



Fact Sheet

Stage 2 PBS Process Improvements

Background

The Australian Government signed a five year Strategic Agreement with Medicines Australia in 2017, a commitment to ensure a viable medicines sector in Australia and a sustainable Pharmaceutical Benefits Scheme (PBS).

A revised pathways framework (the framework) was co-designed by industry and the Department through the Access to Medicines Working Group – Streamlined Pathways Subgroup (AMWG-SPS) during 2017 and 2018. The framework was endorsed by the AMWG and then approved by Minister Hunt in 2018.

Stage 2 PBS Process Improvements

The 2020-21 Budget measure: Improving Access to Medicines – new and amended listings, provided Government approval to implement Stage 2 process improvements. Stage 2 changes to be implemented from 1 January 2021 include:

- ✓ Changes to initial submission categories including introduction of a single submission date;
- ✓ Introduction of resubmission pathways for submissions not recommended by the PBAC;
- ✓ Revised cost recovery arrangements to support implementation of Stage 2 process improvements; and
- ✓ Other improvements, including further expansion of the Department's Health Products Portal (HPP) functionality.

Purpose of proposed changes to initial submission categories

The introduction of revised categories for initial submissions are intended to:

- provide greater transparency on the type of submissions being considered by the Pharmaceutical Benefits Advisory Committee (PBAC) and the level and the complexity of activities required to assess these submissions;
- better align departmental and PBAC work effort and cost recovery arrangements based on the expected complexity of a submission; and
- clearly differentiate between initial submissions and resubmissions.

To facilitate these intended outcomes, the existing 'major' and 'minor' categories will be split into four categories (details outlined in [Overview of initial submission categories and criteria](#)). The existing Committee Secretariat and New Brand categories will remain unchanged.

Benefits of revised initial submission categories:

For consumers:

- ✓ Improved transparency on the complexity of submissions being considered by the PBAC

For industry:

- ✓ Reduced cross-subsidisation of evaluation fees via more granular categories
- ✓ Increased transparency of activities required to assess submission types
- ✓ Ensures continued effective handling of submissions

For PBAC and Department of Health:

- ✓ Increased transparency regarding the amount and complexity of activities required to assess the range of submissions coming forward for PBAC consideration
- ✓ Differentiates between initial submissions and resubmissions
- ✓ Resources focused on the more complex PBAC submissions
- ✓ Aligns work effort and resourcing with the cost recovery fees

See [Overview of initial submission categories and criteria](#) for more information.

Purpose of the resubmission pathways:

- Provide clear and transparent resubmission processes for submissions that are not recommended (rejected) by the PBAC;
- Support the PBAC's decision-making process and provide a framework for the PBAC to assist applicants in the development of their resubmission;
- Support access to medicines through solution-focused pathways where issues can be easily resolved; and
- Enable efficient use of PBAC time by focusing on more complex resubmissions.

To facilitate these intended outcomes, the introduction of four resubmission pathways is proposed: Early Resolution, Facilitated Resolution, Early Re-entry and Standard Re-entry Pathway (see [Summary on resubmission pathways](#)).

Benefits of revised re-submission pathways:

For consumers:

- ✓ Supports access to medicines by enabling resolution of issues more quickly (when possible)

For industry:

- ✓ Two pathways allow for early reconsideration by the PBAC
- ✓ PBAC guidance will assist in the development of a solution-focused resubmission, which should lead to a reduced resubmission rate and reduced time to market
- ✓ Increase the clarity and transparency in PBAC decision making
- ✓ Recognise the need to facilitate medicines that have high added therapeutic value (HATV) (see definition in [Summary on resubmission pathways](#))

For PBAC and Department of Health:

- ✓ Differentiates between initial submissions and resubmissions
- ✓ Aligns work effort, resourcing and cost recovery arrangements

See [Summary on resubmission pathways](#) for more information.

Overview of submission categories and criteria

Category 1 submissions

Category 1 submissions involve a request for PBS or NIP listing of one or more of the following:

- A first in class medicine or vaccine, and/or a medicine or vaccine for a new population.
 - *A first-in-class medicine or vaccine represents a drug or vaccine with a unique mechanism of action that has not been considered by the PBAC.*
 - *A new population could include a disease or medical condition not previously considered by the PBAC.*
 - *A disease is intended to cover whole diseases when all stages and genetic subtypes are considered.*
- OR
- A drug with a codependent technology that requires an integrated codependent submission to the PBAC and MSAC.
- OR
- A drug or designated vaccine with a TGA Provisional determination related to the proposed population.

Category 2 submissions

Category 2 submissions generally relate to a request for PBS or NIP listing of a new medicine or new vaccine, a new indication of a currently listed medicine or vaccine, or to make material changes to a currently listed indication and do not meet the criteria for a Category 1 submission.

