

FAQs

What is the definition of a positive PBAC recommendation that has not been accepted by the applicant?

Any positive recommendation that has a status of 'inactive' on the Medicine Status Website at 20 months after the recommendation was made.

The Department will continue to monitor the behaviour of sponsors over time for any unintended consequences of the 20 months deadline for 'inactive' items.

What is the reasoning for the 20 month review timeframe?

The timeframe was selected to maintain familiarity with the practice that has operated since 1995.

The shorter timeframe is necessary due to the increasing speed with which new evidence and new technologies are becoming available; a recommendation based on the best available information 2 years previously may no longer take account of the availability of new therapeutic agents or new evidence or other changes in circumstances.

The review process enables the committee to make a new decision two years after the initial positive recommendation was made and was not accepted by the applicant.

What level of assessment would be required for a recommendation that meets the criteria for review and potentially remaking, and will this include consultation with clinicians and consumers?

This will be considered on a case by case basis, depending on the individual initial submission.

What information is required from applicants when they are notified that their recommendation is being considered for review?

It will be up to the applicant to provide an explanation as to why they have not pursued the recommended listing, and why the recommendation should remain. The applicant should also outline their proposal for implementation of the recommendation if it remains.

Applicants will be asked to provide a response for the consideration of the PBAC by week 6 of the cycle, either confirming that they have chosen not to proceed with the listing process (in which case the recommendation will be ceased) or requesting that the recommendation be retained (explaining why, as well as providing a date for when they intend to proceed with listing). The response should also assure the PBAC that circumstances contributing to the estimates of cost effectiveness when the initial recommendation was made remain unchanged, and that the assessment of cost effectiveness remains valid at the time of review (i.e. 2 years later) and could include the following:

- an explanation as to why the recommendation has not been implemented,
- justification as to why the recommendation should not be remade, including demonstration that the recommendation is still valid (i.e. nothing has changed)
- an outline of when implementation of the listing will be progressed.

The PBAC agenda papers would include the following documents/information:

- The letter sent to the Applicant by the Department
- Applicant's response to the letter
- Relevant PBAC minutes from the initial positive recommendation.

How will the remade decisions be made public?

Submissions which are being reviewed by the full PBAC committee will be included in the agenda on the PBS website. If the PBAC decides to remake a recommendation, this information will be published on the PBS website as part of the PBAC outcomes, and be made available on the Medicine Status Website [insert link to MSW website. Usual processes for consultation with the applicants will apply.

What is the process if an applicant chooses to pursue listing of a medicine after the positive recommendation is remade to a negative recommendation?

Under the *National Health Act 1953*, medicines can only be listed on the PBS if they have a positive recommendation from the PBAC. If an applicant chooses to pursue PBS listing for a medicine which has been subject to this process, and been given a negative recommendation, they will be required to make a new submission to the PBAC.

What additional costs are involved with listing a medicine if the positive recommendation has been remade?

There will not be a fee associated with the reviewing and remaking process. This process is a variation of what has always been in place.

If an applicant chooses to make a new submission after a recommendation has been remade then the usual fees will apply.

What are the benefits of this proposed new process for patients, clinicians and other stakeholders?

The PBAC considers these changes will improve timely patient access to medicines due to the more proactive approach to managing positive recommendations that have not been accepted and acted on by the applicant.

What if an applicant, at any time following a positive recommendation, advises the Department that they do not wish to continue with the listing process?

The applicant's written notification will be provided to the PBAC at its next meeting, at which time the positive recommendation will be formally rescinded.

What if a positive recommendation stays inactive after being reviewed and retained?

If agreement on how to proceed with listing is still not able to be reached four months following PBAC review (i.e. 28 months post-recommendation), the recommendation will be ceased.