or have interests in the future that would result in the person being unable to participate in matters likely to be considered by the relevant committee that are related to their field of expertise, so as to minimise the possibility of losing access to that expertise.

The TGA cannot prevent a member of one of its expert advisory committees from acquiring further interests during their membership. **However there is an expectation that a person, who once appointed, acquires an interest of the kind that, if the person had that interest at the time of application, a recommendation would not have been made for their appointment, the member will consider resignation from the committee on the basis that the interest is not compatible with continuing membership.** A member proposing to for instance, acquire shares in a company manufacturing or sponsoring therapeutic goods or to accept advisory board membership for that company, or take on a consultancy or other paid work with, or sponsorship from, such a company should consider their position and discuss it with the Chair of the committee, or the Deputy Secretary of the TGA.

Apart from being required to provide information about relevant interests, the potential appointee is asked to declare that they understand that if they are appointed they will be required to comply with the obligations in subregulation 42(4) to disclose an interest in matters coming before the committee and that in such cases the committee will have a discretion under subregulation 42(5) to determine the extent of their involvement in consideration of that matter.

2. Declaration on appointment, followed by annual declarations

Within a month of being appointed (and in any event before the first meeting they attend), members (including the chair) must complete a written declaration of their pecuniary, non-pecuniary and other personal interests. This should include those that, taking into account the nature of the committee's role, functions and responsibilities, may give rise to an obligation on the member to disclose an interest in a matter under subregulation 42(4).

Thereafter, members must complete a declaration of interest at least once a year. This declaration replaces any previous annual or meeting declaration. It should reflect the full range of relevant interests of the member as at the date the declaration is signed.

Common sense should apply in determining the level of detail required on a member's declaration of interest in relation to their business activities. Significant business activity should be declared, but an exhaustive list of minor business contacts is not required.

In relation to the declaration of the interests of members of the immediate family (see discussion above), a member can only declare interests of which they are aware.

As noted above, while members are not expected to declare the detailed nature of personal interests, such as medical conditions or religious beliefs on their annual form, members should be aware that they are required to declare an interest of this nature should an agenda item arise that would require it to be disclosed under Regulation 42(4) (see discussion above).

The relevant secretariat is responsible for the secure storage of the documentation referred to above. It should be noted that, depending on the nature of the information provided, a member's declaration of interest may be provided to the TGA Executive and/or Minister for further assessment.

3. Declarations of additional interests before or at meetings

To cover interests that arise between annual declarations, there are additional declaration of interest processes relating to each meeting (see below). Members should include any interests of the kind that should be included in an annual declaration that have been acquired or that have come into existence since the most recent annual or meeting declaration.

4. Ad-hoc declarations

Under the *Deed of undertaking in relation to confidential information and conflict of interests* (see below), members are required to undertake to notify the Commonwealth and the Chair of any additional interests in writing 'as soon as is reasonably practicable'. If a member becomes aware of such an interest and is not likely to be attending a meeting (and therefore completing a meeting declaration) in the near future, the member should inform the committee secretary directly in writing.

E. Disclosure of interests in relation to matters being considered by the committee

It is recognised and accepted that given the nature of members' professional expertise and the fact that in Australia there are a limited number of people with expertise and experience in relevant fields, members will, from time to time, have an interest in matters being considered by the committee.

Subregulation 42(4) to (7) provides the mechanism for handling such interests. The fact a member has such an interest does not automatically however preclude the person from participating in the matter providing that:

- the member declares the interest if it is 'material' to the matter under subregulation 42(4) of the Regulations
- in the absence of all members who have disclosed an interest in the matter, the committee considers in accordance with Regulation 42(5) whether the member can be present during any deliberation on the matter or take part in any decision on the matter, which may include the committee discussing the nature of the interest, the extent to which it is 'material' and to which it may affect or appear to affect the committee's deliberation of the matter
- the committee takes the necessary action to nullify or mitigate any potential conflict in an open and transparent manner
- the fact that the interest was declared and the manner in which the committee dealt with the disclosure is appropriately recorded in the minutes of the meeting.

