

Department of Health
Technology Assessment and Access Division

Health Technology Assessment Committees

Conflicts of Interest

Process Guide

June 2020

Purpose

To provide consistent guidance for the assessment and management of Conflicts of Interest (Col) by all HTA committee secretariats when considering new nominees for appointment and existing members for reappointment. This document and the principles contained therein, may be applied by other non-HTA committees and expert panels in the Technology Assessment and Access Division as appropriate.

This guidance document is relevant to the following HTA committees and subcommittees:

- Pharmaceutical Benefits Advisory Committee (PBAC)
- PBAC Evaluation Subcommittee
- Medical Services Advisory Committee (MSAC)
- MSAC Evaluation Subcommittee
- MSAC PICO Advisory Subcommittee
- Prostheses List Advisory Committee (PLAC)
- PLAC Clinical Advisory Groups
- PLAC Panel of Clinical Experts (PoCE)
- Stoma Product Assessment Panel
- Life Saving Drugs Program Expert Panel
- Post Market Review reference groups
- Drug Utilisation Subcommittee.

Cols relating to committee and subcommittee nominees are reviewed and managed by the department. This guide provides departmental staff with guidance on assessing Cols declared by nominees and providing advice to the TAAD Executive or Delegate on whether the nominee should proceed to membership (based on their Col declaration).

Note the threshold for acceptable/not acceptable Cols for nominees may differ from that for members. Generally, decision-making committees such as the PBAC or MSAC are expected to have higher thresholds. For example, receiving speaking fees prior to membership of the committee may be acceptable for a nominee but not for a sitting member.

An actual or apparent Col is serious and can undermine the credibility of a process or decision, which may in turn damage the reputation of the committee, the Australian Government and/or the department, eroding public trust.

Note that this process guide focuses on Cols and does not address other assessments required to be undertaken in determining whether a committee/subcommittee member should be appointed or recommended for appointment, such as an assessment of the nominee's relevant skills and the validity of the claims in their CV.

Definition of Col

A Col is defined as a conflict between the public duties and personal interests of a committee/subcommittee/expert panel member that either actually or could improperly influence the member in the performance of his or her duties.

"Personal interests" are matters connected to an individual's personal circumstances. They may cover financial (e.g. shareholdings, small business ownership, company directorships or partnerships) and non-financial private interests (e.g. personal or family relationships or associations), as well as the private, professional or business interests of individuals or groups with whom the person has a close association (e.g. spouse or partner, relatives or close friends).

A Col may be real or apparent. A real conflict of interest occurs when there is an actual conflict between the public duty and personal interests of a member, which improperly influences the member in the performance of his or her duties.

An apparent Col occurs where it appears that a member's personal interests could improperly influence the performance of his or her duties, but this is not in fact the case.

In addition, the personal interests of a member's partner or spouse, family members or close personal friends (including personal relationships formed through work or engagement with local community, including sporting, social, cultural or voluntary activities) can also present a real or apparent Col. This occurs, when those interests may be furthered or advantage gained through policies, activities or decisions which the member has knowledge of, or has direct and substantive influence over.

Declaration of Interests

The assessment and management of committee members' Cols is undertaken annually and prior to each meeting by each committee's Committee Management Group (CMG) and the relevant committee secretariat. Committee members are required to submit a declaration of interest (DoI) at each meeting/teleconference/video conference. The CMG typically comprises of the Chair of the relevant committee or subcommittee (or CAG or expert panel) and the departmental Delegate, usually at least the EL2 and above. More specifically the Delegate would typically be the secretary of the relevant committee. All nominees to relevant HTA committees and subcommittees are also required to complete a *Declaration of interests in support of a nomination for membership of a Department of Health Advisory Committee (Attachment A)*. The following interests are required to be declared for the past five years:

Financial Interests - direct

1. Investments
2. Shareholdings (excluding superannuation that is not self-managed)
3. Trusts
4. Partnerships
5. Directorships
6. Executive or non-executive board memberships (including advisory boards)
7. Paid employment, including
 - a. Consultancies
 - b. Commission fee-paid work
 - c. Paid speaker fees (on a regular or one-off basis)
 - d. Expert advisory fees (provided on a regular or one-off basis)
8. Grants, including
 - a. Fellowships (for the nominee or an employee/student managed by the nominee)
 - b. Research grants (e.g. principal investigator for clinical trials, product development)
 - c. Education grants
9. Hospitality, including
 - a. Travel grants (including flights, accommodation or conference fees, regardless of whether they are linked to speaking responsibilities)
 - b. Food and/or beverage.

Financial Interests – indirect

1. An indirect financial interest can be any of the above direct interests which are held by a family member, close friend or another person with a close personal relationship to the member. These close personal relationships include those formed through work or engagement with local community including sporting, social, cultural or voluntary activities.

