

Conflicts of interest and confidentiality obligations

Guidance for TGA advisory committee members



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This guidance is to assist members, chairs and secretaries of the Therapeutic Goods Administration (TGA) statutory advisory committees (and their subcommittees and working groups), established under Part 6 of the *Therapeutic Goods Regulations 1990* (Regulations), about their:

- declaration of interest requirements
- · management of conflicts of interest related to matters coming before the committee
- · confidentiality obligations



This guidance has been developed by TGA and therefore the use of 'we' and 'us' throughout refers to TGA.

If you have any questions regarding this content, please email committees@health.gov.au

Significance of conflicts of interest

TGA committees provide advice and expertise that is essential to TGA regulatory functions. Members are appointed to provide professional input in relation to matters coming before the committee based upon their specialist knowledge and expertise. The small number of potential members in Australia with the necessary expertise to contribute to our committees means that conflicts of interest can arise.

- A conflict of interest arises when a member's personal interests conflict with committee duties so that the member may not be independent, objective and impartial in relation to those duties.
- An apparent conflict of interest can arise if a personal interest is perceived by a reasonable observer as conflicting with committee duties, whether or not there is an actual conflict.

Any advice or recommendation made by a committee is open to challenge if any of the committee members involved had an **actual** or **perceived** conflict of interest.

Appropriate management of conflicts of interest protects the reputation and integrity of committees by helping to ensure their impartiality and independence. This helps to ensure that the advice and recommendations provided to us reflect the highest standards of professionalism.

Requirement to disclose interests

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 (including the chair) 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.

Subregulation 42(4) of the Regulations requires 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 Minister may, under the Regulations, terminate a member's appointment if the member fails to comply with these disclosure obligations.

Obligations under the Deed of undertaking

You are required to sign the Deed of undertaking in relation to confidential information and conflict of interest (the Deed) upon appointment to the committee. The Deed sets out your obligations related to disclosure of interests.

By signing the Deed, you:

- promise that as at the date of signature, and to the best of your knowledge and after making
 diligent inquiry, you 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 your
 duties as a member, other than the interests (already) declared in the annual declaration of
 interests form
- undertake to notify the Commonwealth and the Chair of the Committee in writing of any
 such interests in relation to a specific matter or proposed matter that is to be dealt with by
 the Committee or otherwise in relation to the performance of your duties as a Member of
 the Committee, of which you become aware 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)
- undertake to comply with your obligations to disclose under subregulation 42(4) as
 described above in relation to any conflicts of interest, and to 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.

Interests that you must declare

You are required to declare any interests of the kind detailed in regulation 42 of the Regulations (as set out above). You should declare both pecuniary (which may include professional) interests and non-pecuniary interests.

Consider the nature of the committee's role, functions and responsibilities when determining whether to declare a particular interest, and whether the interest is a material interest (an interest that could not be considered material need not be disclosed). If in doubt, declare an interest. This allows the committee to readily manage any potential conflict of interest.

Interests of immediate family

Declare relevant interests of your immediate family of which you are aware. Persons comprising your 'immediate family' depend on your particular situation. You would normally include your

spouse/partner and dependent children. Inclusion of other children depends upon the circumstances.

An interest of a family member can be an indirect pecuniary interest if it can affect the committee member financially (for example, a member's spouse who is an employee of a pharmaceutical company can be regarded as an indirect pecuniary interest).

An interest of a family member that could be perceived by a reasonable observer as impacting on the capacity of a member to be independent, objective and impartial in relation to their committee duties requires disclosure.

Pecuniary 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 be described as 'professional interests', such as involvement in sponsored research.

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 listed, but an exhaustive list of minor business contacts is not required.

Some examples of direct and indirect pecuniary interests are listed below.



The lists below are not exhaustive.

If in doubt, declare an interest.

Direct pecuniary interests

Examples of direct pecuniary interests include:

- 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
- Financial involvement with products, services or other matters having any connection with therapeutic goods or any type of paid work

Indirect pecuniary interests

Examples of indirect pecuniary interests include:

- · Paid conference expenses
- · Grants for research or other educational benefits
- · Holding a paid retainer 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:
 - advisory board membership
 - 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
 - clinical trial participation
 - as a researcher, expert adviser or investigator

Non-pecuniary personal interests

A non-pecuniary interest can be:

- · holding strong personal, philosophical or religious beliefs or convictions
- personal circumstances, family or other relationships (for example, a close friend with extensive involvement in the pharmaceutical medicines industry or substantial financial interest in particular therapeutic goods)
- a personal interest or ethical position related to a particular treatment. For example, a
 member, family member or close friend has a specific or uncommon condition whose
 treatment could be affected by a therapeutic good or matter that the committee could
 consider. Treatment for common conditions (for example, hypertension or high cholesterol)
 would not normally be considered as 'material' and therefore would not need to be declared

If the nature of an interest that involves a medical condition or personal beliefs is particularly sensitive, you may volunteer not to participate in the committee's consideration of the matter without needing to provide details.

