

Health Technology Improvement Section
Office of Health Technology Assessment Policy Branch
Technology Assessment and Access Division
Department of Health
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29 April 2019

Dear Sir/Madam

Public consultation on Positive Recommendation Pathways process and guidance

Medicines Australia (MA) welcomes the opportunity to provide comment on the PBS Process Improvements consultation on the Positive Recommendation Pathways process and guidance material. This feedback has been consolidated based on input from the MA representatives on the Streamlined Pathways Subgroup of the Access to Medicines Working Group (AMWG), the Health Economic Working Group and have also included wider perspective from the Medicines Australia membership.

MA has developed detailed comments which can be found in the attachment to this letter, but we have taken the opportunity to highlight the following key issues which are throughout our more detailed comments.

Absence of timelines

A fundamental ask from industry as outlined in the Strategic Agreement is: ‘by the end of year 3 of the Term, reducing the time from PBAC recommendation to listing by an average of 2 months....’, with end of year 3 defined as July 2020.

The work on the Positive Recommendation Pathways process is key to achieving that reduction.

Without indicative timelines and a baseline measurement, MA finds it difficult to see how this objective will be achieved and monitored to ensure that it is, in fact, achieved.

Without indicative timelines, it is also difficult to see how we will be able to “optimise accountability throughout the listing process for industry, the Department and other relevant stakeholders”, which is one of the stated objectives of the improvements. At a MA webinar with patient organisations on 15th April, attendees commented that timelines were an important part of transparency. They also proposed the need for a simplified schematic of PBS processes with estimated timelines for each milestone, to help manage expectations (refer to Attachment B of the MA comment on consumer friendly Medicines Status Website).

MA believes there is already information/metrics available on the key indicative timelines as presented through the Consolidated Outcomes report and at Senate Estimates:

- from positive recommendation to agreement on financial estimates (2.7 mths)
- from positive recommendation to listing (7.8 mths)
- from pricing agreement to listing (up to 6 mths)

From this information, the key timelines at baseline for each step may be calculated. MA requests that the current means and ranges for the relevant publicly disclosed time points be provided and transparent, and included in Table 1 of the Procedure Guidance.

To deliver on the Strategic Agreement's stated goal of 2 months saving from PBAC recommendation to PBS listing, industry has committed to lodge the Notice of Pricing Intent by week 5 and pricing package by week 6 as indicative timelines. MA believes that this adjustment alone will deliver between 3-5 weeks' time saving. Slightly earlier engagement from the Department with regard to the PBS restriction, and any relevant existing Deed information is the commitment sought from the Department to make this possible. In particular, MA requests that PBAC's views on the proposed restriction be provided with the Minutes, and that earlier engagement on any existing Deed is committed to as outlined in Pathway C below.

Additional time savings could be identified as proposed by the Department over the time period July 2019 to June 2020, and coupled with IT and administrative improvements at the back end of the PBS listing process, would – in MA's view - easily deliver the stated objective of 2 months' time from PBAC positive recommendation to PBS listing.

Industry appreciates that timelines will likely be more challenging to meet if pricing agreement cannot be found; however, if joint agreement is achieved, then there is no reason why subsequent timelines for agreeing restrictions and financial estimates cannot be met.

Stop clock mechanism

MA is unclear as to why stop clock mechanisms cannot be applied to Pathways for the benefit of the Department. Time from positive recommendation to PBS listing would still be the important and agreed metric; however, use of the stop-clock mechanism would remove the additional days that a sponsor may take beyond the timelines deemed to be acceptable/indicative to achieve an activity.

Transparency regarding resourcing

The proposed improvements in the Positive Pathways process are associated with considerable additional cost. It is industry's expectation that there will be additional resources applied to the Positive Pathways process, beyond the position of Case Manager.

MA would appreciate a clear articulation of the additional resourcing which will eventuate, particularly where they will be placed to address some of the known barriers. Agreement on financial estimates is an area where industry is currently experiencing pain points, with finalisation of the costing model taking a long and unpredictable period of time. MA is seeking commitment from the Department of Health to increased staffing in this area; which would be well received by industry.

