

STAGE 1 and 2 PBS PROCESS IMPROVEMENTS

2023-24 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 2023 to 30 June 2024. This is the fifth report on Stage 1 PBS process improvements, which were implemented on 1 July 2019. This is the third report for Stage 2 PBS process improvements, which were implemented on 1 January 2021.

STAGE 1 PBS PROCESS IMPROVEMENTS:

Pre-Submission Meetings

- **48** initial pre-submission meetings were requested; **7** withdrawn; **45** accepted; **2** not accepted and **39** meetings have been held.
- **2** subsequent pre-submission meetings were requested; **1** withdrawn; **2** accepted; **0** not accepted and **1** meeting has been held.

Notice of Intent

- **171** *Notice of Intent* forms were received.
- **145** submissions were received.

Notice of Intent for Pricing

- **34.0%** 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, **69.0%** submitted their pricing offer package in week 5 post the PBAC meeting (the earliest opportunity).

Pricing Pathways

- **18.8%** of pricing offer packages were complete when initially provided to the Department.
- **39.0%** 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 **130.1 days** (approx. **4.3 months**) and a median of **130.0 days** (approx. **4.3 months**). This represents **15** out of **52¹** listings.
- For all other applicants, the time from PBAC minutes to PBS listing date was an average (mean) of **160.3 days** (approx. **5.3 months**) and a median of **159.0 days** (approx. **5.2 months**). This represents **37** out of **52¹** 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 **16 days** and a median of **9 days**.

¹ There were 52 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

- **67.3%** of initial submissions were recommended first time (**68** out of **101**).
- **32.4%** of submissions seeking a higher price over the existing alternative(s) were recommended first time (**12** out of **37**).
- 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 **164.7 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 **13**)².
- **84.5%** of cost minimisation submissions were recommended first time (**49** out of **58**).
- The number of days from PBAC minutes to PBS listing for cost minimisation submissions recommended first time was an average of **157.4 days** and a median of **160 days**.
- **6 submissions** returned to PBAC to seek a review of the positive recommendation.

Resubmissions

- **97.4% (37 out of 38)** of all resubmissions were received as per the PBAC nominated pathway, as advised in the *Notice of Intent* form (1 application was withdrawn, totaling 38 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.**
- **13** resubmissions through the Early Re-entry Pathway were received:
 - **84.6% were recommended**
 - **53.8%** were initially Category 1 submissions (7 out of 13)
 - **38.5%** were initially Category 2 submissions (5 out of 13)
 - **7.7%** were initially Major submissions (1 out of 13)
- **3** resubmissions through the Early Resolution Pathway were received:
 - **66.7% were recommended**
 - **100.0%** were initially Category 1 submissions (3 out of 3)
- **1** Facilitated Resolution Pathway submission was submitted; the facilitated resolution workshop was held and the submission was recommended by the PBAC at the following meeting.

² Although thirteen submissions seeking a higher price over the existing alternative(s) were recommended first time, only 0 were listed in 2023-24.