

Reference guide for managing conflicts of interest – for TGA advisory committee members

How Therapeutic Goods Administration (TGA) advisory committees manage members conflicts of interests.

Introduction

This guide provides information for TGA statutory advisory committee members on the **management** of conflicts of interest in the context of committee meetings.

The guide discusses **common scenarios** and general approaches for dealing with them (at **Appendix 1**). It supplements the procedural guidance contained in the [*Conflicts of interest and confidentiality obligations: Guidance for TGA advisory committee members \(May 2018\)*](#).

For the purpose of this guide, the terms ‘conflict of interest’ and ‘material personal interest’ are used interchangeably (noting the relevant legislation uses the terminology of ‘material personal interest’).

The **legal obligations** on statutory advisory committee members come from the *Therapeutic Goods Regulations 1990* (Therapeutic Goods Regulations), the *Public Governance, Performance and Accountability Act 2013* and Rules, and from the Deed of Undertaking (signed on appointment). This guide reflects legal obligations and best practice for managing conflicts of interest.

The processes in this guide should also be followed in relation to the TGA’s **non-statutory advisory committees**.

A: Identifying conflicts of interest

A **conflict of interest or material personal interest** arises when a member’s interests conflict, or may be perceived to conflict, with their committee duties. If an interest (viewed objectively) has the capacity, or the perceived capacity, to affect the ability of the member to be independent, objective and impartial in relation to the matter being considered, a conflict of interest (or material personal interest) arises.

Whether or not the individual member would be improperly influenced is not the issue. The issue is whether a conflict, or the perception of a conflict, exists – and this is judged by a reasonable bystander.

A member is not necessarily excluded from participating in a committee meeting because they have a conflict of interest. Rather, the conflict must be disclosed and managed appropriately.

Part B (below) deals with disclosing conflicts of interest, and **Part C** deals with managing conflicts of interest (with specific scenarios discussed further in **Appendix 1**).

Examples of broad range of possible conflicts

Consistent with the Therapeutic Goods Regulations, conflicts of interest may involve 'direct' or 'indirect' material personal interests. These interests may be 'pecuniary' (i.e., financial in nature) or not.

Therefore, conflicts may involve a **broad range of interests** including:

- financial interests or payments or material benefits of any kind
- employment, contracts or other work
- professional interests or having a professional 'stake' in a matter
- public statements
- strong personal beliefs, or
- the interests of immediate family, close friends or close associates,

where those interests conflict, or may be perceived to conflict, with a member's duties.

A particular interest may give rise to a conflict where it relates to a matter which the relevant committee is considering or that may come before the committee in the future. For example, the interest could relate to a sponsor of a product being considered or to a competitor with a similar product. The following table gives examples of interests that may give rise to a conflict of interest with a member's duties.

Examples of interests that may give rise to a conflict of interest

Direct financial interests	Other financial interests (may be of a direct or indirect nature)	Work or professional interests (may or may not involve payment)	Other interests
Shares, other investments	Paid travel/ conference expenses	Involvement in clinical trial	Strong personal, philosophical or religious beliefs
Employment, contracts, consultancies, commissioned fee-paid work, paid retainer, paid speaking or advising roles	Other hospitality or benefit from a company or organisation involved in the therapeutic goods industry	Roles as a researcher, expert adviser or investigator	Public statements relating to matters before the committee
Grants or sponsorships to member	Research or other grants to employer or institution the member is associated with	Sponsorship of an event	Personal interest in a particular product, e.g., where a member, family member or close friend has a specific condition that could be affected by a therapeutic good that
Directorships, board memberships, partnerships, trusts	A financial interest held by a spouse or close family member, e.g.,	Advisory board role	

Patent rights	owning shares in, or working for, a pharmaceutical company	Ongoing or ad hoc support for a patient or student	the committee is to or may consider
Any other financial involvement or payment in relation to products, services or other matters connected with therapeutic goods		Any other professional involvement with a company or organisation involved with therapeutic goods	

Note: the above examples are not exhaustive. Further, it is not necessary to categorise whether an interest is financial, direct, indirect or otherwise. What is important is to disclose and manage an interest (whatever its type) where that interest conflicts, or may be perceived to conflict, with a member's duties.

B: Disclosing conflicts of interest

Forms to use when disclosing interests

Members are to provide a written declaration of any material personal interest at the following times. There are relevant forms to support this process.

Forms to use when disclosing interests

Declaration point	Form
At time of application	- <i>Declaration of interests in support of application – For membership of a TGA expert advisory committee</i>
On appointment	- <i>Deed of undertaking – In relation to confidential information and conflict of interest</i>
As part of an annual declaration	- <i>Annual declaration of interests – For members of TGA statutory advisory committees</i>
Before or at each committee meeting	- <i>Meeting disclosure of interest declaration</i>
At any other time during the period of membership if a member becomes aware of additional material personal interests (or changes in the nature/extent of interests)	- Members should notify the Committee Support Unit/secretariat and the chair of the committee, in writing, of these interests (or changes) as soon as practicable after becoming aware of the matter

It is the responsibility of the member to complete the relevant forms, following any instructions and return them to the TGA.

Disclosing interests before or at a meeting

For **meetings**, it is important that all interests relevant to agenda items be **declared, or re-declared**, without delay, at or before each meeting even if declared previously (for e.g., in an annual declaration or for a previous meeting).

Whether there is a material personal interest that is relevant depends on the facts, so it is possible that previously declared interests will not be material/relevant in relation to different agenda items.

To facilitate the declaration process, the meeting agenda will be distributed prior to the meeting, along with the *Meeting disclosure of interest declaration* form. Members should provide details on the form about the nature of the interest, which agenda item the interest relates to and how the interest relates to the agenda item (or confirm there are no applicable interests relevant to the agenda items, e.g., indicate a 'Nil' response).

Members should **return their completed form** as soon as possible to ensure declared conflicts of interest can be properly managed. Access to the full meeting papers will generally only be provided after forms have been returned. The Committee Support Unit (CSU) and/or the committee secretariat can provide advice to the committee on disclosing and managing declared conflicts of interest and can assist with managing conflicts including in relation to the possibility of sourcing alternative expertise where feasible. The CSU is generally the first point of contact on conflict of interest matters.

It is also important for members to declare conflicts based on agenda items as early as possible to limit inappropriate access to commercially sensitive information.

C: Managing conflicts of interest

Process for managing conflicts of interest at a meeting

The process for the committee managing conflicts of interest at a meeting includes the steps discussed below. A simplified **flowchart** setting out the steps is at **Part H** of the guide. The CSU and the committee secretariats will support the committee in relation to these processes including in relation to pre-meeting preparation and post-meeting support.

Standing agenda item

- Each committee meeting will have a standing agenda item early on in its agenda to deal with conflicts of interest. The committee may deal with all conflicts at the start of the meeting (but it is also possible to deal with conflicts for each agenda item immediately prior to the discussion of the relevant item). The chair should invite members to declare any conflicts, i.e., material personal interests, in relation to an item(s) on the agenda. Members will have also had the opportunity, before the meeting, to declare material personal interests in relation to an agenda item on the *Meeting disclosure of interest declaration* form and, where they have declared interests, these should be referred to during this standing agenda item.

Default position: member must not be present for particular item

- Once a member has declared a material personal interest in relation to an agenda item, the legislation **prevents** the member from being present/participating in any aspect of the

committee's deliberations in relation to that agenda item **as a default position** *unless the committee determines otherwise*.

- Note: the member is only prevented from being present for/participating in the agenda item(s) in relation to which they have declared an interest (subject to the committee determining otherwise). The member can be present, and participate, in relation to *other* agenda items for the meeting.

Option to abstain

- If the member has chosen to **abstain** and will not be present for the agenda item in relation to which they have a declared interest, this is consistent with the default position in the legislation (that the conflicted member not be present). In these circumstances, there is no need for a formal determination to be made (see below regarding what is to be recorded in the minutes).

