Medicines Australia Submission

Public Consultation – Revised Procedure Guidance – Resubmission Pathways

Medicines Australia is supportive of the introduction of Resubmission Pathways and the formalisation of the pragmatic approach that currently exists today for early reconsideration of some submissions. The intent of the Strategic Agreement was to allow for the ability to co-create solutions together which lead to earlier PBS listing of medicines; and this formed part of the Guiding Principles to the Pathways work at its commencement. Therefore, Medicines Australia is pleased to see the acknowledgement of the need for a solution-focused approach to resubmission discussions.

Medicines Australia also welcomes the following progress on the Resubmission Pathways process:

- ***Clear direction from the PBAC on the issues to be resolved*** – This clear direction enables sponsors, the PBAC, the Department of Health, and other relevant stakeholders, to resolve these issues together.
- ***Introduction of a Facilitated Resolutions Workshop*** – This new forum allows for true co-creation of workable solutions between the sponsor, the PBAC, Department of Health and other relevant stakeholders for medicines deemed by the PBAC to represent high-added therapeutic value (HATV) AND where the PBAC has determined specific matters for resolution could be resolved through a workshop.
- ***Reduced resubmission rate and earlier access for patients*** – The ability to resolve issues in a more timely way and reduce resubmissions is a common goal aligned with the Strategic Agreement; however, it can only occur if both parties (applicant and PBAC) are able to come to an agreed solution.
- ***Industry attendees of Facilitated Resolution Pathways are expected to have the expertise required to discuss the issues identified by the Committee –*** Earlier wording in the draft procedure guidance proposed that: *"Industry attendees are expected to have the authority to determine and agree solutions".* MA expressed concern that it may be difficult for sponsors to make decisions within the workshop in the absence of Global approval. Alternatively, ideas, potential ways forward and an agreed framework might be proposed in these meetings with a commitment to seek approval following the meeting.

Concerns on the Resubmission Pathways Procedure Guidance:

Despite some benefits and improvements in the proposed Resubmissions Pathways process, Medicines Australia remains concerned about a number of elements which are outlined in the table below. In particular, Medicines Australia seeks clarification as to the approach that will be required to resolve the issues associated with 'Positive Recommendations' and 'Deferrals' that involve circumstances or proposed changes that cannot be met by the sponsor.

Outstanding concerns with proposed Resubmission Pathway	***Comment***
Provide clear and transparent resubmission processes for submissions that are not recommended (rejected)	• The Resubmission Pathways process does not provide clear guidance on the process following a 'Positive Recommendations' and 'Deferrals' that involve circumstances or proposed changes that cannot be met by the sponsor. • The Pricing Form Part A for Positive Recommendations provides the following option for a sponsor who cannot progress to post-PBAC activities: *'No, we will submit to the PBAC for re-consideration as a resubmission'.* This suggests that within Stage 1 of the PBS Improvement changes from July 2019, the Department considered that positive recommendations that could not be actioned by the sponsor could be re-considered as a RESUBMISSION, and therefore should be incorporated into the Resubmission Pathways process. • If a 'Positive Recommendations' and 'Deferrals' that involve circumstances or proposed changes that cannot be met by the sponsor are not deemed to be resubmissions, this significantly undermines the relevance of a core metric within the Strategic Agreement: *'50% reduction in the number of resubmissions'*. • Medicines Australia does not believe that procedural fairness is being considered if the sponsor has no grounds to respond to the PBAC requests in a solution-focused and pragmatic way
'formalising solution oriented processes for post rejection discussions'	• In order to remain patient focused, it is important that applicants have a say in these solution-oriented discussions rather than having binding solutions that may be unworkable. Medicines Australia re-iterates that potential solutions should be co-created and remain workable for both the applicant and the PBAC. • Medicines Australia is disappointed that only one of the four proposed pathways, the facilitated workshop, involves a process that allows a solution orientated discussion and requests the approach be applied to the remaining categories.
'It is expected that most of the Category 3 and 4 initial submissions would be nominated for the Early Re-entry Pathway.'	• In the webinar for the consultation, it was specifically stated that there is no connection between the initial and resubmission categories. Therefore Medicines Australia requests that the Department of Health provide the rationale for this statement to better understand this comment. • Clarification is required on why there is a need to be explicit for categories 3 & 4, but not for other initial submission categories and resubmission pathways. • Medicines Australia seeks to understand the apparent inconsistency in streamlining the resubmission process for Category 3 & 4 initial submissions, but not accepting the use of the TGA/PBAC parallel process for these types of initial submissions.

