



INDEPENDENT REVIEW

PHARMACEUTICAL BENEFITS SCHEME

Information for Applicants Seeking Independent Review (PBS)

Eligibility

The Independent Review (PBS) has been established as part of Australia's commitments under the Australia-United States Free Trade Agreement (AUSFTA). It 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.

The circumstances in which Independent Review will be available for an additional indication are set out in Attachment A.

Review Process

As is current practice, the opportunity to discuss an unsuccessful submission with the Chair of the PBAC is still available, and such discussions should normally canvass opportunities for resubmission. *It is important to note that there is no temporal incentive or disincentive for a Sponsor to seek an Independent Review in preference to making a resubmission to the PBAC.*

In circumstances in which new information or evidence is likely to be relevant to the PBAC's reconsideration, resubmission must be pursued rather than Review. A Review is based on information which has already been presented to the PBAC. No new information or evidence beyond that considered by the PBAC may be considered in a Review.

Sponsors are required to complete an Independent Review (PBS) Request Form. This is available from <http://www.pbs.gov.au/info/general/independentreview> or by contacting the Independent Review (PBS) as detailed below.

The request form asks the Sponsor to identify the issue/s about which Review is sought. A Sponsor may also attach a more detailed statement identifying the specific issue/s on which the Review is sought. This must reflect, and be cross-referenced to, the PBAC's reasons for not recommending listing as presented in the PBAC 'short' minutes.

For a Review to be completed and the matter reconsidered in the minimum timeframe (that is, reconsideration at the next PBAC meeting following the meeting at which the application was not recommended), an *Independent Review (PBS) Request Form* must be submitted together with a full set of PBAC documents on USB by COB on the Friday of the seventh week of the following PBAC cycle.

The Convenor will select a Reviewer taking into account the nature of issue(s) on which a Review is sought, and the qualifications and expertise of available Reviewers. It is the Convenor's responsibility to ensure that the selected Reviewer has no real or perceived conflict of interest.

A Sponsor will be notified of the name of the Reviewer after the Reviewer's appointment is finalised. In order to preserve the integrity of the Independent Review a Sponsor must not contact a Reviewer. If clarification is required on any matter subject to Review, the Convenor will make the necessary arrangements for discussions to occur between the Sponsor and the Reviewer. The Convenor will be

present for any consultations, either by way of teleconference or in person.

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 Secondary Reviewer will work in conjunction with, and not independently of, the Reviewer, who will retain the overall responsibility for the timely delivery of the Review.

The Convenor will lodge the Review Report with the PBAC Secretariat and provide a copy to the Sponsor no later than seven weeks before the PBAC meeting at which the findings of the Review will be considered. The Sponsor will then be invited by the PBAC Secretariat to provide a Pre-Committee (if applicable) and/or a pre-PBAC response to the Review Report. The PBAC meeting will consider the findings of the Review together with the Sponsor's comments.

The outcome of the PBAC's reconsideration of the submission and the findings of the Review will be reported to the Minister for Health by the end of the 3rd week of the PBAC cycle. Summary recommendations will be placed on the PBS website by the end of week 6 of the PBAC cycle. A Public Summary Document (PSD) will also be developed and will be available on the PBS website by the end of week 16 of the PBAC cycle.

Further information about the Independent Review (PBS) is available at <http://www.pbs.gov.au/info/general/independentreview> or by contacting:

The Convenor
Independent Review (PBS)
MDP 900
GPO Box 9848
CANBERRA ACT 2601

Telephone: (02) 6289 9760
Email: independentreviewpbs@health.gov.au

Independent Review for Additional Indications of Drugs already listed on the PBS

An Independent Review is available where PBAC, having considered new evidence or additional information in respect of an existing pharmaceutical benefit, has declined to recommend a change in the circumstances in which a prescription may be written for the supply of the existing pharmaceutical benefit. The new evidence or additional information must be considered by PBAC to be relevant to the requested change in the listing.

The following examples illustrate the circumstances eligible for Independent Review under this provision:

- 1) **an entirely different disease or condition** than the disease or condition for which the medicine is already subsidised:
 - o for example, imatinib mesylate (Glivec®), was originally listed for chronic myeloid leukaemia (CML) and subsequently listed for gastrointestinal stromal tumours (GIST). A new application, with new evidence, was made for the reimbursement in respect of GIST. The GIST application would have been eligible for Independent Review in the event of a negative PBAC recommendation.
- 2) **an objectively different subtype** of the same disease:
 - o for example, rituximab (Rituxan®) for CD20 positive, diffuse large B-cell non-Hodgkin's lymphoma and CD20 positive, follicular B-cell non-Hodgkin's lymphoma. Another example would be where treatment effect modification has been demonstrated in different disease subtypes. Independent Review would be available where the PBAC considers a subsequent application with relevant new evidence in relation to the subtype of the disease, but does not recommend a change in listing to provide subsidy for this subtype.
- 3) **the same condition but where treatment is targeting a different population or a different stage of disease**
 - o for example, anastrozole (Arimidex®) for advanced metastatic breast cancer and for adjuvant therapy in early breast cancer. Independent Review would be available where PBAC considers a subsequent application for adjuvant therapy containing relevant new evidence, but does not recommend a change in listing to provide subsidy for this population and stage of disease.

Independent Review will not be available where, in response to a request to modify or extend an existing listing, PBAC makes a positive recommendation, irrespective of whether or not the recommendation is exactly as requested by the Sponsor in its submission to PBAC.

- This means that where a submission is made to PBAC for multiple indications and PBAC recommends *any* of the requested indications, those indications not recommended by PBAC will not be eligible for Independent Review on that occasion.

ATTACHMENT A

- However, if a subsequent submission, containing relevant new or additional information in relation to those additional indications does not result in a positive recommendation by PBAC, this would be eligible for Independent Review under the above provision. A Review would be available in this case only if PBAC rejected the new submission in its entirety, i.e., if PBAC declined to make a recommendation to change the existing listing. However, if PBAC recommends some of the additional indications, but not others, a Review would not be available on that occasion.

Independent review is only available in response to a request and will not be available if PBAC recommends that a drug is de-listed, for example as part of a post-market review.

At the conclusion of each PBAC meeting the PBAC will identify those submissions eligible for Independent Review, in accordance with this guideline.