If determining whether member can participate

- Where the issue of the member's participation is to be determined, the chair (or presiding member, if the chair is the conflicted member or is absent) will ask the committee to **determine** (i.e., decide) whether the conflicted member should be permitted to be present/ participate in relation to the agenda item and, if so, whether subject to any limits or whether the member should be excluded. The **committee** (namely the members who are attending for the meeting minus the conflicted member) **is the relevant decision-maker** for determining whether the conflicted member can be present/participate in relation to the agenda item – with the decision to be that of the majority.
- Note: the legislation requires that the **conflicted member must not be present while the committee undertakes any deliberation/makes a determination** on whether the conflicted member may participate in relation to the agenda item. However, *prior to* deliberations starting, the conflicted member may be asked to provide an outline of the conflict as necessary (but must then leave the room).

Standing conflicts (or other previously declared conflicts)

- The legislation requires material personal interests relevant to agenda items to be declared and managed on a meeting-by-meeting basis.
- Unless the member abstains, the committee is to determine how to manage each declared conflict for a meeting, even if that conflict has previously been declared. However, the committee may rely on its previous reasons, if those reasons still apply and the circumstances are not materially different.
- The committee is not obliged (under the legislation) to make a determination about whether a member may participate or not. If no determination is made, the default position will apply and the member will fully be excluded. Note, the member who has declared an interest must not be present for any deliberation by the committee about managing that declaration, even if a determination is not ultimately made.
- If the committee (or members) would like the member who has declared an interest to participate, then it will be necessary for the committee to make a determination to allow this (with the conflicted member not able to be present for the deliberation/ determination). In the absence of a determination made for the purposes of the current meeting, the default position is that the member cannot be present.

Matters to be recorded in minutes

- **All declared interests** in relation to an agenda item (including where the member has chosen to abstain) **are to be recorded in the minutes** (referring to the member by name, the item number and the nature of the interest). Where the committee member is not present for an agenda item because they have abstained, the **outcome of the member not being present is to be recorded in the minutes**. Where the committee has made a determination regarding participation (or exclusion), **what the committee determined** in relation to this **and the basis for the determination are to be recorded in the minutes**.

See **Part G** below for further discussion and examples on 'Record-keeping in relation to conflict of interests'.

D: Relevant factors in assessing whether a member may be present

The legislation does not set out any specific criteria that the committee must consider in determining whether a member may be present in relation to an agenda item. However, it is important to take steps to manage conflicts of interest, or perceived conflicts, so as not to undermine the credibility and independence of the committee.

Relevant factors in assessing whether a member may be present include:

- the **nature and extent** of the interest and the member's **level of involvement**
- whether the interest is **current** (and the effect of any **passage of time**)
- the **relevance or connection** of the interest to the agenda item
- whether the individual member is the **only readily available source of expertise**
- whether the conflict can be managed by placing **limits** on the participation of the member.

In making the assessment, the committee will need to weigh up the factors in the case (both for and against exclusion) and consider the overall level of significance of the declared interest. The committee should be cautious about allowing participation in any circumstance where there is a real risk of a perception that the member might not bring an objective mind to the matter. Participation should only be permitted in this situation if there are good reasons (e.g., member's expertise required) and subject to considering limits on such participation (see next paragraph).

Note: where expertise cannot reasonably be sourced from another person including by arranging for an alternative expert advisor who would not be similarly conflicted to assist the committee, and the committee is minded to give weight to this factor, any participation in such circumstances should generally be as limited as possible (for example, subject to the facts, this may involve having the member speak to confined questions or issues and then leave the room without participating in the committee's further deliberations on the agenda item).

Useful questions to consider

The committee may find it helpful to consider the following questions in assessing whether a member may be present:

1. What is the **nature and extent or scope** of the interest/involvement?

- Does it involve:

- a direct (or indirect) *financial* benefit?
 - A *professional* interest where the member has a professional stake in a matter (e.g., if there could be a perception that the member might be biased because a particular outcome may affect the credibility of their research or because of public statements they have made)
 - an interest of a *close family member or close friend* - particularly where *direct financial interests* (e.g., shareholdings or employment) of the close family member or close friend are involved
 - another type of interest?
 - Do any aspects increase or decrease its **significance/materiality**?
 - If a member directly receives research funding from a company with a matter being considered by the committee this will be very significant. But if the company provides research funding to a third party with which the member is associated (e.g., a university that employs the member) that is unrelated to the member's work, this would be of far less significance.
 - Consider the nature of the source of any funding. For example, funding from a company whose product is to be considered by the committee (or funding from a competitor) is likely to be of greater significance than funding from a source such as the NHRMC. But check, also, whether there are other factors (beyond the source of funding) which also need to be considered.
 - In relation to interests of family members, friends and associates, the nature, closeness and duration of the relationship or association is likely to be relevant. For example, direct financial interests of a spouse or dependent child will generally be greatly more significant than those of a non-dependent child or a close friend. But financial interests of a friend can still potentially be significant, for example, where the member and the friend also have a financial association.
 - With strong philosophical or religious beliefs, these are most likely to be significant where those beliefs have been publicly expressed and the perception of a conflict might arise *and* the beliefs have some specific relevance to an agenda item.
 - In relation to work or other activities, what is the member's **level of involvement**? Is it of a shorter term or ad hoc nature, or a longer term or more significant nature?
2. *Is the interest **current or recent**? Has sufficient time passed to reduce the level of significance?*
- There is no set time at which an interest will become insignificant – what is a sufficient passage of time will depend on the facts.
 - As a general proposition, three years may be sufficient if the matter has no ongoing relevance or significance.
 - Note: the passage of time may not necessarily reduce significance, or do so as quickly, where a matter is/has been highly significant. For example, where a member may have a strong professional stake in a matter because of their previous close involvement. At a minimum, more time may need to have passed since the involvement.
 - There may be some interests that never lose significance/relevance regardless of the passage of time. For example, having had detailed involvement in the development of the same product that is being considered by the committee.

3. *What is the level of **benefit** (e.g., financial, professional or otherwise) that the member may be perceived to obtain if they participate in the agenda item?*
4. *What is the **relevance or connection** of the interest to the agenda item? Is it highly relevant or closely connected or less so?*
 - Does the interest involve the same product that is being considered by the committee, or a different product of the sponsor that while connected may not necessarily be as directly connected to an agenda item?
 - If a competitor's product is involved, are the similarities such that there is a clear connection with the agenda item, or are there differences that mean the relevance or connection to the agenda item is lessened?
 - Is the interest more remote from the agenda item because of the nature of the agenda item itself (including because the agenda item may be very general or focused in some way)?
5. *Would the absence of the member significantly impede the committee's consideration of the agenda item because advice cannot readily be obtained from **another non-conflicted source**?*
 - Can advice reasonably be obtained from other members of the committee or arrangements made to obtain advice from another expert adviser?
 - Can consideration of the agenda item be deferred to obtain alternative advice?
6. *Can the conflict be managed by placing **limits** on the participation of the member?*
 - For example, could the member contribute their expertise to discussion on confined issues or in response to confined questions without participating in further deliberations?
7. *What is the likely **perception** of a reasonable bystander?*
 - Would they view the member as having or not having the capacity in the circumstances (including with any possible limits on participation) to be independent, objective and impartial when considering the agenda item?

Discussion of particular scenarios

See **Appendix 1** for further guidance, in table format, of various scenarios, relevant factors/considerations, and whether exclusion or participation may generally be indicated. (Scenarios where an immediate family member or close friend hold an interest are considered at the end of the table.) The appropriate course of action always depends on the facts of the case and committee members are reminded to consider the specific facts of the case before them.

