2 June 2023

PBS Improvements Section
Department of Health and Aged Care
pbscostrecovery@health.gov.au

SUBMISSION FROM MEDICINES AUSTRALIA

Medicines Australia appreciates the opportunity to participate in the public consultation on the Draft Cost Recovery Implementation Statement (CRIS) for Listing Medicines on the PBS and Designated Vaccines on the NIP 1 July 2023 – 30 June 2024. As the peak body representing the innovative, research-based medicines industry in Australia, we are committed to ongoing consultations. Our membership considers the activity a fundamental requirement and will engage in the process to collaboratively design and contribute to the cost recovery changes, which are important to improve efficiencies and outcomes, and enable appropriate business planning.

There is significant concern about the magnitude of the indexation increase in charges for key cost recovery items. Unlike the vast majority of increases, which are in the order of 2% to 5%, the increases for the highest-cost charges are increasing by 14% to 20%. The explanatory information in section 3.2.1 of the CRIS addresses the increases as being driven by increased supplier costs of 13.1% for Categories 1, 2, Standard Re-entry and Facilitated Re-entry submissions, and of 23% for ATAGI applications. Medicines Australia seeks greater transparency about the assumptions about increasing complexity and new panel arrangements that have led to these changes and the reasons for a large difference between the increases to ATAGI submission charges compared with PBAC submission charges. Further, given the magnitude of these increases and with implementation proposed within a matter of weeks, commencement from January 2024 is proposed to allow for appropriate business planning.

As a commitment to the Strategic Agreement, Medicines Australia welcomes continued measurement of PBS Process Improvements and will work collaboratively to determine a range of key performance indicators (KPIs) to reduce the time to PBS listing and improve overall patient access to reimbursed medicines.

The key issues of concern and for which Medicines Australia seeks further improvement are as follows.

- Transparency is requested to support the magnitude of the increase for key cost recovery items, where the increase in charges is in the range of 14% to 20%.
- As in previous years, where there has been a significant increase, a commencement date that allows for reasonable business planning is proposed.
- Commitment from the Department of Health and Aged Care (DoHAC) to ongoing consultation on PBS Process Improvements and any additional activities that may be considered for cost-recovery purposes.
- Commitment from the DoHAC to continued measurement of PBS improvements to reduce the time to PBS listing including the processes that occur following a recommendation to list from the PBAC.
- Early engagement to collectively design and contribute to the cost recovery items; however, it is critical that public consultation is undertaken with stakeholders and appropriate business planning is afforded to Sponsors regarding any changes in the fee structure.
- Removal of the statement, *"this partial cost recovery approach may change as a result of any review of the cost recovery arrangements currently in place",* maintaining consistency with the decision not to proceed that was made in 2018.
- Consultation on alternate solutions, to improve equitable application of cost recovery fees as well as ensuring fees are not prohibitive for applicants to enable medicines that meet an unmet

clinical need or vaccines remain viable prospects for PBAC consideration and ultimately available for patients
- Removal, or full exemption, of cost recovery fees for orphan-designated medicines.
- Greater transparency related to the application of DoHAC resources.

Early engagement with Medicines Australia prior to public consultation

Medicines Australia welcomes continued early engagement to collectively design and contribute to the cost recovery items, however it is critical that public consultation is undertaken with stakeholders and appropriate business planning is afforded to sponsors regarding any changes in the cost structure.

For clarity, Medicines Australia welcomed the early engagement on the commencement of Ministerial determination requests to alter stockholding arrangements, however noted there was no public consultation and therefore not all sponsors were informed on the introduction from 1 July 2023.

Medicines Australia is concerned that the "balance management strategy explanation" states "t*he continuing forecast under recovery of expenses represented in the growing size of the cumulative balance is due to the post market review activities that are not cost recovered along with revenue foregone from waivers and exemptions"*. As a new post-market review process is currently being developed as part of the Strategic Agreement and is yet to be finalised, Medicines Australia wants to make explicit that any associated fees and charges have not been considered and must be subject to early engagement and public consultation.

Significant fee changes

Medicines Australia notes that most of the charges are increasing by a modest amount. However, some key fees are increasing by up to 20%, which is excessive, particularly with limited notice to allow for appropriate business planning.

Greater transparency is requested to understand the reasons for the change in the charges listed below.

Charge	Type	Fees from 1 August 2022	Fees from 1 July 2023	Difference	
				Value	%
ATAGI pre-submission evaluation					
Complex Submission	Fee	$177,830	$212,360	$34,530	19.42%
Simple Submission	Fee	$101,520	$116,960	$15,440	15.21%
Submission services (PBAC evaluation)					
Category 1	Fee	$219,990	$252,110	$32,120	14.60%
Category 2	Fee	$166,850	$197,500	$30,650	18.37%
Resubmission – Standard Re-entry	Fee	$164,770	$195,390	$30,620	18.58%
Resubmission – Facilitated Resolution	Fee	$236,610	$269,020	$32,410	13.70%

Based on an analysis of the likely activities required for an innovative medicine to navigate the process to achieve PBS listing, an applicant is likely to incur costs, on average, of over $500,000. This does not include the significant costs related to evidence generation and submission preparation. Based on the fees, it is important to consider the cost may be a significant barrier for entry in Australia.

An example of the cost estimates to achieve PBS listings are:

- **Example A: Innovative Medicine – approx. $603,000, an increase of $67,360 versus 2022–2023**
  - Based on 1 x pre-submission meeting, 1 x Category 1 submission, 1 x Standard Re-entry submission and 1 x Pricing pathway A submission
- **Example B: Vaccine – approx. $480,000, an increase of $67,110 versus 2022–2023**
  - Based on a complex ATAGI submission, 1 x pre-submission meeting, 1 x Category 1 submission

As in previous years, where there has been a significant increase the commencement date should allow for reasonable business planning.