Irrespective of what interests a member has included in their annual or previous meeting declarations, a member must comply with the requirements in subregulation 42(4) in relation to disclosing interests at every meeting they attend as a member.

Subregulation 42(4) to (7) requirements in relation to a committee meeting

Any member (including the Chair) who is aware that he or she has a direct or indirect material personal interest (whether pecuniary or not) in a matter being considered, or about to be considered at the meeting, must disclose, without delay, the nature of the interest at, or before the meeting of the committee. The same rule applies to members of any subcommittee of the committee. A copy of the subregulations is at [Attachment A](#).

1. Being 'aware' of having an interest

It is the responsibility of each member to consider whether their interests are such that an obligation arises under subregulation 42(4) to disclose that interest. Members should, as soon as they become aware of any matter that will be considered at a meeting, carefully consider whether it is a matter in relation to which they have such an obligation, taking into account the subject matter of the item, the nature, currency and extent of the interest they have, the nature of the issues that the committee is being asked to comment on, whether the member is being asked to comment specifically on the matter etc. This will usually be when the list of items on the agenda is sent out by the committee secretariat but should occur whenever consideration of a matter by the committee comes to the member's notice.

It may only be when a matter is actually under consideration by the committee that a member becomes aware of their interest (where for instance, unanticipated issues arise in the discussion). In such a case the member should disclose it without delay (see below).

As the Chair and secretariat have access to member declaration of interests forms they will also be aware of situations where a member would be required to disclose an interest in relation to a matter. In some instances, the Chair or the secretariat may contact the member if they are aware of an interest that the member has not declared.

2. 'Material' interests

Whether a personal interest is 'material' or not to the matter, will be an issue of judgement in all the circumstances of the case. If the interest is so remote or insignificant that it could not reasonably be regarded as being likely to influence any decision the member might make in relation to the matter, then it may not be 'material'.

However, members are advised to 'err on the side of caution' and disclose any interest that could possibly be regarded as 'material' and allow the committee to consider whether it is 'material' and if so, whether the member should participate in consideration of the matter.

3. Disclosing 'without delay'

If, having seen the list of agenda items, or at any later time, a member comes to a view that he or she may have a 'material' interest in the matter, the member should contact the Chair (or acting Chair or Secretary if the Chair is not available) as soon as possible and inform them of the nature of the interest in the relevant matter.

If the member believes that the interest is such that they should not take part in the committee's consideration of that matter, the Chair should be advised as soon as possible. This allows the Chair to consider whether other arrangements need to be put in place for consideration of that item, such as arranging for additional external expertise to be sought.

If a member becomes aware of a material interest in a matter only when the matter is under consideration by the committee, the member must bring it to the attention of the Chair immediately and absent themselves from the room so that the committee can consider, in

accordance with subregulation 42(5), whether and if so to what extent, the member can be present during further consideration of the matter.

If the member is the Chair, the disclosure should be made to the acting Chair or the Secretary of the committee.

4. Disclosing the ‘nature’ of the interest

A member who becomes aware that he or she has an interest in a matter on the agenda has the option, after having declared the nature of the interest as required by subregulation 42(4), of volunteering not to be present during the committee’s consideration of the matter. This would be appropriate where it is clear that the interest is such that a conflict of interest exists or where it may appear to exist to a reasonable observer. It may also be appropriate where the member does not wish to provide details about the nature of the interest for personal reasons.

If the member does not volunteer to not be present then the member will need to provide sufficient detail about the nature, currency and extent of the interest for the committee (in the member’s absence) to come to a view on:

- whether or not the member can be present during any part of the committee’s deliberation on the matter or take part in any decision of the committee on the matter if the member can be present, in what capacity and for how much of the committee’s consideration of the matter (see below).

5. The committee ‘otherwise determines’

The committee would usually consider interests disclosed by a member at the meeting itself. However, it may be that in unusual cases the Chair (or acting Chair where the Chair is disclosing) will need to seek the views of members about the disclosure of a member prior to the meeting if an issue arises about whether agenda item documents will be provided to that member.