Commitment to communication

Beyond the roles and responsibilities outlined for the Case Manager, a commitment to ongoing and continuous communication to sponsors does not feature in the Positive Recommendations Pathways Procedure Guidance.

As Medicines Australia have articulated on numerous occasions, companies feel frustrated by the lack of communication which they experience while awaiting a response from the Department on any number of aspects of the post-PBAC process. This frustration could be easily dealt with through appropriate communication to sponsor companies. While a commitment to acknowledge receipt of a complete package or costing model in the appropriate format within a certain timeline is a start, 5 days to acknowledge a complete package is lengthy. Medicines Australia requests that this administrative milestone be completed in 1-2 days. Additionally, MA requests that initial feedback on the acceptability of both the pricing package and the costing model is provided within 5 days respectively.

Negotiation processes would benefit greatly from better communication. In these stages, having both the sponsor and the Department readily available and committed to achieving agreement on estimates, restrictions, etc. in a timely manner would be a significant improvement on the current process. In the past, communication between the sponsor and the Department occurred soon after the PBAC Minutes were provided to ensure a constructive and solution-focused way forward. We propose that this timely process be re-introduced. Where there is joint agreement, there could be commitment to pre-determined timelines for each of the post-PBAC activities.

Definition of Pathway A (Facilitated Pathway)

To be eligible for Pathway A, the following criteria have been proposed by the Department:

- i) the medicine is expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over any alternative therapies; and
- ii) the medicine addresses a high and urgent unmet clinical need; and
- iii) ***it would be in the public interest for the submission to be recommended to this pathway.***

MA believes the first two points of the criteria should be the only criteria needed to satisfy eligibility for Pathway A. By achieving the first two criteria it would seem that the public interest is met.

At the 22 March 2019 Pathways meeting, the Department confirmed to MA that the PBAC Chair is in the process of defining the meaning of criteria iii), including identifying potential examples whereby a medicine would be in the public interest, and not addressed by i) and ii) alone. Transparency in the definition of 'public interest' is requested.

At this stage, MA's concern is that the addition of the third criteria will lead to the redundancy of Pathway A and therefore requests that it be removed.

Pathway C (Existing C)

MA requests the following process improvements be made:

- ‘Confidential Undertaking’ document be provided by the Department to the sponsor with the PBAC minutes, given the PBAC recommends when a new medicine should be added to an existing Deed.
- Signed ‘Confidential Undertaking’ document to be provided from the sponsor to the Department of Health at the time of submitting the Notice of Intent for Pricing.
- Department of Health to arrange the release of the Deed within 5 working days following the Notice of Intent for Pricing, increasing efficiencies in the sponsor providing the price offer.

MA is aware that the release of the Deed will be prior to the website publication of the PBAC Outcome and does not believe the public announcement is required to release the Deed. Industry is comfortable with this earlier provision of the Deed. The Notice of Pricing Intent form should be the fundamental point of action for the release of the Deed.

Pathway D (No Deed)

MA requests that Pathway D also include medicines where there is no change to an existing deed of agreement, for example, where a new presentation is added. There is no justification for requiring a sponsor to pay the substantially greater fee associated with Deed pathways, when there are no changes to deed terms.

Negotiations, restrictions and financial estimates processes

During the webinar, the Department noted that “financial estimates processes”, “finalising restrictions”, and “negotiation processes” would remain as they currently are. This is disappointing because these are clear areas where improvement is needed and can be achieved. MA notes that it has raised these issues on a number of previous occasions.

- While MA appreciates the need for financial estimates to be communicated and utilised across other Government departments, the current template provided is not user-friendly and has been identified as a potential barrier to progress post-PBAC processes. MA requests that work be done on the template, and in doing so, flags that the Australian Chapter of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) is planning a workshop in late Q2 specific to the Section 4 financial estimates template. ISPOR-AC will be contacting relevant members of the Department to participate in the workshop and MA sees this as a great opportunity to educate and evolve the template to meet the needs of all stakeholders.
- Submission of the pricing package is often reliant on full knowledge with regards to the likely final PBS restriction and/or the details of a relevant existing deed. As noted in the section ‘Absence of timelines’ above, earlier discussion and input on the PBS restriction and/or existing Deed will enable proper financial estimates and costings to be completed in a timely manner.