Non-financial interests

1. Professional interests, including
 - a. Participation in a clinical trial (i.e. not the principal investigator)
 - b. Membership of a non-government organisation (NGO) or professional organisation that accepts sponsorship or other in-kind support from an organisation or company whose interests are within the scope of the committee/subcommittee terms of reference
 - c. Ad-hoc assistance to patients (e.g. access to medicines through pharmaceutical company compassionate access schemes)
2. Personal/private interests, including
 - a. Medical conditions (excluding common conditions such as hypertension, high blood cholesterol or type 2 diabetes)
 - b. Personal beliefs that are well known publicly or semi-privately, that relate to an organisation or company whose interests are within the scope of the committee/subcommittee/advisory or expert panel's terms of reference; or to the Australian Government (including those expressed on social media)
 - c. Public statements in a professional or personal capacity that relate to an organisation or company whose interests are within the scope of the committee/subcommittee/advisory or expert panel's terms of reference; or to the Australian Government.

Steps for reviewing declared CoIs

Under the decision framework below, CoIs can be categorised as:

- Not acceptable and the nomination cannot proceed to appointment or recommendation for appointment to the Australian Government, Minister or Department
- Must cease conflict. A declaration not to enter into any CoI for term of appointment, and current CoI must be divested of, prior to appointment or recommendation for appointment to the Australian Government, Minister or Department to become acceptable
- Acceptable with conditions. Having a CoI in itself does not preclude membership of a committee but appropriate measures must be identified and agreed to. Management of CoI expected on a meeting by meeting basis
- Acceptable. Nomination can proceed to appointment or recommendation for appointment to the Australian Government, Minister or Department, noting that some management of new or unidentified CoI on a meeting by meeting basis may be required
- CoI cannot be determined and further information is required before a decision can be made.

The relevant secretariat team should review and consider the declared CoIs against the decision framework and provide a recommendation to the TAAD Executive/Delegate for a decision on whether the nominee should proceed to appointment or be recommended for appointment.

Before completing the CoI review and making a recommendation to the TAAD Executive/Delegate, the secretariat should also check whether the nominee has been assessed for appointment to other HTA committees/subcommittees and whether their CoI declaration is consistent with previous declarations.

DECISION FRAMEWORK

COI	ACCEPTABILITY	ACTION REQUIRED
FINANCIAL INTERESTS		
Investments (excludes superannuation where not self-managed)	Not acceptable where investments relate to a company or organisation whose interests are within scope of the committee/subcommittee Terms of Reference	COI must be ceased/divested of, prior to appointment
Shareholdings (member controlled irrespective of whether the member is on the share register; unlisted managed fund if member could influence investment decisions)	Not acceptable where shareholdings relate to a company or organisation whose interests are within scope of the committee/subcommittee Terms of Reference	COI must be ceased/divested of, prior to appointment
Trusts (member controlled; or where member could influence investment decisions)	Not acceptable where trust relates to a company or organisation whose interests are within scope of the committee/subcommittee Terms of Reference	COI must be ceased/divested of, prior to appointment
Partnerships	Not acceptable where partnership relates to a company or organisation whose interests are within scope of the committee/subcommittee Terms of Reference	COI must be ceased prior to appointment
Associations (including charities, NGOs)	Not acceptable where role relates to senior management (e.g. Board) and the association has received funding from a company or organisation whose interests are within scope of the committee/subcommittee Terms of Reference and the board member or association stands to <u>gain direct commercial or pecuniary</u> advantage	COI must be ceased prior to appointment
	<u>Acceptable with conditions</u> where role relates to senior management (e.g. Board) and the association has received funding from a company or organisation whose interests are within scope of the committee/subcommittee Terms of Reference and NO real or perceived commercial or pecuniary advantage is received	COI must be managed on an ongoing, meeting by meeting basis
Directorships	Not acceptable where role relates to a company or organisation whose interests are directly within scope of the committee/subcommittee Terms of Reference	COI must be ceased prior to appointment
Executive or non-executive Board Memberships (including advisory boards)	Not acceptable where role relates to a company or organisation whose interests are directly within scope of the committee/subcommittee Terms of Reference	COI must be ceased prior to appointment. See <i>'professional interests'</i> on page 7.
Direct employment (self or a close family member)	Not acceptable where it relates to a company or organisation whose interests are within scope of the committee/subcommittee Terms of Reference	Nomination cannot proceed
Current Consultancies	Not acceptable where it relates to a company or organisation who are applicants to the	COI must be ceased prior to appointment.

