



INDEPENDENT REVIEW

PHARMACEUTICAL BENEFITS SCHEME

Responsibilities of the Convenor in the Conduct of Reviews under the Independent Review (PBS)

The Convenor of the Independent Review (PBS) (“Convenor”) must ensure the efficient operation of a Review and that the Reviewer performs the services required in compliance with the *Contract in relation to Services for the Independent Review (PBS)* including:

Timeframes

The Convenor is responsible for ensuring that Reviews are conducted in a timely manner in which there is no incentive, or disincentive, for Sponsors to seek a Review in preference to making a resubmission to the Pharmaceutical Benefits Advisory Committee (PBAC). In particular, the Convenor must ensure that Reviews are finalised and reconsidered at the second PBAC meeting following the meeting at which the application was rejected if a duly completed *Independent Review (PBS) Request Form* (“IRR Form”) is received from the Sponsor by COB on the Friday of the seventh week of the PBAC cycle after the relevant PBAC meeting.

If an IRR Form is received later than this time the findings of the Review must be reconsidered at a later PBAC meeting in accordance with the *Timelines for the Independent Review (PBS)*.

The Convenor must ensure that Reviews are conducted and completed in accordance with the *Timelines for the Independent Review (PBS)* and that sufficient time is allowed at the end of the Review for the *Final Review Report* to be considered by a PBAC Sub-Committee (if applicable) and for the Sponsor to have the opportunity of providing a Pre-Committee (if applicable) and/or a Pre-PBAC response.

Independence

The Convenor must ensure that the Independent Review (PBS) is independent of Sponsors, PBAC, the Department and its staff and/or contractors.

No new Information or Evidence

The Convenor must ensure that no new information or evidence on the drug or medicinal preparation (“drug”) subject to Review, beyond that which was considered by the PBAC, is accepted by the Independent Review (PBS).

In circumstances where Reviewers conduct literature searches during the Review process, the Convenor must ensure that the body of literature will not constitute new and additional information not considered by PBAC. This literature may form part of the body of knowledge and expertise required for the Reviewer to conduct the Review.

Steps in the Conduct of Reviews

(a) Compliance of Review Applications

The Convenor is responsible for:

- (i) ensuring that each application for Review relates to a drug in respect of which the PBAC has declined to:
 - (a) make a recommendation to list on the PBS; or
 - (b) recommend an extension of the listing of an already listed drug. In these circumstances PBAC must have identified the submission as eligible for Review in accordance with the eligibility requirements in Attachment A of the document *Information for Applicants Seeking Independent Review (PBS)*.
- (ii) ensuring that an application for Review is submitted by the Sponsor to the Independent Review (PBS) on the IRR Form;
- (iii) ensuring that an IRR Form received by the Convenor is fully completed, signed by a representative of the Sponsor and duly witnessed;
- (iv) notifying the Sponsor of any deficiencies in the information provided on the IRR Form and requesting that these be rectified;
- (v) rejecting a Review application if a deficiency in the information provided on an IRR Form is not rectified by the Sponsor;
- (vi) ensuring that the IRR Form sufficiently identifies the issue(s) the subject of the Review application and that the issue(s) reflects one or more of the PBAC's reasons for not recommending the listing or the extension of the listing of the drug on the PBS;
- (vii) rejecting a Review application if the IRR Form does not sufficiently identify the issue(s) that are to be the subject of the Review application and/or if the issue(s) put forward by the Sponsor do not reflect the PBAC's reasons for not recommending the listing or the extension of the listing of the drug on the PBS; and
- (viii) notifying both the Sponsor and the Department of Health of the Convenor's decision in relation to the eligibility of the Review application.

(b) Selection and Engagement of Reviewers

The Convenor is required to select and engage Reviewers according to the *Responsibilities of the Convenor in the Engagement and Remuneration of Reviewers* and must use the *Independent Review (PBS) Conflict of Interest Guidelines and Declaration for Reviewers*, *Confidentiality Agreement for Reviewers* and the *Contract in relation to Services for the Independent Review (PBS)*.

