



INDEPENDENT REVIEW

PHARMACEUTICAL BENEFITS SCHEME

Instruction for Secondary 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 as a Secondary Reviewer 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 Secondary Review

You have been appointed as a Secondary Reviewer because there are disparate issues in contention and/or because the Reviewer has identified issues that are subject to Review that she/he believes are outside his/her areas of expertise, and the Convenor has decided to appoint a Secondary Reviewer.

As a Secondary Reviewer you are required to work in conjunction with, and not Independent of the Reviewer who will have the overall responsibility for the Review. As part of this arrangement you are required to consider all available documents, information and other written material that the Convenor has provided to you. No new information beyond that which has been provided by the Convenor can be considered by you in your work as a Secondary Reviewer.

You should focus your consideration on the issues identified by the Convenor for your Review and not comment on the recommendation made by the PBAC. The Review will thus function as a 'second look' at the issue(s) in dispute that are within the scope of the Review. This means that your final report is advisory in nature and as such is for the consideration of the PBAC preceded 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.

The following deliverables must be delivered to the Reviewer and copied to the Convenor by the stipulated dates in your *Contract in relation to Services for the Independent Review (PBS)* ('Contract'):

- *Weekly Progress Reports*;
- *Secondary Reviewer's Draft Report*; and
- *Secondary Reviewer's Final Report*.

The Reviewer may provide feedback and comments to you on these deliverables as appropriate. The Reviewer will also incorporate and summarise the findings of your *Final Report* into the *Final Review Report* that she/he is responsible for. The Reviewer will also make your *Final Report* an attachment to the *Final Review Report*.

Further information about your responsibilities as a Secondary Reviewer is contained in your Contract.

Timelines and Reviewer's Deliverables

The dates stipulated in your Contract for the completion and delivery of the progress reports, the *Draft Report* and the *Final Report* are critical and non-negotiable given the timeframes involved with the PBAC meeting cycle and processes.

The Secondary Reviewer's *Draft Report* and the *Final Report* require a description of the general process of the Review and must focus on the specific issues that you are considering as a Secondary Reviewer. Where possible you are encouraged to utilise the *Suggested Template* and the structure and format contained therein to record your findings. Any person(s) that you consult as part of your work as a Secondary Reviewer will need to be identified in your *Draft Report* and *Final Report*.

Secondary Reviewer's attendance at the PBAC meeting

The Secondary Reviewer's *Final Report* will be provided by the Convenor to the PBAC who will reconsider the Sponsor's original application in light of findings from the Review. 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 on the work you completed on the Review.

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 complete the work you are required to undertake for 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 your work for the Review.

You should be aware that the Sponsor will be informed of your identity once you have agreed to be a Secondary Reviewer and have signed the Contract. *Under no circumstances should you initiate contact with the Sponsor, the 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.



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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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