- Negotiation processes would benefit greatly from better communication, as highlighted above ('Commitment to communication'). In these stages, having both the sponsor and the DOH readily available and committed to achieving agreement on estimates, restrictions, etc. in a timely manner would be a significant improvement on the current process. Where there is joint agreement, there could be commitment to pre-determined timelines for each of the post-PBAC activities.

Monitoring outcomes and measuring effectiveness

The current agreed metric between Government and MA is six months from pricing agreement to PBS listing. As noted in the Streamlined Pathways Consolidated Outcomes document to the Minister in July 2018, the mean time from PBAC positive recommendation to PBS listing is currently 7.8 months. Under the Strategic Agreement, there is a commitment to *'by the end of year 3 of the Term, reducing the time from PBAC recommendation to listing by an average of 2 months....'*, with end of year 3 defined as July 2020. Therefore, MA is requesting that outcomes be monitored, with the goal of achieving a mean of six-months from PBAC positive recommendation to PBS listing by July 2020. The metric of time from PBAC positive recommendation to PBS listing is a key measure of effectiveness, not time from pricing agreement.

Please find enclosed MA's detailed comments on the procedure guidance documents for Positive Pathways and Notice of Intent for Pricing.

Thank you for the opportunity to provide feedback on the Positive Recommendation Pathways process and guidance material set for implementation July 1 2019. MA believes that the work done so far by the AMWG Streamlined Pathways Subgroup has been extremely positive. However, in order to truly deliver improvements in efficiency, transparency and timeliness of the PBS listing process, MA requests that the AMWG Streamlined Pathways Subgroup continue to meet and engage during the caretaker period to work through remaining issues as identified above and attached in the lead up to July 1 2019.

If you would like to discuss any aspect of this submission further, please feel free to contact Betsy Anderson-Smith on banderson-smith@medaus.com.au.

Yours sincerely



Dr Vicki Gardiner
Director, Policy and Research
Medicines Australia

Page / Form	Area	Medicines Australia (MA) Comment
3	Costing Model	<p>MA understands the need for standard templates but also highlights the need for flexibility given not all medicines are the same, changes may be required, and the current template has a number of areas for improvement that require resolution. MA has highlighted concerns with the template previously and the risk of costing models being rejected due to failure to comply with a template that is not fit-for-purpose, would not be welcomed.</p> <p>To address the issues, MA requests that work be done on the template, and in doing so, flags that the Australian Chapter of ISPOR-AC is planning a workshop in late Q2 2019 specific to the Section 4 financial estimates template.</p> <p>ISPOR-AC will be contacting relevant members of the Department to participate in the workshop and MA sees this as a great opportunity to educate and evolve the template to meet the needs of all stakeholders.</p>
5	Pathway A (facilitated pathway)	<p>MA proposed the following definition:</p> <ol style="list-style-type: none"> I. The medicine is expected to provide a substantial and clinically relevant improvement in efficacy or reduction of toxicity, over any alternative therapies; AND II. The medicine addresses a high and urgent unmet clinical need; AND III. It would be in the public interest for the submission to be recommended to this pathway. <p>MA believes the first two points of the criteria should be the only criteria needed to satisfy eligibility for Pathway A. By achieving the first 2 criteria it would seem that the public interest is met.</p> <p>MA's concern is that the addition of the third criteria will lead to the redundancy of Pathway A and therefore requests that it be removed.</p>
6	Pathway C (existing Deed)	<p>MA requests the following process improvements be made</p> <ol style="list-style-type: none"> 1. 'Confidential Undertaking' document be provided by the Department to the sponsor with the PBAC minutes, given the PBAC recommends when a new medicine should be added to an existing Deed 2. Signed 'Confidential Undertaking' document to be provided from the sponsor to the Department of Health at the time of submitting the Notice of Intent for Pricing. 3. Department of Health to arrange the release of the Deed within 5 working days following the Notice of Intent for Pricing, increasing efficiencies in the sponsor providing the price offer. <p>MA is aware that the release of the Deed will be prior to the website publication of the PBAC Outcome and does not believe the public announcement is required to release the Deed. Industry is comfortable with this earlier provision of the Deed. The Notice of Pricing Intent form should be the fundamental point of action for the release of the Deed.</p>
6	Pathway D (no Deed)	<p>MA requests that the guidance states that Pathway D also includes medicines where there is no change to an existing Deed of Agreement – such as new presentation.</p>

