

2 June 2020

PBS Improvements Section  
Department of Health and Ageing

**By email: [PBSImprovements@health.gov.au](mailto:PBSImprovements@health.gov.au)**

Dear PBS Improvements,

### **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 2020 – 30 June 2021.

### **Ongoing Consultation Process**

Medicines Australia is committed to ongoing consultations on both the PBS Process Improvements and the fee structure (and associated CRIS) to support them. Given the unprecedented environment, Medicines Australia acknowledges the delay in Government decision making on stage 2 PBS process improvements and the associated cost recovery changes. As an integral part of the response to the COVID-19 pandemic, Medicines Australia members continued to bring new medicines to Australian patients during this exceptional period.

Medicines Australia looks forward to a constructive, ongoing dialogue with the Department that will involve early discussion on when the revised 2020-2021 CRIS will be released that outlines the Stage 2 PBS process improvements and associated fee changes.

### **ATAGI Fees**

Medicines Australia appreciates the Department responding to industry's position on the need to apply lower ATAGI fees to better reflect the activities undertaken. Medicines Australia welcomes continued discussion with the Department to continue to review the processes and fees for listing vaccines on the NIP to ensure that these are fair, equitable and reflect efficient activities in providing the evaluation service.

### **Deed Management Fees**

Medicines Australia notes that the Government is "currently considering the further delay of deed management fees until Stage 2 PBS process improvements are considered". Medicines Australia seeks to meet with the Department in the near future to discuss the issues raised in our previous submission to the cost recovery consultation paper on 16 March 2020, in relation to the new fees for deed management, ensuring our concerns are addressed prior to introduction. A copy of our previous submission is attached for your reference.

## **Price Increase Fees**

Medicines Australia notes that the fees for a price increase request and Ministerial discretion, as proposed in February 2020, are not being proceeded with in the draft CRIS- can the Department please confirm that this is the situation. The significant increase in these fees were of concern to Medicines Australia and its members.

In addition, Medicines Australia raised concerns about the application of price increase fees. In the February 2020 consultation document, the Department 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.”

The draft 1 July 2020 – 30 June 2021 CRIS does not indicate how the price increase fees will be charged. Unless the Department is able to establish that each item code requires the same set of activities and costs, the basis of the proposed policy to apply one fee for each item code appears unwarranted. Accordingly, Medicines Australia’s position is that it remains strongly opposed to this approach as overly costly and imposes unreasonable regulatory burden. For this reason, Medicines Australia cannot agree to this position and seeks urgent consultation on this issue.

## **Equitable Application of Fees**

Medicines Australia members have raised a concern about the equitable application of the fees, and the potential unintended consequence on the ability of applicants to list lower revenue products and maintain those listings.

Given the substantial increase in fees, particularly for major submissions, Medicines Australia believes that there needs to be further consultation and consideration by the Department of the waiver provisions and potential alternatives to the fee structure to ensure that lower value medicines and vaccines remain viable prospects for PBAC consideration. For example, some of our members have proposed 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/vaccine reaches its projected revenue or waived in its entirety.

## **General Comments**

With regard to the format of the CRIS, there have been iterative changes to the information presented in each successive CRIS which hampers its utility as an instrument of transparency:

Previous CRIS versions (for example the 2018-19 CRIS) presented the number of FTE Departmental staff in each section (PBAC Secretariat, PBS listings, Evaluation, etc) that are engaged in cost-recovered functions. This breakdown has been absent from the most recent versions and is essential to understanding how the Department’s costs relate to the fees charged. This analysis should be restored to the final CRIS before its approval and publication later in 2020.

Previous versions also provided a breakdown of the types of costs incurred to provide each service by direct cost, indirect cost, and other cost. Again, this breakdown is absent from the draft 2020-21 CRIS for items other than ATAGI submissions and is an essential component for transparency. This level of detail and transparency should be restored before the CRIS is finalised and published.

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. We would like to see the Stage 2 PBS process improvements implemented from January 2021.

Medicines Australia seeks to hear from the Department on when a meeting can be arranged to address the issues outlined in this letter relating particularly to the deed management and price increase fees.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'E. De Somer', written in a cursive style.

Elizabeth De Somer  
CEO  
Medicines Australia

**Attachments:**

Medicines Australia submission to the February 2020 Draft Cost Recovery Implementation consultation.  
Submission is dated March 16, 2020