

## STAGE 1 and 2 PBS PROCESS IMPROVEMENTS

### 2021-22 Metrics Report

The 2017 [Strategic Agreement](#) between the Commonwealth and Medicines Australia included objectives within Clause 10.3 to be addressed in PBS process improvement outcomes, with the overall aim of improving the efficiency, transparency and timeliness of the PBS listing processes. PBS process improvements included the development of key metrics through a two-stage process. On 1 July 2022, a new [Strategic Agreement was put in place, which includes the continuation of process improvements, outlined in Cause 6.1, building on those addressed in the previous agreement.](#) The metrics provided below have been aggregated based on de-identified data in alignment with the main objectives of the Strategic Agreement and will be published annually.

The data set (below) includes metrics covering 1 July 2021 to 30 June 2022 for Stage 1 and Stage 2 PBS process improvements. This is the third year reporting on Stage 1 PBS process improvements since these changes began on 1 July 2019. This is the first report for Stage 2 PBS process improvements since they were implemented on 1 January 2021.

#### Stage 1:

##### Pre-Submission Meetings

- **42** initial pre-submission meetings were requested; **8** withdrawn; **41** accepted; **1** not accepted and **34** meetings have been held.
- **4** subsequent pre-submission meetings were requested; **3** accepted; **1** withdrawn and **3** were held.

##### Intent to Apply

- **194** *Intent to Apply* forms were received.
- **144** submissions were received.

##### Notice of Intent for Pricing

- **34%** 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, **76%** submitted their pricing offer package in week 5 post the PBAC meeting (the earliest opportunity).

##### Pricing Pathways

- **37%** of pricing offer packages were complete when initially provided to the Department.
- **72%** 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 of

**101.8 days** (approx. 3.4 months) with a median of **96.5 days** (approx. 3.2 months). This represents 20 out of 44<sup>1</sup> listings.

- For all other applicants, the time from PBAC minutes to PBS listing date was an average of **143.3 days** (approx. 4.8 months) with a median of **141 days** (approx. 4.7 months). This represents 24 out of 44<sup>1</sup> 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 of **22.3 days** with a median of **12 days**.

## Stage 2:

### Initial submissions

- **56%** of initial submissions were recommended first time (59 out of 105).
- **11%** of submissions seeking a higher price over the existing alternative(s) were recommended first time (4 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 **158 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 1)<sup>2</sup>.
- **75%** of cost minimisation submissions were recommended first time (27 out of 36).
- The number of days from PBAC minutes to PBS listing for cost minimisation submissions recommended first time was an average of **143 days** and a median of **126 days**.
- No submissions returned to PBAC to seek a review of the positive recommendation.

### Resubmissions

- **96%** (48 out of 49) of all resubmissions were received as per the PBAC nominated pathway, as advised in the *Intent to Apply* form.
- **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 Major submission.
- **14** resubmissions through the Early Re-entry Pathway were received:
  - **79%** were recommended
  - **43%** were initially Category 1 submissions (6 out of 14)
  - **14%** were initially Category 2 submissions (2 out of 14)
  - **43%** were initially Major submissions (6 out of 14)
  - There were no Category 3, Category 4 or Minor submissions that were resubmitted through the Early Re-entry Pathway.
- **5** resubmissions through the Early Resolution Pathway were received:
  - **60%** were recommended
  - **20%** were initially Category 1 submissions (1 out of 5)
  - **40%** were initially Category 2 submissions (2 out of 5)

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<sup>1</sup> There were 44, PBAC-recommended listings implemented on the PBS from 1 July 2021 to 30 June 2022 where pricing services were required.

<sup>2</sup> Although four submissions seeking a higher price over the existing alternative(s) were recommended first time, only one was listed in 2021-22.

- **40%** were initially Major submissions (2 out of 5)
- There were no Category 3, Category 4 or Minor submissions that were resubmitted through the Early Re-entry Pathway.
- **1** Facilitated Resolution Pathway submission was received:
  - The single resubmission through the Facilitated Resolution Pathway was initially a Category 1 submission.
  - The outcome for the single Facilitated Resolution Pathway resubmission was recommended.