Note: because conflicts of interest are also considered when persons are applying for membership of a TGA advisory committee, some of the scenarios outlined in the table may be unlikely to arise unless a member acquired interests after the appointment process. See further below regarding 'Broader issues in managing conflicts of interest'.

E: Summary of key factors for and against exclusion

In summary, in high level terms (and focusing on the more common scenarios in the table in Appendix 1), factors going towards exclusion, in circumstances where the declared interest is relevant to/connected with the agenda item, are:

- a direct financial payment/ interest
- significant involvement (even if no direct payment or honorarium), for example:
 - designer or lead researcher of a clinical trial, main author of relevant paper
 - position on a pharmaceutical company advisory board
- where there has been an ongoing relationship/ involvement.

Countervailing factors (i.e., against exclusion) may be where:

- the interest, involvement or relationship was of an ad hoc or a confined nature or involved a different context
- there has been sufficient passage of time to mitigate the interest:
 - as a general proposition three years may be sufficient but, as noted, there is no set time at which an interest will become insignificant, and some interests may potentially never lose significance/relevance
- expertise cannot reasonably be obtained from another source.

Options regarding exclusion or participation

In determining at a meeting whether a member may be present during an agenda item, the options for the committee include:

- fully excluding the member from all discussions, and decisions (e.g., regarding the advice or recommendations to be given), on the agenda item
- excluding the member from discussions, and decisions, on the agenda item but allowing the member to respond to confined questions or issues
- excluding the member from decisions on the agenda item but allowing participation in discussions prior to this
- allowing the member to fully participate in committee discussions and decisions on the agenda item.

F: Broader issues in managing conflicts of interest

The *Conflicts of interest and confidentiality obligations: Guidance for TGA advisory committee members (May 2018)* refers to the initial process for persons applying for membership of a TGA advisory committee (along with providing general procedural guidance for members once they are appointed).

Declarations of interest are sought in support of applications for membership. The TGA can then assess whether these interests could affect the person's ability to effectively perform their role on the committee, if appointed. Persons with existing interests (not able to be mitigated by being divested or ceased) that would prevent, or substantially limit, them from performing a committee role effectively are not considered for appointment.

Similarly, for the duration of the member's appointment, if an interest disclosed by a member raises broader issues (beyond the committee meeting itself) such as whether the member's

continuing role on the committee may be an issue, this should be raised with the chair of the committee and the committee secretariat.

G: Record-keeping in relation to conflict of interests

All records relating to conflict of interest issues will be stored securely by the TGA in the Department's record management system. These include declaration of interest forms and the minutes of the committee meetings.

Committee meeting minutes

The minutes of the committee meeting are to record the following:

- each conflict of interest disclosure made by a member in relation to an agenda item (including where a member chose to abstain):
 - referring to the member by name and the agenda item number, and
 - describing the interest in a way sufficient to understand the nature of the interest and why it may conflict with the agenda item.
- where a determination about participation was made:
 - what the committee determined in respect of whether the member was able to fully participate, participate subject to certain limits, or was to be excluded from participation, and
 - the basis for the determination – particularly where a member was allowed to participate/ participate with limits. It is important that there be sufficient detail to show the justification for the determination.
- where the outcome was the default position that a conflicted member was not present, i.e., without a determination being made (for e.g., where the member was abstaining), the outcome of the member abstaining and not being present is also to be recorded.

Recording these details also helps to support consistency of approach in the future by allowing committees to refer to previous minutes on how previous disclosures were dealt with.

There is no one form of wording, or format, that must be used for the part of the minutes relating to conflicts of interest. However, the following are examples of how the relevant details could be recorded:

Example 1 (determination made - not able to participate)

“Disclosure of interests

Item x.xx - PRODUCT NAME – Prof A declared she was currently a member of an advisory board for the sponsor of this product.

The Committee determined, in the absence of Prof A, that she could not participate in relation to this agenda item because of this existing role with the sponsor.”

Example 2 (default outcome where member not present)

“Disclosure of interests

Item x.xx: The Committee received a declaration of interest from Dr B who holds shares in the sponsor company X. Dr B noted his wish to abstain from this item.

The Committee noted for the record that Dr B was not present for this item.”

Example 3 (determination made - able to participate subject to limits)

“Disclosure of interests

Item x.xx - PRODUCT NAME - Dr C declared that she had been on an advisory board for the sponsor (finishing in 2018) for product Y. She received no payment for this work.

In the absence of Dr C, the Committee considered the role she had with the sponsor (though for a different product) and that this role finished four years ago. The committee determined that despite the passage of time, limited participation only was warranted because of the previous advisory role. The committee decided Dr C could speak to confined questions on the item but could not be involved in any formal deliberations or recommendations.”

Example 4 (determinations made - able to participate fully)

“Disclosure of interests

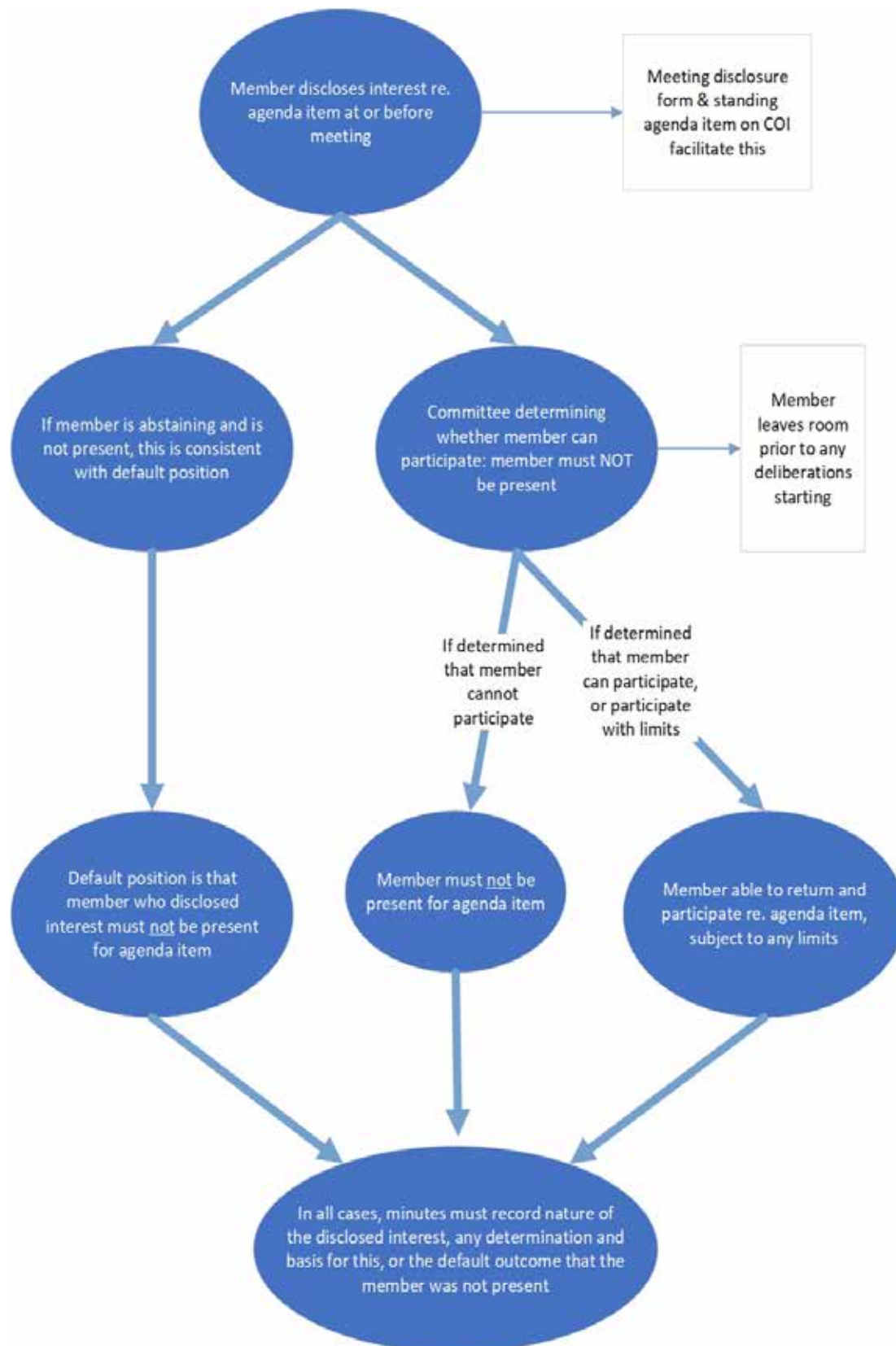
Re item x.x, Dr D declared he had been an investigator in a clinical trial for another of the sponsor’s products for an unrelated disease. He enrolled a number of patients at one site but did not have any influence over the trial protocol. The sponsor made payments to the hospital where Dr D worked for separate research but Dr D had no access to, or involvement with, this funding.