What does the committee consider in determining whether a member should be present?

Any member who discloses a material personal interest in relation to a matter for consideration by the committee cannot be present during any deliberation, or take part in any decision, on that matter by the committee, unless the committee “otherwise determines” (subregulation 42(5)).

Neither that member, nor any other member who has disclosed such an interest in the same matter, can be present when the committee makes a determination about whether or not the member can participate in the consideration of the matter (subregulation 42(6)). This ensures that the personal interests of each member cannot be seen to influence how the personal interests of another member are managed by the committee.

There are no legislative rules about how a committee determines whether a member who has disclosed an interest in a matter should be present or absent during deliberations on the matter or take part in any decision on the matter. The committee should be guided in its consideration by the principle that its deliberations on a matter not be ‘tainted’ (or be seen to be tainted) by any suggestion that members were not able to bring an independent, objective and impartial view to the matter, not influenced by the member’s personal interests.

The committee should consider whether the nature, currency and extent of the member’s interest would mean in fact that the member cannot bring an independent, objective and impartial view to consideration of the matter. As well, whether a reasonable observer might conclude that the member cannot bring an independent, objective and impartial view to that consideration.

Over time the committee will develop precedents about how particular situations are dealt with; these will help guide the committee in considering future disclosures made by members of that committee. There must be consistency in how the committee deals with what might be seen as similar fact situations, the records kept of previous decisions of the committee would provide a source of information for that purpose (with appropriate privacy considerations). However, each situation in which the committee has to determine how to deal with a member's disclosure has to be treated on its merits, taking account of the particular facts.

Even though each of the TGA committees are subject to the same rules on disclosure, there is no requirement or expectation that they would necessarily come to the same conclusion about disclosure by a member given their different subject matters, functions and membership.

What options does the committee have in managing conflicts?

There are a number of options available to committees for managing a conflict of interest. In coming to a view about the 'materiality' of the interest, and depending on the nature of the interest and the item, they might include:

- allowing the member to participate fully in the deliberation by the committee and in any decision about making recommendations
- allowing the member to participate in discussion but not in making a decision about a recommendation
- allowing the member to be present to answer questions and provide specific advice on particular matters or of a technical nature, but not to participate in discussion or in making a decision about a recommendation
- excluding the member wholly from consideration of the matter.

The extent of interest which will be acceptable is a question of judgement, but given the sensitivity of so many of the issues coming before TGA committees, a conservative approach is recommended. If the appearance of a conflict of interest is likely to undermine or raise questions about the credibility of the committee's deliberations, the committee should take appropriate action to avoid or minimise that impact.

In assessing the appropriate response, members of the committee should take account of both the actual conflict and the perception of conflict. The perception of a conflict of interest is as important as (and much more common than) any actual conflict of interest.

In determining whether there is a possible conflict (or perception of one), it is not necessary to show that the person's conduct is affected, but only that there is an actual or perceived conflict between the member's interests and his or her obligations as a member of a committee. There will always be borderline cases, where arguments both for and against the view that a conflict will exist; for example, a member of a committee may honestly believe that a shareholding in a pharmaceutical company would not affect his or her ability to make an impartial decision in respect to a product manufactured by the company, and that his or her objectivity would not be impaired. However, the fact that there are, or there may be perceived to be, two competing interests is what is relevant in determining the existence of a conflict, notwithstanding that the member maintains that they are able to disregard one of those interests.

What the committee decides to do in any given situation may be affected by the committee's consideration of the availability of the necessary advice and expertise for the purposes of consideration of the matter. Where the interest is so 'material' and there is a risk of a perception

of conflict, the committee may decide to defer consideration of the matter so an alternative source of advice or expertise can be secured.

This should only occur in rare cases where the member is unable to disclose his or her interest sufficiently early, consequently precluding the Chair from making alternative arrangements.

F. Obligations under the Deed of undertaking in relation to interests

The obligations in relation to disclosure of interests are supported by the obligations set out in the Deed of undertaking in relation to confidential information and conflict of interest, which members are required to sign before participating in committee business (but after they have completed their Annual declaration of interests).

