Medicines Australia and members' response to the proposed new policy on rescinding Pharmaceutical Benefits Advisory Committee positive recommendations

Overview

Medicines Australia refers to the proposed policy to rescind unimplemented positive Pharmaceutical Benefits Advisory Committee (PBAC) recommendations and provides an overview of sponsor feedback.

While Medicines Australia understands the wider perspectives of unimplemented positive PBAC recommendations, sponsors do make every effort to proceed with a positive recommendation given the significant resources utilised to list a new medicine on the PBS.

Medicines Australia would like to re-emphasise that sponsors do want to bring new medicines to the Australian market.

It is important that the Department of Health (the Department) collaboratively engage with sponsors to understand the reasons for unimplemented PBAC recommendations and to consider, in consultation with the industry, whether changes can be considered to address any significant issues. In addition, Medicines Australia wants to continue to work with the PBAC and the Department to improve the listing processes – this is one of the objectives of the Strategic Agreement. The collaboration between the Department and Medicines Australia as part of the Strategic Agreement has been demonstrated with the current pathways project. Medicines Australia sees this proposed policy change within that realm and requests that the PBAC further consult with Medicines Australia on this issue and to carefully consider the consequences of any policy change on access to new medicines.

Summary of issues

Medicines Australia members have expressed a range of concerns in relation to this policy, relating to:

- The proposed timeframe (16 months) for first consideration of a rescission being unnecessarily short and unfair.
- The proposed one-week turnaround time for a sponsor's response being inadequate.
- The additional costs (both financial and non-financial) associated with a resubmission of a rescinded recommendation is unreasonable.

Medicines Australia members seek clarification and consultation on several issues, including:

- The definition of an unimplemented positive recommendation.
- The criteria for review and the number of products meeting these criteria in the last 5 years.
- The reasoning for the 16-month review timeframe.
- The level of re-assessment utilised when considering rescission, for example would ESC and DUSC be involved?

Members' requests

- A forum with the PBAC Chair to seek clarification on the rationale for the change, and how the proposed change will be beneficial to patients, clinicians and other stakeholders. Medicines Australia requests that this occur prior to the matter being further considered by the PBAC.
- Members also request a wider consultation, including patient groups, to allow appropriate examination of the proposal and to explore alternative solutions and prevent unintended consequences. This approach would be consistent with the approach to consultation on other changes to existing PBAC and PBS processes.
- Metrics on the number and disease areas for unlisted medicines more than 16 months following a positive PBAC recommendation, to better understand the background to unimplemented recommendations, so that any changes are fit for purpose across a variety of situations.

Detailed comments from Medicines Australia members' comments

Definition of unimplemented recommendations

1. What is considered an unimplemented recommendation? For example, would a review be only applicable where sponsors have not initiated the listing process at all following recommendation or any recommendation which has not been listed within the proposed rescission timeframe? Members seek clarification and closer consultation on the definition in the proposal, as this is a critical question.

Operation of current policy and post-PBAC processes

2. Sponsors emphasise that the current arrangement is working well and has not been controversial or challenged to date (PBAC minutes, paragraph 4.13). Changes in the current arrangements could hinder patient access to innovative and life-saving medicines.
3. Post-PBAC process involves several steps, including agreement and finalisation of the PBAC-recommended conditions of the listing including the PBS restrictions; negotiation of and execution of any applicable deed of agreement representing the final agreement on price and cost, medicine quality and availability checks to ensure medicines will be available in Australia from the listing date; and government processes relating to the listing, including financial approval and legislation. While Department figures indicate post-PBAC processes for most medicines is an average 9 months[1], Medicines Australia notes that a small cohort of complex medicines[2] requires lengthier negotiations with the Department following recommendation by the PBAC.

Proposal to consider rescinding from 16 months

4. Sponsors challenge the stated rationale of a review four PBAC meetings (i.e. 16 months) after its positive recommendation for the unimplemented recommendation, including the unnecessarily short timeframe between the first review and subsequent review only two meetings later (6th meeting following positive recommendation – 24 months).
5. Sponsors note significant issues with regards to 'class' deeds in that sponsors are not aware of the deed details until post PBAC recommendation. There are typically no adjustments made to an existing deed subsidisation caps to account for multiple sponsors educating prescribers about treatments thereby increasing uptake rates.
6. Sponsors note that in many instances the delay in the listing process of a positive recommendation is due to the complex pricing negotiations with the Department (i.e. sponsors not being able to have constructive, collaborative negotiations with the Department).
7. Complications imposed by such actions as international price referencing and negotiations with parent companies given the potential implications in overseas markets, can complicate price negotiations, resulting in delay in the listing process.
8. While the fast tracking of TGA submissions has increased the likelihood of a PBAC submission being one of the first reimbursement submissions globally for a drug, the absence of an established global pricing policy also contributes to longer negotiations with the Department.
9. Members seek clarification and appropriate assurances regarding their rights to appeal if a positive recommendation is rescinded following a review.
10. Medicines Australia notes that consumer groups and prescribers should be consulted when a recommendation is being considered for rescission.

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[1] SQ19-000058 - https://www.aph.gov.au/api/qon/downloadattachment?attachmentId=fe2eb549-d266-4318-a68d-b3fe3cdec762

[2] SQ19-000057 - https://www.aph.gov.au/api/qon/downloadattachment?attachmentId=188cd8ae-bd4f-41ec-852c-1fc6daf619fc

Procedural fairness and resubmission

11. The proposed one-week turnaround time to a request from the Department for a sponsor to respond to the outstanding PBAC recommendation is unreasonable. It is imperative that sponsors are given sufficient time to carefully consider the matter.
12. How will the PBAC undergo the similar level of assessment and consideration of the evidence when considering rescinding a recommendation as taken when making the recommendation. A typical major submission involves the expert assessment by the Drug Utilisation Sub-Committee (DUSC) and the Economics Sub-Committee (ESC). What will be the role of DUSC and ESC when considering rescinding a positive recommendation?
13. Are sponsors required to lodge a new major submission if recommendation is rescinded?
    The proposed changes will create unnecessary burden and unreasonable cost for sponsors in a resource constrained environment and against the backdrop of the highest evaluation and processing fees in the world.

Strategic Agreement

14. The Strategic Agreement targets a 50% reduction in the number of resubmissions to the PBAC. Rescission of recommendations, rather than support to facilitate post PBAC listing processes, does not contribute to the reduction of resubmission churn. To facilitate the successful listing on the PBS, this small cohort of positive recommended medicines should be supported through the post-PBAC processes through constructive consultations, without risk of a rescission. This would be a far better outcome for patients. The Access to Medicines Working Group provides an appropriate forum to further consider this proposal and its impact on the Strategic Agreement.