COI	ACCEPTABILITY	ACTION REQUIRED
	committee/subcommittee Terms of Reference unless agreed to by CMG	If divestment is not feasible and appointment occurs at the discretion of the CMG, Col must be managed on an ongoing basis
Past Consultancies	<u>Acceptable with conditions</u> where it relates to a company or organisation whose interests are within scope of the committee/subcommittee Terms of Reference	Col must be managed with the department, on an ongoing, meeting by meeting basis
Commission fee-paid work	Not acceptable where it relates to a company or organisation whose interests are within scope of the committee/subcommittee Terms of Reference unless agreed to by CMG	Col must be ceased prior to appointment If divestment is not feasible and appointment occurs at the discretion of the CMG, Col must be managed on an ongoing basis
Paid speaker fees (on a regular basis)	Not acceptable where it relates to a company or organisation whose interests are within scope of the committee/subcommittee Terms of Reference	Col must be ceased prior to appointment
Paid speaker fees (one-off basis)	<u>Acceptable with conditions</u> where it relates to a company or organisation whose interests are within scope of the committee/subcommittee Terms of Reference	Col must be managed with the department
Expert advisory fees (provided on a regular basis)	Not acceptable where it relates to a company or organisation whose interests are within scope of the committee/subcommittee Terms of Reference	Col must be ceased prior to appointment
Expert advisory fees (one-off basis)	<u>Acceptable with conditions</u> where it relates to a company or organisation whose interests are within scope of the committee/subcommittee Terms of Reference	Col must be managed with the department
Retainer	Not acceptable where it relates to a company or organisation whose interests are within scope of the committee/subcommittee Terms of Reference	Col must be ceased prior to appointment
Current fellowships* (nominee or an employee/student managed by the nominee)	<u>Acceptable with conditions</u> at the discretion of the CMG	Col must be managed with the department (and CMG), on an ongoing basis if divestment is not feasible
Current research grants* (e.g. principal investigator for clinical trials, product development)	<u>Acceptable with conditions</u> at the discretion of the CMG	Col must be managed with the department (and CMG), on an ongoing basis if divestment is not feasible
Education grants*	Not acceptable if current and is provided by a company or organisation whose interest are within scope of the committee/subcommittee Terms of Reference	Col must be ceased/divested of prior to appointment

COI	ACCEPTABILITY	ACTION REQUIRED
Ownership of a patent for a therapeutic good or medical device/technology	Not acceptable if direct holder of the patent (patent owner and inventor) and/or receiving royalty payments directly (personal benefit)	Nomination cannot proceed
	<u>Acceptable with conditions</u> if inventor and beneficiary. Royalty or other financial payments received by institutions/labs (i.e. no direct financial benefit). Perceived Col are managed. Note: Competitors interest must be declared.	Col must be managed with the department, on an ongoing basis if divestment is not feasible
Inventor of a therapeutic good or medical device/technology	<u>Acceptable with conditions</u> if not the patent holder (i.e ownership of the patent held by others). Perceived Col are managed. Note: Competitors interest must be declared.	Col must be managed with the department, on an ongoing basis.
Travel grants (including flights, accommodation or conference fees regardless of whether it is linked to speaking responsibilities)	<u>Acceptable with conditions</u> , if grants were provided by a company or organisation whose interests are within scope of the committee/subcommittee Terms of Reference	Nomination can proceed at the discretion of the Delegate. Travel grants in the last five years should be declared
Food and/or beverage (e.g. corporate dinners)	Acceptable	Nomination can proceed
INDIRECT FINANCIAL INTERESTS		
Financial interests held by family	Not acceptable if related/provided by a company or organisation whose interests are within scope of the committee/subcommittee Terms of Reference	Col must be ceased/divested of prior to appointment
Financial interests held by close friends	Acceptable	Nomination can proceed
PROFESSIONAL INTERESTS		
Member of advisory board (non-remunerated)	<u>Acceptable with conditions</u> where it relates to a company or organisation whose interests are within scope of the committee/subcommittee Terms of Reference	Col must be managed with the department (and CMG).
Participation in clinical trials – principal investigator	<u>Acceptable with conditions</u> where it relates to a company or organisation whose interests are within scope of the committee/subcommittee Terms of Reference	Col must be managed with the department (and CMG).
Participation in a clinical trial (not the principal investigator)	Acceptable	Nomination can proceed
Member (not senior) of an NGO or professional organisation/association that accepts sponsorship or other in-kind support	<u>Acceptable with conditions</u>	Col must be managed with the department (and CMG). Members participate as advisors. No voting rights on subsidy issues in matters directly relevant to the organisation/association.
Ad-hoc assistance to patients (e.g. access to medicines through pharmaceutical	<u>Acceptable with conditions</u>	Col must be managed with the department (and CMG). Members participate as advisors. No voting rights on

COI	ACCEPTABILITY	ACTION REQUIRED
company compassionate access schemes)		subsidy issues in matters directly relevant the Col.
PERSONAL INTERESTS		
Medical condition	<u>Acceptable with conditions</u>	Col must be managed with the department (and CMG). Members may participate as advisors. No voting rights on subsidy issues in matters directly relevant to the condition or if necessary Member to leave the room during discussion. If family member with the condition, managed similarly.
Personal beliefs	Acceptable	Nomination can proceed
Public statements made in a professional or personal capacity	Not acceptable where strong and frequent statements have been made in support/not support of a company or organisation (or their products) whose interests are within scope of the committee/subcommittee Terms of Reference	Nomination cannot proceed

* if provided by a company or organisation whose interests are within scope of the committee/subcommittee Terms of Reference

Once the TAAD Executive/Delegate has made a decision on the status of the nominee's Col, the secretariat should follow one of the following options:

1. Not acceptable – nomination cannot proceed

Where a Col is determined to be not acceptable and cannot be ceased/divested of (or the nominee declines to do so), the secretariat should write to the nominee advising them of the decision. A proforma letter is at [Attachment B](#). Where the nominee was nominated to represent an organisation rather than in their personal capacity, the proforma should be adapted to advise the nominating organisation/body that the nominee cannot proceed due to their declared Col (details of the Col should not be included in this letter).