By signing the Deed a member:

- promises that as at the date of signature, and to the best of their knowledge and after making diligent inquiry, they do not have any direct or indirect interests which may, given the nature, role and responsibilities of the Committee, constitute or give rise to an actual or potential conflict of interest or the perception of one in relation to the performance of their duties as a member, other than the interests (already) declared to the Commonwealth in the Annual declaration of interests form
- undertakes to notify the Commonwealth and the Chair of the Committee in writing of any such interests that they become aware of while a member as soon as reasonably practicable (this will normally be through completion of the annual and meeting declarations of interests but may require an ad hoc notification)
- undertakes to comply with his or her obligations to disclose under subregulation 42(4) to (7) as described above in relation to any conflicts of interest and otherwise take such steps as the committee may reasonably require to resolve or to otherwise deal with the matter.

The Commonwealth can, under the Deed, sue a member for any losses or costs in relation to any liability arising from a breach of the member's obligations under the Deed.

Process for dealing with potential conflicts of interest

1. Relevant documents

The TGA has robust procedures in place to support the committees in assessing and dealing with conflict of interest. The approach to conflict of interest issues is reviewed regularly to ensure it maintains currency with legal and departmental requirements. The secretariat will provide the following documents at the appropriate times.

- Declaration of interests in support of an application for membership of a TGA committee form.
- Annual declaration of interests form, for a member of a TGA committee to be completed within a month of appointment and annually thereafter
- Meeting disclosure of interests form to be completed by members in relation to matters on the agenda at each meeting attended (this document can also be used to declare interests which have recently arisen/that occur on an ad hoc basis)

When completed, these documents will contain sensitive personal, and occasionally commercially confidential data. The information can only be used for the purposes of recording, reviewing and managing conflict of interest issues. Access to such documents is controlled and will only be granted to employees with a genuine need to know, in connection with reviewing conflict of interests and related issues. For more information on the approach that TGA takes on confidential information please see our website <<https://www.tga.gov.au/publication/tga-approach-disclosure-commercially-confidential-information-cci>>.

2. Prior to the meeting

Once all agenda items are identified, the secretariat will provide a copy of the proposed agenda to the members. The list of agenda items will be sent together with the meeting declaration form and a request for the member to consider whether there are any items in relation to which the member may need to disclose an interest. The member should contact the Chair and secretariat as soon as possible about any such interest. If the member comes to the view that their interest is of such a nature that he or she should not be present during consideration of the item on the committee the Chair should be informed as soon as possible so the opportunity can be taken, if necessary, to put alternative arrangements in place, for instance, by inviting additional speakers to attend or changing the speakers list. In such a case the agenda item documents may not be provided to the member.

Any member proposing to attend the meeting should complete the meeting declaration form prior to the meeting so that the speakers' lists can be determined before the agenda papers are released.

Any person who is not a member but is invited to attend a particular meeting will also be asked to disclose any relevant interests to the Chair prior to the meeting, by completing a meeting declaration form.

3. Meeting procedures

Each committee meeting will have a standing item on its agenda to consider conflicts of interest. At the commencement of each meeting or as appropriate, the Chair of the meeting will invite members to declare any previously undeclared actual or potential conflicts of interest in relation to any item on the agenda. Any member with a potential conflict in any agenda item must declare it at this time, whether or not it has been declared to the Chair before the meeting.

If the member has volunteered not to participate in the committee's consideration of the agenda item as a result, the nature of the interest can be identified in general terms. Otherwise, the member will need to disclose sufficient information that will allow the committee to come to a view about whether a potential conflict of interest exists (whether actual or perceived).

The committee must determine for each agenda item in relation to which any member has declared a potential conflict of interest (and who has not volunteered to be absent during consideration of that item), whether, and if so, to what extent, the member may be present during the committee's consideration of that item. The committee will normally consider the question of whether members who have made a declaration should be present during the relevant item only when that item is reached on the agenda at which time those members should leave the room.

