



# **INDEPENDENT REVIEW**

## **PHARMACEUTICAL BENEFITS SCHEME**

### **Conflict of Interest Guidelines and Declaration for Prospective Reviewers**

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#### **Eligibility**

A person who currently has a direct shareholding in, or directorship of, a company which has a drug or medicinal preparation (hereafter “drug”) listed on the Pharmaceutical Benefits Scheme (PBS), or in a company which is likely to be the innovator, or the sponsor of a drug which will be submitted for the consideration of the Pharmaceutical Benefits Advisory Committee (PBAC) within the next two years may not be added to the Register of Prospective Reviewers or appointed as a reviewer to the Independent Review (PBS).

In addition a person who is part of, or who has been part of a PBAC external Evaluation Group, or a staff member of, or a contractor to, such a group may not be appointed as the reviewer if that Evaluation Group was involved in preparing any evaluation for the PBAC or its sub-committees of the drug in question.

#### **Conflict of Interest**

A conflict of interest arises where there is a reasonable concern that a person’s performance of his or her duties in one capacity may be affected by other interests. This may be found where a person has an interest of their own in a matter which may affect or be perceived to affect their obligations in undertaking a review. A conflict may also exist where a person has a duty or loyalty to a person or organisation which may affect or be perceived to affect his or her obligations as a reviewer.

It is not necessary to show that the person's performance is affected, but only that there is a conflict between the two sets of interests. So, for example, a reviewer may be adamant that a direct shareholding in a pharmaceutical company would not affect his or her ability to review a drug manufactured by that company or another company, and indeed their objectivity may not be impaired in the slightest, but the fact that there are two competing interests is what is relevant in determining the existence of a conflict, notwithstanding that the reviewer is able to disregard one of those interests.

The existence of a conflict of interest may not automatically result in a prospective reviewer’s disqualification to be considered to be a reviewer. Certain types of conflict are regarded as incompatible with the Independent Review (PBS), such as current shareholdings or directorships in pharmaceutical companies. In some cases, where the conflict is negligible, disclosure alone may be sufficient.

The level of conflict which will be acceptable in any given set of circumstances is a matter for the Convenor but given the sensitivity of issues being considered by the Independent Review (PBS) the Convenor will generally adopt a conservative approach. If there is any doubt as to whether or not a conflict of interest exists, persons should err on the side of disclosure of interests.

## **Reviewer Conflict of Interest Declarations**

Prospective reviewers are in the first instance requested to complete and return the *Prospective Reviewer Conflict of Interest Declaration* at Attachment A. This declaration will be securely kept with your Expression of Interest to be a reviewer and will be used to add you to the Register of Prospective Reviewers. This register will be used by the Convenor to contact and select a reviewer after an application for review has been lodged with the Office of the Independent Review (PBS).

At the time when a reviewer is being considered to undertake a review (s)he will be asked to complete the more detailed *Reviewer Conflict of Interest Declaration* at Attachment B. This declaration is more detailed and includes questions on the personal interests of a prospective reviewer in relation to the particular drug which is subject to review.

### **Types of Interests to be considered**

The conflict of interest declarations ask for prospective reviewers to provide information on three types of interests as discussed below:

- Pecuniary interests;
- Professional interests; and
- Personal interests.

### **Pecuniary Interests**

*Pecuniary interests* may be direct or indirect, and concern the actual and potential interests a person or that person's immediate family may have for material gain from companies or organisations involved in or associated with the development, manufacture, marketing or distribution of drugs.

Pecuniary interests include but are not limited to interests that a person may have or may have had in relation to a person or organisation that:

- has a drug or medicinal preparation listed on the PBS;
- has applied to have such a product listed on the PBS;
- may submit a product to the PBAC for consideration in the next two years.

The relevant interests include but are not limited to:

- shares, directorships, partnerships;
- any type of paid work or consultancy that has been completed or is currently being undertaken or that may potentially be performed in the future;
- current or the past receipt of funding for conference and/or travel expenses;
- past or present hospitality of any kind.

Current interests in managed funds must also be declared if they have a particular focus on the health sector and/or the pharmaceutical industries or if there is a degree of knowledge or control over the holdings of the fund.

### **Professional interests**

*Professional interests* include situations where a person or that person's immediate family have no present pecuniary interest, but have a professional interest in companies or organisations involved in or associated with the development, manufacture or marketing of drugs.

Examples of professional interests include but are not limited to situations in which there is or there has been an investment in the success of a drug or the validity of a process such as involvement in:

- clinical trials;
- research and development;
- consulting or advising;
- investigations;
- evaluations.

An example might be where a reviewer has conducted an evaluation of a drug in the past in which the reviewer stands to make no money from the product but may be perceived as having a professional interest in defending the validity of the evaluation.

