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PBS Improvements Section
Department of Health and Aged Care
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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 2024 – 30 June 2025. 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.

Several of the fee increases proposed for the next financial year are generally in line with CPI. However, there are a number of fee increases proposed that are significantly higher than the CPI increase of 3.5% referred to in Section 3.2.1 of the CRIS consultation document. These seem to be driven primarily by a 6% increase in overhead costs. Medicines Australia would welcome more detail on these overhead cost increases, along with a quantification of the cited increase in IT costs including the costs associated with the depreciation of the HPP. We note the ongoing time and motion study and the anticipated reflection of the results of this study into next year's CRIS. We look forward to the results of the time and motion study being presented at the August 2024 AMWG meeting.

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 5% or more (significantly above the CPI increase of 3.5%).
- 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 any activities that may be considered for cost-recovery purposes, including reforms recommended as part of the HTA Policies and Methods review, which is due to conclude in May 2024.
- Early engagement with Medicines Australia to collectively design and contribute to the cost recovery items, noting the Department's need to fit within Budget processes. 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.
- Removal, or full exemption, of cost recovery fees for orphan-designated medicines.
- Greater transparency related to the application of DoHAC resources.

Significant fee changes

Medicines Australia notes that many of the charges are increasing in line with CPI. However, some key fees are increasing by 5% or more, which is significantly above the CPI increase of 3.5%, with little transparency around the other factors driving these cost increases.

The PBS pricing pathways are all increasing by at least 6% over the previous financial year. Feedback from sponsor companies indicates that the post-recommendation processes, including the pricing negotiations and finalisation of the budget impact modelling, are not as efficient as possible. Sponsors

have experienced significant delays in finalisation of pricing for individual submissions while the DoHAC made proposed changes to financial estimates that were inconsistent with either the PBAC's recommendations or prior accepted approaches. In many cases, extensive changes to the modelling resulted in marginal impacts to the overall budget impact.

For example, one sponsor reported that, after financial estimates that were projected to be budgetary saving were largely agreed to (after minor changes), two months passed before further communication from the Department, comprising further questions around model assumptions that were previously substantiated in the PBAC submission. It is uncertain why such a time difference existed given these circumstances.

Another issue within the process is the timeliness with which the Department determines the completeness of the pricing package. While this needs to be completed within three to five business days of the package being made available, this certainly is not always the case. Clearly, there are efficiencies that could be made to the post-PBAC negotiation process that could mitigate the need for substantial fee increases.

Further, we note that the fee for Ministerial determinations for changes to minimum stockholding requirements is increasing by 6.3%. This fee was introduced for the first time in the previous financial year to cover a new process relating to the newly introduced minimum stockholding requirement developed under the current Strategic Agreement between the Commonwealth and Medicines Australia. This process is due for review in July 2024, as agreed with the Department of Health and Aged Care (DoHAC).

It is yet to be proven that the minimum stockholding requirements have achieved the intended outcome of fewer stock shortages or outages, or that the process of applying for Ministerial determination of a different minimum quantity has worked effectively. From the industry's perspective, the process of applying for Ministerial determination has been administratively burdensome, resource-intensive, iterative and inefficient. There are several ways in which this process could be improved to increase efficiencies for both the DoHAC and the industry. We question the need for the significant 6.3% increase in a fee for a process with unproven efficacy, and request that this fee increase be removed, or at least significantly reduced, until after the review of the process is completed. We welcome the opportunity to provide feedback on the Ministerial determination process during its review in July 2024 and look forward to working with the Department on ways to improve this process.