Declare membership of professional organisations but membership of sporting clubs or societies is not normally required.

Determining whether to disclose an interest

You are responsible for determining whether your interest gives rise to an obligation to disclose that interest. As soon as you become aware of any matter that will be considered at a meeting, carefully consider whether to disclose that interest.

Take into account:

- · the subject matter of the item
- the nature, currency and extent of your interest
- the nature of the issues that the committee is commenting on
- whether you are being asked to comment specifically on the matter. This is usually
 determined when agenda items are sent out but should occur whenever consideration of a
 matter by the committee comes to your attention. It may only be when a matter is actually
 under consideration that you become aware of an interest (for example, where
 unanticipated issues arise in the discussion)

The committee Chair and secretariat have access to your declarations of interests and are aware of situations where members are required to disclose an interest in relation to a matter. The Chair or secretariat may contact you if they are aware of an interest that you have not declared.

Interests are declared before appointment to a committee and at various times during membership, as detailed below.



You are asked to declare that you understand that, if appointed, you are required to comply with the obligations under Regulation 42 of the *Therapeutic Goods Regulations 1990* to disclose an interest in matters coming before the committee. In such cases, the committee will have discretion to determine the extent of your involvement in consideration of that matter.

In support of an application

You need to submit a <u>Declaration of interests in support of application</u> for membership of a TGA advisory committee. This declaration includes current and likely future pecuniary and non-pecuniary interests, and those held over the previous five years. We can then assess whether these interests could affect your ability to effectively perform your role on the committee, if appointed.

If you plan to acquire shares, accept advisory board membership, take on consultancy or sponsorship for a company that manufactures or sponsors therapeutic goods, you need to discuss your position with the Chair of the committee, or the TGA Deputy Secretary.

TGA cannot prevent you from acquiring further interests during your committee membership. An interest that, if declared at the time of application, would have precluded your appointment is **not** compatible with continuing committee membership. We would expect you to consider resignation from the committee in this circumstance.

On appointment and annual declarations

You are required to sign the Deed of undertaking in relation to confidential information and conflict of interest (the Deed) upon appointment to the committee.

You will then need to complete a written declaration of pecuniary and non-pecuniary interests within a month of being appointed (and before attending a meeting). We will ask you to complete an Annual declaration of interests at least once a year. Include the full range of relevant interests at the date the declaration is signed. This replaces any previous declaration.

Members are not expected to declare the detailed nature of personal interests, such as medical conditions or religious beliefs on their annual form, but are only required to declare an interest of this nature should an agenda item arise that may give rise to a conflict of interest.

Before meetings

You are required to declare before each meeting any interests that you have acquired or developed (including in response to specific agenda items) since the most recent annual or meeting declaration.

The secretariat will provide you with proposed agenda items, a Meeting disclosure of interests declaration form and a request for you to consider whether there are any items in relation to which you may need to disclose an interest.

Contact the Chair and secretariat as soon as possible if you believe you have an interest that may mean you should not be present during consideration of the item by the committee. Alternative arrangements can then be made if required (such as arranging additional external expertise or changing the speakers list). You may not receive some agenda items in this circumstance.

Complete the meeting disclosure of interest declaration form before the meeting if you plan to attend the meeting so that the speakers list can be determined before the agenda papers are released.

Non-members who are invited to attend a meeting will also be asked to disclose any relevant interests to the Chair before the meeting, by completing a meeting declaration form.

At meetings

There is a standing item on the agenda of each committee meeting to consider conflicts of interest. At the start of each meeting, or as appropriate, the Chair will invite you to declare any actual or potential conflicts of interest in relation to any item on the agenda. You must declare a potential conflict in any agenda item at this time, whether or not you have declared it to the Chair before the meeting.

You may only become aware of an interest when it is actually under consideration by the committee and unanticipated issues arise in the discussion. In this instance, disclose the interest immediately to the chair.