Where a conflict may arise from work that the reviewer has previously undertaken, the reviewer must provide details of all work done, the sponsoring company, the drug or medicinal preparation, the indication/s worked on, when the work commenced and when the work finished.

### **Personal interests**

Information about personal interests is requested at the *Reviewer Conflict of Interest Declaration* at Attachment B when a prospective reviewer is being considered to undertake a particular review.

*Personal interests* include any non-pecuniary interest which may conflict, or give the appearance of being in conflict with a reviewer's obligations in undertaking a review. This may occur in situations in which a person or that person's immediate family may be perceived to have personal reasons for their approach to a drug or issue.

Examples of personal interests include but are not limited to situations in which a reviewer or a person that is close to that reviewer:

- suffers from a condition which may be treated by the drug subject to review or a rival of this product;
- has involvement in an interest group whose activities may impact on the PBAC's or the Independent Review (PBS) sphere of reference;
- where a reviewer has strong personal beliefs about a certain type of product or therapy.

### **Conflict of Interest arising after a reviewer's appointment**

If a reviewer finds that he or she has a new or potential direct or indirect pecuniary interest, or other conflict or potential conflict of interest, in a matter that is being considered or is to be considered on a review, the reviewer must notify the interest to the Convenor of the Independent Review (PBS) and may not further proceed with the review unless the Convenor consents to the reviewer proceeding with the work needed for that particular review.

### **Records**

Declaration, disclosures, agreements, consents and exclusions arising out of correspondence and/or discussions will be formally recorded and kept on file by the Convenor of the Independent Review (PBS). These may be accessed by the Commonwealth and other agencies for audit and accountability purposes. The storage of this information will be in accordance with the Information

Privacy Principles (IPPs) under the *Privacy Act 1988* (Cth). Further information about the IPPs can be found at <http://www.privacy.gov.au/publications/ipps.html>

## Independent Review (PBS) Register of Prospective Reviewers

### PROSPECTIVE REVIEWER CONFLICT OF INTEREST DECLARATION

I acknowledge that I have read and understood the information contained above in the *Independent Review (PBS) Conflict of Interest Guidelines and Declaration for Prospective Reviewers*. I understand that this declaration will form part of the records of the Register of Prospective Reviewers being kept and maintained by the Convenor of the Independent Review (PBS).

Particulars of my pecuniary and professional interests and those of my immediate family, of which I am aware, are set out below.

I hereby declare the following pecuniary and professional interests of myself and my immediate family:

#### Type of Interest

<b>(a) Pecuniary interests in companies or organisations involved in or associated with the development, manufacture, marketing or distribution of drugs and medicinal preparations such as:</b>	<b>Myself</b>	<b>Immediate Family</b>
Current shareholdings	No/Yes	No/Yes
Current holdings in managed funds which have a particular focus on the field of the health and/or pharmaceutical industries or if there is a degree of knowledge or control over the holdings of the fund	No/Yes	No/Yes
Current indirect or beneficial interests in a company or organisation or in a trust which holds shares or investments in such a company or organisation	No/Yes	No/Yes
Past, present or potential future directorships, board memberships or other offices	No/Yes	No/Yes
Past, present or potential future paid employment or contracting work, including consultancies, commissions, presentations and advising work, whether as an individual or on behalf of another organisation or person	No/Yes	No/Yes
Past, present or potential future funding for research, education or sponsorships	No/Yes	No/Yes
Other	No/Yes	No/Yes
<b>(b) Grants or funding of any kind from companies or organisations involved in or associated with the development, manufacture, marketing or distribution of drugs and medicinal preparations</b>	<b>Myself</b>	<b>Immediate Family</b>
For travel or conference expenses in the last 7 years	No/Yes*	No/Yes*
For travel or conference expenses in the period prior to the last 7 years. If Yes, please <b>summarise</b> the nature of the grant/s or funding received in this time period.	No/Yes*	No/Yes*

<b>(c) Hospitality of any kind received from companies or organisations involved in or associated with the development, manufacture, marketing or distribution of drugs and medicinal preparations</b>		
Valued at \$1,000 or more which has been received at any time	No/Yes*	No./Yes*
Valued at less than \$1,000 which has been received in the last 7 years. If Yes, please <b>summarise</b> the nature of the hospitality received in this time period.	No/Yes*	No/Yes*
<b>(d) Professional interests of any kind in or associated with the development, manufacture or marketing of drugs and medicinal preparations or the validity of a process such as involvement in:</b>	<b>Myself</b>	<b>Immediate Family</b>
Current or past research and development	No/Yes*	No/Yes*
Current or past clinical trials	No/Yes*	No/Yes*
Current or past advising, consulting or investigations	No/Yes*	No/Yes*
Current or past evaluations (including work for or being part of a PBAC Evaluation Group)	No/Yes*	No/Yes*
Other	No/Yes*	No/Yes*

\*If you have answered 'yes' in parts (b) or (c) above, please give the required details, including the organisation, the type of grant, funding or hospitality received, and if it was received by you or your immediate family. Please attach additional pages if necessary.

