**STAGE 1 and 2 PBS PROCESS IMPROVEMENTS**

 **2022-23 Metrics Report**

Clause 6.1 of the 2022-2027 [Strategic Agreement](https://www.pbs.gov.au/general/medicines-industry-strategic-agreement-files/MA-Strategic-Agreement-Signed.pdf) between the Commonwealth and Medicines Australia includes a continued focus on HTA process improvements to facilitate earlier patient access to medicines. The metrics in this report have been co-designed and jointly agreed by the parties, in alignment with the main objectives of the Strategic Agreement. They are based on aggregated and de-identified data.

The metrics below cover Stage 1 and Stage 2 PBS process improvements for the period 1 July 2022 to 30 June 2023. This is the fourth report on Stage 1 PBS process improvements, which were implemented on 1 July 2019. This is the second report for Stage 2 PBS process improvements, which were implemented on 1 January 2021.

**STAGE 1 PBS PROCESS IMPROVEMENTS:**

# Pre-Submission Meetings

* **42** initial pre-submission meetings were requested; **4** withdrawn; **36** accepted; **2** not accepted and **36** meetings have been held.
* **0** subsequent pre-submission meetings were requested.

# Notice of Intent

* **171** *Notice of Intent* forms were received.
* **102** submissions were received.

# Notice of Intent for Pricing

* **34.2%** of applicants with a *recommended* outcome lodged their notice of intent for pricing form by week 4 post the PBAC meeting (the earliest opportunity).
* Of these applicants, **55.6%** submitted their pricing offer package in week 5 post the PBAC meeting (the earliest opportunity).

# Pricing Pathways

* **30.3%** of pricing offer packages were complete when initially provided to the Department.
* **68.9%** of utilisation and cost model templates were initially provided to the Department in the correct format.
* For applicants who lodged their *notice of intent for pricing* form in week 4 and their pricing offer package in week 5, the time from PBAC minutes to PBS listing date was an average (mean) of **124.7 days** (approx. **4.1** **months**) and a median of **125.0 days** (approx. **4.1** **months**). This represents **7** out of **31**[[1]](#footnote-1) listings.
* For all other applicants, the time from PBAC minutes to PBS listing date was an average (mean) of **176.2 days** (approx. **5.8** **months**) and a median of **157.0 days** (approx. **5.2** **months**). This represents **24** out of **31**1 listings.
* The time from the Department confirming the pricing offer package was lodged correctly to the department and the applicant reaching in principle pricing agreement was an average (mean) of **37 days** and a median of **33.5 days.**

# STAGE 2 PBS PROCESS IMPROVEMENTS:

**Initial submissions**

* **49.0**% of initial submissions were recommended first time (**50** out of **102**).
* **23.9%** of submissions seeking a higher price over the existing alternative(s) were recommended first time (**11** out of **46**).
* The number of days from PBAC minutes to PBS listing for submissions seeking a higher price over the existing alternative(s) recommended first time was an average of **156 days**.
* **0%** of submissions seeking a higher price over the existing alternative(s) submitted their *notice of intent for pricing* form at the earliest opportunity in week 4 and their pricing offer package in week 5 (**0** out of **11**)2.
* **66.7%** of cost minimisation submissions were recommended first time (**14** out of **21**).
* The number of days from PBAC minutes to PBS listing for cost minimisation submissions recommended first time was an average of **182 days** and a median of **187 days.**
* No submissions returned to PBAC to seek a review of the positive recommendation.

# Resubmissions

* **90.2%%** (**37** out of 41) of all resubmissions were received as per the PBAC nominated pathway, as advised in the *Notice of Intent* form (4 applications were withdrawn, totaling 41 resubmissions).
* **1** resubmission through the Standard Re-entry Pathway was received that did not accept the PBAC nominated pathway.
	+ **The single resubmission through the Standard Re-entry Pathway was initially a Category 1 submission.**
* **12** resubmissions through the Early Re-entry Pathway were received:
	+ ***66.7****% were recommended*
	+ **33.3**% were initially Category 1 submissions (4 out of 12)
	+ **66.7**% were initially Category 2 submissions (8 out of 12)
* **5** resubmissions through the Early Resolution Pathway were received:
	+ ***20.0****% were recommended*
	+ **40.0**% were initially Category 1 submissions (2 out of 5)
	+ **60.0**% were initially Category 2 submissions (3 out of 5)
* **1** Facilitated Resolution Pathway submissions was submitted; however, the submission was withdrawn following the facilitated resolution workshop.

2 *Although eleven submissions seeking a higher price over the existing alternative(s) were recommended first time, only 4 were listed in 2022-23.*

1. *There were 31 PBAC-recommended listings implemented on the PBS from 1 July 2022 to 1 July 2023 where pricing services were required.* [↑](#footnote-ref-1)