



Australian Government
Department of Health
Therapeutic Goods Administration

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For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

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:

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None

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)

None

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

A list of education and research grants awarded to NCIRS, University of other Institutions in which I'm involved are provided in my CV, pages 7-8 and are currently also available with each ACV meeting DOI provided. I do not receive any funding or education grants from pharmaceutical companies, nor does the NCIRS.

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

Airfares and accomodation from WHO provided for travel/teaching at WHO training workshops and/or for WHO advisory committee meetings (anticipated value ~ \$2000 AUD in 2022)

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)

None

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:
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- 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.

Provided Expert Legal Reports for Crown solicitors for two Australian jurisdictions on COVID-19 and COVID-19 vaccines (standard expert witness remuneration provided at hourly rate)

- Kassam A & Ors v Hazzard & Ors (2021/249601) NSW Crown Solicitors Office
- Henry N & Ors v Hazzard & Ors (2021/252587) NSW Crown Solicitors Office
- Ray Phillips & Ors v Chief Health Officer & ANOR. NT Department of Attorney General and Justice 2022

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:

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- 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**.

None

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;
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- 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	Professor Kristine Macartney		
Signature	s11C(1)(a)	Date	per 4 Sept 2022



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

I have been a member of industry DSMB for Serum Institute of India, GSK, and Clover either directly or via my role in CEPI SPEAC meta-DSMB. I do not receive compensation, although my employer MCRI is compensated for my time.

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)

Nil

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

Nil

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

Nil

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)

Nil

Section 2 Professional interests

Please list:

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- 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.

I have been previously a local investigator for vaccine trials with Pfizer, GSK, Novavax, Merck and Astra-zeneca. I do not receive compensation, although my previous employer Monash Health is compensated for my time.

Section 3 Other interests

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Deed

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I declare that:

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Name	Jim Buttery		
Signature	s11C(1)(a)	Date	4 Sept 2022



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NIL

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NIL

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NIL

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

NIL

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)

NIL

Section 2 Professional interests

Please list:

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NIL

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- I have provided current and accurate information in this declaration.

Name	MADELINE HALL		
Signature	s11C(1)(a)	Date	05/08/2022



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Name	Vicky Sheppeard		
Signature	s11C(1)(a)	Date	4 September 2022



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Annual declaration of interests

For members of TGA statutory advisory committees

Member name

JEANINE BIGOTT

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: conflicts of interest and confidentiality obligations* can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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.

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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

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 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.

5. Declaration

Name	JEANNE MAREE BYGOTT		
Signature	s11C(1)(a)	Date	13/12/21

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.



Australian Government
 Department of Health
 Therapeutic Goods Administration

TGA use only

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Annual declaration of interests

For members of TGA statutory advisory committees

Member name	Allen Cheng
Committee name	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: conflicts of interest and confidentiality obligations](http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: Conflicts of interest and confidentiality obligations*.

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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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.

1a. I do not hold shares directly in any companies involved in healthcare or pharmaceutical manufacture/distribution

1e. President of the Australasian Society for Infectious Diseases

1f. Paid consultant for Walmart (relating to an outbreak investigation) and Australian Strep A Vaccine Initiative (ASAVI).

2c. Per previous declarations, I am/have been site investigator on clinical trials. I have not received funding directly or indirectly; funding has been provided to my institution to provide for a study nurse.

2e. President of the Australasian Society for Infectious Diseases

5. Declaration

Name	Allen Cheng		
Signature	<div style="background-color: black; color: red; font-size: small; padding: 2px;">s11C(1)(a)</div>	Date	21/2/2022

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.



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Annual declaration of interests

For members of TGA statutory advisory committees

Member name	Diane Walsh
Committee name	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: conflicts of interest and confidentiality obligations](http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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	<input type="checkbox"/> Yes x No	<input type="checkbox"/> Yes x No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes x No	<input type="checkbox"/> Yes x No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes x No	<input type="checkbox"/> Yes x No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes x No	<input type="checkbox"/> Yes x No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	X Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes x 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.	X Yes <input type="checkbox"/> No	X Yes <input type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes x No	<input type="checkbox"/> Yes x 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.	<input type="checkbox"/> Yes x No	<input type="checkbox"/> Yes x No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes x No	<input type="checkbox"/> Yes x 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.	<input type="checkbox"/> Yes x No	<input type="checkbox"/> Yes x No
k. Other pecuniary interests	<input type="checkbox"/> Yes x No	<input type="checkbox"/> Yes x 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.	<input type="checkbox"/> Yes x No	<input type="checkbox"/> Yes x No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes x No	<input type="checkbox"/> Yes x No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input type="checkbox"/> Yes x No	<input type="checkbox"/> Yes x No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input type="checkbox"/> Yes x No	<input type="checkbox"/> Yes x No
e. Other professional interest.	X Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes x No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes x <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes x <input checked="" type="checkbox"/> 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)
	<input type="checkbox"/> Yes x <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes x <input checked="" type="checkbox"/> No

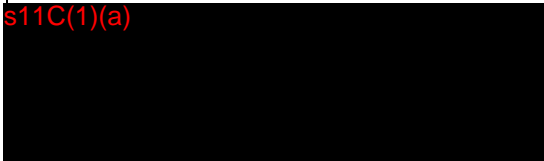
For interests declared in Sections 1 to 4 above, please provide details below, including the type of interest, the relevant company/organisation and whether the interest is held by you or by your immediate family or other person. Please attach additional pages where required.

