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# **Pre-submission 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 PRE-SUBMISSION BRIEFING PAPER (briefing paper[[1]](#footnote-1)) provides the Department with the information required to adequately prepare for pre-submission meetings with applicants. Advice provided by the Department at pre-submission meetings is non-binding on the Department and applicants. The Procedure Guidance provides further information on the pre-submission meeting process.  A complete PRE-SUBMISSION BRIEFING PAPER (briefing paper) must be provided in preparation for every pre-submission meeting with the Department, and submitted to the [PBAC pre-submission meetings team](mailto:PBACpresubmissionmeetings@health.gov.au) at least **10 business days before** the scheduled pre-submission meeting date in word format. Please do not submit a scanned or pdf version of the form. Pre-submission services will not be provided in response to an applicant’s request if a completed briefing form is not provided within this timeframe.  The PRE-SUBMISSION BRIEFING PAPER (briefing paper) constitutes an essential component of the Pharmaceutical Benefits Scheme (PBS) Cost Recovery process. |
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### **Before completing the Pre-submission Briefing Paper (briefing paper):**

It is recommended that applicants familiarise themselves with the *National Health (Pharmaceutical and Vaccines – Cost Recovery) Regulations 2009* (the Regulations) and the PBS Cost Recovery Administrative Guidelines.These Regulations and guidelines include important information about the PBS Cost Recovery framework and applicable fees for service.

### **Completing the Pre-submission 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 pre-submission discussion. To make best use of the 60 minutes available for the discussion, it is recommended that applicants provide sufficient information to support development of the PBAC submission.

Departmental advice may be sought in relation to specific issues including restrictions, comparators, clinical data, economics and financials. However, the Department cannot confirm or agree with proposed economic models, claims or approaches.

**Within 10 business days** of receipt of this form, the Department will provide written notification to the applicant (authorised representative identified in the Application Form for Pre-submission Services) confirming the meeting date and the fee payable for pre-submission services.

An applicant may withdraw a Pre-submission Meeting Request Form (meeting application) and briefing paper at any time. The applicant is entitled to a full refund of any pre-submission fees paid if withdrawn (in writing) before the earlier of: within **11th business day after** notification of the fee payable is given; or **the last business day before** the pre-submission meeting is to be held.

**Office of Health Technology Assessment Branch**

**Department of Health**

**GPO Box 9848, Canberra ACT 2601**

| **Meeting Date:** | Click or tap to enter a date. |
| --- | --- |
| **Meeting Time:** | Click or tap here to enter text. |
| **Location:** | Choose an item. |
| **Name of Company or supplier of the Drug/Vaccine (applicant):** | Click or tap here to enter text. |
| **Drug / Vaccine name:** | Click or tap here to enter text. |
| **PBS Indication/condition to be treated:** | Click or tap here to enter text. |
| **Applicant attendees (name and position):** | Click or tap here to enter text. |

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

**Agenda**Use headings below that are relevant to the meeting and keep to order as per sections 1-4 of the [PBAC Guidelines](http://www.pbs.gov.au/industry/listing/procedure-guidance/files/procedure-guidance-listing-medicines-on-the-pbs.pdf). Please briefly outline the key areas for discussion with the Department and provide indicative timing for each agenda item.

**Pre-submission meeting purpose -** briefly outline the key issues for discussion with the Department:

| Click or tap here to enter text. |
| --- |

| **Item** | **Topic** | **Indicative timing** |
| --- | --- | --- |
| 1. | Background | X minutes |
| 2. | Population (disease, drug, PBAC timelines, TGA indication, proposed PBS restriction) | X minutes |
| 3. | Treatment algorithm and main comparator | X minutes |
| 4. | Clinical evidence | X minutes |
| 5. | Economic evaluation | X minutes |
| 6. | Estimated utilisation and financial estimates | X minutes |
| 7. | Other:   * Summary of meeting discussion | 5 minutes |
| Total | | 60 minutes |

