



INDEPENDENT REVIEW

PHARMACEUTICAL BENEFITS SCHEME

Instructions for Reviewers and Suggested Template

The purpose of this document is to provide you with guidance on the conduct of the Review which you have contracted to undertake for the Independent Review (PBS).

Independent Review (PBS)

An independent review is available to any applicant whose submission to the Pharmaceutical Benefits Advisory Committee (PBAC) has not resulted in a recommendation to list the drug on the Pharmaceutical Benefits Scheme (PBS), or where the PBAC has declined to recommend an extension of the listing of an already listed drug. Further information on the eligibility requirements for Independent Review is contained in the document *Information for Applicants Seeking Independent Review (PBS)* from the Independent Review (PBS) website at <http://www.pbs.gov.au/info/general/independentreview>.

Conduct of the Review

You are required to consider all available documents, information and other written material relating to the issues in dispute that were made available to the PBAC. No new information beyond that which was provided to the PBAC can be considered by the Review.

You should focus your consideration on the issues identified by the Sponsor and not comment on the recommendation(s) made by the PBAC. The Review will thus function as a 'second look' at the issue(s) in dispute, meaning that the *Final Review Report* is advisory in nature and as such is for the consideration of the PBAC, as well as, if applicable, by the PBAC Drug Utilisation Sub-Committee and/or the PBAC Economics Sub-Committee.

If during the course of the Review you encounter any unforeseen events or circumstances that may or will affect your ability to conduct the Review you should immediately notify the Convenor of the Independent Review (PBS).

Should you believe that clarification is required on any matter/s you should contact the Convenor in the first instance. The Convenor will then determine if, and in what circumstances, clarification will be sought and will make the necessary arrangements to enable this to proceed.

Timelines and Reviewer's Deliverables

The dates stipulated in your *Contract in relation to Services for the Independent Review (PBS)* ('Contract') for the completion and delivery of the progress reports, the *Draft Review Report* and the *Final Review Report* are critical and non-negotiable given the timeframes involved with the PBAC meeting cycle and processes.

You will need to provide the progress reports to the Convenor by email and/or telephone conference by the end of the fifth and tenth weeks of the Review. You will also need to complete and deliver the *Draft Review Report* and the *Final Review Report* by the dates specified in your Contract.

The *Draft Review Report* and the *Final Review Report* require a description on the general process of the

Review and must focus on the specific matters in dispute. Where possible you are encouraged to utilise the *Suggested Template* and the structure and format contained therein to record your findings. Any person(s) consulted in the context of the Review will need to be identified in the *Draft Review Report* and *Final Review Report*.

Reviewer's attendance at the PBAC

The *Final Review Report* will be provided to the PBAC who will reconsider the Sponsor's original application in light of the Review findings. The Sponsor will also be asked to provide comments on your findings to the PBAC. To facilitate this process you may be asked to attend a PBAC meeting to present and discuss your findings.

You will be contacted by the Convenor if you are required to present and discuss your findings at the PBAC meeting. At this time the Convenor will also provide you with details on the PBAC meeting and travel arrangements.

Professional and Confidentiality requirements

Under the Contract, you must undertake the Review with the upmost professional skill, competence, care and diligence. As part of this requirement you must ensure the confidentiality and security of all the material that is supplied to you, and produced by you, as part of the Review.

As a Reviewer, you should be aware that the Sponsor will be informed of your identity once you have agreed to undertake the Review and have signed the Contract. *Under no circumstances should you initiate contact with the Sponsor, Department or another party. The Sponsor should not under any circumstances contact you directly. If you are contacted by a Sponsor or another party you should immediately notify the Convenor.*

You are reminded that you are not permitted to publicly discuss the Review, the Review process or the selection process for Reviewers.

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.

If, during the course of the Review you believe you have acquired a direct or indirect pecuniary interest, or other conflict of interest, in a matter that is being considered, you must immediately notify the interest to the Convenor and you should not proceed further with the Review unless, or until, you receive the approval of the Convenor.

Secondary Reviewers

Where there are disparate issues in contention or if a Reviewer identifies issues subject to review that she/he believes are outside his/her areas of expertise, the Convenor may at his/her absolute discretion decide to contract a Secondary Reviewer. If a Secondary Reviewer is appointed, that person will be required to work in conjunction with, and not independently of, you as the Reviewer.

If a Secondary Reviewer is appointed you will continue to have overall responsibility for the Review and will have some additional responsibilities. In particular you will be required to ensure the quality and completion of the Secondary Reviewer's deliverables and provide feedback and comments to the Secondary Reviewer on these deliverables as appropriate. You will also be expected to incorporate and summarise the findings of the Secondary Reviewer into the *Final Review Report* and make the Secondary Reviewer's *Final Report* an attachment to the *Final Review Report*. Further information about these additional responsibilities is contained in the Contract.