The Committee determined (in the absence of Dr D) that he be able to fully participate in relation to the item. The committee was of the view that Dr D did not have a significant level of involvement or influence in the trial and had received no direct financial benefit.

Re item x.y, Dr S declared a standing conflict regarding her role as a site investigator only in a clinical trial sponsored by the sponsor company. Dr S received no payment.

In the absence of Dr S, the Committee determined she was able to fully participate given the low level of involvement and no financial benefit.”

H: FLOWCHART ON MANAGING CONFLICTS OF INTEREST AT A MEETING



Appendix 1: Scenarios – whether exclusion or participation generally indicated

INVOLVEMENT IN CLINICAL TRIALS (e.g., run by sponsor, competitor, company that will be affected by committee advice)

Scenario	Relevant factors/ considerations ¹	Usual or suggested general approach for dealing with scenario in terms of exclusion or participation	Example ²
1. Involvement in clinical trial run by company (<u>sponsor</u>) for <u>same product</u> to be considered by committee.	<ul style="list-style-type: none"> Interest concerns product being considered and is directly connected with the agenda item. Level of involvement member has/had with clinical trial. Level of benefit obtained by member personally (e.g., any financial, professional or other benefit). Time elapsed since involvement. Note: whether member bound by any confidentiality agreements/ 	<p>There are many ways in which a person might be involved in a clinical trial. The appropriate approach will depend highly on the facts.</p> <p>Where a member was personally involved at a significant level (e.g., as designer of trial, or author of report/papers) – exclusion would generally be indicated. Even if a significant period of time has elapsed there is likely an ongoing professional interest or stake in the matter (e.g., perception the member may have an interest in defending their research).</p> <p>Where a member was involved as one of a team of researchers/investigators and did not receive any payments or professional benefits</p>	<p>X declared she was a primary investigator for a clinical trial sponsored by company Y (the sponsor) for the same product of the sponsor to be considered by the committee. X had been heavily involved in development of the protocol for the trial, had attended regular international investigator's meetings at the company's expense, and received honoraria for her work on the trial. X was involved in analysis of the trial results and was third author on the main results paper for the trial. Noting X had received direct payments from the company, had a significant level of involvement and received professional benefit from this, the committee determined to exclude X from participating.</p> <p>Z was an investigator on the same trial. She enrolled a number of patients in the trial at one trial site but did not have any influence over</p>

¹ See fuller discussion in main text of Reference Guide on relevant factors in assessing whether a member may be present.

² This column provides examples of committees managing declarations of interests (based on actual or hypothetical circumstances).

	<p>clauses as part of their work for the clinical trial may also affect whether they can be impartial or would be perceived to be impartial.</p>	<p>(e.g., as author of papers), participation, with limits as considered necessary, may be indicated.</p>	<p>the trial protocol. She was not an author on any of the published papers resulting from the trial. Company Y made payments to her hospital department but, Z had no access or involvement in relation to this funding. The committee determined that Z did not have a significant level of involvement in the trial, had no influence on the outcome and received no direct financial or professional benefit. Z was able to fully participate.</p> <p>A's case involved similar facts to Z's. However, A was also listed on some of the trial publications as a member of the product 'study group' – even though, in fact, he had no involvement in development of the trial protocol or analysis of the trial results. The committee noted although it may have appeared to some observers (not apprised of all the facts) that the member was actively involved, the committee found that on the actuality of the facts, the member was not involved with the trial protocol and had no significant level of involvement. A was able to fully participate.</p>
<p>2. Involvement in clinical trial run by company (<u>sponsor</u>) for <u>different product</u>.</p>	<ul style="list-style-type: none"> As for scenario 1, except interest concerns a different product and is not as directly connected with the agenda item. 	<p>If committee member recently received a direct financial benefit (e.g., a payment) from the sponsor exclusion generally indicated. The same general approach would apply where the member was personally</p>	<p>X was involved in a clinical trial for an unrelated product of sponsor. X was a site investigator only. X received no personal financial benefit – full participation allowed.</p>

	<ul style="list-style-type: none"> Where a different product is involved, the perception of a conflict arising may generally be lower. However, the perception of a conflict may still arise due to the association with the company. 	<p>involved at a significant level.</p> <p>Participation may be indicated if:</p> <ul style="list-style-type: none"> no direct financial benefit or other significant benefit (because of significance of role), or a significant period of time has elapsed (e.g., over 3 years) and no other factors indicating exclusion. 	
<p>3. Involvement in clinical trial run by <u>competitor</u>, e.g., where product is <u>similar</u> to that being considered by committee.</p>	<ul style="list-style-type: none"> As for scenarios 1 and 2. 	<p>Generally, adopt similar approach to that in scenario 1 – consider nature/level of role, benefits received and time elapsed since involvement. If member recently received a direct financial benefit (e.g., a payment) from the competitor or had a significant role, exclusion generally indicated.</p> <p>If the product is different the significance will generally be lower. But there are still cases where the perception of a conflict could arise even if the product is different e.g., if there has been a recent payment from, or an ongoing association, with the company.</p>	

4. Where committee members making a <u>more general decision</u> (e.g., a scheduling decision) not a product-specific decision, and significant involvement in conducting/managing clinical trial (or other research) funded by company which will positively or adversely affected by the general decision.	<ul style="list-style-type: none"> As for scenario 1, except relevance of interest to agenda item slightly more indirect because committee making general decision rather than product specific decision. 	Generally excluded from both discussions and decisions (on advice/recommendations) even if a significant period of time has elapsed unless strong countervailing factors (e.g., expertise cannot otherwise be sourced). Any participation should be as limited as possible (e.g., answering specific questions without participating in further discussions or decision making).	X, an academic, was involved in conducting a clinical trial funded by company which would be affected by the advice of the scheduling committee. X's interest was non-pecuniary – committee asked X to provide factual input to assist in informing it (as expertise sought by committee could only be sourced from the member). However, member was excluded from the further discussion and decision making of the committee.
5. Funding of a <u>clinical trial nurse</u> by sponsor or competitor to institution with which the member is associated.	<ul style="list-style-type: none"> Consider background to funding – is it linked to member (or member's project)? Consider purpose of clinical trial nurse – who/what does this benefit? Level of funding. 	<p>Depends on facts.</p> <p>May be reasonable to characterise benefit as pertaining to the efficient running of the trial rather than as a specific personal benefit to the member – so that participation (or participation subject to limits) may be indicated. If facts indicate the funding is an 'in-kind' financial benefit linked to the member, exclusion may be indicated.</p>	

FUNDING OF RESEARCH GRANT TO MEMBER AND/OR TO INSTITUTION MEMBER IS ASSOCIATED WITH (by sponsor or competitor)

Scenario	Relevant factors/considerations	Usual or suggested general approach for dealing with scenario in terms of exclusion or participation	Example
6. Funding of research grant by company	<ul style="list-style-type: none"> Interest concerns product being 	If level of connection/role/any personal benefit is	