Appropriate arrangements will be put in place to achieve the same outcome for a meeting conducted by teleconference or videoconference.

The Regulations make it clear that no member who has declared an interest in an agenda item can be present during the committee's consideration and determination in relation to that interest. Affected members should therefore facilitate that consideration by leaving the room

when the committee comes to consider the matter of their presence during consideration of the agenda item.

Where the member who is disclosing the interest is the Chair, another member chosen by the members present must preside at the meeting for this purpose.

Any person who is not formally a member but who has been invited to participate will also be required to disclose any interests at this time.

4. Consideration by the committee of a disclosure

It is a matter for the person chairing the meeting and remaining members to come to a view about:

- the process by which they come to a decision about the involvement (if any) of a member who has disclosed an interest in an item on the agenda
- the extent of the involvement (if any) of the member in consideration of the agenda item.

The committee may find that it does not have sufficient information to come to a view about either of those matters. It may therefore be necessary for the person chairing the meeting to seek additional information from the member about the nature of the interest to allow the committee to come to a view (refer section E above).

5. Keeping of records

A record must be kept of the interest declared and the decision of the committee (including, where the decision is to allow the member to be present, the conditions (if any) under which the member was present and/or the nature of the member's participation in the committee's consideration of the agenda item). That information will be kept on file.

Subregulation 42(5) states that the disclosure of interests by members must be recorded in the minutes of the meeting. The secretariat will:

- record in the minutes of the meeting a member's specific disclosure of interests for each agenda item
- keep copies of any declarations of interests on file.

There must be a clear record of whether, having declared an interest, a member was or was not present when the committee considered the relevant agenda item. If they were present but only for limited purposes (for instance, just to answer technical questions or for discussion, but not for the framing of the recommendation), that must also be recorded in the minutes.

If the committee agrees that a member can participate in the relevant agenda item, the record should include an indication of the nature of the interest and the outcome of consideration by the committee of whether the member should be present for consideration of the relevant agenda item. Consideration should be given to how much detail about the interest has to be recorded, particularly if the interest is personal. The same applies if the committee decides that the member should not be present. This helps ensure consistency of approach by allowing the committee to refer to the outcomes of previous disclosures.

On the other hand, if the member volunteers to absent themselves from consideration of a particular matter, it would not normally be necessary to record in the minutes more than the fact that the person disclosed an interest in that matter and that they volunteered to absent themselves. However, there may be situations where the recording of more information about the nature of the interest would be appropriate.

Under the Regulations, the recommendations of the committee are required to be published. Other committee outcomes may also be published at the discretion of the TGA.

Disclosure of interests or the outcome of such disclosures will not be published by the TGA.

G. Obligations under the Deed in relation to confidentiality

Committee members will, on occasion, be provided with confidential material and by participating in committee business, and become aware of confidential information. Members must not use or disclose this material to anyone outside the committee (unless authorised to do so) and must treat this material with the utmost care and discretion and in accordance with the terms of the Deed which they are required to sign. A committee member must not participate in committee business until the Deed has been completed.

'Confidential information' means any information or document made available to a member of a committee by the TGA that is by its nature confidential, is designated by the Commonwealth as confidential, or the member knows or ought to know is confidential. It does not, however, include information which is in the public domain or becomes public knowledge other than by a breach by a member of his or her obligations of confidentiality under the Deed.

By signing the Deed a member:

- undertakes to keep secret and confidential all confidential information and not to directly or indirectly disclose it to any person, other than another committee member or an officer of the Department of Health or where disclosure is approved in writing by the Commonwealth
- agrees that where approval is given, to not disclose the information unless the other person has agreed to keep the information confidential and to comply with any conditions imposed by the Commonwealth
- undertakes not to make use of any confidential information other than to fulfil their role as a member or where disclosure is required by court order or by statute
- undertakes to return all confidential information to the Commonwealth on ceasing to be a member and to return or dispose of all confidential information as directed from time to time, at such times and in such manner as directed.

