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# **Facilitated Resolution Pathway Workshop Briefing Paper**

### **IMPORTANT INFORMATION**

### **Privacy and your personal information**

Your personal information is protected by law, including the *Privacy Act 1988* and the Australian Privacy Principles, and is being collected by the Australian Government Department of Health for the purposes of your organisation applying or intending to apply to list a medicine on the [Pharmaceutical Benefits Scheme](http://www.pbs.gov.au/info/industry/listing/listing-steps).

If you do not provide this information, your organisation will be unable to apply for these benefits.

You can get more information about the way in which the Department of Health will manage your personal information, including our privacy policy, at <http://www.pbs.gov.au/info/general/privacy-policy>**.**

| The FACILITATED RESOLUTION PATHWAY WORKSHOP BRIEFING PAPER (briefing paper) should reflect the issues raised in the ratified PBAC Minutes and discussed at the post-PBAC meeting with the Chair. The briefing paper provides the PBAC and the Department with the information required to adequately prepare for the workshop with applicants. Any advice provided by members of the PBAC, the applicant or the department in a workshop is in no way binding on the PBAC, the department, applicant, evaluation groups or sub-committees of the PBAC. The Procedure Guidance provides further information on the facilitated resolution workshop process.A complete FACILITATED RESOLUTION PATHWAY WORKSHOP BRIEFING PAPER (briefing paper) must be provided in preparation for every Facilitated Resolution Pathway workshop with the PBAC, and submitted to the and submitted via the HPP at least **5 business days before** the scheduled workshop date in word format. Please do not submit a scanned or pdf version of the form.  |
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### **Completing the Facilitated Resolution Pathway Workshop Briefing Paper (briefing paper):**

This form is a template only and is provided to guide best practice consistent with sections 1 to 4 of the PBAC Guidelines. Please only complete the sections of this form relevant to your submission, noting that not all sections must be completed. The information provided in this form will guide the workshop discussion. To make best use of the maximum 180 minutes available for the discussion, it is recommended that applicants provide sufficient information to support development of the PBAC submission.

**Office of Health Technology Assessment Branch**

**Department of Health**

**GPO Box 9848, Canberra ACT 2601**

| **Workshop Date:** |  |
| --- | --- |
| **Workshop Time:** |  |
| **Location:** |  |
| **Name of Company or supplier of the Drug/Vaccine (applicant):** |  |
| **Drug / Vaccine name:** |  |
| **PBS Indication/condition to be treated:** |  |
| **Applicant attendees (name and position):** |  |

In the case of contractors assisting in the preparation of this submission, please also provide the name of the contracted organisation.

**Agenda**Notes:

* Key areas for discussion at the workshop are based on issues for resolution as outlined in the ratified PBAC Minutes and discussed at the post-PBAC meeting with the Chair.
* Please provide an indicative timing and the speaker for each agenda item.
* Aim to keep this table under one page.

| **Item** | **Issue for discussion**  | **Company response** | **Speaker/Lead** | **Indicative timing** |
| --- | --- | --- | --- | --- |
| 1. | PBAC introduction |  | PBAC Chair | 5 minutes |
| 2. | [Cite paragraph of the PBAC Minutes (use abbreviated referencing in tables), identify matter] | [Identify how the Company intends to address. Provide attachments to support discussion if required] | [Speaker] | [Timing] |
| 3. |  |  |  |  |
| 4. |  |  |  |  |
| 5. |  |  |  |  |
| 6.  | Other: * Summary of workshop discussion
 |  |  | 5 minutes |
| Total |  |  | 180 minutes |

Please insert additional rows if required.

Example only

| **Item** | **PBAC topic**  | **Company response** | **Speaker/Lead** | **Indicative timing** |
| --- | --- | --- | --- | --- |
| 2. | Example text: Proposed the use of a 10 year time horizon (para 7.12). | Example text: maintain 20-year time horizon and propose a Managed Access Program to justify accepting a longer time-horizon. | Example text: John Smith | Example text 20 minutes |

**Further briefing information**

If required, include more detail on the company response to each topic here. Keep detail succinct and informative for the workshop.

Example: Item 2

[Summary paragraph]

| **Question(s)/points for discussion:** |  |
| --- | --- |

**Attachments**

It is recommended that applicants provide all the information necessary for the workshop discussion in this form. Please only add attachments if required for discussion at the workshop.

**Declaration**

**I declare that:**

|[ ]  I am authorised to make this request on behalf of the applicant. |
| --- |
|[ ]  The information I have provided in this form is complete and correct to the best of my knowledge. |

**I understand that:**

|[ ]  Giving false or misleading information is a serious offence. |
| --- |
|[ ]  Consistent with the *National Health (Pharmaceuticals and Vaccines–Cost Recovery) Regulations 2022*, a fee will be payable for the Facilitated Resolution Pathway which includes the workshop. This fee is non-refundable. |

| **Printed name:** |  |
| --- | --- |
| Authorised for electronic signature. |  |

A complete FACILITATED RESOLUTION PATHWAY WORKSHOP BRIEFING PAPER must be submitted electronically in word format. Please do not submit a scanned or PDF version of the form.