2. Must cease/divest COI prior to appointment

Where a COI is determined to be not acceptable unless the Col is ceased/divested of prior to the appointment proceeding, the secretariat should write to the nominee advising them of this and requesting they take the necessary steps to cease/divest and then advise the secretariat once done. A proforma letter is at [Attachment C and C1](#).

3. Acceptable with conditions – nomination can proceed

Where a Col is determined to be acceptable with conditions, the secretariat should write advising the nominee of the conditions and of a duty to disclose the Col at relevant meetings if steps to cease/divest the Col are not feasible. (This is separate to the nominee declining to do so without reason in which case Option 2 applies.)

The secretariat must be advised of agreement to manage the Col. Failure to disclose Col/Dols at committee meetings may result in appointment being terminated. The declaration of cessation/divestment is at [Attachment C1](#).

4. Acceptable – nomination can proceed

Where no Col is determined, the nomination can proceed without further action in relation to Col issues. A proforma letter is at Attachment D.

5. Col cannot be determined – further information required

Where a Col cannot be accurately reviewed and a decision made (e.g. details of the financial or non-financial interest are insufficient), the secretariat should write to the nominee and request further information relating to the declared Col. A proforma letter is at Attachment E.

Col Management strategies

When a Col matter is to be managed or further clarification is sought, the secretariat should always give the member an opportunity to explain how they were intending to manage the conflict.

NOTE that some Cols may require ongoing management if the nominee becomes a member of a Committee. This may reflect a 'wash-out' period agreed by the department and relevant chair that allows for the individual, a period of time to remove potential Cols. Other mitigation steps may include:

Col type	Mitigation action
High risk Direct personal financial interest on specific* matters subject to Committee deliberation.	Col/DoI, documented, advise CMG. Barred from accessing documents relating to the matter and absent from discussion and any decision related to the matter. In exceptional situations (no other expert available), at the discretion of the Chair, attendance to take questions may be allowable. DoI and action expressly Minuted.
Medium risk Direct personal financial interest; non-specific (i.e. matters that do not refer directly to the matter under Committee discussion).	Col/DoI, documented, advise CMG. Participation in discussion allowed unless ruled out by the CMG/Chair. No voting rights.
Medium-low risk Personal non-financial on specific or non-specific matters	Col/DoI documented. Participation allowed unless ruled out by the Chair.
Low risk Non-personal financial on specific or non-specific matters.	Col/DoI documented. Participation allowed unless ruled out by the Chair.

*Specific interest are matters directly related to the ToR of the Committee.

Competitor interests

If a committee member is aware that a product under consideration is, or may become, a competitor of a product developed, manufactured, sold or supplied by a company in which the member has a current personal financial or family financial interest, they should declare an interest. The chair of the advisory body should consider whether the individual should take part in the proceedings.

Failure to disclose

Members must be made aware that a consequence for failing to disclose an interest (without a reasonable excuse) may result in the termination of appointment. Accordingly, members should be encouraged to consult the relevant secretariat if they are uncertain about whether to disclose an interest.

Nominees/members with high risk, ongoing and serious Col that cannot be adequately managed should not be appointed or participate in committee duties unless the nominee/member relinquishes the Col.

General application principles

It is important to note that some committee members/nominees may have some interactions with the commercial sector or may be members of institutions that receive financial support (grants) or royalties from intellectual property. This would not automatically disqualify a nominee or a member from participating in an advisory committee. All such interactions must be declared.

The nominee's position and role in the grant or in receiving the royalties should be considered. For example if the nominee is the principal investigator involved in major trial design and analysis etc and is the main recipient of a grant investigating a product (drug or test), then this would disqualify the nominee. If a nominee is a member of a research team involved in broader research and all dealings concerning the trial was managed by an independent institution according to transparent standard operating procedures of the institution, an appointment may be recommended and Col managed.

If a nominee clinician was on the executive/conference or planning committee and was aware or involved in seeking support funding for the event 10 years ago, then this should be seen as a low risk. If they are currently involved in such an endeavor, then it should be seen as medium/medium-low risk (See risk table).

In all cases, the secretariat should consider availability of relevant expertise in the field, length and 'depth' of the Col (to determine risk) and ability to mitigate in their advice to the TAA Executive/Delegate. Decisions are on a case-by-case basis depending on the severity of the risk of the Col. Any advice and management plan must be clear, transparent, consistent and defensible. A folio of actions (register of Col and any associated actions) in regard to Col should be maintained to ensure consistency of approach across all committees.

This process guide and suggested management strategies do not replace but support standard operating procedures in the running of a meeting. Therefore the practice of declaring interest or Col at the start of meetings or per agenda item as appropriate should remain.

In some situations, secretariats should be mindful to ask members of an organisation to identify themselves and the organisation, if not there as a nominee from the organisation. For example, if a nominee is a member of TSANZ but not there as the TSANZ nominee then this conflict should be declared. This may not be relevant to all committees or advisory groups, only those that are sensitive to the situation. Likewise for members who play similar roles in a different committee/group but for a different purpose. For example, Medicines Australia may be on PBAC ESC and have their own economics committee (the HERG). If known, the secretariat should ask on nomination or declaration, about how the person intends to manage any potential Col, if this was an issue for the committee.