6	Lodge the Notice of Intent for Pricing – “expected time of the offer”	MA understands the date is important for resource allocation and while every intent will be made to make a pricing submission on the nominated date there may be an unexpected delay or alternatively the offer may be available earlier. MA wants it to be clear that the date selected is the <u>intended</u> date and any deviation should be communicated by the sponsor to the Department.
3, 7	Submission of a pricing package	<p>MA seeks clarity on why a minimum of 7 days is required after lodgement of the Notice of Intent for Pricing and requests that the Department remove the minimum timeframe.</p> <p>Given the process improvements are intended to increase efficiencies and reduce overall timeframe, the minimum of 7 days is against the intended outcome. While pricing submission complexity may differ, in a cost-minimisation case a pricing offer may be submitted at the same time as lodgement of the Notice of Intent for Pricing.</p>
3, 7	Negotiation Phase – “pricing package check” and “costing model”	<p>While a commitment to acknowledge receipt of a complete package or costing model in the appropriate format within a certain timeline is a start, 5 days to acknowledge a complete package is lengthy. MA requests that this administrative milestone be completed in 1-2 days. Additionally, MA requests that feedback on the acceptability of both the pricing package and the costing model is provided within 5 days.</p> <p>Negotiation processes would benefit greatly from better communication. In these stages, having both the sponsor and the DOH readily available and committed to achieving agreement on estimates, restrictions, etc in a timely manner would be a significant improvement on the current process. In the past, communication between the sponsor and the Department occurred soon after the PBAC Minutes were provided to ensure a constructive and solution-focused way forward. We propose that this timely process be re-introduced. Where there is joint agreement, there could be commitment to pre-determined timelines for each of the post PBAC activities.</p>
5, 7, 9 Notice of Intent for Pricing	Case Manager	<p>MA requests the case manager is assigned at the time when the Notice of Pricing Intent form is submitted. This is aligned with the role of the case manager to facilitate communication and the application of the cost recovery fees.</p> <p>MA notes there are a number of inconsistencies between the procedural guidance and the Notice of Pricing Intent Form regarding the timing of assigning the case manager.</p>
8	Monitoring outcomes and measuring effectiveness	<p>The goal is to achieve a mean 6-month timeframe from PBAC positive recommendation to PBS listing by July 2020.</p> <p>MA believes there is already information/metrics available on the key timelines as presented through the Consolidated Outcomes report and at Senate Estimates:</p> <ul style="list-style-type: none"> • From positive recommendation to agreement on financial estimates (2.7 months) • From positive recommendation to listing (7.8 months) • From pricing agreement to listing (up to 6 months)

		<p>While monitoring outcomes is a requirement to identify areas for improvement, it is not acceptable to delay improvements until further metrics are made available.</p> <p>Industry has committed to lodge the Notice of Pricing Intent by week 5 and pricing package by week 6 as indicative timelines. MA believes that this adjustment alone will deliver between 3-5 weeks' time saving. Earlier engagement from the Department with regard to the PBS restriction, and any relevant existing Deed information is the commitment sought from the Department to make this possible.</p> <p>Additional time savings could be identified as proposed by the Department over the time period July 2019 and June 2020, and coupled with IT and administrative improvements at the back end of the PBS listing process, would – in MA's view - easily deliver the stated objective of 2 months' time from PBAC positive recommendation to PBS listing.</p>
8	Transitional Arrangements	MA request a revised PBAC cycle timeframe calendar be available as soon as possible, prior to 1 July 2019, to ensure all applicants are aware of the process and are aligned on the deadlines. This is critical for planning and smooth transition.
6 Notice of Intent for Pricing	Definition of "withdrawn" and "inactive"	<p>MA requests a clear definition of "withdrawn" and "inactive", and to make clear the consequences for sponsors of selecting these outcomes.</p> <p>MA requests there be no confusion between "withdrawn" and "inactive". This will also facilitate understanding of status on the Medicines Status Website.</p>
Notice of Intent for Pricing	Minor changes to the wording	MA has recommended minor changes to the Notice of Pricing Intent Form. For ease, the recommended changes have been included as track changes.