Ad-hoc declarations

You are required to notify the Commonwealth and the Chair of any additional interests in writing 'as soon as is reasonably practicable', under the Deed of undertaking in relation to confidential information and conflict of interest.

Process for managing declarations

Subregulation 42(4) to (7) of the Regulations details the process for managing any declarations of potential conflicts of interest. Disclosing an interest does not automatically preclude you from participating in the matter.

The process detailed in the Regulations is as follows:

- you must declare the interest without delay if it is 'material' to a matter being considered or about to be considered at a meeting. You are required to declare an interest at or before a meeting even if you have declared it in your annual declaration or at a previous meeting
- in the absence of all members who have disclosed an interest that may conflict with an agenda item, the committee must consider whether any member that has declared an interest can be present during any deliberations on the agenda item or participate in any decision on the matter
- a member that has disclosed an interest must not be present during any deliberation of the committee about the agenda item or take part in any decision of the committee about that agenda item, unless the committee determines otherwise
- the disclosure must be recorded in the minutes of the meeting.

If you are the Chair, the disclosure should be made to the acting Chair or the Secretary of the committee.

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 a member's disclosure before the meeting if there is an issue about whether to provide agenda item documents to that member.

Option to abstain from committee consideration

You have the option of volunteering not to be present during the committee's consideration of an agenda item where you have declared an interest. This is appropriate when it is clear that a conflict of interest exists or may appear to exist to a reasonable observer.

If you volunteer not to participate in the committee's consideration of the agenda item, the nature of the interest can be identified in general terms. You can volunteer not to participate if the interest involves a medical condition or personal beliefs that are particularly sensitive, without needing to provide details. You may not receive agenda papers in this circumstance.

If you volunteer to abstain 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.

The legislation does not prescribe how a committee should determine whether a member who has disclosed an interest in an agenda item should be present during deliberations or take part in any discussion on the agenda item. However, the committee takes into consideration:

- the principle that its deliberations on a matter should 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
- whether the nature, currency and extent of the member's interest would mean that the member cannot bring an independent, objective and impartial view to consideration of the matter
- whether a reasonable observer might conclude that the member cannot bring an independent, objective and impartial view to that consideration (the perception of a conflict of interest is as important as (and much more common than) any actual conflict of interest).

If the Chair is disclosing the interest, present members will choose another member to preside at the meeting for this purpose.

The extent of interest that is acceptable is a question of judgement. A conservative approach is recommended due to the sensitivity of many issues coming before our committees.

In determining whether there is a possible conflict (or perception of one), it does not need to be demonstrated that your conduct is affected, but only that there is an actual or perceived conflict between your interests and your obligations as a committee member.

If you do not opt to abstain from committee consideration

If you do not volunteer to abstain from the agenda item then you need to provide sufficient detail about the nature, currency and extent of your interest. This allows the committee (in your absence) to decide how any conflict should be managed. Depending on its nature, options might include:

- allowing you to participate fully in the deliberation by the committee and in any decision about making recommendations
- allowing you to participate in discussion but not in making a decision about a recommendation
- allowing you to be present to answer questions or 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
- total exclusion from consideration of the matter

We will record 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 example, to answer technical questions or for discussion, but not for the framing of the recommendation), this will 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 matter. 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.

Consistency of committee decisions

Each committee will develop precedents about how to manage particular situations involving declarations of conflicts of interest.

Records of previous committee decisions (with appropriate privacy considerations) may help guide the committee in considering future disclosures of members and ensure consistency in their management.

All the circumstances surrounding each disclosure of interest must be considered when forming a decision about a member's disclosure.

Although the same principles are relevant in determining how to manage conflicts of interest across various committees, 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.

Invitees and subcommittee members

Non-committee members will sometimes be invited to attend a committee meeting. Subcommittees that may, under the Therapeutic Goods Regulations 1990, be established by a committee may also have participants who are not members of the committee itself.

When you are invited to a meeting (other than as an observer) you will be sent modified meeting disclosure of interests by the secretariat. Complete, sign and return this form either at, or before, the meeting.

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-members attending a meeting will also be asked to sign a Non-member Deed of undertaking and a non-member meeting declaration of interest form that covers the person's obligations in relation to confidential information.

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

The same approach applies to invitees as those that apply to committee members. 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 guidance on the TGA website to 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 nonmembers 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.