<p>(<u>sponsor</u>) to member and/or institution member is associated with – for research regarding <u>same product</u> that is being considered by committee.</p>	<p>considered and is directly connected with the agenda item.</p> <ul style="list-style-type: none"> • Was grant to member (or member's project)? Or to institution (or another person within that institution)? • Was company able to approve or control grant going to member or to member's project (or, for e.g., were there blind funding arrangements)? • Level of connection member has/had with research. • Time elapsed since funding provided. 	<p>significant, exclusion would generally be indicated. This would generally include where:</p> <ul style="list-style-type: none"> • the company was able to approve or control the grant going to the member or their project, or • a direct payment is made to the member from the grant, or • the member is heavily involved in the research being funded (even if time has lapsed there is likely an ongoing professional interest or stake in the matter). <p>If level of connection /role/any personal benefit is less significant (and no direct payment to member), participation, with appropriate limits as considered necessary, may be indicated. For example:</p> <ul style="list-style-type: none"> • where grant is paid to institution for a research project unrelated to the member's work – full participation may be indicated • where member has minor/ad hoc role in funded research – participation (or participation 	
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		with limits) may be indicated.	
7. Funding of research grant by company (<u>sponsor</u>) to member and/or institution member is associated with – for research on <u>different product</u> .	<ul style="list-style-type: none"> As for scenario 6, except interest concerns a different product and is not as directly connected with the agenda item. However, the perception of a conflict may still arise due to association with company. 	<p>If member does not receive any direct financial or other significant benefit from the grant or if significant time has elapsed since the funding was provided (e.g., over 3 years), participation may be indicated.</p> <p>Exclusion may be indicated if the member directly benefits from the grant (e.g., payments are made to the member from the grant, or the grant funds a significant research project of the member, or the company was able to approve or control the grant going to the member or their project).</p>	Company (sponsor) funded student research project that X was supervising on a topic that was unrelated to product/item before the committee. The committee considered the primary benefit was to the student. X allowed to participate fully.
8. Funding of research grant by <u>competitor</u> to member and/or institution member is associated with - for research on product <u>similar</u> to that to be considered by committee.	<ul style="list-style-type: none"> As for scenarios 6 and 7. 	<p>Generally, adopt a similar approach to that in scenario 6.</p> <p>In addition, if product not sufficiently similar, significance/relevance would be lower so that participation may be indicated if member does not receive any direct benefit or significant time has elapsed. But consider if the perception of a conflict could arise due to association with the competitor.</p>	

FUNDING OF RESEARCH GRANT (FROM ANY SOURCE) TO DEVELOP SIMILAR PRODUCT TO THAT BEFORE COMMITTEE

Scenario	Relevant factors/ considerations	Usual or suggested general approach for dealing with scenario in terms of exclusion or participation	Example
<p>9. Funding of research of the member to develop <u>similar product</u> to that before committee – matter is at <u>stage of commercialisation agreement and late-stage product</u>.</p>	<ul style="list-style-type: none"> • Degree of similarity of products (the more similar the products the closer the connection of the interest with the agenda item). • Level of involvement in research. • Level of benefit obtained by member personally (e.g., any payment to member or intellectual property interests in product). • Source of funding (is it from company whose product the committee is to consider or competitor or independent source (e.g., NHMRC or ARC). 	<p>This scenario (late-stage context) would usually be considered of high significance where a product is similar to that before the committee and is the subject of a commercialisation agreement – exclusion would generally be indicated.</p> <p>Note: exclusion will usually be appropriate in this scenario regardless of the source of the funding or whether the member may financially benefit from the commercialisation of the product. This is because of the close association of the member with an alternative product (to that before the Committee) and a likely perception that they might act to advantage their own product (in a late-stage context) unless this perception is not reasonable in the particular circumstances.</p>	
<p>10. Similar to above but <u>commercialisation</u></p>	<ul style="list-style-type: none"> • As for scenario 9 	<p>This interest is of slightly less significance than that in scenario 9,</p>	

<u>grant only at concept stage.</u>		but there could still be a perception that the member might act to advantage their own product – exclusion would generally be indicated (though facts indicating a minor role, no potential to financially benefit from commercialisation, and/or funding from an independent source may be countervailing factors).	
11. Similar to above but only at <u>pre-commercialisation (research publication) stage.</u>	<ul style="list-style-type: none"> As for scenario 9. 	<p>This scenario (in comparison to the above two scenarios) has a lower level of significance, noting there is not yet any product to take to market, so that participation, or participation subject to limits, may be indicated.</p> <p>Where funding is from an independent source and/or the member would not financially benefit from commercialisation, this may also support an outcome where participation, or participation subject to limits, may be indicated.</p>	<p>X was working on research which was government funded. Any application to the TGA in relation to the product ultimately to be developed would be at an unknown time in the future. When agenda item concerned discussion on chemistry issues, X able to participate in discussion but not take part in any decisions/recommendations. When agenda item on clinical issues, X able to fully participate fully.</p>

PATENT RIGHTS FOR SIMILAR TECHNOLOGY TO THAT BEFORE COMMITTEE

Scenario	Relevant factors/ considerations	Usual or suggested general approach for dealing with scenario in terms of exclusion or participation	Example
<p>12. <u>Member</u> has rights in a patent for <u>similar technology</u> to that to be considered by committee.</p>	<ul style="list-style-type: none"> • Whether member has the rights to exploit the patent (whether as a patent holder or licence holder) – or whether the member has divested those rights, for e.g., by granting an irrevocable licence to use the patent to another party. • Steps taken to divest interest – but caution is needed if licencing arrangements may be revoked or licence only granted for a fixed term, or if only some aspects of interest are divested. • Degree of similarity of products (the more similar the products the closer the connection of the interest with the agenda item). 	<p>Generally, exclusion would be indicated where member has the rights to exploit a patent for similar technology to that to be considered by the committee, unless strong countervailing factors (e.g., interests largely divested).</p>	

13. <u>Organisation</u> member is (or has been connected with) has rights to exploit patent (whether as a holder of the patent or licensee) for <u>similar technology</u> to be considered by committee.	<ul style="list-style-type: none"> Degree of similarity of products. Nature of member's connection with the organisation/ degree of any benefit member may obtain. 	Depends highly on facts but, tend towards exclusion or participation with limits unless circumstances indicate it is unlikely the member could be perceived to be influenced (e.g., connection with patent holder/licensee is no longer current or patent/licence is held by a large organisation, such as a university, in an area unrelated to the member's work).	X associated with commercial entity that held patent/provisional patent. Entity had not lodged an application with the TGA though may in future. When agenda item concerned discussion on chemistry issues, X able to participate in discussion but not in any decisions/recommendations. When agenda item on clinical issues, X able to participate fully.
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FUNDING OF TRAVEL (from sponsor, competitor, or other source)

Scenario	Relevant factors/ considerations	Usual or suggested general approach for dealing with scenario in terms of exclusion or participation	Example
14. Funding of travel, e.g., to conference, from company (<u>sponsor</u>) with product to be considered by committee.	<ul style="list-style-type: none"> Extent of funding Subject matter and nature of conference Whether the member is speaking and nature of speech. Any other factors connecting member to sponsor/ is there an ongoing relationship? Time elapsed since funding provided. 	<p>Exclusion generally indicated where there is direct payment by the sponsor of the member's travel and accommodation unless:</p> <ul style="list-style-type: none"> sufficient time has elapsed to mitigate the significance of the funding, and/or the funding was very minor AND there were no ongoing connections with sponsor. <p>The key issue is likely to be the fact of the funding itself (i.e., the fact that funding was received from the</p>	<p>X declared that sponsor paid (within the last year) for her return business class airfare, accommodation and registration to attend a conference in Istanbul. The conference was organised by the relevant international society. X presented a paper at the conference on her research. (Her research was not funded by the sponsor and was not related to the sponsor's product being considered.) Committee considered the key matter was that the member had received a significant financial benefit from the sponsor in relation to this travel. X was not able to participate in relation to the agenda item.</p> <p>Y declared that the sponsor paid (within the last year)</p>