If you have answered 'yes' in part (d) above, please give details, including the type of interest, the organisation and whether the interest is or was held by yourself or your immediate family. Please attach additional pages if necessary.

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Dotted lines for text entry

**Prospective Reviewer**

**Witness**

NAME.....

NAME.....

Signature.....

Signature.....

Date.....

Date.....

## Independent Review (PBS)

### REVIEWER CONFLICT OF INTEREST DECLARATION

I acknowledge that I have read and understood the information contained above in the *Independent Review (PBS) Conflict of Interest Guidelines and Declaration for Reviewers*.

Particulars of my pecuniary, professional and personal interests and those of my immediate family, of which I am aware, are set out below. I acknowledge that this is more detailed and updated declaration to the *Prospective Reviewer Conflict of Interest Declaration* that I completed previously and have declared all interests including those interests that are still current that I declared in the earlier declaration.

I am aware that it is a condition of the *Contract in relation to Services for the Independent Review (PBS)* that a reviewer must notify the Convenor of the Independent Review (PBS) should a situation arise where an interest of mine, which includes any interest of a member of my immediate family, whether pecuniary or otherwise, is in conflict, has the potential to be in conflict, or might be perceived to be in conflict with my duty as a reviewer to the Independent Review (PBS).

I hereby declare the following pecuniary, professional and personal interests of myself and my immediate family:

#### Type of Interest

<b>(a) Pecuniary interests in companies or organisations involved in or associated with the development, manufacture, marketing or distribution of drugs and medicinal preparations such as:</b>	<b>Myself</b>	<b>Immediate Family</b>
Current shareholdings	No/Yes*	No/Yes*
Current holdings in managed funds which have a particular focus on the field of the health and/or pharmaceutical industries or if there is a degree of knowledge or control over the holdings of the fund	No/Yes*	No/Yes*
Current indirect or beneficial interests in a company or organisation or in a trust which holds shares or investments in such a company or organisation	No/Yes*	No/Yes*
Past, present or potential future directorships, board memberships or other offices	No/Yes*	No/Yes*
Past, present or potential future paid employment or contracting work, including consultancies, commissions, presentations and advising work, whether as an individual or on behalf of another organisation or person	No/Yes*	No/Yes*
Past, present or potential future funding for research, education or sponsorships	No/Yes*	No/Yes*
Other	No/Yes*	No/Yes*



<b>(b) Grants or funding of any kind from companies or organisations involved in or associated with the development, manufacture, marketing or distribution of drugs and medicinal preparations</b>	<b>Myself</b>	<b>Immediate Family</b>
For travel or conference expenses in the last 7 years	No/Yes*	No/Yes*
For travel or conference expenses in the period prior to the last 7 years. If Yes, please summarise the nature of the grant/s or funding received in this time period.	No/Yes*	No/Yes*
<b>(c) Hospitality of any kind received from companies or organisations involved in or associated with the development, manufacture, marketing or distribution of drugs and medicinal preparations</b>		
Valued at \$1,000 or more which has been received at any time	No/Yes*	No./Yes*
Valued at less than \$1,000 which has been received in the last 7 years. If Yes, please summarise the nature of the hospitality received in this time period.	No/Yes*	No/Yes*
<b>(d) Professional interests of any kind in or associated with the development, manufacture or marketing of drugs and medicinal preparations or the validity of a process such as involvement in:</b>	<b>Myself</b>	<b>Immediate Family</b>
Current or past research and development	No/Yes*	No/Yes*
Current or past clinical trials	No/Yes*	No/Yes*
Current or past advising, consulting or investigations	No/Yes*	No/Yes*
Current or past evaluations (including work for or being part of a PBAC Evaluation Group)	No/Yes*	No/Yes*
Other	No/Yes*	No/Yes*
<b>(e) Personal interests such as:</b>	<b>Myself</b>	<b>Immediate Family</b>
Medical condition for which the drug or treatment subject to review or a rival product	No/Yes*	No/Yes*
Strong personal beliefs about the drug or treatment subject to review or a rival product	No/Yes*	No/Yes*
Other	No/Yes*	No/Yes*

\*If you have answered ‘yes’ to any item above, please give details, including the type of interest, the organisation and whether the interest is held by you or by your immediate family. Please attach additional pages if necessary.

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