# PBS Process Improvements Stage 2

# **Frequently Asked Questions**

Please refer to the Stage 2 PBS process improvements [Fact Sheet](https://www.pbs.gov.au/general/process-improvements/Fact-Sheet-PBS-Process-Improvements-Stage-2.pdf) for background information and an overview of the submission categories and resubmission pathways.

**Table 1: Stage 2 summary**

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| **What’s changed?** | **What stayed the same?** |
| * **Four submission categories:**
* Categories 1 and 2 – for submissions **requiring** evaluation; and
* Categories 3 and 4 – for submissions that **do not** require evaluation.
 | * Committee Secretariat and New Brand submission categories.
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| * Categories 2 and 3 are the **default** categories.
* Categories 1 and 4 only apply where a submission meets one or more of the **specific criteria.**
 | * 17 week PBAC cycle, submission requirements, evaluation processes and PBAC decision making.
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| * **Single submission date** – day one of the PBAC meeting cycle.
 | * Intent to Apply requirement for all submissions (including resubmissions) to the PBAC.
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| * **Four resubmission pathways:**
* Standard Re-entry - applicant driven pathway (not PBAC nominated);
* Early Re-entry – PBAC nominated;
* Early Resolution– PBAC nominated; and
* Facilitated Resolution – PBAC nominated
 | * Early PBAC reconsideration.
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1. **What should I do if I am unsure of my submission category?**

Applicants who are uncertain of the submission category should contact the PBAC Secretariat.

In addition, the department will continue to validate submission categories (including resubmissions). Stage 2 changes will not affect existing validation processes.

Please refer to the [Cost Recovery Administrative Guidelines](https://www.pbs.gov.au/info/industry/listing/elements/fees-and-charges) for information on the validation process.

1. **How do I submit a resubmission?**

All submissions to the PBAC, including resubmissions are lodged through the Health Products Portal.

1. **Will stage 2 changes affect parallel processing?**

No. Current arrangements for parallel processing will remain unchanged. Parallel processing will be available for Category 1 and 2 submissions.

Further information about parallel processing is available at the PBS website under [TGA and PBAC Parallel Process and Requirements](https://www.pbs.gov.au/info/publication/factsheets/shared/tga-pbac-parallel-process).

1. **Will stage 2 changes affect codependent submissions?**

There are no changes to the lodgement timing for codependent submissions.

Category 1 applies for integrated codependent submissions; and Category 2 applies for streamlined codependent submissions.

1. **Which category would a submission requesting a change in restriction be?**

Category 3 applies to any request to change the restriction level of a listed medicine (e.g. Restricted benefit, Authority Required – in writing, Authority Required – telephone/electronic, Streamlined Authority).

1. **Can the PBAC still choose to defer a submission?**

Yes. The PBAC will defer making a decision where there is *specific or missing information* that cannot be obtained from the applicant and is required for PBAC decision-making (e.g. TGA delegate’s overview or MSAC advice in relation to a codependent technology).

1. **If the PBAC nominates a resubmission pathway, is the sponsor obliged to use that pathway?**

Where PBAC nominates a resubmission pathway, a sponsor can elect to accept or reject that resubmission pathway. Should the sponsor reject the PABC-nominated resubmission pathway, they have the option of using the Standard Re-entry Pathway.

1. **Will applicants receive the same level of advice and guidance from the PBAC for a Standard Re-Entry Pathway?**

Yes. The PBAC will endeavour to clarify any issues for resolution in the ratified Minutes.

1. **For a submission not recommended by the PBAC, how quickly can an applicant enter into a resubmission pathway?**

Lodgement of a resubmission depends on the PBAC nominated pathway:

* Early Re-entry and Early Resolution submissions are to be lodged on Friday of week 7 of the current or the next PBAC meeting cycle.
* Facilitated Resolution submissions can be lodged at the submission due day after the workshop in either week 17 or week 34.
* Standard Re-entry submissions can be lodged at any submission due day (week 17).
1. **Can I address issues other than those specified by the PBAC if I accept an Early Re-entry or Early Resolution Pathway?**

No. Applicants who accept an early pathway nomination must only address the issues specified by the PBAC.

Where an applicant chooses to address issues other than those identified by the PBAC (including a subset of issues), the Standard Re-entry Pathway would apply.

1. **If the PBAC holds a stakeholder meeting, how will that process fit with the resubmission categories?**

Following a stakeholder meeting, applicants would be required to resubmit their application using the Standard Re-entry Pathway.

1. **Will deed management fees apply for drugs joining an existing deed?**

Yes. The five-year rebate management fee will apply to all Pricing Pathway A, B and C and deed renewal applications received on or after 1 January 2021.

1. **Would a refund apply if a company ceases a deed arrangement early?**

No. As the standard deed term for all new deed arrangements is five years, a refund would only apply where a deed arrangement is not entered into. Based on current data, less than 2% of deeds have ceased early.

The department will continue to monitor the number of deeds that cease before five years.
If a high number is identified the department will review this approach.