		<p>sponsor) unless the above type of factors or other countervailing factors apply.</p> <p>If the purpose of attending the conference was to speak on the product to be considered by the committee, this would generally heighten the significance of the circumstances: see further below on 'Public statements about a product'.</p>	<p>for return economy airfares, accommodation and registration to attend a conference at another city in Australia. The conference was organised by the relevant Australian society. Y did not present a paper at the conference. The Committee determined that Y was not able to participate with the Committee noting Y had received a direct financial benefit from the sponsor within the last year.</p> <p>Z previously (more than 3 years ago) received minor funding from sponsor to attend conference and speak briefly about a case-study about a different disease. The presentation was educational/factual in nature. Given passage of time, minor level of funding, and general nature of the presentation, Z was able to participate fully.</p>
15. Funding of travel, e.g., to conference, from <u>competitor</u> .	<ul style="list-style-type: none"> As for scenario 14. 	Generally, adopt a similar approach to that in scenario 14.	
16. Funding of travel, e.g., to conference, from <u>university</u> or <u>conference organiser</u> .	<ul style="list-style-type: none"> As for scenario 14. Plus, consider the effect of the source of the funding – including whether funding is connected to sponsor or competitor and, if so, whether they are the sole funding source or one of a number of 	Participation (or participation with limits) may generally be indicated (unless other factors against this, e.g., may need to consider whether funding has a connection to sponsor or competitor and impact of this connection). Impact may be mitigated where funding comes from multiple sources.	

	sources providing funding.		
17. Funding of travel from <u>industry association</u> .	<ul style="list-style-type: none"> • As for scenario 16. • Connection to the agenda/ level of significance may be lessened in this scenario because funding is from industry association rather than sponsor or competitor. • But important to consider facts and context – for e.g., is funding from an association representing pharmacists where there is a possible connection with a scheduling decision that might benefit pharmacists – and need to consider any likely perceptions about the facts. 	Full participation may be generally indicated, i.e., where relevance to the agenda item is less significant because the source of the benefit is from a more general source such as an industry association (as opposed to a more specific source such as a sponsor or competitor) - unless other factors against participation. Need to consider facts relating to the nature of the body and any impact on agenda item and decision/recommendation to be made.	

HOSPITALITY (from sponsor, competitor or other source)

Scenario	Relevant factors/ considerations	Usual or suggested general approach for dealing with scenario in terms of exclusion or participation	Example
18. Meals, afternoon teas, gifts from company (<u>sponsor</u>) of product before committee – or from <u>competitor</u> .	<ul style="list-style-type: none"> Value of meal, gift or other hospitality. Timing of hospitality, e.g., how close in time to committee meeting. 	Hospitality of a minor nature (unless there are other factors e.g., hospitality directed at a member immediately before committee meeting) would generally be of low or lower significance so that full participation would generally be indicated.	
19. Hospitality as per scenario 18 but from <u>industry association</u> .	<ul style="list-style-type: none"> As for scenario 18. Connection to the agenda/ level of significance is likely to be lower in this situation. But could be significant depending on facts (for e.g., if hospitality from a body such as a pharmacy body that might be connected with a scheduling decision) and depending on any perceptions that may arise. 	Full participation generally indicated (unless other factors against participation).	

CURRENT OR RECENT EMPLOYMENT/ CONTRACT/ CONSULTANCY or BOARD MEMBER/ DIRECTOR (generally with sponsor or competitor)

[See further below re Advisory Boards]

Scenario	Relevant factors/considerations	Usual or suggested general approach for dealing with scenario in terms of exclusion or participation	Example
<p>20. Member has <u>current</u> employment, contract, consultancy, board membership or directorship with company (<u>sponsor</u>) of product committee is to consider.</p>	<ul style="list-style-type: none"> • Nature and extent of role – including whether relationship is ongoing or limited in some way • Level of benefit (financial benefits, professional or other benefits) • Connection between interest and the agenda item – but this factor will generally not be significant/determinative in this context because a perception of a conflict would likely arise from the general relationship with the sponsor. 	<p>This scenario is of high significance given the member is currently in a paid role with the sponsor of the product before the committee. Exclusion would generally be indicated.</p> <p>If the current role is of a very limited nature, for e.g., a very limited, ad hoc contract, there may be some scope to consider participation subject to appropriate limits.</p>	<p>X had contract with device manufacturer and was paid to provide training services to other health practitioners on how to use a medical device. X not able to participate where agenda item involved the manufacturer.</p> <p>Y currently being paid by company Z to work with a communications company and several other clinicians to provide advice on the development of an education program for GPs about the use of anti-anginal treatments. Company Z has final sign-off on the content of the program. Agenda item concerns a safety review of one of Company Z's products (a registered medicine) for the prevention of angina. Y was not able to participate as he was being paid by company Z and had significant involvement with company Z.</p>

<p>21. Where employment, contract, etc, with <u>sponsor</u> has <u>ceased</u>.</p>	<ul style="list-style-type: none"> • Nature and extent of previous role. • Level of benefit (financial benefits, professional or other benefits). • Connection between previous interest and agenda item. • Are there ongoing ties/ perception of an ongoing relationship even though role has ceased? 	<p>If role is very recent (especially less than 3 years ago) or member's professional interest or stake remains significant, generally adopt approach in scenario 20.</p> <p>If passage of time since previous role considered sufficient (including in terms of mitigating perceptions of inability to be impartial because of previous involvement), participation, or participation subject to limits, may be indicated.</p>	<p>X declared that he was a paid consultant to company Y, involved in developing the company's submission to PBAC for PBS listing of Y's product just over 3 years ago. The agenda item concerned a safety review of Y's product (a registered medicine). The committee was of the view that X had a close involvement with company Y involving paid work and active advocacy for the medicine. X was excluded from participating.</p> <p>Z had a contract, more than 3 years ago, for a limited role developing factual, educational material for an unrelated product for the sponsor of a product now before the committee. Z had no ongoing ties with the sponsor. Z was able to fully participate.</p>
<p>22. Where <u>current</u> employment, contract, etc with <u>competitor</u>.</p>	<ul style="list-style-type: none"> • As per scenario 20. • Note: access to commercially sensitive information may also be an issue. 	<p>Adopt similar approach to scenario 20 – which considers nature/extent (significance) of role.</p>	
<p>23. Where employment or other role with <u>competitor</u> has <u>ceased</u>.</p>	<ul style="list-style-type: none"> • As per scenario 21. 	<p>Follow approach in scenario 21.</p>	<p>X had recently worked on direct competitor's related product including within the last year. X was excluded from participation.</p> <p>Y had worked on an unrelated product made by a direct competitor, Z, around 3 years ago. Y had no involvement in working on any of Z's products that were comparable to the product of the sponsor that was being considered by the</p>

			committee. Y had no further contact with Z. Y was able to fully participate.
<p>24. Member has a pecuniary interest in a company which is <u>not</u> a sponsor or competitor but which would be <u>affected by committee's decision</u> (e.g., owner of a pharmacy selling a medicine or veterinarian business selling/using products affected by a scheduling decision).</p>	<ul style="list-style-type: none"> • Nature and extent of interest extent to which member might be perceived to be influenced by the interest • Consider whether any further facts affect level of connection with or relevance to agenda item • Note: access to commercially sensitive information may also be an issue. 	<p>This may be complex to assess and will depend on the facts.</p> <p>In the example of a pharmacy owner or veterinarian being involved in a scheduling decision involving changing the schedule in which a drug appears, generally exclusion would be indicated subject to the following:</p> <ul style="list-style-type: none"> • may be an exception if strong countervailing factors (for e.g., expertise cannot otherwise be sourced). An option in such circumstances would be to confine the matters that the member may speak to; • an alternative approach allowing for participation, or participation with some limits, may be available either where the role itself was confined or if there were further facts that meant the level of connection or relevance to the agenda item was low. 	