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

Charge	Type	Fees from 1 July 2023	Fees from 1 July 2024	Difference	
				Value	%
Submission services (PBAC evaluation)					
Intent to Apply (PBAC and ATAGI)	Fee	$430	$456	$26	6.05%
First pre-submission meeting	Fee	$15,440	$16,407	$967	6.26%
Second pre-submission meeting	Fee	$20,980	$22,286	$1,306	6.22%
Category 3 submission	Fee	$42,460	$44,704	$2,244	5.28%
Category 4 submission	Fee	$32,940	$34,955	$2,015	6.12%
Secretariat Submission	Fee	$11,560	$12,329	$769	6.65%
Generic Submission	Fee	$6,410	$6,827	$417	6.51%
Resubmission – Early resolution	Fee	$41,190	$43,482	$2,292	5.56%
Resubmission – Early re-entry	Fee	$41,040	$43,329	$2,289	5.58%
Pricing Pathway A	Fee	$139,850	$148,503	$8,653	6.19%
Pricing Pathway B	Fee	$110,770	$117,549	$6,779	6.12%
Pricing Pathway C	Fee	$73,350	$77,763	$4,413	6.02%

Pricing Pathway D	Fee	$19,620	$20,889	$1,269	6.47%
Pricing Secretariat	Fee	$12,000	$12,774	$774	6.45%
Price Increases	Fee	$4,980	$5,298	$318	6.39%
Ministerial Discretion Request	Fee	$6,910	$7,347	$437	6.32%
Ministerial determination (stockholding request)	Fee	$4,880	$5,188	$308	6.31%

It is clear that these fee increases are driven primarily by capital costs. An analysis of the direct, indirect and capital costs from the 2023–2024 CRIS and the same costs in the current draft CRIS show that the percentage increase in direct and indirect costs are increasing by around 3 to 5% compared with the previous CRIS, while capital costs are increasing by around 28% for most fees. The capital costs for price increase requests, Ministerial discretion and Ministerial determinations for a different minimum stockholding quantity are increasing by 56 to 59%. It is not clear to Medicines Australia why the IT depreciation is so significant, or why the depreciation attributed to price increases, Ministerial discretion and Ministerial determinations is double that of most fees.

Estimated unit cost per activity	**Difference 2023–24 to 2024–25, %**		
	Direct costs	**Indirect costs**	**Capital**
ATAGI Pre-submission Evaluation			
Complex Submission	0.72%	4.62%	--
Simple Submission	0.71%	4.66%	--
Pre-Submission Meetings			
1st Pre-Submission Meeting	3.27%	4.61%	28.1%
2nd Pre-Submission Meeting	3.23%	4.59%	28.1%
Notice of Intent Submissions			
Notice of Intent	3.20%	4.76%	28.6%
Submission Services (PBAC Evaluation)			
Category 1	3.29%	4.70%	28.1%
Category 2	3.12%	4.77%	28.1%
Category 3	2.72%	4.75%	28.1%
Category 4	3.02%	4.78%	28.1%
Resubmission - Standard re-entry	3.12%	4.76%	28.1%
Resubmission - Facilitated resolution pathway	2.97%	4.69%	28.1%
Resubmission - Early resolution	2.87%	4.74%	28.1%
Resubmission - Early re-entry	2.87%	4.74%	28.1%
Secretariat Submission	3.20%	4.76%	28.1%
Generic Submission	3.19%	4.67%	28.0%
PBS Pricing Services			
Pricing Pathway A	3.19%	4.71%	28.1%
Pricing Pathway B	3.21%	4.70%	28.1%
Pricing Pathway C	3.26%	4.72%	28.1%
Pricing Pathway D	3.17%	4.71%	28.1%
Pricing Secretariat	3.16%	4.73%	28.1%

PBS List Management Services			
Price Increases	3.16%	4.75%	56%
Ministerial Discretion Request	3.24%	4.58%	59%
Ministerial determination (stockholding request)	3.23%	4.56%	59%

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, in excess of $600,000. This does not include the significant costs related to evidence generation, TGA cost recovery fees and submission preparation. Based on the fees, it is important to consider that cost recovery 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. $632,842, an increase of $30,052 (5%) versus 2023–2024**
  - 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: Orphan drug – approx. $369,000, an increase of $18,023 (4.9%) versus 2023–2024**
  - 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.

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 states, "*The appropriateness of this partial cost recovery approach will continue to be reviewed as required under the Australian Government Charging Framework".* The statement raises 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 the industry.

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 both the 2022–2023 and the 2023–2024 CRIS consultations. 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 associated with 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, as was the case previously.

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,

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