Following lodgement of the resubmission, the nominated pathway will be validated against the PBAC's nomination	• To enable sponsors to fully understand the timing implications, Medicines Australia seeks to understand what happens when the resubmission pathway nominated by the sponsor and the PBAC are not aligned. For additional insight from Medicines Australia, refer to initial submission category consultation on a review process.
The PBAC can still defer making a decision pending the provision of specific additional or missing information that cannot be provided by the applicant and is relevant and important to the Committee's decision	• Medicines Australia requests that examples be provided to ensure clarity to the reader. Would an example be pending a TGA outcome? Additional transparency is requested to be included in the procedure guidance • What happens if the applicant cannot provide the missing information; - e.g. bespoke analyses not approved by Global to be made public?
Where the PBAC considers a medicine to be high added therapeutic value (HATV), the PBAC can nominate an early resolution or facilitated resolution pathway	• As part of the metrics generated to assess the improvement in PBS processes, it would be useful to capture 'the number and proportion of medicines nominated by the PBAC as HATV', and therefore eligible for one of the resolution pathways.
An Intent to Apply exception is required for the early resolution and early re-entry pathways	• The procedure guidance should clarify why this exception is required, as it is perceived as adding potentially unnecessary red tape to the process. • The procedure guidance should also clarify who initiates this Intent to Apply exception.
For Early Resolution and Early Re-entry Pathways, the lodgement deadline is Monday Week 7	• Medicines Australia requested that this timeline be extended to of the end of Week 7 and the PBAC agenda to be posted at an alternate time. • Medicines Australia will consult with member companies on an alternate time for the publication of the agenda and will provide our position in January 2020. • If the timelines cannot be adjusted further, it will be important to monitor how many submissions can meet the timelines at an appropriate level of "quality" in the small window of opportunity – it will be important to consider if adjustments should be made in the future.
Facilitated workshops: The first opportunity to resubmit is Week 17 in the current cycle (same as the current Major resubmission timelines). However, dependent on the workshop outcomes, applicants may choose to lodge their resubmission in Week 17 of a subsequent cycle ~~(the lodgement deadline for initial submissions).~~	• Medicines Australia requests that the redacted text be deleted as it is confusing and appears unnecessary.
Facilitated workshop attendees will include the applicant, the PBAC Chair and Deputy Chair, the department, and if necessary, other experts (based on the issue/s to be addressed)	• Medicines Australia requests clarity on who requests the experts and recommends that it be a joint decision of the sponsor, Department and PBAC at the post-PBAC meeting. • Medicines Australia believes there is value in having other members of PBAC attend as required; eg discussant • Agreed outcomes on agenda topics and attendees from the post-PBAC meeting would be helpful, aligned with the approach for pre-submission meetings
Facilitated workshop outcomes will be prepared by the department and confirmed by the PBAC Chair and Deputy Chair and may be published as part of the Public Summary Document	• Medicines Australia submits that outcomes from these workshops should not be published. While the consultation papers states outcomes 'may be published,' the Excel document states the outcomes are 'not published' • Publication of the outcomes may be a barrier to open discussion if these are to become public comments that are not agreed between all participants.

	• Workshops are intended to assist sponsors with the resubmission and not to assist in the PBAC's decision making. • There is no comment about sponsor input into these outcome statements. There appears to be no recourse for redaction or correction which is a fundamental process that is requested by Medicines Australia to be included. • Medicines Australia proposes that under this process, the Department of Health must seek confirmation from the sponsor on the proposed outcomes of the meeting to ensure shared understanding of the way forward, consistent with the outcome documents for pre-submission meetings.
Facilitated workshops will occur in Week 8 (following PBAC consideration)	• Medicines Australia requests the Department of Health consider reassessing timing of facilitated resolution workshops; flexibility may be required depending on availability of attendees. • How does this work for the Nov meeting given Christmas holiday break?
Resubmission Pathway validation	• Medicines Australia expresses concern around the potential for delays for patient access if not all issues to be addressed are considered by the sponsor. • Medicines Australia requests consideration for open discussion of the issues at the post-PBAC meeting to agree on what is relevant for consideration in the resubmission. • It would be helpful to understand what criteria will be applied by the PBAC Executive to decide what is relevant for consideration at the next PBAC meeting versus through Standard Re-entry • Medicines Australia requests that the Department provide the timing (ie week number) for when the PBAC Executive will determine if the resubmission will go through to the next meeting.
Government agreed changes to cost recovery arrangements would be consulted on publicly through the Cost Recovery Implementation Statement (CRIS) process	• It has been consistently communicated by Medicines Australia that sponsors require sufficient time to plan and prepare for these fee changes. Medicines Australia has asked that consultations on these fees occur as soon as possible, and no later than March 2020. • For sponsors to utilise these pathways and for patients to gain timely access to medicines, reasonable fees will be required.

Medicines Australia's Recommendations:

Medicines Australia proposes that:

- There be flexibility and pragmatism within the process to ensure that 'Positive Recommendations' and 'Deferrals' that involve circumstances or proposed changes that cannot be met by the sponsor be included in the resubmission pathways. There will be delays in patient access if a 'Positive Recommendations' and "Deferrals' that involve circumstances or proposed changes that cannot be met by the sponsor cannot progress unless accepted as per PBAC advice or another initial submission is lodged.
- The timing of the Resubmission Pathways needs to be reassessed to ensure deadlines can be reasonably met to ensure joint solutions can be achieved.
- Pragmatic ways forward are not lost through formalising and over-engineering the resubmission process.