16 March 2020

PBS Improvements Section
Department of Health
Via email: PBSImprovements@health.gov.au

Dear PBS Improvements Section,

Medicines Australia would like to take this 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 2020 – 30 June 2021. Outlined below are industry level issues around what is presented in the CRIS, as well as some more general comments in relation to Stage 2 of PBS Improvements proposed for implementation from 1 July 2020.

The comments below relate to the following key issues:

- Consultation process
- Alignment between CRIS document and proposed PBS improvements
- ATAGI fees
- Total cost of submissions
- Magnitude of cost increases
- Facilitated resolution pathway
- Deed management fees and rebate management fees
- PBS List management fees
- Additional resources, service standards and independent audit and
- Need for continued consultation

Consultation Process

Medicines Australia is committed to timely and open consultations on both the PBS Process Improvements and the associated activity and structure (including the CRIS), which are important to achieve improved efficiencies and outcomes. It should be noted that consultations on cost recovery prior to the release of the CRIS were limited with minimal transparency. Medicines Australia has engaged in this process in good faith through the Access to Medicines Working Group (AMWG) subgroups, which are bound by confidentiality, but is disappointed that detailed information was not shared prior to the CRIS consultation document being released.

The consultation process, starting end of February 2020 for the CRIS to be implemented on 1 July 2020, provides inadequate time to ensure agreement to the proposed fees. Nor does it allow for the necessary business planning required for the management of the new fees as well as significant fee increases. Consideration should be given to agreeing a more practical timetable for implementation, as was the case for the increases and new fees announced in the industry forums of February 2018 and February 2019. Medicines Australia seeks to collaboratively design and contribute to the cost recovery changes and would appreciate early and open communication when decisions are made that affect this process.

Medicines Australia is also concerned that the draft CRIS is based on PBS Improvements to be implemented from 1 July 2020, where the proposed changes have not been finalised and are subject to ongoing consultation. Medicines Australia has also requested clarity on a number of processes, where clarity can lead to changes in the assessment of the cost associated with the activity. It is premature to

confirm and implement cost recovery fees for the revised and new processes until the details of those processes and the associated activities are known.

Alignment between CRIS document and proposed PBS Improvements

Medicines Australia requests that any new terminology or process needs to be consulted on and communicated to ensure clarity for all applicants and stakeholders.

Medicines Australia constantly stresses the need for consistency and alignment between the CRIS and Streamlined Pathways documents and is disappointed new language has been introduced as part of this consultation.

Specifically, the definitions of Initial submission categories (p.6) should not include new language or reflect changes to a category that has not previously been considered. For example: "Category 2" includes an "an application for a variation to an existing listing may be a Category 2 submission if is requires the PBAC to apply a health advantage test". No discussion with Medicines Australia has included mention of a health advantage test and as such the wording should be removed. The description and activity should reflect the most recent wording that has been subject to consultation i.e "for all submissions that require evaluation of new clinical or economic information that do not meet the criteria for Category 1 submission (current major submissions)".

ATAGI Fees

Medicines Australia appreciates the Department responding to industry's position on the need to lower ATAGI fees to better reflect the activities undertaken. The total cost of vaccine evaluation, through the ATAGI and PBAC processes, remains very high and creates concern that this will become a barrier to access. Medicines Australia welcomes continued discussion with the Department to continue to review the processes and fees for listing vaccines on the NIP and/or PBS to ensure that these are fair, equitable and reflect efficient activities in providing the evaluation service and seeks clarification on the expected timing for this dialogue, to ensure that any further efficiencies are identified and implemented as soon as possible.

Total cost for submissions

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, over $500,000. . This does not include the significant cost 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 are:

- Example A: approx. $640,000. A product classified as high added therapeutic value – with 2 pre-submission meetings, Category 1 initial submission, facilitated resolution, and accepting pathway A for pricing;
- Example B: approx. $645,000. A new product adopting a "standard" pathway – 1 pre-submission meeting, Category 2 initial submission, 2 x standard re-entry with an additional pre-submission meeting and adopting pathway B for pricing;
- Example C: approx. $480,000. A new product adopting a "standard" pathway – 1 pre-submission meeting, Category 2 initial submission, 1 x standard re-entry with an additional pre-submission meeting and adopting pathway B for pricing.

Magnitude of Cost Increases

There is limited transparency on the reasons for the increases in some fees, as highlighted in the table below. Based on an analysis of the fee increases, Medicines Australia seeks further information on how the parameter changes lead to significant percentage increases in some fees. The term, parameter changes, appears ambiguous and it seems unlikely that such significant cost changes can only be attributed to IT and depreciation costs as well as changes to departmental salaries and wages.