It is worth reiterating that the purpose of the HTA Committee Col process guide is to provide high level guidance to HTA committees secretariats to manage Col, particularly when considering nominations for new members for appointment or reappointing members. This is principles based (risk, availability of expertise and Delegate's/Chair's discretion). Several suggestions and examples have been made to assist secretariats in managing the committees on an ongoing basis, but it is not intended to capture all Col scenarios. The principles and examples in the framework, together with the CMG of the committees, should be sufficient to apply the appropriate actions.

Record Keeping

The secretariat must record the details of each nominee, the details of the Col and the decision made by the TAAD Executive/Delegate in the HTA committee Col nominee database.

Copies of the *Declaration of interests in support of a nomination for membership of a Department of Health Advisory Committee* should also be saved.

Version Control

Version	Date	Author	Change description
1.0	24 June 2020	Technology Assessment and Access Division	



Australian Government
Department of Health

Declaration of interests in support of a nomination

For membership of a Department of Health HTA Committee

Nominee name

Committee name

1. Declarations of interests

The External Committees of the Department of Health (the Department) undertake a vital role in providing advice and expertise that is essential to the Minister and the Department in carrying out their functions. Individuals with specialist knowledge and expertise are appointed to a Committee for the purpose of providing expert advice in relation to matters coming before the Committee. It is assumed therefore that members will apply their professional expertise and experience in relation to matters coming before the Committee.

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

In order to allow any such potential conflicts of interest to be managed, the Department requires the member to notify of the existence of any interests that, taking into account the nature of the Committee's role, functions and responsibilities, may give rise to such a conflict or the perception of one in relation to any matters likely to come before the Committee. This is done by means of a declaration of interests prior to appointment, at appointment and where necessary or as required annually thereafter, on an ad hoc basis when circumstances of a member change, as well as before, or at, meetings of the Committee.

Under the Department's procedures for advisory Committee membership, members are to disclose the nature of any direct or indirect material personal interest (whether pecuniary or not) of which they are aware in a matter being considered at a Committee meeting without delay at or before a meeting. Prospective Committee members are also required to agree to such undertaking by completing and returning the "Deed of Undertaking - In relation to confidential information and conflict of interest".

The Department's management oversight of conflict of interest matters for HTA Advisory Committees and its subcommittees is vested in the Committee Management Group (CMG). This group then provides advice where any possible conflict of interest is identified by assessing and recommending to the Committee whether the member should participate in any consideration by the Committee of that matter. The CMG will then inform the Committee of its recommendation for determination by the Committee. Any disclosures and the Committee's determination of it must be recorded in the minutes of the meeting. These requirements are designed to minimise any risk that the consideration of any matter by the Committee, by the participation of a member who has, or may appear to have, a conflict of interest, will be called into question. **A conflict will arise if a person's personal interests (whether financial or not) conflict with their obligations as a Committee member such that the person may not be independent, objective and impartial in relation to those duties. An apparent conflict of interest will arise if, whether or not there is an actual conflict of interest, a conflict of interests may be perceived by a reasonable observer.**

For the purposes of considering whether a person is suitable for appointment to a Committee, an assessment is made of the range and nature of material interests a potential appointee currently has, has had over the past five years or is likely to have. An assessment can then be made whether the range and nature of those interests are such that, were the person to be appointed as a member of the Committee, the effective performance of his or her role on the Committee could be affected by those interests.

You are therefore requested to provide details of any of your interests (whether pecuniary or not) under each of the headings below. This information will be retained by the Department and will be collected, stored, used and disclosed in accordance with secrecy provisions of relevant legislation (for example information collected about individuals when an officer is performing functions under the *National Health Act 1953*) the *Privacy Act 1988*. The information will only be used for the purposes of considering your application to become a member of the Committee and should you be appointed to the Committee, for the purpose of assisting the Department in the management of any potential conflict of interest while you are a member of the Committee.

A checklist is provided at the end of this document to assist you in identifying whether you or your family have any interests that you need to declare.

(a) Financial interests

If you are receiving or have received funds or any other benefit from, or are aware of obtaining or being eligible for any future advantage or benefit from companies, investments, trusts or other institutions (particularly those with an interest in, or having a connection with the development, manufacture and distribution or use of a product or service relevant to the Committee's responsibility), it is possible that a potential conflict of interest may arise if you are appointed to a Committee. You are asked to list the names of the companies, investments, trusts or partnerships from which you currently receive, or are likely in the near future to receive, or have at any time during the past five years received, funds, any advantage or benefit, under the following headings:

Shareholdings, executive or non-executive board membership (including advisory boards) (over the past 5 years or likely)

Date/s	Company / Organisation and interest	Payment amount & period	Still current Y/N

Paid employment, including consultancy, commissioned fee-paid work, paid speaker, paid expert adviser (over the past 5 years or likely)

Date/s	Please provide details including payer (Please also indicate whether payments made directly to you or a third party (e.g. university, hospital, research body))	Payment amount & period	Still current Y/N

Fellowships, research or education grants (over the past 5 years or likely)

Date/s	Please provide details including payer (Please also indicate whether payments made directly to you or a third party (e.g. university, hospital, research body))	Payment amount & period	Still current Y/N