Examples:

A new medicine for a condition that is currently treated OR a new vaccine against a disease for which there is a current vaccine. OR

A listed medicine for an additional condition OR a listed vaccine for an additional population. OR

One or more material changes to an existing listing that requires a full evaluation (clinical, economic and/or financial evaluation).

Category 3 submissions

Category 3 submissions generally relate to requests to change existing listings that do not change the population or cost-effectiveness of the medicine or vaccine that do not meet the criteria for a Category 4 submission.

Examples:

- *A new biosimilar medicine where the reference medicine is already listed for the same population. OR*
- *A medicinal food. A food that is a therapeutic good within the meaning of paragraphs (a) and (b) of the definition of therapeutic goods in section 3 of the Therapeutic Goods Act 1989). OR*
- *The request is to change the restriction level of a listed medicine (e.g. Restricted benefit, Authority Required – in writing, Authority Required – telephone/electronic, Streamlined Authority).*

Category 4 submissions

Category 4 submissions involve a request for one or more of the following:

- Listing of a new pharmaceutical item of a listed medicine.
- Consideration as an exempt item (Exempt item as per subsection 84AH of the *National Health Act 1953*).

- Including a listed medicine on the prescriber bag, or varying an existing prescriber bag listing.
- A change/new manner of administration of a listed medicine.
- A change to the maximum quantity and/or number of repeats of a listed medicine.
- A change or addition to the prescriber type(s) of a listed medicine.

Summary of resubmission pathways

For all submissions with a 'not recommended' PBAC outcome, the PBAC will nominate a resubmission pathway based on their independent assessment of the issues for resolution and whether a medicine or vaccine represents 'High Added Therapeutic Value' (HATV).

When determining if a medicine or vaccine is HATV, the Committee will consider the following:

- the medicine or vaccine addresses a high and urgent unmet clinical need; and
- the medicine or vaccine is expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over any alternative therapies.

This aligns with the requirements under the Pricing Pathway A criteria outlined in the *National Health (Pharmaceutical and Vaccines–Cost Recovery) Regulations 2009*.

Early Resolution Pathway:

For medicines or vaccines deemed by the PBAC to represent HATV AND where the PBAC considers that the remaining issues could be easily resolved, including when:

- new clinical study data requiring evaluation is not considered necessary by the PBAC to support new clinical claims to be made in the resubmission; and
- a revised model structure or input variable changes (beyond those specified by the PBAC) are not necessary to support any new economic claims, or to estimate the utilisation and financial impacts to be made in the resubmission.

Facilitated Resolution Pathway:

A Facilitated Resolution Pathway may be nominated by the PBAC where the PBAC considers the issues for resolution could be explored through a workshop and where the medicine or vaccine meets the HATV criteria. Applicants who accept this pathway are eligible for a solution-focussed workshop with one or more members of the PBAC. Facilitated Resolution workshop

The workshop agenda will be based on the issues for resolution outlined in the PBAC Minutes. This can be further clarified during the post-PBAC meeting with the Chair.

Applicants should note the following:

- Workshops will be a maximum of 3 hours in duration.
- The departmental representatives and applicant attendees should be finalised at the post-PBAC meeting with the Chair. The applicant must ensure at least one attendee has the authority to make decisions on behalf of the company as a whole regarding the feasibility of any option(s) being explored to address PBAC's issues for resolution (in accordance with the workshop agenda).
- An applicant's decision to participate in a workshop does not influence the PBAC's considerations of the submission, and does not guarantee that the submission will result in a PBAC recommendation.
- Any advice provided by members of the PBAC, the applicant or the department in a workshop is in no way binding on the PBAC, the department, applicant, evaluation groups or sub-committees of the PBAC.
- An applicant must form their own judgments about how to use the explorations of the workshop and any advice provided during this workshop in the development of the submission.

- It is recommended that all applicants, including those that have attended a Facilitated Resolution Pathway workshop, should consult the [PBAC Guidelines](#) when preparing their submission.

Early Re-entry Pathway:

An Early Re-entry Pathway may be nominated by the PBAC where the PBAC considers that the remaining issues could be easily resolved and the medicine or vaccine does not represent High Added Therapeutic Value (HATV) for the proposed population. This would include circumstances where:

- new clinical study data requiring evaluation is not considered necessary by the PBAC to support new clinical claims to be made in the resubmission; and
- a revised model structure or input variable changes (beyond those specified by the PBAC) are not necessary to support any new economic claims, or to estimate the utilisation and financial impacts to be made in the resubmission.

Standard Re-entry:

The Standard Re-entry Pathway is the default pathway for resubmissions and also applies where:

- an applicant chooses not to accept the PBAC nominated resubmission pathway; or
- an Early Re-entry or Early Resolution Pathway has been nominated by the PBAC and an applicant decides to address issues other than those identified by the PBAC (including a subset of issues); or
- an applicant decides to lodge later than the allowable timelines for the other pathways.