1.e – Self – Former director and Chair Northern Territory Primary Health Network – retired 30.1.2021

- Member NPS Medicines Consumer Advisory Group
- Member ACSQHC – Primary Care Committee
- Member RACGP – Expert Committee - Standards

s47F

5. Declaration

Name	Diane Walsh		
Signature	 s11C(1)(a)	Date	14 December 2021

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.



Australian Government
 Department of Health
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Annual declaration of interests

For members of TGA statutory advisory committees

Member name	Adrienne Torda
Committee name	Australian Committee on Vaccines

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: conflicts of interest and confidentiality obligations](http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.

5. Declaration

Name	Adrienne Torda		
Signature	s11C(1)(a)	Date	15/12/21

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.



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Annual declaration of interests

For members of TGA statutory advisory committees

Member name

Kristine Macartney

Committee name

Advisory Committee on Vaccines

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: conflicts of interest and confidentiality obligations](http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.

2D. Director of the National Centre for Immunisation Research and Surveillance

5. Declaration

Name	Kristine Macartney		
Signature	s11C(1)(a)	Date	25.01.2022

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.



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Annual declaration of interests

For members of TGA statutory advisory committees

Member name	Jim Buttery
Committee name	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: conflicts of interest and confidentiality obligations](http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> 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)
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> 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.

<p>In the last 3 years have been a local investigator on clinical trials for many vaccine manufacturers - Merck (PCV15), GSK (RSV), Pfizer (RSV) and Astrazeneca (RSV). I have also served on DSMB for SSI (COVID vaccine), Clover (COVID vaccine), GSK (therapeutic hepatitis B vaccine/therapy), COVALIA, and MCRI. I do not receive compensation for any of these but my employers (Monash Health for clinical trials, MCRI for DSMB) receive compensation for my time.</p>
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5. Declaration

Name	Jim Buttery		
Signature	s11C(1)(a)	Date	24 Feb 2022

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.



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Annual declaration of interests

For members of TGA statutory advisory committees

Member name	MADELINE HALL
Committee name	ADVISORY COMMITTEE ON VACCINES

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: conflicts of interest and confidentiality obligations](http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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	<input type="checkbox"/> Yes <input type="checkbox"/> X No	<input type="checkbox"/> Yes <input type="checkbox"/> X No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input type="checkbox"/> X No	<input type="checkbox"/> Yes <input type="checkbox"/> X No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input type="checkbox"/> X No	<input type="checkbox"/> Yes <input type="checkbox"/> X No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input type="checkbox"/> X No	<input type="checkbox"/> Yes <input type="checkbox"/> X No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input type="checkbox"/> Yes <input type="checkbox"/> X No	<input type="checkbox"/> Yes <input type="checkbox"/> X 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.	<input type="checkbox"/> Yes <input type="checkbox"/> X No	<input type="checkbox"/> Yes <input type="checkbox"/> X No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input type="checkbox"/> X No	<input type="checkbox"/> Yes <input type="checkbox"/> X 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.	<input type="checkbox"/> Yes <input type="checkbox"/> X No	<input type="checkbox"/> Yes <input type="checkbox"/> X No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input type="checkbox"/> X No	<input type="checkbox"/> Yes <input type="checkbox"/> X 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.	<input type="checkbox"/> Yes <input type="checkbox"/> X No	<input type="checkbox"/> Yes <input type="checkbox"/> X No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input type="checkbox"/> X No	<input type="checkbox"/> Yes <input type="checkbox"/> X 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.	<input type="checkbox"/> Yes <input type="checkbox"/> X No	<input type="checkbox"/> Yes <input type="checkbox"/> X No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes <input type="checkbox"/> X No	<input type="checkbox"/> Yes <input type="checkbox"/> X No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input type="checkbox"/> Yes <input type="checkbox"/> X No	<input type="checkbox"/> Yes <input type="checkbox"/> X No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input type="checkbox"/> Yes <input type="checkbox"/> X No	<input type="checkbox"/> Yes <input type="checkbox"/> X No
e. Other professional interest.	<input type="checkbox"/> Yes <input type="checkbox"/> X No	<input type="checkbox"/> Yes <input type="checkbox"/> X No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
N/A	<input type="checkbox"/> Yes X No	<input type="checkbox"/> Yes X 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	<input type="checkbox"/> Yes X No	<input type="checkbox"/> Yes X 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.

N/A

5. Declaration

Name	MADELINE HALL		
Signature	s11C(1)(a)	Date	17/01/2022

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.



