Australian Government

Department of Health
Therapeutic Goods Administration

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Annual declaration of interests

For members of TGA expert advisory committees

Member name	[redacted]
Committee name	Advisory Committee on Vaccines (ACV)

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. Members must have specialist knowledge and expertise in one or more designated areas and are appointed to a committee for the purpose of providing expert advice in relation to matters coming before the committee. It is assumed therefore that members will apply their professional expertise and experience in relation to matters coming before the committee.

This is not what the conflict of interest rules are concerned with. These rules are about ensuring that there can be no perception that, taking 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 members to notify 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* can be found on the TGA website. (http://www.tga.gov.au/about/committees-expert-guidelines.htm)

Under regulation 42 of the Therapeutic Goods Regulations 1990 (Appendix 1) members of advisory committees of the TGA 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[1]. 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.

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[1] More information can be found in the *TGA Advisory Committee Guidelines: Declarations of interests, managing conflicts of interest and confidentiality obligations*.

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 interest may be perceived by a reasonable observer.

As a member of the committee you are required to provide details of any of your interests (whether pecuniary or not) under each of the headings below. You should also list relevant interests of your immediate family. This information will be retained by the TGA and will be collected, stored, used and disclosed in accordance with the *Privacy Act 1988* (Note: for general privacy information, go to http://www.tga.gov.au/about/website-privacy.htm). The information will only be used for the purpose of assisting in the management of any potential conflict of interest while you are a member of the committee. You should provide details about all current relevant interests, whether or not you have previously provided that information to the TGA.

You are also required to list relevant interests of your immediate family **but only to the extent you are aware of them**. Just who is a member of your "immediate family" for this purpose will depend on your particular situation. A spouse/partner will normally be included and children may be, depending on the circumstances (for instance where they are dependent). You should consider whether the nature of the relationship with the particular family member is such that **their interests could be perceived by a reasonable observer as impacting on your capacity to be independent, objective and impartial in relation to your duties as a committee member**.

1. Pecuniary interests

A pecuniary interest may include, but is not limited to, any of the following:

a. current shareholdings which the member controls (including through a self-managed superannuation fund), irrespective of whether the person's name is on the share register;

b. current shareholding through an unlisted managed fund or trust, if the person could significantly influence investment decisions;

c. other sources of funds or other benefits or advantage (including partnerships and trusts);

d. ownership of a patent for a therapeutic good or ownership of such a patent by employer;

e. board memberships (executive or non-executive) or other offices in a company in the last 3 years;

f. paid employment, contracting, consultancy, commissioned fee-paid work or work as a paid speaker or paid expert adviser in the last 3 years;

g. grants for overseas travel, research or education or paid conference expenses in the last 3 years;

h. holding a retainer or receiving pay for a company that manufactures or is a sponsor of therapeutic goods in the last 3 years;

i. significant hospitality in the last 3 years; and/or

j. a financial involvement in any therapeutic goods, or other products, services or matters having any connection with therapeutic goods, in the last 3 years.

2. Professional interests

A professional interest may include, but is not limited to:

a. involvement in any company or organisation involved in the development, manufacture or marketing and distribution of therapeutic goods in the last 3 years, including membership of advisory board;

b. accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years;

c. provision by such a company or organisation of ad hoc support for a patient or student in the last 3 years;

d. participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years;

e. involvement at any time as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.

3. Non-pecuniary interests

A non-pecuniary interest may include, but is not limited to: the holding of strong personal, philosophical or religious beliefs or convictions; family or other relationships (such as the research of a member of the family being subsidised by a pharmaceutical company); a medical condition of the member or of the family or a close friend.

Members are only asked to list these personal (non-pecuniary) interests which may conflict, or give the appearance of being in conflict, with their obligations in relation to the committee such that they may not be independent, objective and impartial in relation to those obligations.

You or a member of your immediate family or close friend may have a specific or uncommon condition the treatment of which could be affected by a therapeutic good or other matter that could be considered by the committee, or you may have some other personal interest or ethical position in relation to a particular treatment. You may choose not to disclose such an interest on this form. However, subregulation 42(4) would require you to declare such an interest if it was "material" in relation to a matter to be considered by the committee. In such a case you have the option of indicating to the chair that you will not participate in the Committee's consideration of the matter rather than the committee determining whether you should participate.

