

HTA Improvement Section
Technology Assessment and Access Division
Department of Health
PBSimprovements@health.gov.au
17 February 2019

Dear Sir/Madam,

Consultation on the Draft Cost Recovery Implementation Statement (CRIS) for Listing Medicines on the PBS and Designated Vaccines on the NOP 1 July 2019 – 30 Jun 2020

Medicines Australia welcomes 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 2019 – 30 June 2020.

Medicines Australia represents the discover-driven pharmaceutical industry in Australia. Our member companies invent, manufacture and supply innovative medicines and vaccines to the Australian community. Those medicines keep Australians out of hospitals, prevent disease and play a pivotal role in ensuring a productive and healthy community.

Outlined below are industry level issues on what is presented in the CRIS, as well as some more general comments in relation to specific proposed changes being implemented this year.

Consultation Process

Medicines Australia is committed to on going consultations on both the PBS Process Improvements and the fee structure (and associated CRIS) to support them. It should be noted that consultations on cost recovery prior to the release of the CRIS were limited to a sub-group of the Access to Medicines Working Group (AMWG) which was bound by confidentiality. Medicines Australia engaged in this process in good faith to collaboratively design and contribute to the cost recovery changes and would appreciate early and open communication when decisions are made that impact this process. For example the Mid-Year Economic and Fiscal Outlook (MYEFO 2018-19) figures were finalised without industry consultation, resulting in some fee changes that were unexpected and have potential flow-on consequences for their implementation.

Medicines Australia acknowledges that stage two of streamlining changes will be implemented from mid-2020 and will require further changes to cost recovery to reflect the new submission types. Furthermore, we would like to reiterate our desire to commence consultation for the next CRIS given that this will involve substantial changes for our industry members.

Alignment between CRIS document and the Streamlined Pathways Process

There is a concern that there are inconsistencies between the CRIS and the Streamlined Pathways guidance documents, as these should be aligned. For example, the case manager role is described in the CRIS associated with high clinical priority and significant budget

impact submissions, whereas in Streamlined Pathways documents they are for high clinical priority submissions only. It is essential that there is consistency and alignment between the CRIS and Streamlined Pathways documents.

Value for money through demonstrated KPIs

A key driver for the cost recovery activity was efficiency and transparency. The industry is expected to pay for Phase 1 of the streamlined pathways process (positive recommendation pathways), however there are no details about the KPIs associated with these new processes. Further details on how efficiencies will be measured as a result of these new streamlined processes should be included in the CRIS. Any new or further KPI's should be discussed and mutually agreed with Industry.

Transitional arrangements

Following the release of the CRIS, and the Department's response to questions raised at the information sessions in late January, detailed procedure guidance will be essential to industry understanding of how the CRIS will operate in practice. Particularly in relation to the transitional arrangements listed for implementation from July 2019 (Section 3.2.3 of the CRIS). It is imperative that the Department provide this guidance to Industry as early as possible.

Deed management fees

Medicines Australia welcomes the Department's decision not to impose levies as proposed in February 2018. We are however disappointed that there is an annual fee for deeds (Section 3.2.4 of the CRIS). This seems, for all intents and purposes, like a levy with another name. The rationale for an ongoing fee in addition to the new/existing deed fee is not clear from the CRIS document. Therefore, Medicines Australia does not agree with this annual deed fee proposal, however, accepts that where there is a meaningful change to the Deed, it would be reasonable to have a fee associated with this activity. Of course, the definition of meaningful change needs to be clearly articulated.

Vaccines – Cost Recovery

Medicines Australia would like to reiterate its position regarding the introduction of cost recovery for vaccines, and that it does not agree with the proposed implementation of fees for ATAGI advice from 1 July 2019. Vaccines manufacturers have been consulting with the Office of Health Protection (OHP) and have agreed in-principle to cost recovery, but this was contingent on agreed and understood process improvements and reconsideration of the costs once OHP had finalised their tender for evaluation services. The Medicines Australia Vaccines Industry Group will need to engage further with OHP to work further on the process which from industry's perspective is not developed and the costs need further consideration in the context of duplication by the TGA and the PBAC.

The introduction of a proposed fee for ATAGI evaluation of \$295,420 for a complex submission, in addition to the \$221,520 fee for a PBAC evaluation means vaccines submissions will incur fees in excess of half a million dollars. This is excessive, especially considering the duplication of effort between the two advisory groups, particularly in the clinical assessment. Medicines Australia believes strongly that efficiencies should be sought for both sponsors, and the Department by removing this duplication, and unnecessary cost. Therefore, Medicines Australia continues to propose a further consultation session to

understand the new proposed vaccine process (including ATAGI's role) and have a further discussion regards to the validity of such fees and the commensurate structure of the fees between ATAGI and the PBAC process. In addition, such an increase in fees, there should be strong consideration to staggering such a fee increase over a two-year period.