Unauthorised disclosure of confidential information by a member may make him or her liable for prosecution under section 70 of the *Crimes Act 1914*. The Commonwealth can also sue a member for any losses arising from a breach of the member's obligations under the Deed in relation to confidential information.

The secretariat will provide members with instructions about how confidential material should be handled and disposed of.

In order to minimise the risk of confidential information being disclosed:

- agenda papers and other committee documents of a confidential nature will normally be provided in electronic form through access to a secure website; Govdex <www.govdex.gov.au>
- members are asked not to save any committee documents of a confidential nature onto hard drives or, if that is not practical in particular circumstances, for the material to be deleted as soon as it is no longer needed for committee business

- any USBs on which confidential committee documents or information is stored are to be returned to the secretariat after the relevant meeting
- any hard copies of materials provided to members, or which members have printed, are to be held securely and returned to the TGA or destroyed by secure means.

Communication with the public and media

Neither the Chair nor other members should communicate publicly about committee business or about matters that have come to their knowledge as members of the committee unless expressly authorised to do so.

Members are advised that no contact is to be made with the media on committee or departmental matters and any approaches from the media are to be directed to the committee secretary. This does not prevent a member from speaking on behalf of their organisation or in a professional capacity.

However, members should take care not to speak or to give the impression of speaking, on behalf of the Department of Health, the TGA or the committee, unless authorised to do so. In this context, it is suggested that members explicitly state the capacity in which they are speaking. Members should also consider the appropriateness of providing comment where, for instance, in the circumstances or because of the subject matter, there is a risk that a comment will be (mis)interpreted as speaking on behalf of the TGA or as a member of the committee (irrespective of any disclaimers).

H. Other matters

Freedom of Information (FOI)

Under the *Freedom of Information Act 1982* (FOI Act) a person has a right to access documents held by the TGA unless the documents are exempt. One of the grounds of exemptions is 'personal information', the disclosure of which would be 'unreasonable' and would not be in the public interest. Another ground of exemption is that release of the document may have a substantial adverse effect on the proper and efficient conduct of the operations of an agency.

The fact that the effect of the release of information about a member's personal interests (such as members' declarations of interests) or about the member's contributions to discussion on an agenda item might be that those with appropriate qualifications and expertise would be less inclined to make themselves available to assist the TGA in the carrying out of its regulatory functions through membership of an advisory committee, would be relevant to the application of these exemptions.

If documents containing personal information about a member of a committee was relevant to an FOI request, that member would be consulted about the release of that information. Under the FOI Act that information could not be released by the TGA unless and until the opportunity to have that matter reviewed by the Office of the Australian Information Commissioner and the Administrative Appeals Tribunal had been provided to the member.

Working documents

Each document (whether in hard copy or in electronic form) created, sent and received in the course of carrying out duties as a member of a committee is potentially a Commonwealth Record and must be kept by the TGA in line with Commonwealth legislation. Commonwealth Records can include: emails, minutes of meetings, presentations and associated notes.

In this context, members should be aware that committee documents on which they have made comments, or documents prepared by members for use in committee meetings, that are in the possession of the TGA will need to be identified if they come within the scope of an FOI request. Whether any exemption may be applicable in relation to those documents will be assessed on a case-by-case basis.

Comcover arrangements

The TGA's insurance policy with the government insurer, Comcover, provides members of the TGA's committees with the same extent of cover for liability and professional indemnity in relation to their work on the committee as a TGA employee for their work. However, that cover does not extend to serious or wilful misconduct.

As with most insurance policies incidents that could potentially be the subject of litigation must be notified to the insurer, and there are time limits for notifying such incidents. It is particularly important that members notify the TGA as soon as they become aware of a potential incident (for example, accidentally losing or mislaying confidential information provided by the TGA). Details of the policy are located on the finance website <<http://www.finance.gov.au/comcover/insurance/>>.

Invitees at committee meetings and members of subcommittees

On occasions a person who is not a member of a committee will be invited to attend a meeting of a committee. Subcommittees that may, under the Regulations, be established by a committee may also have participants who are not members of the committee itself.