<p>25. Member is an employee, director or board member of a <u>peak body</u> (industry or professional) whose members may be positively or adversely affected by a decision (e.g., a scheduling decision).</p>	<ul style="list-style-type: none"> • Level of potential benefit or loss • Extent to which member might be perceived to be influenced by the interest • Note industry body may not have a product-specific focus, so relevance of interest to agenda item may be lower than other cases 	<p>This may be complex to assess.</p> <p>For e.g., for scheduling decisions, the views and expertise of the industry member can be highly relevant to the committee's decision-making (including providing expertise on aspects of manufacturing that cannot readily be obtained from another source), so that participation may be warranted (with any limits on participation as necessary).</p>	
<p>26. Member has their <u>own consulting or other business</u> that relates to regulation of therapeutic goods, e.g., regulatory affairs business.</p>	<ul style="list-style-type: none"> • Has the member's company provided advice on the product before the committee or to the sponsor or a competitor more generally? • Relevance and significance of interest to the agenda item. • Availability of expertise particularly in the 	<p>This will depend on the facts.</p> <p>If the member has not provided consulting services for the sponsor (or a competitor) or in relation to the specific substance being considered, participation will generally be indicated (unless there are other factors against participation).</p> <p>If the member has provided consulting services for the sponsor (or a competitor), exclusion will generally be</p>	

	scheduling context.	<p>indicated unless countervailing factors.</p> <p>If a member has provided consulting services in relation to a specific substance, for e.g., in a scheduling context, it can be noted there are often a limited number of experts in particular fields. Where this is the case, the general approach may be for the member to be allowed to speak to the agenda item and respond to any further questions asked by the committee but then to be excluded from the formal deliberations.</p>	
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CURRENT OR RECENT ROLE ON ADVISORY BOARD/COMMITTEE (in relation to sponsor or competitor)

Scenario	Relevant factors/ considerations	Usual or suggested general approach for dealing with scenario in terms of exclusion or participation	Example
27. Member has <u>current</u> role on Advisory Board/Committee for company (<u>sponsor</u>) of product before committee.	<ul style="list-style-type: none"> Nature and extent of role – including whether role is ongoing or limited in some way. Whether role is generally non-remunerated other than for modest fees. Level of professional benefit/ professional stake. 	<p>This scenario may be complex to assess and will depend on the facts.</p> <p>Similarly, to employment situations, this will often be of high significance (whether payment is received or not) because of the close relationship with the company and potential to have been involved in aspects regarding marketing of the product so that exclusion will generally be indicated.</p>	<p>X currently sits on an advisory board for an unrelated product of a sponsor who had another product being considered by the committee. X's role on the advisory board was an ongoing one of close to two years duration to date. Given X's relationship with the sponsor, X was not able to participate in relation to the agenda item.</p> <p>Y was in an advisory role with a company with a product before the committee. Y received no payment for this role. The agenda item related to a general matter rather than</p>

	<ul style="list-style-type: none"> • Connection with or relevance of role to agenda item - though this factor may be of less significance, subject to the facts, given a perception of conflict would likely arise from the fact of the advisory relationship (see, also, examples re member X and member Y). • Note advisory boards for therapeutic goods may often advise on the marketing of a product. 	May be cases where participation, subject to necessary limits, is appropriate (e.g., this may include where advisory role was a short-term role to provide advice on an unrelated/confined matter).	focusing on specific products – the item related to general regulatory requirements that apply to a broad class of goods. Y allowed to participate to provide technical advice on the regulatory requirements.
28. Where Advisory Board/Committee role with <u>sponsor</u> has <u>ceased</u> .	<ul style="list-style-type: none"> • Nature and extent of previous role/ whether role was non-remunerated/ professional benefit or stake/ connection with agenda item. • How much time has elapsed? • Are there ongoing ties or perception that significance of 	<p>If role is very recent (especially less than 3 years ago) or member's professional interest or stake remains significant, adopt approach in scenario 27.</p> <p>If passage of time since previous role considered sufficient (including in terms of mitigating perceptions of inability to be impartial given previous involvement), participation, or participation subject to limits, may be indicated.</p>	<p>X had a previous advisory role for sponsor, approximately 1 year ago, for which X received an honorarium. X had some ongoing ties with sponsor including more recent participation at an event sponsored by the sponsor regarding the product that was to be considered by the committee. X excluded from participating in agenda item.</p> <p>Y declared that she sat on an advisory board for an unrelated product of the sponsor (which had another product being considered by the committee) for a period of one year with her involvement ending two</p>

	previous advisory relationship/role has not abated?		years ago. Committee noted past involvement with company was still recent. Y excluded from participating.
29. Where <u>current</u> Advisory Board/Committee role with <u>competitor</u> .	<ul style="list-style-type: none"> As per scenario 27. Note: access to commercially sensitive information may also be an issue. 	Follow similar approach to that in scenario 27.	X declared that he sits on the advisory board for a competitor product to the product being considered by the committee. Given X's relationship with a competitor, X was not able to participate in relation to the agenda item.
30. where Advisory Board/Committee role with a <u>competitor</u> has <u>ceased</u> .	<ul style="list-style-type: none"> As per scenarios 27 and 28. 	Follow similar approach to that in scenario 28.	

SHARES, STOCK OPTIONS OR EQUITY (in sponsor or competitor)

Scenario	Relevant factors/considerations ³	Usual or suggested general approach for dealing with scenario in terms of exclusion or participation	Example
31. Member holds shares or stock options or equity in company (<u>sponsor</u>) of product committee is to consider.	<ul style="list-style-type: none"> Are shares under member's control or, for e.g., are they owned and controlled by a non-self-managed superannuation fund)? Value or number of shares may 	<p>Where a member has shares or has other financial interests/equity in a company, exclusion would generally be indicated.</p> <p>Note if shares are not under the member's control (for e.g., if they are acquired by a member's superannuation fund where that fund is not self-managed), this is</p>	<p>X held shares in the sponsor company whose product was being considered by the committee. X not able to be present for agenda item.</p> <p>Y previously held shares in sponsor company. Y chose to sell shares before matter came up at any meeting. Therefore, no issues regarding Y being able to fully participate in relation to agenda item involving this</p>

	<p>not be a particularly useful factor as perceptions may differ on significance but may be of some relevance.</p> <ul style="list-style-type: none"> Is shareholding combined with any other influencing role in company? 	<p><u>not</u> a significant interest and participation is indicated.</p> <p>Where a member has sold / divested their share-holding this removes any conflict.</p>	<p>sponsor given Y had divested their shareholding.</p>
<p>32. Member holds shares or stock options or equity in <u>competitor</u>.</p>	<ul style="list-style-type: none"> As per above. Consider whether any different background facts re competitor's situation affect level of connection with or relevance to agenda item – but the perception of a conflict may still arise because of the general association with the competitor. Note: access to commercially sensitive information may also be an issue. 	<p>Generally, adopt approach in scenario 31.</p> <p>In addition, if facts re competitor have less connection to agenda item (e.g., because products not overly similar), participation, with any appropriate limits as necessary, may be indicated – although could still be a perception that might act against interests of sponsor due to general financial interest in competitor. Therefore, approach in this setting is highly dependent on facts.</p>	

PUBLIC STATEMENTS ABOUT A PRODUCT (including in media, literature, at conferences)