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Received: Click or tap to enter a date.

Payment: Click or tap to enter a date.

Processed: Click or tap to enter a date.

Notice of Intent for Pricing

Explanatory text (from the Procedure Guidance) will be included on this page.

Draft for consultation

Part 1 Applicant and drug details

Applicant name:

Click or tap here to enter text.

Medicine/vaccine name:

Drug Name:	
Trade Name:	
Presentation:	
Strength:	
PBS indication recommended by PBAC:	

Commented [A1]: It is recommended the table match the request in the "Intent to Apply" form. This is important for consistency

Part 2 Applicant intent

Please select **one** of the three options below.

Do you intend to submit a Pricing Offer to the Department?

<input type="checkbox"/>	No, the submission is withdrawn
<input type="checkbox"/>	No, we will submit to the PBAC for re-consideration

By ticking 'no' you acknowledge the information provided above may be reported publicly.

Commented [A2]: Definition of what "withdrawn" means, especially in terms of future engagement and future PBS price offer submission for the product.

<input type="checkbox"/>	Yes. Intended Pricing Offer lodgement date: Click or tap to enter a date. Please complete the remainder of this form.
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COST RECOVERY: Applicants are recommended to review the cost recovery fees at <http://www.pbs.gov.au/info/industry/listing/elements/fees-and-charges>.

There is no cost recovery fee associated with the applicant declaring the option "no" – the submission is withdrawn or the submit to the PBAC for re-consideration. The cost recovery fees will be initiated following the submission of "yes" you intend to submit a pricing offer.

Commented [A3]: It is important to highlight the cost recovery aspects given the significant changes to the cost of post-PBAC fees.

You are only required to complete the following sections if you intend to lodge a Pricing Offer.

Part 3 Pathway A

Did the PBAC recommend a 'Facilitated Pathway' listing for this submission?

<input type="checkbox"/> No.	
<input type="checkbox"/> Yes	Should you choose to proceed with this pathway, a case manager will be assigned by the Department following receipt of your completed Pricing Offer form-Notice of Pricing Intent form

Part 4 Listing Pathway

Based on your listing requirements please select the relevant pathway from the list below – refer to the PBAC Procedure Guidance for listing pathway criteria.

Selected pathway will be confirmed following receipt of your Pricing Offer. [Please refer to the Procedure Guidance for further definition of the pathway.](#)

Commented [A4]: Add link once it is available

<input type="checkbox"/>	Pathway A Note: This pathway may only be selected if recommended by the PBAC
<input type="checkbox"/>	Pathway B – involves negotiation of a new Deed
<input type="checkbox"/>	Pathway C – involves negotiation of an existing Deed
<input type="checkbox"/>	Pathway D – for simple listing arrangements that do not involve a Deed
<input type="checkbox"/>	Secretariat Pathway – for submissions considered a Secretariat listing that do not require PBAC consideration

Part 5 Listing details

Is a Managed Entry Scheme (MES) or Managed Access Program (MAP) proposed?

<input type="checkbox"/>	No.
<input type="checkbox"/>	Yes, a Managed Entry Scheme (MES)
<input type="checkbox"/>	Yes, a Managed Access Program (MAP)

Is a non-MAP/MES Risk Sharing Arrangement (RSA) proposed?

<input type="checkbox"/>	No.
<input type="checkbox"/>	Yes.

Is a Special Pricing Arrangement (SPA) proposed?

<input type="checkbox"/>	No.
<input type="checkbox"/>	Yes.