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Annual declaration of interests

For members of TGA statutory advisory committees

Member name	Vicky Sheppeard
Committee name	Advisory Committee on Vaccines

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: conflicts of interest and confidentiality obligations](http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Section 3. Non-pecuniary interests

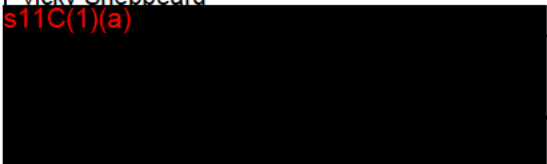
Interest	Myself	Immediate family or other relationship (of which you are aware)
N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

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)
Nil	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> 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.

5. Declaration

Name	Vicky Sheppard s11C(1)(a)		
Signature		Date	18 Jan. 22

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.



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Annual declaration of interests

For members of TGA statutory advisory committees

Member name	Ines Rio
Committee name	Therapeutic Goods Administration Advisory Committee on Vaccines

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: conflicts of interest and confidentiality obligations](#) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
Chair and Non Executive Director of Melbourne Primary Care Network, General practitioner at North Richmond Community Health, Senior Medical Staff at The Royal Women's Hospital, Medical Officer for the City of Melbourne	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.

Section 1/2/3:

Chair and Non Executive Director of Melbourne Primary Care Network (trading as North Western Melbourne PHN)

- Held by me
- Incorporated organisation I receive a fixed stipend for


Section 2/3:

General practitioner at North Richmond Community Health – by me and self-employed. Provide vaccination advice and services and refer for vaccination. Involvement in vaccination strategy, policies and procedures and clinical governance.

Senior Medical Staff at The Royal Women's Hospital – by me and pennant part time. Provide vaccination advice and services and refer for vaccination. Involvement in vaccination strategy, policies and procedures and clinical governance.

Medical Officer for the City of Melbourne – by me and contract. Oversee vaccination strategy, clinical governance, services and programs by Maternal Child Health, nurse immunisers and others at The City of Melbourne.

5. Declaration

Name	Ines Rio		
Signature		Date	15/12/2021

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.



Australian Government
Department of Health
 Therapeutic Goods Administration

TGA use only

This form, when completed, will be classified as '**For official use only**'.

For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <http://www.tga.gov.au/about/tga-information-to.htm>.

Annual declaration of interests

For members of TGA statutory advisory committees

Member name Joseph Torresi

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: conflicts of interest and confidentiality obligations](#) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.

<ol style="list-style-type: none"> 1. Independent Data Monitoring Committee, Chair; Controlled Study of Immunogenicity and Safety of the Investigational vYF Candidate Vaccine in Comparison to Stamaril® in Adults. Sponsor: Sanofi Pasteur 2. COVID19 medical advisor to (consultancies); <ol style="list-style-type: none"> (a) Epworth Eastern hospital and Epworth Health (b) Knox Private Hospital and Healthscope (c) The Australia Football League (AFL) (d) International Basketball Federation (FIBA) (e) International Cricket Council (ICC) (f) Tennis Australia (g) ExxonMobil 3. Unrestricted educational grants from Sanofi Pasteur for (a) Southern Cross Travel Medicine Conference 2018,19,20 (b) ACTM COVID and Travel medicine guidelines (c) The Practical Course in Vaccine and Immunisation Science, Doherty Institute and NCIRS
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5. Declaration

Name	Joseph Torresi		
Signature	s11C(1)(a)	Date	15th December 2021

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.



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<https://www.tga.gov.au/treatment-information-provided-tga>.

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.

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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.

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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)

ACV membership 2019 - current

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)

Paid employment as Partner at
Sullivan Nicolaides Pathology

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

n/a

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

n/a

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)

MAP Superannuation Fund (balanced option)

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.

ACV membership 2019 - current

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.

n/a

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	Jeanine Maise BYGOTT		
Signature	s11C(1)(a)	Date	14/8/21



Australian Government
Department of Health
 Therapeutic Goods Administration

TGA use only

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Declaration of interests in support of application

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Declarations of interests

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None

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)

None

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

None

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

None

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)

s47F

NTPHN - Director

Section 2 Professional interests

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- 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.

no

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:

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none

Deed

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Name	Diane Walsh - Signature unable to be attached - signed copy will be provided by email.		
Signature		Date	16.08.2021



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Department of Health
 Therapeutic Goods Administration

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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)

Australian Medical Council - Medical Workforce Digital Capabilities Advisory Group

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

Research projects that I am an investigator on that have received grants:

Antibiotic Allergy Testing - Sydney Partnership for Health, Education, Research and Enterprise (SPHERE)/ Triple I Clinical Academic Group / Infection, Inflammation and Immunity Theme, \$75,000 - I received none of this funding personally

Education projects that I have received funding for (internally at UNSW):

Development of a Capstone - preparation for practice course, \$12,676.88

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

Nil

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)

Nil

Section 2 Professional interests

Please list:

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Section 3 Other interests

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- I have provided current and accurate information in this declaration.

