

STAGE 1 and 2 PBS PROCESS IMPROVEMENTS

2022-23 Metrics Report

Clause 6.1 of the 2022-2027 [Strategic Agreement](#) 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- **42** initial pre-submission meetings were requested; **4** withdrawn; **36** accepted; **2** not accepted and **36** meetings have been held.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 **31¹** 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 **31¹** 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**.

¹ There were 31 PBAC-recommended listings implemented on the PBS from 1 July 2022 to 1 July 2023 where pricing services were required.

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.