Travel grant or conference fees or other hospitality (greater than \$100) (over the past 5 years or likely)

Date/s	Please provide details including payer and purpose (e.g. attendance, speaking, poster presentation etc.)	Payment amount & period	Still current Y/N

Any other direct or indirect pecuniary interest (e.g. other investments, partnerships, trusts, ownership of a patent for a therapeutic good or ownership by employer, investments in self-managed superannuation fund) (over the past 5 years or likely)

Date/s	Please provide details of interest including payer	Payment amount & period	Still current Y/N

(b) Professional interests

Please list:

- any involvement in a company or organisation involved in the development, manufacture or marketing and distribution of therapeutic goods or the provision of medical services, including:
 - * membership of advisory board, in the last 5 years or likely;
 - * accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 5 years or likely;
 - * provision by such a company or organisation of ad hoc support for a patient or student of the potential committee member in the last 5 years or likely;
- participation in clinical trials (whether as principal investigator, contributor of patients or otherwise) in the last 5 years or likely;
- involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 5 years or likely.

Date/s	Organisation and Interest	Payment amount & period	Still current Y/N

(c) Other interests

Please list any other interests **of the kind such that, were you to be appointed as a member of the Committee, a perception of conflict might arise in relation to matters that could before the Committee** including the following:

- any interests that would, but for the 5 year time period, come within (a) or (b) above;
- personal interests such as strong personal, philosophical or religious beliefs or convictions or personal or family relationships; and
- any financial, professional or other interests of your immediate family or others in a close personal relationship of which you are aware.

Date/s	Please provide a description of the interest	Payment amount & period	Still current Y/N

2. Deed

If you are appointed to the Committee you will be required to sign a deed about the obligations of members in relation to confidential information and the requirements to disclose interests of the kind described above in relation to conflicts of interest.

3. Declaration

I declare that:

I have read the document “Department of Health Advisory Committee Guidelines - Declaration of interests, managing conflicts of interest and confidentiality obligation” and understand, the responsibilities of a member of a Departmental advisory Committee. In particular I acknowledge the obligation to disclose any direct or indirect material personal interest (whether pecuniary or not) in any matter being considered, or about to be considered, by such a Committee at any of its meetings;

I understand that if I were to be appointed to be a member of a Departmental advisory Committee I would be bound by that obligation;

I understand that if I were to be appointed to be a member of a Departmental advisory Committee I would be required to sign the Deed of undertaking in relation to confidential information and conflict of interest;

I understand that if I were to be appointed to be a member of a Departmental advisory Committee I would be required to complete the relevant Committee declaration about my pecuniary and non-pecuniary interests; and

I have provided current and accurate information in this declaration.

I understand the above requirements to provide accurate and current information and that any failure to declare any direct or indirect material personal interest in the following circumstances may result in termination of my appointment;

- a. If when I applied for appointment to the committee I failed to declare any direct or indirect material personal interests,
- b. If I am appointed to the committee I fail to declare any direct or indirect material personal interest or update my declaration from my application,
- c. If I fail to update or declare any direct or indirect material personal interest on my annual declaration,
- d. If I fail to update or declare any direct or indirect material personal interest on an ad-hoc basis, where the personal interest is relevant and should be disclosed, and
- e. If I fail to declare any direct or indirect material personal interest at meetings of the relevant Departmental advisory Committee.

Name (please
print)

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Signature

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Date

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Declaration checklist

Section 1. Pecuniary interests

Interest	Myself		Immediate family or other relationship (of which you are aware)	
Current shareholdings which the member controls (including through a self-managed superannuation fund), irrespective of whether the member's name is on the share register	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Y	<input type="checkbox"/> N
Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Y	<input type="checkbox"/> N
Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Y	<input type="checkbox"/> N
Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Y	<input type="checkbox"/> N
Board memberships (executive or non-executive) or other offices in a company in the last 5 years or likely	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Y	<input type="checkbox"/> N
Paid employment, contracting, consultancy commissioned fee-paid work or work as a paid speaker or paid expert adviser in the last 5 years or likely	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Y	<input type="checkbox"/> N
Grants for overseas travel, research or education or paid conference expenses in the last 5 years or likely	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Y	<input type="checkbox"/> N
Holding a retainer or receiving pay for a company that manufactures or is a sponsor of therapeutic goods in the last 5 years or likely	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Y	<input type="checkbox"/> N
Significant hospitality in the last 5 years or likely	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Y	<input type="checkbox"/> N
A financial involvement in any therapeutic goods, or other products, services or matters having any connection with therapeutic goods, in the last 5 years or likely	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Y	<input type="checkbox"/> N

Interest	Myself		Immediate family or other relationship (of which you are aware)	
Other pecuniary interests	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Y	<input type="checkbox"/> N

Section 2. Professional interests

Interest	Myself		Immediate family or other relationship (of which you are aware)	
Involvement in any company or organisation involved in the development, manufacture or marketing and distribution of therapeutic goods in the last 5 years, including membership of advisory board	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Y	<input type="checkbox"/> N
Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 5 years or likely	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Y	<input type="checkbox"/> N
Provision by such a company or organisation of ad hoc support for a patient or student in the last 5 years or likely	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Y	<input type="checkbox"/> N
Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 5 years or likely	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Y	<input type="checkbox"/> N
Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 5 years or likely	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Y	<input type="checkbox"/> N
Other professional interest	<input type="checkbox"/> Y	<input type="checkbox"/> N	<input type="checkbox"/> Y	<input type="checkbox"/> N