Name

Adrienne Torda

Signature

s11C(1)(a)

Date

30/07/2021



Australian Government
 Department of Health
 Therapeutic Goods Administration

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- CHAIRPERSON OF BOARD, MELBOURNE PRIMARY CARE NETWORK. CHAIR OF CLINICAL COUNCIL; TRADING AS NORTH WESTERN MELBOURNE PRIMARY HEALTH NETWORK (NWMPHN)
 - MEMBER OF AUSTRALIAN DEPARTMENT OF HEALTH COVID-19 CALD COMMITTEE AND VACCINE COMMITTEE
 - MEMBER OF NOTIFICATION COMMITTEE OF MEDICAL BOARD OF AUSTRALIA
 - MEMBER AUSTRALIAN MEDICAL ASSOCIATION (AMA) COUNCIL VIC; MEMBER FEDERAL AMA COUNCIL OF GENERAL PRACTICE AND EXECUTIVE COMMITTEE; IMMEDIATE PAST CHAIR AMA VIC GENERAL PRACTICE SECTION

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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)

General Practitioner, North Richmond Community Health
Senior Medical Staff, The Royal Women's Hospital
Medical Officer Health, City of Melbourne

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

Nil

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

Nil

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)

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Section 2 Professional interests

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No

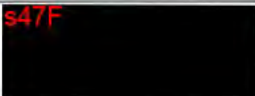
Deed

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- 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;
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- 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	Ines Rio		
Signature		Date	15/08/2021



Australian Government
Department of Health
Therapeutic Goods Administration

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Declarations of interests

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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)


Not applicable

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. Expert adviser consultancies: COVID Adviser (1) Australian Football League, (2) International Cricket Competition (ICC) (3) FIBA (4) Epworth Health
2. Member, National Medical Council, Healthscope

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

1. MRFF COVID-19 Vaccine Candidate Research APP2013957, . AdaptiVax-CoV: A Novel Self-adjuvanting SARS-CoV2 VLP Vaccine to Produce Humoral and T cell responses to S, E and M proteins. 2021-2023
2. Frontier Health and Medical Research Fund, c -FIND: Using CRISPR Frontier Infection Diagnostics to Detect, Prevent and Respond to Infectious Threats. 2019-2020
3. Australian Centre for Hepatitis and HIV Virology. A personalised therapeutic approach for HBV associated liver cancer. 2020-2021
4. NHMRC Project Grant APP1126379. Developing a quadrivalent HCV vaccine. 2017-2019
5. Australia- India Strategic Research Fund App No. 12777293-146. Preclinical trials of a quadrivalent hepatitis C virus vaccine.2015-2016
6. Jack Ma Foundation. Development of an Active Vaccination Platform for COVID-19. 2020-2021 

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

1. 16th Meeting of the International Society of Travel Medicine, Washington, USA, May 2019. Invited speaker
2. International Speakers Tour: Vaccine preventable Infections, 20-25th Oct 2018 Invited speaker: Japanese Encephalitis Vaccines (Vietnam, Philippines, Indonesia, Singapore)
3. Australian Health Abroad, Surgical Training Meeting, Tavarua, Fiji, 1-8th Sept, 2018
4. 3rd Southern Cross Conference of Travel Medicine, Australasian College of Tropical Medicine, 8th to 9th Sept 2018, Brisbane, Australia
5. 15th Meeting of the International Society of Travel Medicine, Barcelona, Spain May 2017
Invited speaker
6. Sino-Australian Summer Symposium on Emerging Pathogens, Beijing China, July 4-5 2017
Invited symposium speaker 

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)

Not applicable

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.

1. Chair of the Independent Data Monitoring and Safety Board: VYF02: Controlled Study of Immunogenicity and Safety of the Investigational vYF Candidate Vaccine in Comparison to YF-VAX in Adults. Sanofi Pasteur
 2. MRFF COVID-19 Vaccine Candidate Research APP2013957, . AdaptiVax-CoV: A Novel Self-adjuvanting SARS-CoV2VLP Vaccine to Produce Humoral and T cell responses to S, E and M proteins. 2021-2023

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**.

Not applicable

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	Joseph Torresi		
Signature	s11C(1)(a)	Date	30/08/2021



Australian Government
Department of Health
 Therapeutic Goods Administration

TGA use only

This form, when completed, will be classified as 'For official use only'.
 For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at
<http://www.tga.gov.au/about/tga-information-to.htm>.

Annual declaration of interests

For members of TGA statutory advisory committees

Member name	JEANINE BYGOTT
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: conflicts of interest and confidentiality obligations* can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: Conflicts of interest and confidentiality obligations*.

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Reference/Publication R15/91939

TGA Health Safety
Regulation

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)

Document 20

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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Section 3. Non-pecuniary interests

Interest:	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.

5. Declaration

Name	JEANINE MARIE BYGOTT		
Signature	s11C(1)(a)	Date	14/12/20



Australian Government
 Department of Health
 Therapeutic Goods Administration

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Annual declaration of interests

For members of TGA statutory advisory committees

Member name	Allen Cheng
Committee name	Advisory Committee on Vaccines (ACV)

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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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
Acting Victorian Chief Health Officer	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.

1 (a) Shareholdings in non-pharmaceutical companies (AGL, Elders, Transurban, Woolworths).

1 (e) President of Australasian Society for Infectious Diseases.


