Medicines Australia Submission

Public Consultation – Revised Procedure Guidance – Initial Submission Categories and Single Submission Date

Medicines Australia welcomes process improvement to the Pharmaceutical Benefit Scheme (PBS) that delivers greater efficiency, transparency and timeliness of PBS listings.

Medicines Australia acknowledges the continued improvements made to Stage 1 of the PBS improvement process, in particular the pre-submission meetings, including:

- **Providing access to a pre-submission meeting during the 17 week cycle** – the availability of pre-submission meetings during the 17 week cycle reduces planning complexity and allows more flexibility of presenting key clinical data in a timely manner.
- **Allowing a meeting to occur between 8 and 16 weeks prior to submission lodgement** – this is a welcome improvement, as it addresses concerns that key data may not have been available at the original requirement of 16 weeks prior to submission lodgement, potentially causing a delay in making a submission to the PBAC.
- **Flexibility in allowing 2 pre-submission meetings prior to submission lodgement** – this flexibility is an important option for applicants, noting the majority of submissions are expected to seek only one pre-submission meeting.
- **Ability to continue to evolve PBS Improvement process based on metrics and Industry feedback** – Medicines Australia welcomes continued open dialogue with the Department of Health to improve PBS submission processes and ensure ongoing improvements in efficiency, transparency and timeliness of PBS listings.

Concerns on the Initial Submission Category:

The table below lists Medicines Australia's remaining concerns with the proposed initial submission categories.

Outstanding concerns with proposed Initial categories	***Comment***
The ability to differentiate between initial submissions and resubmissions	• As stated in the Strategic Agreement, Medicines Australia is targeting a 50% reduction in the number of resubmissions to the PBAC. • Part of this important metric is dealing with 'rejections', 'deferrals' and 'positive recommendations' that involve circumstances or proposed changes that cannot be met by the sponsor. Whilst some applicants of submissions may be able to accept the variation proposed in the recommendation and proceed to listing, there are other instances where the applicant will need the recommendation re-considered by the PBAC because it cannot proceed. It is the latter that causes the greatest concern for Medicines Australia. Medicines Australia proposes that any subsequent submission, addressing the variation that cannot be accepted by the applicant, must logically and reasonably be considered as a resubmission and not as an initial submission. Medicines Australia provides further clarity on its position in its response to the resubmission pathway consultation.
Consistency in definition and terminology	• To avoid submission categorisation errors and confusion, it is critical all documents are consistent with the language and terminology that is adopted and used in existing documents (including legislation and regulations) describing the criteria and processes for PBAC submissions. For example, for interventions the terminology switches between medicine, drug and vaccine.

	• For example, currently the Microsoft word document shared in the consultation uses a different terminology and description versus Attachment B to describe the initial categories, which may create confusion and misclassification by sponsors. • Significant concern remains around the use of "novel" and "currently untreated medical condition" in the criteria for Category 1, including how this will be defined to ensure there is consistency in application and decision-making. The definitions of novel and currently untreated should be clear to all participants in the PBAC process and the criteria for determining novel and currently untreated should be transparent. In particular, this will assist applicants in accurately predicting the applicable category for any submission. • The limited acknowledgement of Vaccines in Category 1 applications is of significant concern, noting that there is no unique statement referring to 'or where a vaccine is currently not available against a disease'
Clarity on each initial submission category	• The current description for the initial submission category introduces a level of complexity, which does not necessarily support the streamlining of processes nor provide a greater level of transparency of activity that is required for each submission. • To support the transition and create sponsor confidence in the categories, Medicines Australia requests that the Department of Health undertake an exercise whereby submissions considered at the July 2019, November 2019 and March 2020 PBAC meeting are classified under the new categories to assess the issues that may arise with the proposed classification system. The results of this exercise should be shared with Medicines Australia and used to further refine the definitions as appropriate. • Medicines Australia requests additional examples, including what would be considered as Category 1.
Initial submission category validation	• Medicines Australia seeks clarification on the process to validate the category. While the intent is to establish well-defined descriptions of each category, there will be exceptions, and there may be disagreement on the proposed and accepted category between applicants and the Department of Health. Given the level of investment required to prepare and lodge a submission, it is important that there is a timely mechanism available to appeal the submission category, within the submission period, to ensure there is procedural fairness in a manner that does not create the risk of delay for any submission. • Medicines Australia welcomes the acknowledgement that a submission may proceed to the intended PBAC meeting if sufficient information is available. However, clarity is required on the process and mechanism if a sponsor is subject to an increased cost recovery fee due to the re-classification. Given the re-classification may be associated with a higher cost recovery fee, the applicant may be required to seek further internal approval to proceed, resulting in implications to the applicant, process for Department of Health resource allocation and overall patient access.
Co-dependent initial submission timelines	• Under the current system, co-dependent initial submissions must be submitted one month earlier than standard PBAC submissions to allow for MSAC review processes. • In the initial submission categories procedure guidance, it is unclear if the single submission date will also apply to co-dependent submissions and when pre-submission meetings should be held. • Medicines Australia requests further clarification be documented within the procedure guidance to clarify these issues for applicants.
Cost Recovery	• Medicines Australia requests public consultation on the Cost Recovery Implementation Statement (CRIS) as soon as possible. This is critical to support both the introduction of the initial submission categories but to support

	appropriate business planning. As has been the case for the introduction of changes in 2019, it is essential for applicants to have sufficient time to make business plans for the forthcoming changes, in advance of implementation.

Concerns on the Single Submission Date:

Medicines Australia acknowledges the introduction of a single submission date allows streamlining of Department of Health and PBAC processes and resources. However, the introduction of the single date must not delay access to new medicines, including those subject to a re-submission pathway or where PBAC re-consideration is required for a 'positive recommendation' that involve circumstances or proposed changes that cannot be met by the sponsor.

Medicines Australia's Recommendations:

Medicines Australia proposes that:

- A 50% reduction in the number of resubmissions to the PBAC is a significant metric in the Strategic Agreement. To realise this reduction, it is important that the PBS process improvements are achieved not only in the proposed resubmission pathways, but also on managing submission which receive a 'positive recommendation' that involve circumstances or proposed changes that cannot be met by the sponsor. Medicines Australia submits that any subsequent submission to address the variation that cannot be accepted by the applicant, must logically and reasonably, be considered as a resubmission and not an initial submission.
- There is significant concern that the proposed initial submission categories are not clearly defined and add complexity to the process which does not represent added value to the PBS listing process. If the Department of Health is committed to maintaining the categories, further clarity is required to create confidence in the process. Medicines Australia requests that the Department of Health undertake an exercise whereby the submissions on the public agenda for July 2019, November 2019 and March 2020 PBAC meetings be classified under the new categories to assess the issues that may arise with the proposed classification system. The results of this exercise should be shared with Medicines Australia and used to further refine the definitions as appropriate
- Significant concern remains around the use of "novel" and "currently untreated medical condition" in the criteria for Category 1.
- A timely appeals mechanism be developed to provide the applicant confidence that procedural fairness is available, especially given the level of investment required in preparing and lodging a submission. The timely mechanism must enable a submission, based on sufficient data being available, to be considered at the PBAC meeting originally intended by the applicant. Clarity on the process and mechanism is required if a sponsor is subject to an increased cost recovery fee due to the re-classification.
- The introduction of a single submission date must not delay access to new medicines, including those subject to a resubmission pathway or where PBAC re-consideration is required for a 'positive recommendation' that involves circumstances or proposed changes that cannot be met by the sponsor.