



INDEPENDENT REVIEW

PHARMACEUTICAL BENEFITS SCHEME

Responsibilities of the Convenor in the Engagement and Remuneration of Reviewers

The Convenor must ensure that independent and suitable reviewers are engaged in an efficient manner according to these guidelines. The strict application of these guidelines will ensure that reviews are professionally and independently conducted and that this is recognised and accepted by all stakeholders.

Timeframes

It is essential that the Convenor acts in a timely and efficient manner as per the *Timelines for the Independent Review (PBS)* to select and contract an independent and qualified reviewer.

Preparation for Reviews

The Convenor is required to establish, maintain and manage a suitable pool of prospective reviewers for the Independent Review (PBS) including:

- the Register of Prospective Reviewers which includes Expressions of Interest (EOI) and Conflict of Interest documentation received from prospective reviewers;
- advertising to increase the number of prospective reviewers available;
- advertising to ensure that there are sufficient prospective reviewers available from the various fields of expertise including, but not limited to:
 - clinical pharmacology;
 - epidemiology;
 - pharmacoepidemiology;
 - health economics;
 - biostatistics; and
 - internal medicine subspecialties.

Independence

An essential criterion for the selection of reviewers is independence. The *Australia-United States Free Trade Agreement (AUSFTA) & the Pharmaceutical Benefits Scheme (PBS) Statement on the Implementation of Australia's AUSFTA Commitments* by the Minister of Health and Ageing in February 2005 states that the independent review process will be independent of the sponsor, the Pharmaceutical Benefits Advisory Committee (PBAC) and of the staff of, or contractors of the Department of Health and Ageing (the Department).

The *Independent Review (PBS) Conflict of Interest Guidelines and Declaration for Prospective Reviewers* document sets out clear guidelines and examples of potential conflicts of interest. This document also contains the *Prospective Reviewer Conflict of Interest Declaration* and the *Reviewer Conflict of Interest Declaration*. The Convenor is required to utilise this documentation and undertake a full and proper assessment of a prospective reviewer's declaration to ensure independence and preclude any conflict of interest prior to contractual arrangements being entered into with a particular reviewer.

If a reviewer informs the Convenor during the course of a review that a conflict has arisen in regard to a matter that is being considered or is to be considered in the review, the Convenor must undertake a full and proper assessment of the conflict and determine what action, if any, needs to be taken in the circumstances.

All *Conflict of Interest Declarations* and any disclosures, consents, agreements, and exclusions arising out of correspondence and/or discussions relating to conflict of interest and the Declaration must be recorded and kept on file by the Convenor.

It may also be appropriate to undertake independent research on prospective reviewers to ascertain if there is information on the public record that has not been made known to the Convenor or staff of the Independent Review (PBS). Discussions with potential reviewers will also assist in determining independence.

Relevant Expertise

The second essential criterion for the selection of reviewers is recognised expertise in the issue(s) in dispute as identified in a Sponsor's application for review.

The Convenor is required to consider the Expressions of Interests (EOI) that the Independent Review (PBS) has received from experts in the relevant disciplines. If there are difficulties in finding a reviewer with the required expertise the Convenor may seek advice from the Contract Manager on ways forward including details on suitability qualified persons that the Department has on its panels.

If a suitable reviewer cannot be identified, it may be useful to approach academic institutions such as:

- School of Population Health, Program Evaluation Unit, University of Melbourne;
- Centre for Health Economics, Monash University;
- Discipline of Clinical Pharmacology, School of Medical Practice and Population Health, University of Newcastle;
- School of Economics, University of New South Wales;
- Pharmaceutical Medicine and Drug Development Program, University of New South Wales;
- Centre for Health Economics Research Evaluation (CHERE), University of Technology, Sydney; and
- Victorian College of Pharmacy.

This list is not exhaustive.

In addition it may be useful where specialist clinical advice is required to approach the Royal Australasian College of Physicians, or other specialist colleges as appropriate.

It should be noted that because of the nature of the work involved in preparing or evaluating submissions to PBAC, persons with the most appropriate expertise may not necessarily have an extensive publication record or hold a senior academic position. A degree in a relevant related discipline combined with appropriate experience may provide relevant expertise.

Care needs to be taken in considering the engagement of representatives from specific disease-related interest groups as these organisations may have an interest in the outcome of the review and may be funded by the pharmaceutical industry.

Use of Secondary Reviewers

In circumstances in which there are disparate issues in contention or if a reviewer identifies issues subject to review that s/he believes are outside his or her areas of expertise, the Convenor may decide to contract a Secondary Reviewer. In such instances the Convenor must ensure that the Secondary Reviewer works in conjunction with, and not independently of, the Primary Reviewer, who will retain the overall responsibility for the timely delivery of the review.

Contract Management

The Convenor is responsible for organising the contractual arrangements with reviewers and for contract management during the course of reviews.

In finalising the arrangements to engage a selected reviewer the Convenor must use the *Contract in relation to Services for the Independent Review (PBS)* (the reviewer contract) and the relevant timeframes contained in *Timelines for the Independent Review (PBS)*.

The Convenor may not change the clauses of the reviewer contract without the prior approval of the Contract Manager. The Convenor must only make the necessary insertions and changes to the Schedule Items of the reviewer contract to specify details relevant to the particular review. The Contractor must not make major or substantive changes to the Schedule Items contained in the reviewer contract without the prior approval of the Contract Manager.

The remuneration of the reviewer will be determined by the Convenor, up to a maximum amount, as determined from time to time by the Secretary of the Department of Health and Ageing.