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N

Section 4. Other interests not required to be listed above but that could give rise to an obligation of disclosure to the Committee

Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N

Dear XXX

APPLICATION FOR APPOINTMENT / RE-APPOINTMENT

XXX COMMITTEE/SUBCOMMITTEE/CLINICAL ADVISORY GROUP / PANEL OF EXPERTS

Thank you for your application for appointment / reappointment to the xxxx Committee/Subcommittee/Clinical Advisory Group/Panel of Clinical Experts. To ensure consistency between all of its advisory committees and attain a level of best practice, the Department of Health has assessed your application for appointment/ reappointment in line with Division 2 of Part 2-2 of the *Public Governance, Performance and Accountability Rule 2014* and the Department of Health Conflict of Interest (Col) Policy (attached).

In the application of the Department's Col policy, we must ensure that actual or perceived conflicts are considered, declared and managed appropriately. Cols may arise in relation to a wide range of interests, including but not limited to, shareholdings; travel, research or education grants; consultancies; fellowships; directorships or board memberships; providing general or specific advice to a person who has a pecuniary interest in the outcome of Committee consideration; and personal relationships with persons associated with a company that has a pecuniary interest in the outcome of Committee consideration.

All future appointees and re-appointees to Committees / Subcommittees / Clinical Advisory Groups / Panel of Clinical Experts will be required to consider the above actual or perceived Cols and make appropriate declarations that no such Cols exist or will be created for the duration of the appointment/re-appointment.

The Department has assessed your declared Cols and identified that you have an actual or perceived Col as detailed below:

- Commercial interest in X,Y,Z

The Department has determined that this Col cannot be appropriately managed to remove the actual or perceived Col in line with the Department's policy and as a consequence you have not been found suitable for appointment/re-appointment to the xxxx Committee/Subcommittee/Clinical Advisory Group / Panel of Clinical Experts at this time.

Please note that while the Department has only identified the above Cols as relevant to your appointment/ reappointment, there is still an obligation for you to disclose or identify to the Department other Cols that you consider to be relevant to your appointment/ reappointment.

If you require any further assistance or information please contact xxxx on telephone xxxx.

I would like to take this opportunity to thank you for your contributions to the xxxx Committee/Subcommittee/Clinical Advisory Group / Panel of Clinical Experts and very much appreciate your willingness to serve in this capacity.

Yours sincerely

Dear xxx

APPLICATION FOR APPOINTMENT / RE-APPOINTMENT

XXX COMMITTEE/SUBCOMMITTEE/CLINICAL ADVISORY GROUP/PANEL OF CLINICAL EXPERTS

Thank you for your application for appointment /reappointment to the xxxx Committee/Subcommittee/Clinical Advisory Group / Panel of Clinical Experts. To ensure consistency between all of its advisory committees and attain a level of best practice, the Department of Health has assessed your application for appointment/ reappointment in line with the Department of Health Conflict of Interest (Col) Policy (attached).

In the application of the Department's Col policy, we must ensure that actual or perceived conflicts are considered, declared and managed appropriately. Cols may arise in relation to a wide range of interests, including but not limited to, shareholdings; travel, research or education grants; consultancies; fellowships; directorships or board memberships; providing general or specific advice to a person who has a pecuniary interest in the outcome of Committee consideration; and personal relationships with persons associated with a company that has a pecuniary interest in the outcome of Committee consideration.

All future appointees and re-appointees to Committees / Subcommittees / Clinical Advisory Groups / Panel of Clinical Experts will be required to consider the above actual or perceived Cols and make appropriate declarations that no such Cols exist or will be created for the duration of the appointment/re-appointment.

In assessing your declaration for appointment/reappointment, the Department has identified that you currently have the following actual or perceived conflicts which do not align with the Department's policy:

- INSERT CONFLICT(S) HERE

Please note that while the Department has only identified the above Cols as relevant to your appointment/ reappointment, there is still an obligation for you to disclose or identify to the Department other Cols that you consider to be relevant to your appointment/ reappointment.

In order to be considered for appointment/re-appointment, you will need to complete the attached declaration to confirm that you will cease and not commence, for the duration of your appointment any of the following relevant to your declaration:

- shareholdings
- travel, research or education grants
- consultancies
- fellowships
- directorships or board memberships
- providing general or specific advice to a person who has a pecuniary interest; or
- personal relationships with persons associated with a company that has a pecuniary interest

Please note that until we receive a completed declaration, the Department will not be in a position to offer you appointment/reappointment and you will be unable to attend Committee/Subcommittee /CAG/PoCE meetings.

Please note that if you are reappointed to the committee, the Department will require you to declare interest in the following circumstances and failure to disclose any actual or perceived conflicts without a reasonable excuse may result in termination of the appointment;

- a. Annually on your annual declaration,
- b. On an ad-hoc basis, where the personal interest is relevant and should be disclosed, and
- c. At meetings of the relevant Departmental advisory Committee.