INDEPENDENT REVIEW
PHARMACEUTICAL BENEFITS SCHEME
Review Report Suggested Template

DRUG FORM – MAIN INDICATION

INDEPENDENT REVIEW BY **{REVIEWER’S NAME AND HONORIFICS}**

Requested PBS listing: {as per documents to the PBAC}

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
{AUSTRALIAN APPROVED NAME}	{n}	{n}	\$.{}	{Brand name} {Sponsor}
{Forms(s)} {strength(s)}				

{Section 100 {specify program}} {Authority required} {Restricted benefit} {Unrestricted}
 {Wording of any restriction as in submission}

Scope of the Review

[List the specific matters identified for the Review.]

- []
- []
- [], etc

Findings of the Review

- Matter 1
- Reviewer’s summary of finding(s), etc
- Matter 2 (if applicable)
- Reviewer’s summary of finding(s), etc

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{Target month} 201{ } PBAC meeting

DESCRIPTION OF THE REVIEW

Details of the Reviewer

Name: [(with full honorifics)]

Work title (if relevant): []

Timing of Review

Review commenced: [the date the contract is signed by the Convenor of the Independent Review (PBS) and the Reviewer].

Review finalised: [the date the Reviewer lodged the Review for PBAC consideration with the Convenor of the Independent Review (PBS)].

Scope of the Review

[List the specific matters identified for the Review.]

- []
- []
- [], etc

General process of the Review

Materials considered: [Specify all documents considered, including the following].

- Submission to the [month] [year] PBAC meeting – describing all parts Reviewed (covering letter, main body, [] volumes of appendices, [] volumes of references, electronic version of the model, etc)
- Pre PBAC documents as relevant, such as PBAC Secretariat Overview, PES Commentary, DUSC Secretariat Commentary, Pre-Sub-Committee Response, ESC Advice, DUSC Advice, RWG Advice, Pre-PBAC Response (not all may exist for a particular submission or be in scope for the Review)
- PBAC documents (“Short Minutes”, “Long Minutes”, “PBAC Outcome”, “Public Summary Document”)
- Request for Independent Review from Sponsor (identify company in full)
- Any other relevant literature considered during the Review (emphasise important papers or types of papers, with a full reference list to be at the end of the Review document)
- Any other documentation of other (agreed) consultations.

Briefly describe the process of the Review, including how you addressed the matters for Review.

If any consultation was agreed with the Convenor to be necessary during the conduct of the Review, for example to (a) recruit and manage a Secondary Reviewer on a matter outside the expertise of the Reviewer, or (b) clarify matters with parties involved in preparing documents previously considered by the PBAC, the following information should be summarised here.

- A summary of the agreed questions defined for each consultation.
- A summary of the methods used to address these questions in each case (eg Secondary Reviewer, face-to-face consultation with defined party(ies) who prepared document(s) considered by the PBAC).

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MATTER(S) FOR REVIEW

(Body of the Review with a separate section starting with a new page for each specific matter in the Review)

First Review matter in scope (title of issue)

- Matter as detailed in applicant's letter requesting Independent Review
- Summary of materials considered by the PBAC relevant to the matter (wherever each material is relevant)
 - Submission (giving source details – page references, tables, etc)
 - PBAC Secretariat Overview
 - PES Commentary
 - DUSC Secretariat Commentary
 - Pre-Sub-Committee Response
 - RWG Advice
 - ESC Advice
 - DUSC Advice
 - Pre-PBAC Response
 - PBAC Minutes
- Reviewer's understanding of the matter to be Reviewed
- Contribution and description of any agreed consultations with any other parties to clarify one or more elements of this matter of the Review – possibilities could include:
 - The Sponsor (details of the individuals, including full details of experts associated with the applicant)
 - The PBAC (Chair and/or any other member authorised by the Chair)
 - The relevant Sub-Committees (Chair and/or any other member authorised by the Chair)
 - The Department (Secretariats to the PBAC or its Sub-Committees)
 - Other content experts on the matter (including full details of all individuals)
 - Others
 - Statement of consultation question(s).
 - Date(s), time(s), venue(s) and individual(s) participating in each consultation.
 - Nature of consultation (face-to-face meeting, email, telephone etc).
 - Results of each consultation.
 - Description of the process to consolidate the input from the consultation(s).
 - Any other details as considered appropriate.
 - Conclusion with a statement of how the consultation(s) contribute to the consideration of this matter of the Review.
- Reviewer's detailed consideration of this matter of the Review, including a discussion presenting the Reviewer's thoughts about this matter of the Review.
- Reviewer's summary of finding(s) on this matter of the Review.

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MATTER(S) FOR REVIEW (Cont'd)

REPEAT, starting with a new page for each of the **second matter for Review, third matter for Review, etc.**

If a Secondary Reviewer is engaged to contribute to the Review, their findings will be incorporated into the *Review Report*. The findings of the Secondary Reviewer will be presented in the same way as the Reviewer. It will be the responsibility of the Reviewer to consolidate the findings of the Review. The Reviewer will provide a detailed consideration of all the issues identified by the Sponsor.

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