Scenario	Relevant factors/ considerations	Usual or suggested general approach for dealing with scenario in terms of exclusion or participation	Example
33. Public statement about <u>same product of sponsor</u> before committee.	<ul style="list-style-type: none"> Nature/ relevance of statement including whether statement concerns: <ul style="list-style-type: none"> – factual matters only, or – advocacy (and, if so, whether it is general advocacy or more particularised), or – direct statements in support of or against a company or their product. Context in which statement made, e.g., did member also refer to committee duties or would a link be made to those duties. Any benefit obtained or other factors connecting 	<p>If independent, impartial and balanced scientific comment as part of ordinary work outside of and not linked to the committee (nor to the sponsor) then participation may be indicated. For example, where statements only of a factual nature.</p> <p>If statements would be seen (by a reasonable observer) to be partial, i.e., in support of or against a company or their product (or products in a sufficiently connected class) to be considered by the committee, then exclusion indicated.</p> <p>Similarly, if perception is that statements show a bias towards/against the sponsor, exclusion indicated.</p> <p>Careful consideration should be given where a payment is also made.</p>	<p>Dr X was interviewed (not in her capacity as a committee member) and made a factual statement that doses of a particular vaccine (to be considered by the committee) were to be taken x weeks apart. Committee of the view this was an impartial, factual comment. Dr X was able to fully participate.</p> <p>Dr Y declared he was often asked for media comment about the general role/use of antidepressants in anxiety disorders because of his past research in this area. This research did <u>not</u> include the sponsor's particular product (an antidepressant) which the committee was to consider. Dr Y considered that, in commenting, he provided an evidence-based assessment of the appropriate use of antidepressants. The committee was of the view that Dr Y's statements involved relaying information relating to research and did not involve being an advocate for any particular medicine. Dr Y had only spoken on the basis of his own past research and had not made any reference to the work of the committee. Dr Y was able to fully participate.</p>

	<p>member to company (e.g., payment for presentation in which statement made; ongoing relationship with company).</p> <ul style="list-style-type: none"> Careful consideration will need to be given where a payment or honorarium is made to the member. It is not unreasonable for an individual to be recompensed for time spent and expenses incurred in, for example, educational presentations. However, consideration needs to be given to whether the circumstances involve public statements promoting a company's product or reflect a relationship with a company which might be perceived to result in some sense of reciprocity or 		
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	<p>obligation by the member.</p> <ul style="list-style-type: none"> How much time has elapsed since statement? 		
34. Public statement about <u>different product of sponsor</u> .	<ul style="list-style-type: none"> As for scenario 33. 	May generally adopt approach in scenario 33 – in addition, where statement about a different product, significance may be somewhat lower but note may still be a perception of link with sponsor.	
35. Public statement about <u>competitor's similar product</u> .	<ul style="list-style-type: none"> As per above. Consider if less relevant if product not sufficiently similar. 	<p>May generally adopt similar approach to that in scenario 33.</p> <p>In addition, if product not sufficiently similar, significance/ relevance would be lower so that participation may be indicated but note still need to consider any perceptions.</p>	

PERSONAL INTEREST IN PRODUCT BEING INCLUDED IN REGISTER DUE TO MEDICAL CONDITION

Scenario	Relevant factors/ considerations	Usual or suggested general approach for dealing with scenario in terms of exclusion or participation	Example
36. Member has personal interest in product committee is to consider as member (or family member or close friend) has <u>medical condition</u> that could be treated or is being	<ul style="list-style-type: none"> Consideration s include that sensitive personal information may be involved. Member may wish to abstain – may wish to 	<p>This scenario may be complex to assess (unless member wishes to abstain in any event).</p> <p>Where advice by the committee may lead to product, that would generally be unavailable, becoming available and this</p>	

treated by the product.	<p>discuss matter with chair or secretariat prior to meeting in first instance.</p> <ul style="list-style-type: none"> How significant/relevant would the committee's advice on the product be – including in terms of treatments available? 	<p>would offer new treatment options, exclusion would generally be indicated.</p> <p>The interest may not be as significant if committee only considering another form of a treatment that is already available.</p> <p>Products/treatments for common conditions (for e.g., hypertension or high cholesterol) would not normally be considered to give rise to a material personal interest and therefore would not need to be declared or, if declared, full participation would still be indicated.</p>	
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STRONG PERSONAL, PHILOSOPHICAL OR RELIGIOUS BELIEFS

Scenario	Relevant factors/considerations	Usual or suggested general approach for dealing with scenario in terms of exclusion or participation	Example
37. Member has strong personal, philosophical, or religious beliefs.	<ul style="list-style-type: none"> Considerations include that sensitive personal information may be involved Member may wish to abstain in any event – may wish to discuss matter with chair or secretariat prior to meeting in first instance. 	<p>This scenario may be complex to assess (unless member wishes to abstain in any event).</p> <p>Consider level of connection / relevance of personal interest to agenda item and whether there is a perception that the belief may impact on a member's ability to be impartial.</p>	

	<ul style="list-style-type: none"> • Level of connection /relevance between belief and agenda item. • Have the beliefs been expressed (for e.g., in a public or semi-private setting). • Can be instances where a strong belief (even if not expressed) may impact on a member's ability to be impartial. 		
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INTERESTS OF IMMEDIATE FAMILY (e.g., spouse, partner, dependent children)

Scenario	Relevant factors/ considerations	Usual or suggested general approach for dealing with scenario in terms of exclusion or participation	Example
38. Immediate family member of member holds interest that relates to a matter being considered by committee, i.e., member's declared interest arises because of family member's interest in a matter.	<ul style="list-style-type: none"> • Note there is a close connection, or perception of a close connection between the member and their immediate family member's interest. • See the relevant factors/considerations in the table for the type of 	<p>Generally, the same approach applies in terms of exclusion, participation, or participation with limits, as would apply if the member held the interest themselves.</p> <p>See the usual or suggested general approach for the scenario in question.</p> <p>As noted, in the 'relevant factors/ considerations' column, careful consideration should be given where the immediate family</p>	X's spouse held shares in a pharmaceutical company whose product was to be considered by the committee. X not able to participate.

	<p>scenario in question.</p> <ul style="list-style-type: none"> Careful consideration should be given, in particular, to where the immediate family member has a <u>direct financial interest</u> (for e.g., paid work, ownership of a business, shareholdings, receipt of other direct payments) or an advisory board role (even if non-remunerated) that may relate to a matter being considered by the committee (because of the high significance of these type of interests). Where an immediate family member's interest does not involve any direct financial interest or advisory board role, the level of significance of the interest may be lower but this will be subject to the facts. 	<p>member has a direct financial interest or advisory board role given the high significance of these type of interests.</p>	
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INTERESTS OF A CLOSE FRIEND

Scenario	Relevant factors/ considerations	Usual or suggested general approach for dealing with scenario in terms of exclusion or participation	Example
39. Close friend of member holds interest.	<ul style="list-style-type: none"> • Generally, this situation may be viewed differently to that involving an immediate family member's interest. • Whether or not the interest is declared is ultimately a matter of judgment for the member. • While the nature, extent and currency of the interest are relevant factors, there may generally be distinguishing factors in circumstances involving a friend because the relationship is, or is likely to be perceived as being, more at arm's length. In such circumstances, a member may still be perceived as being able to be independent, objective and impartial in relation to their 	<p>Full participation would generally be indicated (unless there are other factors against participation).</p> <p>However, where the circumstances concern a close friend that has a medical condition that could be treated by a product the committee is to consider, see approach in scenario 36 above.</p>	

	<p>committee duties.</p> <ul style="list-style-type: none"> • The member may also have limited awareness of the circumstances in question. • There may still be other factors against participation, for e.g., any financial interrelationship between the member and the friend. • Careful consideration may also need to be given to scenarios where having a personal relationship may be potentially more significant, for e.g., where a close friend has a medical condition that could be treated by a product the committee is to consider (see scenario 36 above). 		
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