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Declaration of interests in support of application

For membership of a TGA expert advisory committee

Declarations of interests

The external committees of the TGA undertake a vital function in providing advice and expertise that is essential to the TGA in carrying out its regulatory functions. Members¹ must have specialist knowledge and expertise in one or more designated areas and are appointed to a committee for the purpose of providing expert advice in relation to matters coming before the committee. It is assumed therefore that members will apply their professional expertise and experience in relation to matters coming before the committee.

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

In order to allow any such potential conflicts of interest to be managed, the TGA 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 annually thereafter, as well as before, or at, meetings of the committee. A copy of the *TGA Advisory Committee Guidelines; declaration of interests, managing conflicts of interest and confidentiality obligations* along with copies of the annual declaration of interests and meeting disclosure of interest forms can be found on the [TGA website](#).

¹ For the purpose of this Declaration, a member is defined as a member of a committee or an expert advisor

Under the Therapeutic Goods Regulations 1990 members of advisory committees of the TGA established under those Regulations are required 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 the meeting. The committee then manages any possible conflict of interest by determining whether the member should participate in any consideration by the committee of that matter. The member must not, unless the committee agrees, be present during the committee’s deliberation of a matter in relation to which the member has disclosed an interest. The member must not be present during the committee’s deliberation about whether that member should be so present. Any disclosure must be recorded in the minutes of the meeting.

These rules 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 duties as a committee member such that the person may not be independent, objective and impartial in relation to those duties. An apparent conflict of interest will arise if, 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 forthcoming. 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 person’s ability to effectively perform his or her role on the committee could be affected by those interests.

Section 1 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, therapeutic goods²), it is possible a potential conflict of interest may arise with any role you assume as a future committee member. 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:

1.1 Share holdings, executive or non-executive board membership (including advisory boards) (over the past 5 years or likely to be forthcoming)

² ‘Therapeutic goods’ are broadly defined as a goods which are represented in any way to be, or is likely to be taken to be, for therapeutic use including medicines, medical devices and biological products.

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

1.3 Fellowships, research or education grants (over the past 5 years or likely to be forthcoming)

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

1.5 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 to be forthcoming)

Section 2 Professional interests

Please list:

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

Section 3 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**.

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.

Declaration

I declare that:

- I have read, at Appendix 1, and understand, the responsibilities of a member of a TGA expert advisory committee under the Therapeutic Goods Regulations 1990, particularly 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 the a TGA expert advisory committee I would be bound by that obligation;
- I understand that if I were to be appointed to be a member of a TGA expert 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 TGA expert advisory committee I would be required to complete an annual declaration about my pecuniary and non-pecuniary interests; and
- I have provided current and accurate information in this declaration.

Name			
Signature		Date	