1 (f) Commissioned reports for Commonwealth including TGA.

2 (c) Site Investigator to recruit patients for hospital research funding for employment of study nurses provided by the following companies: Roche for Influenza antiviral; MSD for Pneumococcal vaccine in bone marrow transplant patients; Janssen Cilag P/L for clinical trial for influenza antiviral therapeutic agent;

Chief investigator on following trials: SARS-CoV-2 Australian Convalescent Plasma Study (MRFF funding); REMAP-CAP trial (NHMRC funding); dexamethasone PADDI trial (NHMRC funding); antibiotic ASAP trial (NHMRC funding).

3. Acting Victorian Chief Health Officer

5. Declaration

Name	Allen Cheng		
Signature		Date	4/1/2021

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.



Australian Government
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TGA use only

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Annual declaration of interests

For members of TGA statutory advisory committees

Member name	Prof Lisa Nissen
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: conflicts of interest and confidentiality obligations](http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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	No	No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	No	No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	No	No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	No	No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	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
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	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.	No	No
i. Significant hospitality in the last 3 years.	No	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.	No	No
k. Other pecuniary interests	No	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
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	Yes	No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	No	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
e. Other professional interest.	Yes	No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
Nil	No	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)
Nil	No	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.

Membership/boards: Interim Pharmacy Round Table (QLD Health) (current), Vaccination Technical Working Group (QLD Health) (current), AHPRA Scheduled Medicines Expert Committee (current), Australian Pharmaceutical Formulary Advisory Board (current), Advancing Practice Advisory Board (current), Pharmacy Practitioner Development Advisory Committee (current), Hepatitis Queensland (Board Member - non-exec until June 2018), Pharmaceutical Society of Australia (QLD) Branch Committee (Past president, finished 2017), Podiatry Board of Australia Scheduled Medicines Expert Committee (Past - finished 2017), Optometry Board of Australia Scheduled Medicines Expert Committee (Past - finished 2017), Family Planning QLD Board (Past - finished 2014), National E-Health Transition Authority – Stakeholder Reference Forum (SRF): Medicine Management (Past - finished 2014)

Paid: Queensland University of Technology, AHPRA (sitting fee for expert committees)

Grants: Research Funding Partnership (QLD Health) Urinary Tract Infection Pilot, Vanguard Grant (Heart Foundation)

Professional interests: Abbvie Biopharmaceuticals - HCV Community Pharmacy Advisory Board (2015) - advice on development of pharmacy education program as part of access changes to HCV medications. Non-remunerated position

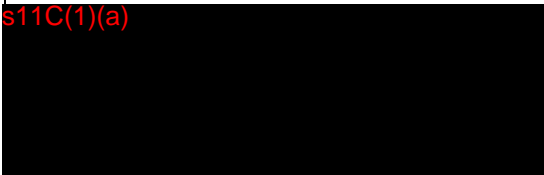
Medreleaf Australia (Medicinal Cannabis) (2017 - current) - Research and Education Advisor for health professional education program. Non-remunerated position

Vanguard Grant - Heart Foundation (2017 - completed) - investigation of medication literacy in diabetes patients with cardiovascular risk

Research Partnership (QLD Health) Urinary Tract Infection Pilot (current) - Community Pharmacists providing UTI treatment

(Other advisory roles / boards listed above)

5. Declaration

Name	Prof Lisa Nissen		
Signature	 s11C(1)(a)	Date	12/1/2021

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.



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Annual declaration of interests

For members of TGA statutory advisory committees

Member name Diane Walsh

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, conflicts of interest and confidentiality obligations](http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations), can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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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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	No	No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	No	No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	No	No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	No	No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	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.	s47F	
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	No	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.	No	No
i. Significant hospitality in the last 3 years.	No	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.	No	No
k. Other pecuniary interests	No	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.	No	No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	No	No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	No	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
e. Other professional interest.	No	No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
Member – Consumers Health Forum	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)
	No	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.

<p>Northern Territory PHN – Director and Chair</p> <p>s47F</p> <p>ATAGI – appointed 2020</p> <p>Member – Consumers Health Forum</p>

5. Declaration

Name	Diane Walsh		
Signature	s11C(1)(a)	Date	17/12/2020

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.



Australian Government
 Department of Health
 Therapeutic Goods Administration

TGA use only

This form, when completed, will be classified as 'For official use only'.

For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <http://www.tga.gov.au/about/tga-information-to.htm>.

Annual declaration of interests

For members of TGA statutory advisory committees

Member name	Adrienne Torda
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: conflicts of interest and confidentiality obligations](http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Section 3. Non-pecuniary interests


Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.

5. Declaration

Name	Adrienne Torda		
Signature		Date	14/12/2020

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.



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 For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at
<http://www.tga.gov.au/about/tga-information-to.htm>.

Annual declaration of interests

For members of TGA statutory advisory committees

Member name	Kristine Macartney
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: conflicts of interest and confidentiality obligations](#) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: Conflicts of interest and confidentiality obligations*

Document 25
These rules are designed to minimise any risk that the consideration of any matter by the committee, or 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.