Resources and service standards

Medicines Australia requests that the CRIS document articulate, in a transparent manner, how the cost recovery fees are used respecting resources and staffing at the DoHAC. Publicly available metrics that reflect improvements in the transparency and efficiencies of resources directed to the PBS listing process should be developed in consultation with Medicines Australia.

Removal of levy-related activity

The draft 2023–2024 CRIS acknowledges that in 2018–19 the former Government decided not to apply a PBS listing levy and the relevant activities continue to be funded by the Government via an appropriation to the DoHAC. However, the CRIS consultation continues to state, "*this partial cost recovery approach may change as a result of any review of the cost recovery arrangements currently in place".* The statement continues to raise concern for the industry as this is not a long-term solution and should not be considered in isolation.

Medicines Australia requests the above *italicised* statement be removed from the CRIS statement. Any future consideration of changes to the structure of cost recovery fees would be subject to consultation with Industry. The removal of the statement is further supported by the DoHAC response in Table 9 of the 2023–2024 CRIS that '*there is currently no proposed policy change for existing partial cost recovery arrangements. The Department remains committed to ongoing industry consultation on any future proposed changes to the structure of cost recovery fees*.'

Equitable application of fees

Medicines Australia members continue to raise concerns about the equitable application of the cost recovery fees, and the difficulty for applicants to list or seek waivers or exemptions for lower revenue products that address an unmet clinical need.

Given the cumulative size of the fees to seek listing on the ARTG and the PBS/NIP, Medicines Australia seeks consideration of alternative fee structures, ensuring medicines that meet an unmet clinical need and vaccines remain viable prospects for PBAC consideration and are ultimately made available to patients.

Medicines Australia is seeking a consultation on alternative solutions, including:

- A risk-share approach to the fees for medicines and vaccines that have a projected revenue of less than $5–10 million per year. For these products, 50% of the fees could be charged up front, whilst the remaining 50% could be charged once the medicine or vaccine reaches its projected revenue or waived entirely.
- A phased payment based on the size of the company or a fee structure reflective of the expected revenue for an individual product.

The application of equitable fees is not a new concept and has been applied by HTA agencies such as NICE in the United Kingdom. NICE separates costs based on company size (large versus small) and for small companies, fees are significantly less.

Medicines Australia notes that these suggestions were provided as part of the 2022–23 CRIS consultation and the DoHAC noted that the feedback '*may be considered for future cost recovery arrangements*' (Table 9, CRIS 2023–2024). Medicines Australia would welcome the opportunity to discuss these alternative solutions in more detail.

Medicines Australia also remains concerned about the significant fees applicable to orphan medicines and is seeking a fee exemption for all cost recovery elements (not just the first submission). Given the evidence generally available for an orphan population, the submissions for orphan drugs may be seen as

having a higher degree of uncertainty. If the evidence base is limited, and this is seen as uncertain, the economic analyses are also considered uncertain. This uncertainty means that a first-time positive recommendation from the PBAC is the exception rather than the rule for orphan medicines. As such, achieving a positive recommendation requires subsequent submissions to address the uncertainty, which is a significant cost and may have a negative impact on the financial viability of the medicine in question. Medicines Australia requests that the fees related to orphan medicines be fully exempt.

Independent Review

Medicines Australia notes the commitment made in paragraph 6.9.2 of the Strategic Agreement, 'to undertake a review during 2022 of the PBS activity-based cost model to assess the appropriateness of the list of cost recovered activities in the administration of the PBS and the cost allocations to them having regard to the Australian Government Charging Framework and Australian Government Cost Recovery Guidelines'.

Medicines Australia notes that an Independent Review of the activity-based costing model was completed in June 2022. As stated in the CRIS, the review recommended, among other things, a full cost model refresh during the 2022–23 financial year, with outcomes to be reflected in updates for the 2023–23 financial year. The CRIS states that the time and motion study is ongoing, and any amendments will only commence for the 2024–25 financial year. Medicines Australia wishes to understand why this has not been completed in readiness for the 2023–24 financial year. Medicines Australia also calls for an update on the status of the other recommendations of the Independent Review. The status and outcomes of the 2022–23 refresh should also be made publicly available, in advance of the consultation on the 2024–25 CRIS, in addition to the publication of the Portfolio Charging Review planned for the 2023–24 financial year. This will assist companies in preparing for any changes that may arise. Again, the introduction of significant changes should be accompanied by an adequate planning period and not necessarily imposed from 1 July 2024.

Medicines Australia also notes that the scope of the independent review was limited to the PBS cost model and that, as per the Strategic Agreement, a broader independent audit is still required of the fees, additional services provided, and whether the fees are the most efficient cost and resources for effective service delivery as outlined in the Department of Finance Cost Recovery Guidelines. A mutually agreed third party should undertake this independent audit. Any future increases in fees beyond CPI should not be implemented until after this audit has been completed, and any recommendations discussed by the DoHAC and Medicines Australia.

Final comments

Medicines Australia remains committed to working with the DoHAC to deliver equitable, transparent and fit for purpose process improvements to the listing of medicines on the PBS and ensuring timely and affordable access to new medicines for all Australians. In the spirit of open and constructive consultation we look forward to an ongoing dialogue about cost recovery for the activities occurring to establish and maintain access to medicines and vaccines for Australians.

Yours sincerely,

Anne-Maree Englund
Head of Strategic Policy Implementation
Medicines Australia