(c) Efficient and Effective Conduct of Reviews

The Convenor is responsible for ensuring the efficient and effective conduct of Reviews including:

- (i) ensuring that the Reviewer selected to perform the Review does so in compliance with the Contract in relation to Services for the Independent Review (PBS) (the Reviewer contract);
- (ii) using their best endeavours to ensure that the essential timeframes for the completion and delivery of the Reviewer's progress, draft and final reports are met.
- (iii) notifying the name of the Reviewer to the Sponsor and the PBAC Secretariat no later than ten Business Days after the day in which the Reviewer contract is executed;
- (iv) ensuring that there is no direct contact concerning a Review between the Reviewer and:
 - the Sponsor;
 - the Department, its staff and/or contractors (other than the Convenor and staff assisting the Convenor);
 - a member of the PBAC; and
 - any other stakeholder who may be reasonably be expected to have some interest in the outcome of the Review.
- (v) ensuring that a Reviewer addresses the issue(s) identified by the Sponsor in the IRR Form and not the recommendation made by the PBAC;
- (vi) ensuring that all information considered by the PBAC is provided to the Reviewer for consideration; and
- (vii) immediately informing the Contract Manager of any events or circumstances that will or may affect the conduct of a Review and/or the timely completion date of a Review.

(d) Clarification and Assistance

The Convenor will be responsible for resolving any issues raised by a Reviewer during the course of a Review including requests for assistance. This includes requests for clarification on any matter/s relating to a Review or a request for assistance in an area outside the Reviewer's area of expertise.

If a Reviewer makes a request for clarification the Convenor will determine if the request is reasonable and the arrangements necessary to facilitate the Reviewer's request. In such situations the Convenor may determine that a meeting between the Reviewer and the Sponsor and/or the Department or its employees/contractors is necessary to facilitate this clarification. The Convenor must be present in any discussions between the parties by way of telephone conference or in person. The Convenor must ensure that these discussions are documented on file.

Where there are disparate issues in contention or if a Reviewer identifies issues subject to Review that s/he believes are outside his/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.

Completion of Reviews

The Convenor is responsible for ensuring that Reviews conducted under Independent Review (PBS) are completed, including:

- (i) ensuring that the Reviewer completes and delivers the Draft and Final Review Reports on or before the due date specified for this report in the Reviewer contract;
- (ii) providing the Final Review Report to the PBAC Secretariat with a copy to the Sponsor at least seven weeks before the PBAC meeting at which the findings of the Review will be discussed;
- (iii) making arrangements (if necessary) for the Reviewer to present and discuss his or her findings at the meeting of the PBAC at which the PBAC will consider the Final Review Report;
- (iv) requesting a signed tax invoice from the Reviewer and ensuring that the Reviewer's invoice complies with the requirements for invoices in the Reviewer contract; and
- (v) promptly organising payment of the Reviewer's fees on the receipt of a correctly completed invoice in accordance with the Reviewer contract.

Conflict of Interest

If a Reviewer informs the Convenor during the course of a Review that a conflict or a potential conflict has arisen in regard to a matter that is being considered or is to be considered in a Review, the Convenor must:

- (a) immediately inform the Contract Manager and the Sponsor of the possible conflict;
- (b) ascertain the views of both the Contract Manager and the Sponsor to the possible conflict;
- (c) undertake a full and proper assessment of the possible conflict and determine what action, if any, needs to be taken in the circumstances;
- (d) inform the Reviewer, Contract Manager and Sponsor of his or her decision on the possible conflict; and
- (e) inform the Contract Manager and the Sponsor of the actions that have been or will be taken to address the matter.

Termination of Reviewer

If a Reviewer is terminated for any reason under the *Contract in relation to Services for the Independent Review (PBS)*, the Convenor must promptly notify the Contract Manager and the Sponsor:

- (a) that the Reviewer has been terminated pursuant to this contract; and
- (b) the arrangements that the Convenor has made or will put in place to complete and finalise the Review.