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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

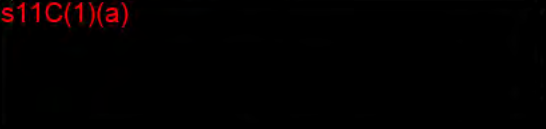
Section 4. Other interests not required to be listed above but that could give rise to an obligation of disclosure to the Committee

Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.

For noting only, as Director of NCIRS
 NCIRS is funded by the Australian Government to support Government on a range of key areas related to use of vaccines in Australia, including in pharmacovigilance

5. Declaration

Name	Kristine Macartney		
Signature		Date	15 Jan 2021

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.



Australian Government
 Department of Health
 Therapeutic Goods Administration

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Annual declaration of interests

For members of TGA statutory advisory committees

Member name	Jim Buttery
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: conflicts of interest and confidentiality obligations](http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> 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)
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> 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.

<p>I have served as a PI on sponsored vaccine trials of RSV vaccines or monoclonal antibodies (MedImmune, GSK, Pfizer), and influenza vaccine safety (seqiris). I do not receive any remuneration for this, but Monash Health is compensated for my time. Until October 2020, I worked as the head of Monash Kids Research which conducts sponsored clinical trials in medicines and vaccines. I also work as a vaccine safety researcher performing non-sponsored research involving all vaccines in the Australian market.</p>
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5. Declaration

Name	Jim Buttery		
Signature	s11C(1)(a)	Date	15 Jan 2021

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.



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Annual declaration of interests

15 DEC 2020
 s11C(1)(a)

For members of TGA statutory advisory committees

Madeline Hall
 Nurse Practitioner

Member name

MADELINE HALL

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: conflicts of interest and confidentiality obligations](#) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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.

s11C(1)(a)

2. Professional interests

15 DEC 2020

Madeline Hall
Nurse Practitioner

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.

15 DEC 2020

s11C(1)(a)

Madeline Hall
Nurse Practitioner

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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Madeline Hiaff
Nurse Practitioner

s11C(1)(a)

15 DEC 2020

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.

N/A

Madeline Hall
Nurse Practitioner

s11C(1)(a)

15 DEC 2020

5. Declaration

Name	MADELINE HALL		
Signature	s11C(1)(a)		
	Date	15/12/2020	

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.

Madeline Hull
Nurse Practitioner

15 DEC 2020

s11C(1)(a)



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Annual declaration of interests

For members of TGA statutory advisory committees

Member name	Rosemary Ffrench
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: conflicts of interest and confidentiality obligations](http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
None	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

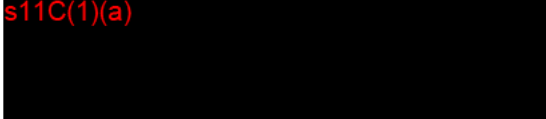
Section 4. Other interests not required to be listed above but that could give rise to an obligation of disclosure to the Committee

Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> 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.

<p>Director, Cobaw Community Health</p> <p>Executive Manager, Clinical and Research Services, National Serology Reference Laboratory, St Vincent's Institute (0.8FTE)</p> <p>Principal Fellow, Burnet Institute (0.1FTE)</p> <p>Adjunct Associate Professor, Monash University, Department of Immunology and Pathology</p> <p>Chief Investigator, NHMRC Development grant - Development of a rapid point of care test for sepsis</p> <p>Chief Investigator, Burnet Doherty Consortium – Development of serology assays for COVID-19</p> <p>Sponsorship provided by Seqirus/CSL for Australasian Vaccines and Immunotherapeutics Development conference (2018, 2020) – funding to support holding the conference and for awards – no direct financial benefit to A/Prof Ffrench.</p>

5. Declaration

Name	Rosemary Ffrench		
Signature		Date	1.1.2021

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.



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Annual declaration of interests

For members of TGA statutory advisory committees

Member name	Vicky Sheppeard
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.

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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: conflicts of interest and confidentiality obligations](http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Section 3. Non-pecuniary interests

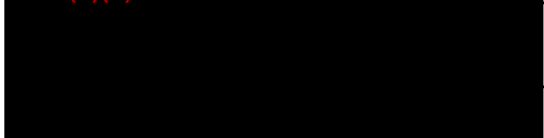
Interest	Myself	Immediate family or other relationship (of which you are aware)
Nil	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

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)
Nil	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> 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.

5. Declaration

Name	Vicky Sheppard s11C(1)(a)		
Signature		Date	17 December 2020

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.



This form, when completed, will be classified as 'For official use only'.
 For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at
<http://www.tga.gov.au/about/tga-information-to.htm>.

Annual declaration of interests

For members of TGA statutory advisory committees

Member name	JEANINE BYGOTT
Committee name	ADVISORY COMMITTEE ON VACCINES

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: conflicts of interest and confidentiality obligations can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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.

Non-pecuniary interests

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.

If 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.

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 **ception 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 your 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.

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,

I now.

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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Section 3. Non-pecuniary interests


Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.

5. Declaration

Name	JEANINE BYGOTT		
Signature		Date	30/12/20.9

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.