Please complete and sign the attached declaration and return to: xxx

If you require any further assistance or information please contact xxx on telephone xxx.

[I would like to take this opportunity to thank you for your contributions to the xx Committee/subcommittee/CAG/PoCE and your willingness to continue to serve in this capacity.]

Yours sincerely



Australian Government

Department of Health

DECLARATION OF CESSATION / DIVESTMENT

XXX COMMITTEE/SUBCOMMITTEE/CLINICAL ADVISORY GROUP/PANEL OF CLINICAL EXPERTS

I,, declare that I have taken all possible steps to divest myself of and/or ceased association with the following conflicts of interest which were declared during my application for appointment/reappointment which were:

[list Conflicts identified during application assessment here]

I declare that I have taken all possible steps to divest myself of and/or ceased association with the following Conflicts of Interest which were declared during my application for appointment/reappointment and have been advised that it is not feasible to divest/cease the below.

I agree to declare these conflicts in the following circumstances and agree to work with the Department to manage the conflict of interest.

- a. If I am appointed to the committee,
- b. On my annual declaration,
- c. On an ad-hoc basis, where the personal interest is relevant and should be disclosed, and
- d. At relevant meetings.

I accept that failure to declare the interests may result in termination of my appointment.

I declare that my professional and pecuniary interests now comply with the Department of Health's Conflict of Interest policy allowing me to be eligible for appointment /reappointment to XXX Committee/Subcommittee/Clinical Advisory Group/Panel of Clinical Experts.

Furthermore I declare that I will not commence, for the duration of my appointment any of the following relevant to my appointment:

- Shareholdings
- travel, research or education grants
- consultancies
- fellowships
- directorships or board memberships
- providing general or specific advice to a person who has a pecuniary interest; or
- personal relationships with persons associated with a company that has a pecuniary interest.

Yours sincerely

Nominee

Dear XXXX

**OFFER OF APPOINTMENT/REAPPOINTMENT
XXXX COMMITTEE/SUBCOMMITTEE/CLINICAL ADVISORY GROUP**

The Department of Health has assessed your application for appointment/reappointment in line the with Department of Health Conflict of Interest (COI) Policy (attached) to the xxxx Committee/Subcommittee/Clinical Advisory Group/Panel of Clinical Experts. I am pleased to offer you appointment/reappointment as a member of the xxxx Committee/ Subcommittee/ CAG/PoCE.

To confirm your acceptance of this offer of appointment/reappointment, please complete the attached Instrument of Appointment/Acceptance of Appointment and return it to xxxx.

In the application of the Department's Col policy, we must ensure that actual or perceived conflicts are considered, declared and managed appropriately. Cols may arise in relation to a wide range of interests, including but not limited to shareholdings; travel, research or education grants; consultancies; fellowships; directorships or board memberships; providing general or specific advice to a person who has a pecuniary interest in the outcome of Committee consideration; and personal relationships with persons associated with a company that has a pecuniary interest in the outcome of Committee consideration.

All future appointees and re-appointees to Committees / Subcommittees / Clinical Advisory Groups / Panel of Clinical Experts will be required to reconsider the above actual or perceived Cols and make appropriate declarations that no such Cols exist or will be created for the duration of the appointment/re-appointment.

If you require any further assistance or information please contact xxxx on telephone xxxx.

I would like to take this opportunity to thank you for your contributions to the xxxx Committee /Subcommittee/CAG/PoCE and your willingness to continue to serve in this capacity.

Yours sincerely

Dear xxxx

**APPLICATION FOR APPOINTMENT/REAPPOINTMENT
XXXX COMMITTEE/SUBCOMMITTEE/CLINICAL ADVISORY GROUP**

Thank you for your application for appointment/reappointed to the xxxx Committee/Subcommittee/Clinical Advisory Group /Panel of Clinical Experts. To ensure consistency between all of its advisory committees and attain a level of best practice, the Department of Health has assessed your application for appointment/reappointment in line with the Department of Health Conflict of Interest (Col) Policy (attached).

In the application of the Department's Col policy, we must ensure that actual or perceived conflicts are considered, declared and managed appropriately. Cols may arise in relation to a wide range of interests, including but not limited to shareholdings; travel, research or education grants; consultancies; fellowships; directorships or board memberships; providing general or specific advice to a person who has a pecuniary interest in the outcome of Committee consideration; and personal relationships with persons associated with a company that has a pecuniary interest in the outcome of Committee consideration.

All future appointees and re-appointees to Committee / Subcommittee / Clinical Advisory Groups / Panel of Clinical Experts will be required to consider the above actual or perceived Cols and make appropriate declarations that no such Cols exist or will be created for the duration of the appointment/reappointment.

I note that you have declared X,Y,Z research interest.

In order to make a complete assessment of your declared Cols, I require more specific information in relation to:

- Your role/position in xxxx

Please provide this information to xxxx as soon as possible to allow the assessment of your appointment/reappointment to be completed.

If you require any further assistance or information please contact xxxx on telephone xxxx.

I would like to take this opportunity to thank you for your contributions to the xxxx Committee/Subcommittee/CAG/PoCE and your willingness to continue to serve in this capacity.

Yours sincerely