

Summary of Resubmission Pathways

For all submissions with a 'not recommended' PBAC outcome from the March 2021 PBAC meeting onward, 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

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 other pathways.

FACT SHEET – Stage 2 PBS Process Improvements

<https://www.pbs.gov.au/general/process-improvements/Fact-Sheet-PBS-Process-Improvements-Stage-2.pdf>