Australian Government
Department of Health
 Therapeutic Goods Administration

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<http://www.tga.gov.au/about/tga-information-to.htm>

Annual declaration of interests

For members of TGA statutory advisory committees

Member name	Allen Cheng
Committee name	Advisory Committee for Vaccines

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: conflicts of interest and confidentiality obligations](http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: Conflicts of interest and confidentiality obligations*.

Document 31
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)

Document 31

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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

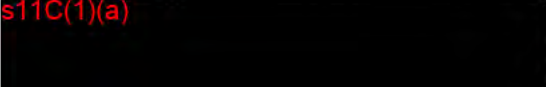
Section 4. Other interests not required to be listed above but that could give rise to an obligation of disclosure to the Committee

Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.

Investigator in REMAP-CAP trial (testing multiple registered medications for the treatment of pneumonia). Board member (and President Elect) of the Australasian Society for Infectious Diseases. My institution has received funding from Janssen, Roche and Merck to recruit participants in clinical trials; I did not receive any funding personally, either directly or indirectly, for participation and am not involved in the design or reporting of these trials.

5. Declaration

Name	Allen Cheng		
Signature		Date	4/5/2020

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.



Australian Government
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TGA use only

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For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <http://www.tga.gov.au/about/tga-information-to.htm>.

Annual declaration of interests

For members of TGA statutory advisory committees

Member name

Prof Lisa Nissen

Committee name

Advisory Committee on Vaccines

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: conflicts of interest and confidentiality obligations](#) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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	No	No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	No	No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	No	No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	No	No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	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
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	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.	No	No
i. Significant hospitality in the last 3 years.	No	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.	No	No
k. Other pecuniary interests	No	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
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	Yes	No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	No	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
e. Other professional interest.	Yes	No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
nil	No	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)
nil	No	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.

Membership/boards: Interim Pharmacy Round Table (QLD Health) (current), Vaccination Technical Working Group (QLD Health) (current), AHPRA Scheduled Medicines Expert Committee (current), Australian Pharmaceutical Formulary Advisory Board (current), Advancing Practice Advisory Board (current), Pharmacy Practitioner Development Advisory Committee (current), Hepatitis Queensland (Board Member - non-exec until June 2018), Pharmaceutical Society of Australia (QLD) Branch Committee (Past president, finished 2017), Podiatry Board of Australia Scheduled Medicines Expert Committee (Past - finished 2017), Optometry Board of Australia Scheduled Medicines Expert Committee (Past - finished 2017), Family Planning QLD Board (Past - finished 2014), National E-Health Transition Authority – Stakeholder Reference Forum (SRF): Medicine Management (Past - finished 2014)

Paid: Queensland University of Technology, AHPRA (sitting fee for expert committees)

Grants: Research Funding Partnership (QLD Health) Urinary Tract Infection Pilot, Vanguard Grant (Heart Foundation)

Professional interests: Abbvie Biopharmaceuticals - HCV Community Pharmacy Advisory Board (2015) - advice on development of pharmacy education program as part of access changes to HCV medications. Non-remunerated position

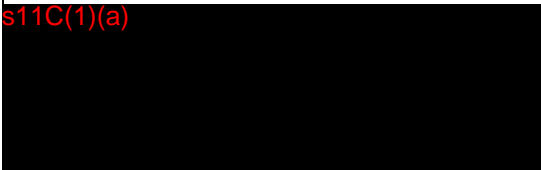
Medreleaf Australia (Medicinal Cannabis) (2017 - current) - Research and Education Advisor for health professional education program. Non-remunerated position

Vanguard Grant - Heart Foundation (2017 - current) - investigation of medication literacy in diabetes patients with cardiovascular risk

Research Partnership (QLD Health) Urinary Tract Infection Pilot (current) - Community Pharmacists providing UTI treatment

(Other advisory roles / boards listed above)

5. Declaration

Name	Prof Lisa Nissen		
Signature	 s11C(1)(a)	Date	10/1/2020

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.



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Annual declaration of interests

For members of TGA statutory advisory committees

Member name	Diane Walsh
Committee name	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: conflicts of interest and confidentiality obligations](http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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)
s47F Director – NT PHN - Chair	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.

s47F Director – NT PHN - Chair As listed above
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5. Declaration

Name	Diane Walsh		
Signature	s11C(1)(a)	Date	3/2/2020

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.



Australian Government
 Department of Health
 Therapeutic Goods Administration

TGA use only

This form, when completed, will be classified as 'For official use only'.

For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <http://www.tga.gov.au/about/tga-information-to.htm>.

Annual declaration of interests

For members of TGA statutory advisory committees

Member name	Adrienne Torda
Committee name	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: conflicts of interest and confidentiality obligations](http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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)
Clinical evaluator for TGA	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.

5. Declaration

Name	Adrienne Torda		
Signature	s11C(1)(a)	Date	8/3/2020

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.



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<http://www.tga.gov.au/about/tga-information-to.htm>.

Annual declaration of interests

For members of TGA statutory advisory committees

Member name

Kristine Macartney

Committee name

Advisory Committee on Vaccines

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: conflicts of interest and confidentiality obligations](#) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.