4. Interests not otherwise listed

You should also list any interests which are not required to be listed above (including for instance where the interest would, but for the 3 year time period come within 1 or 2 above) **if those interests are such that a perception of a conflict of interest could arise in relation to any matter that could come before the committee and you would be required to disclose that interest**. For instance, your involvement as a consultant for a pharmaceutical company may have occurred just outside the relevant period. However, if that involvement was of such a nature that if a particular product of that company was being considered by the Committee you would need to disclose that involvement under subregulation 42(4), you should declare that involvement as an interest here.

5. Declaration

I understand that if I am aware of any direct or indirect material personal interest (whether pecuniary or not) in a matter to be considered, or about to be considered, at a meeting of the committee, I am required under subregulation 42(4) of the Therapeutic Goods Regulations 1990 to disclose the nature of that interest, without delay, before or at the meeting.

I understand that in accordance with subregulations 42(5) and (6) of the Regulations, the committee can discuss and determine the issue of whether I should participate in any deliberation or decision on that matter in my absence and that my disclosure and the outcome of the committee's determination will be recorded in the minutes of the meeting. I understand that under subregulation 42(5) I cannot, unless the Committee agrees, be present during the committee's deliberation, or take part in any decision, on any matter or matters in relation to which I have disclosed an interest.

I understand that:

- this completed form will be kept as records in TGA files;
- the information will be collected, stored, used and disclosed in accordance with the requirements of the *Privacy Act 1988*.

I declare:

- the particulars of my pecuniary, professional, non-pecuniary and other interests, and
- interests **of which I am aware** of my immediate family and other persons that may be relevant as set out under 3 above,

as below.

Section 1. Pecuniary interests (Please tick all boxes)

Interest	Myself	Immediate family or other relationship (of which you are aware)
a. 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	☐ Yes ☒ No	☐ Yes ☒ No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	☐ Yes ☒ No	☐ Yes ☒ No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	☐ Yes ☒ No	☐ Yes ☒ No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	☐ Yes ☒ No	☐ Yes ☒ No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	☒ Yes ☐ No	☐ Yes ☒ No
f. Paid employment, contracting, consultancy, commissioned fee-paid work or work as a paid speaker or paid expert adviser in the last 3 years.	☒ Yes ☐ No	☐ Yes ☒ No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	☒ Yes ☐ No	☐ Yes ☒ No
h. Holding a retainer or receiving pay for a company that manufactures or is a sponsor of therapeutic goods in the last 3 years.	☐ Yes ☒ No	☐ Yes ☒ No
i. Significant hospitality in the last 3 years.	☐ Yes ☒ No	☐ Yes ☒ No
j. A financial involvement in any therapeutic goods, or other products, services or matters having any connection with therapeutic goods, in the last 3 years.	☒ Yes ☐ No	☐ Yes ☒ No
k. Other pecuniary interests	☐ Yes ☒ No	☐ Yes ☒ No

Section 2. Professional interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
a. Involvement in any company or organisation involved in the development, manufacture or marketing and distribution of therapeutic goods in the last 3 years, including membership of advisory board.	☒ Yes ☐ No	☐ Yes ☒ No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	☐ Yes ☒ No	☐ Yes ☒ No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	☐ Yes ☒ No	☐ Yes ☒ No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	☐ Yes ☒ No	☐ Yes ☒ No
e. Other professional interest.	☐ Yes ☒ No	☐ Yes ☒ No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
N/A	☐ Yes ☒ No	☐ Yes ☒ No

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)
N/A	☐ Yes ☒ No	☐ Yes ☒ No

For interests declared in Sections 1 to 4 above, please provide details below, including the type of interest, the relevant company/organisation and whether the interest is held by you or by your immediate family or other person. Please attach additional pages where required.

[redacted]

5. Declaration

Name	[redacted]		
Signature		Date	29/1/19

Therapeutic Goods Regulations 1990 - Reg 42

Miscellaneous

Disclosure of interests

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

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

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

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