When such a person is invited to a meeting (other than as an observer) they will be sent by the secretariat a modified meeting disclosure of interests form to be completed, signed and returned either at, or before, the meeting.

The same rules apply to invitees as apply to members of the committee. The person should, as soon as they become aware that they have a direct or indirect material personal interest (whether pecuniary or not) in a matter being considered or about to be considered by the committee, disclose that nature of the interest. They will also be directed to a copy of the guidelines on the [TGA website](#) so they can see the types of interests they should be considering.

The person, unlike members of the committee, is unlikely to have completed any declarations of interest that are accessible to the Chair and Secretary. Moreover, in most cases the person's invitation to attend a meeting will be prompted by the need for their expertise to be available in relation to a particular matter or item. The issue of possible interests that would need to be disclosed in relation to matters that will be considered at the relevant meeting may need to be discussed with potential invitees in order to assist the Chair in identifying appropriate non-member persons to attend. The Chair will, however, be relying on the person to be very careful in assessing whether there are any interests to disclose. It is very important that the Chair be notified as soon as possible if there is likely to be an interest to be disclosed so alternative arrangements can be made if necessary.

Whether or not an interest is disclosed to the Chair before the meeting, the person will be required to disclose any interest at the meeting and it will be treated as if the person were a member.

All non-member persons attending a meeting will also be asked to sign a modified Deed that covers the person's obligations in relation to confidential information.

Attachment A

Therapeutic Goods Regulations 1990—Regulation 42

42 Miscellaneous

When committee may establish subcommittees

2) A committee, with the approval of the Secretary, may establish subcommittees, consisting of members and other persons.

3) The function of the subcommittee is to inquire into, and report to the committee on any matter referred to the subcommittee that is within the functions of the committee.

Disclosure of interests

4) A member of a committee who is aware that he or she has a direct or indirect material personal interest (whether pecuniary or not) in a matter being considered, or about to be considered at a meeting of the committee must, without delay, disclose the nature of the interest at, or before, the meeting of the committee.

5) The disclosure must be recorded in the minutes of the meeting and the member must not, unless the committee otherwise determines, either be present during any deliberation of the committee about the matter or take part in any decision of the committee about that matter.

6) When a committee is making a determination about a member who has made a disclosure, the member, and any other member who has a direct or indirect pecuniary interest in the matter to which the disclosure relates, must not either be present during any deliberation of the committee or take part in making the determination.

7) A member of a subcommittee appointed by a committee, who is aware that he or she has a direct or indirect material personal interest (whether pecuniary or not) in a matter being considered, or about to be considered, at a meeting of the subcommittee must, without delay, disclose the nature of the interest at, or before, the meeting of the subcommittee.

Version history

| Version | Description of change | Author | Effective date |
|---------|--|---|----------------|
| V1.0 | Initial publication | Committee Support Unit | 08/08/2011 |
| V1.1 | Minor formatting changes | Committee Support Unit | 16/09/2011 |
| V1.2 | Minor content updates | Committee Support Unit | 11/08/2012 |
| V1.3 | Minor content updates | Committee Support Unit | 27/11/2012 |
| V1.4 | Minor formatting and accessibility changes | Committee Support Unit | 05/03/2013 |
| V1.5 | Department name change. 'Department of Health and Ageing' now changed to 'Department of Health' | Committee Support Unit | 09/10/2013 |
| V1.6 | Minor content updates and formatting changes for TGA style and accessibility | Committee Support Unit | October 2014 |
| | <ul style="list-style-type: none"> • Version history updated • "Commercially confidential" updated • Table of Contents updated • Hyperlinks updated • Footers updated | Principal Legal Advisor Regulatory Engagement, Education and Planning Branch | March 2015 |

| Version | Description of change | Author | Effective date |
|----------------|---|------------------------|-----------------------|
| V1.8 | Minor accessibility changes Removal of concluded working group (UDWG) | Committee Support Unit | April 2015 |
| V1.9 | Deletion of reference to committees until new regulations are in force (January 2017) | Committee Support Unit | August 2016 |

Historical document

Historical document

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