<p>2d. Director of the Australian National Centre for Immunisation</p>
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5. Declaration

Name	Kristine Macartney		
Signature		Date	09/04/2020

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.



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<http://www.tga.gov.au/about/tga-information-to.htm>.

Annual declaration of interests

For members of TGA statutory advisory committees

Member name	Professor James (Jim) Buttery
Committee name	ACV Meeting

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; conflicts of interest and confidentiality obligations](#) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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)
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.

2b - was president of WSPID to Dec 2017 with industry (vaccine manufacturer) sponsorship of our biannual scientific congress.

2c - PI on sponsored ^{vaccine} trials for Janssen (RSV), GSK (RSV), Seqirus (Flu), Merck (pneumococcal). No payment to me.

2d - my research is in vaccine safety, predominantly post licensure

5. Declaration

Name	Professor James (Jim) Buttery		
Signature	s11C(1)(a)	Date	15 APR 2020



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<http://www.tga.gov.au/about/tga-information-to.htm>.

Annual declaration of interests

For members of TGA statutory advisory committees

Member name	MADLINE HALL
Committee name	ADVISORY COMMITTEE ON VACCINES

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: conflicts of interest and confidentiality obligations](http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: Conflicts of interest and confidentiality obligations*.

Document 87
These rules are designed to minimise any risk that the consideration of any matter by the committee or 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) Document 37

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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.

5. Declaration

Name	MADELINE HALL		
Signature	s11C(1)(a)	Date	09/04/2020

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.



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Annual declaration of interests

For members of TGA statutory advisory committees

Member name	A/Prof Rosemary Ffrench
Committee name	Advisory Committee on Vaccines

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: conflicts of interest and confidentiality obligations](http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Section 3. Non-pecuniary interests

Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

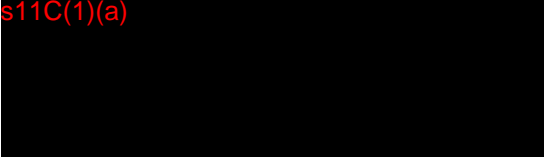
Section 4. Other interests not required to be listed above but that could give rise to an obligation of disclosure to the Committee

Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.

<p>Board Membership, Director, Cobaw Community Health</p> <p>Employers; National Serology Reference Laboratory (NRL), St Vincent's Institute of Medical Research; Burnet Institute</p> <p>As Principal Scientist of NRL, have executive involvement in the development of QC and QA products registered by the TGA. NRL is also accredited by TGA as a GMP facility for manufacture of blood products, cells, and tissues</p> <p>Conference sponsorship; Australasian Vaccines and Immunotherapeutics Development, CSL, Seqirus (no direct financial benefit)</p> <p>NRL Annual Scientific Workshop, IVD manufacturers including Abbott, Roche, Diasorin (no direct financial benefit)</p>
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5. Declaration

Name	A/Prof Rosemary Ffrench		
Signature	 s11C(1)(a)	Date	01.01.2020

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.



Australian Government
 Department of Health
 Therapeutic Goods Administration

TGA use only

This form, when completed, will be classified as 'For official use only'.

For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <http://www.tga.gov.au/about/tga-information-to.htm>.

Annual declaration of interests

For members of TGA statutory advisory committees

Member name	Vicky Sheppeard
Committee name	Advisory Committee on Vaccines

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: conflicts of interest and confidentiality obligations](http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations) can be found on the TGA website. (<http://www.tga.gov.au/publication/conflicts-interest-and-confidentiality-obligations>)

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 meeting¹. 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.

¹ More information can be found in the *TGA Advisory Committee Guidelines: 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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Current shareholding through an unlisted managed fund or trust, if the member could significantly influence investment decisions	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Other sources of funds or other benefits or advantage (including partnerships and trusts)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Ownership of a patent for a therapeutic good or ownership of such a patent by employer	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Board memberships (executive or non-executive) or other offices in a company in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
g. Grants for overseas travel, research or education or paid conference expenses in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
i. Significant hospitality in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
k. Other pecuniary interests	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
b. Accepting sponsorship of an event or for a professional organisation from such a company or organisation in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
c. Participation in a clinical trial (whether as a principal investigator, contributor of patients or otherwise) in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
d. Involvement as a researcher or in any other capacity in relation to therapeutic goods or their development in the last 3 years.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
e. Other professional interest.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Section 3. Non-pecuniary interests

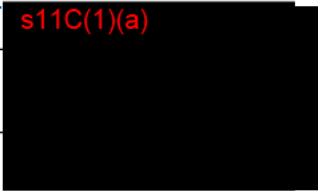
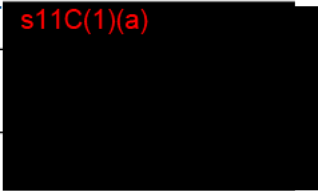
Interest	Myself	Immediate family or other relationship (of which you are aware)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

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)
	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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.

5. Declaration

Name	Vicky Sheppard s11C(1)(a) 		
Signature		Date	27 April 2020

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.