How we manage your personal information

The secretariat provides the following documents to members:

- · declaration of interests in support of an application for committee membership
- annual declaration of interests form to be completed within one month of appointment and then annually
- meeting declaration of interests form to be completed in relation to matters on the agenda at each meeting attended. This document can also be used to declare interests that have recently arisen or occur on an ad hoc basis

These completed documents contain sensitive personal, and occasionally commercially confidential, data. The information can only be used for recording, reviewing and managing conflict of interest issues. Access to such documents is controlled and only granted to members with a genuine need to know or in connection with reviewing conflict of interests and related issues. We have obligations under the *Privacy Act 1988* to protect your personal information.

For more information see **Privacy information** on our website.

The relevant secretariat is responsible for the secure storage of conflict of interest documentation. Depending on the nature of the information, your declaration of interest may be provided to the TGA Executive and/or Minister for further assessment.



We will not publish disclosure of interests or the outcome of such disclosures.

Freedom of Information (FOI)

Under the *Freedom of Information Act 1982* (FOI Act) a person has a right to access documents held by TGA unless the document is 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. If the release of information about the personal interests (such as declarations of interests) or contributions by a committee member to discussion on an agenda item might have the effect that existing and/or potential experts are less inclined to make themselves available for membership of a TGA advisory committee, this exemption may be relevant.

If a document containing your personal information was relevant to an FOI request, you would be consulted about the release of that information. Under the FOI Act, that information could not be released by us unless and until you were provided the opportunity to have the matter reviewed by the Office of the Australian Information Commissioner and the Administrative Appeals Tribunal.

Committee documents

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

In addition to the published recommendations of a committee, we also keep records that are not published. Each document (hard copy or electronic) that is created, sent and received while carrying out committee member duties is potentially a Commonwealth record and must be kept by us.

Commonwealth records can include:

- emails
- meeting minutes
- presentations

associated notes

Committee documents where you have made comments or prepared for committee meetings that are in our possession will need to be identified if they come within the scope of an FOI request.

Applicability of an exemption in relation to these documents will be assessed on a case-by-case basis.

Your information handling obligations

Confidentiality of information

You will on occasion be provided with confidential material and by participating in committee business become aware of confidential information. You must not use, or disclose this material to anyone, outside the committee (unless authorised to do so).

Confidentiality obligations under the Deed

You must treat this material with the utmost care and discretion and in accordance with the terms of the Deed. You must not participate in committee business until you have signed and returned the Deed.

'Confidential information' means any information or document made available to a member of a committee by 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 to 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 use or 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; <u>Govdex</u>
 https://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 TGA or destroyed by secure means

Communication with the public and media

In relation to communicating with the public and media:

- **Q** Do **not** communicate publicly about committee business or any matters that have come to your knowledge as a committee member, unless expressly authorised to do so
- **û** Do **not** make contact 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 you from speaking on behalf of your organisation or in a professional capacity.

Take care not to speak or to give the impression of speaking, on behalf of the Department of Health, TGA or the committee, unless authorised to do so. In this situation, you should explicitly state the capacity in which you are speaking.

Consider the appropriateness of providing comment where, for instance, in the circumstances or because of the subject matter, there is a risk that any comment will be (mis)interpreted as speaking on behalf of TGA or as a member of the committee (irrespective of any disclaimers).

Insurance for committee members

Comcover arrangements

The TGA insurance policy with the government insurer, <u>Comcover</u>, provides TGA committee members 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.

There are time limits for notifying the insurer of incidents that could potentially be the subject of litigation. It is extremely important that members notify TGA as soon as they become aware of a potential incident (for example, accidentally losing or mislaying confidential information provided by us).

Forms for advisory committee members

The following form is available on the TGA website for you to complete:

<u>Declaration of interests in support of application</u> for membership of a TGA advisory committee

The forms below will be provided to you to complete once you are appointed to a TGA committee:

- Deed of undertaking in relation to confidential information and conflict of interest (the Deed)
- Annual declaration of interests for members of TGA advisory committees
- Meeting disclosure of interest declaration for members of TGA advisory committees. You
 will receive this form before each meeting in order to disclose interests relevant to the
 meeting agenda

Therapeutic Goods Regulations 1990



The legislation below is current as of 1 January 2018.

As regulatory requirements are amended from time to time, it is important to access the current official versions of the legislation available on the <u>Federal register of Legislation</u>.

42 Miscellaneous

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	15/08/2012
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	Departmental 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
V1.7	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
V2.0	Major content and structural changes to meet best practice and accessibility requirements	Committee Support Section, Regulatory Guidance Team and Legal Services Branch	May 2018

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605 https://www.tga.gov.au

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