Fee	Previous Fee	Proposed Fee	Fee % change
Intent to Apply	$400	$430	7.5
Pricing Pathway A*	$120,410	$140,980	17.1
Pricing Pathway B*	$93,300	$111,490	19.5
Pricing Pathway C*	$58,520	$73,660	25.9
Pricing Pathway D	$19,510	$19,870	1.8
Pricing Secretariat	$10,490	$12,740	21.4
Price Increase request	$2,370	$5,040	112.7
Ministerial Discretion Request	$3,540	$7,040	98.9

*Including the new proposed mandatory rebate management fee.

Facilitated Resolution Pathway

Medicines Australia requests clarity on the cost of the facilitated resolution pathway and ensuring the proposed fee will only incur costs for activities undertaken.

The facilitated resolution pathway, at a cost of $238,230, is the highest of all fees proposed. It is not clear what activities are included in the pathway and given the significance it is assumed it includes the standard re-entry fee of $166,220, equating to approximately $72,000 for the facilitated workshop. The CRIS states that this additional cost is due to the costs associated with the proposed workshop with one or more members of the PBAC. This cost seems excessive for a three-hour workshop.

Given there remains a degree of uncertainty of process, including clarity on the number of PBAC members attending such a workshop, Medicines Australia requests further clarification on how the fee was derived and will be administered. Given it is unknown when a sponsor may re-enter with a PBAC submission to address the outcomes agreed upon in the 3-hour workshop (may be immediate for the next PBAC meeting, subsequent meeting or undetermined), it is unclear whether an applicant will receive a refund or how the fees will be accrued, based on if and when the activity occurs.

Deed management fees and rebate management fees

The consultation paper outlines proposed fees for rebate management, deed variation and deed renewal requests. Medicines Australia seeks further clarification of these fees as it is unclear from the CRIS what activities these fees would cover, and how they would be administered. Medicines Australia has concerns with how the operation of the rebate management fee and the deed renewal fee may occur in particular.

Last year (in the context of the CRIS 2019-20 discussions) the DoH undertook to work with industry to clarify the services being provided in the deed management fee. Medicines Australia requests that these fees should not be implemented until there has been further consideration to arrive at a mutually agreeable position, as there has not been progress and sharing of the agreed-upon work as outlined by the Department in the 2019-20 CRIS.

PBS List management fees

It is unclear why the fees for a price increase request and Ministerial discretion are being increased by 113% and 99% respectively. The consultation document states this is a result of "parameter changes". Medicines Australia's understanding from the paper is that parameter changes are being applied to all the fees. In this context, the significant increases in the price increase and Ministerial discretion fees appear out of step. Medicines Australia seeks further clarity around the application of parameter changes for these fees.

In addition, Medicines Australia has real concerns about the application of price increase fees. The Department has advised that:

> *"cost recovery is based on per drug or per item for price increase applications. After internal clarification we are able to confirm list management applications will be invoiced and charged a separate fee for each request, even if each request relates to the same drug or is for the same therapy (e.g. two different strengths). List management services (including price increase requests) apply per specific listing item (e.g. drug X, 20mg, oral), not per drug."*

Medicines Australia cannot agree to this position and seeks an urgent meeting to discuss the rationale for a fee based on a listing item.

Additional Resources, Service Standards and Independent Audit

The increase in fees is substantial and the CRIS document does not clarify how the additional funds will be utilised. The CRIS document should articulate in a transparent manner how the increase in fees will result in an increase in resources and staffing at the Department of Health. Publicly available metrics that reflect improvements in timeliness of submissions should be developed as a priority in consultation with the AMWG Transparency and Efficiencies subgroup.

Medicines Australia acknowledges that stage two of streamlining changes will be implemented from mid-2020 which requires further changes to cost recovery to reflect the additional service being provided to industry. To date there has not been discussion on or any agreed position between the Department of Health and Medicines Australia in relation to what service standards and metrics should be met. Medicines Australia requests that the Department develop and formalise metrics for discussion with the AMWG prior to end of 2020 and implement by the end of 2021 including an assessment of service performance.

Medicines Australia requests an independent audit of the increased fees, additional services provided, and if 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 Department and Medicines Australia.

Need for continued consultation

Any future CRIS amendments in future years should result in early engagement and consultation (including outlined timelines/milestones) with Medicines Australia, to reach agreement and confirmation on timings of implementation. In some cases, the increases to costs proposed in this CRIS (and likely future CRISs) will need serious consideration above country as to whether bringing new medicines to Australia is still a viable exercise. It is also essential that applicants are consulted early, and

genuinely, regarding increases to costs for business planning and to ensure that the medicines industry remains viable – a core pillar of Australia's National Medicines Policy.

As per the Strategic Agreement, Medicines Australia remains committed to working with the Department 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.

Medicines Australia seeks to hear from the Department on when a meeting can be arranged to address the above-mentioned issues prior to any further progress on implementation of the revised cost recovery fees.

Yours Sincerely

Elizabeth de Somer
CEO
Medicines Australia