Orphan drugs

Medicines Australia appreciates the Department's acknowledgement of the feedback received from Industry relating to the proposed cost recovery fees for a medicine which has been designated as an orphan drug, the result of which is the revised criterion which allows a fee exemption for a first submission to the PBAC within 12 months of TGA registration for an orphan medicine. However, whilst the CRIS states that "This approach will both support patient access to innovative medicines that treat conditions that may not have an equivalent on the PBS and incentivise a single submission approach supporting timely patient access to these innovative medicines", this is not necessarily the reality for medicines so designated. The key reason that a medicine is designated an orphan is due to the small patient population for which it is indicated. It therefore follows that the evidentiary base informing a submission for PBS listing for an orphan medicine is less robust than a submission for a drug which is indicated for much bigger populations.

Given the less robust evidence, the submissions for orphan drugs are 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 '1st 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 (potentially requiring at least one more major) to resolve the uncertainty which, under the revised criteria, will incur cost recovery fees.

Furthermore, in addition to the cost recovery fee(s) for the subsequent submission(s), there is the impost of the other new cost recovery fees previously not applied, including, but not limited to, the pre-submission meeting and the development of a Deed to cover the listing. These additional fees for orphan indications, and the possibility of this having a negative impact on the financial viability of the medicine in question, may result in the sponsor having to make the difficult decision not to pursue reimbursement in Australia, which is a very small market within the global context.

Other comments

Overall, 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.

I would like to take this opportunity to reiterate the previous concerns raised in the letter of 20 December 2018 to Adriana Platona, First Assistant Secretary, Technology Assessment and Access Division. Medicines Australia feels that the following issues outlined in the letter were not well addressed in the CRIS:

- Legislation/regulation changes required and timing of these: details in the CRIS are vague.

- Service standards: there is no detail on what baseline service industry can expect in return for these fees, irrespective that no service improvements are being delivered on the existing processes.
- Independent reviewer: Medicines Australia is still supports the need for an independent review of the increases to the fees – particularly those associated with new processes. There is no bench mark for the effort and activities involved with the process being implemented under Streamlined Pathways. An independent review of those activities and the associated costs are an important step towards industry support. buy-in.

POINTS OF CLARIFICATION FOR THE CRIS 2019-20

2.1.2 How was the cost recovery implemented according to the government decision?

- Page 6 – ‘Changes for further development and consultation include better aligning the PBAC process with TGA, ATAGI, MSAC processes and clinical evaluations.’
 - Medicines Australia looks forward to updates on the progress of these changes and alignments.

3.2.3 Demand driven regulatory activities from streamlining process improvements

- Page 6, 2019-20 CRIS – ‘Key performance indicators will also be developed to reflect the changes to processes and included in a future CRIS once agreed by Government.’
 - Medicines Australia is committed to continuing to work with the Department on ensuring KPIs and performance measures developed are fit for purpose.
- Page 10 – ‘Transitional arrangements to be implemented from July 2019 with detailed procedure guidance will be developed for consultation in early 2019’.
 - As mentioned above guidance on how and when the new fees will apply and operate is imperative - e.g. joining a new deed
- Page 11 – Positive recommendation pathways (previously pricing fees). The aim is to increase certainty, timeliness, efficiency and transparency following a positive recommendation by the PBAC.
 - Medicines Australia looks forward to working with the Department to develop performance measures to ensure these aims are being realised through the PBS Process Improvements.
 - KPIs to measure each of these parameters should be incorporated in the department’s self-assessment and included in the Annual Report.
- Medicines Australia seeks to clarify that if a sponsor does not intend to make a pricing offer, they should not have to pay for a notice of pricing intent.
- “Fees will be charged at the time of seeking to initiate an activity”: this is a major change particularly when combined with the significant increase in pricing fees. Pricing fees have always been charged in arrears not in advance. Medicines Australia suggests that perhaps 50% of the fee be charged when the activity is initiated, and 50% paid on PBS listing.

3.3.1. Costs breakdown

- Table 7: It is not clear from the CRIS what constitutes a “new” vs “existing” deed. Medicines Australia believes the higher “new” deed fee should only apply when

starting from scratch with a completely new deed. Where there is an existing deed that only requires modification – i.e. for a new entrant or an indication expansion, it should be clear that the “existing” deed fee applies.

7. Key performance measures

- Page 19 Table: Ensuring access to innovative, clinically effective and cost-effective medicines through the PBS – why is there only an 80% target for submissions for new medicines that are recommended by PBAC and then listed on the PBS within six months of agreement of budget impact and price? Should this not be 100% considering the activities will be fully cost recovered from this CRIS going forward.
- In addition to the above KPI, time from PBAC recommendation to PBS listing should also be included as a KPI to measure the success of the positive recommendation pathways.
- It is outlined in the Strategic Agreement that the PBAC will target a 50 per cent reduction in the number of PBAC resubmissions. Medicines Australia believes that this target should also be a key performance measure for the PBAC.

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 essential that sponsors 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.

The independent review of the activities and fees associated with the new processes for both listing medicines on the PBS and vaccines on the NIP in this CRIS and future CRISs will be essential to securing industry support. To that end Medicines Australia will seek a meeting with the Department to discuss how this process can get underway.

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.

Yours Sincerely,



Dr Vicki Gardiner
Director
Policy & Research
Medicines Australia