**Is this a co-dependent submission?**

|  | No. | | |
| --- | --- | --- | --- |
|  | Yes | Please provide the MBS item descriptor: | Click or tap here to enter text. |
| **Please specify whether ‘INTEGRATED’ or ‘STREAMLINED’ if known:** | Click or tap here to enter text. |
| Have you previously met with (or intend to) the Department to discuss the MBS component? | Please select |
| Click or tap to enter a date. |

**Briefing information**

Please only complete the sections below (including questions for the Department) relevant to your submission. Guidance text is provided in blue under each of the headings. It is recommended that applicants provide all the information necessary for the pre-submission discussion in this form. Please add attachments as required.

1. **Background**

* If relevant, please provide a brief history of previous PBAC submissions or pre-submission meeting history.
* Identify the targeted lodgement date of the submission to PBAC
* Identify the corresponding lodgement date of the application to TGA
* Identify the proposed or agreed TGA processing pathway
* Identify the expected date of TGA delegate’s overview if known

1. **Population**

* Present a brief outline of the disease
* Identify the proposed medicine and any unusual aspects which warrant discussion (eg type of medicine, manner or setting of preparation or administration, dosing)
* Specify proposed/approved TGA indication
* The eligibility criteria of the key source(s) of evidence of comparative effectiveness, including any subgroups from this evidence relevant to the proposed population
* Any relevant expert opinion or clinical guidelines
* The proposed draft PBS restriction(s)

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

**3. Treatment algorithm and main comparator**

* Summarise the current and proposed clinical management algorithms in diagrammatic form, and explain the clinical need for the proposed medicine.
* Identify the possible alternative therapies and nominate the main comparator with reference to the PBAC Guidelines; identify any issues arising fromsection 101(3B) of the National Health Act 1953 where relevant.

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

1. **Clinical Evidence**

* Present a brief outline of the most up-to-date results of the key source(s) of evidence of comparative effectiveness and safety to be relied upon in your submission.
* Summarise the clinical meaningfulness of any uncommon or novel study endpoints being relied upon, and summarise the clinical meaningfulness of the effect sizes being relied upon in key studies.
* Identify any elements of the clinical evidence that are a departure from PBAC guideline advice.
* Summarise the clinical claim and the corresponding type of economic evaluation.

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

1. **Economic evaluation**

* Present a brief outline of the economic evaluation.
* In relation to the proposed medicine, nominate the proposed price, or price range or reference against which the price will be determined (the cost per patient, either per episode or per appropriate period of time – such as a year).

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

1. **Estimated utilisation and financial estimates**

* Present a brief outline of the approach (epidemiological/market share/both) to estimating utilisation forecasts, primarily of the proposed medicine, but also of relevant changes in other in-scope health resources which warrant discussion.

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

1. **Other**

* Present sufficient information of any other matters which warrant discussion, such as a proposal for a Managed Entry Scheme (MES) / Managed Access Program (MAP).
* Any omissions from this outline would need to be justified, and identified in the record of the meeting as appropriate
* This outline would need to be expanded for a pre-submission meeting before an integrated co-dependent submission
* Briefing templates should not include detailed data, full study and trial reports, complex model structures, nor should they included promotional material for the company or medicine.

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

**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) Amendment Regulations 2019*, a fee will be payable for pre-submission services provided by the Commonwealth. |

| **Printed name:** | Click or tap here to enter text. |
| --- | --- |
| Authorised for electronic signature. | Click or tap to enter a date. |

A complete PRE-SUBMISSION BRIEFING PAPER must be submitted electronically in word format. Please do not submit a scanned or PDF version of the form.

\*The applicable fee amount and the payment options will be outlined in the request for payment notification and the invoice, including terms of trade advice, sent by the Department. The notice will be issued within 10 business days of submission of a completed Application for Pre-submission Services and briefing paper.

1. This form is made under regulation 1A.8 of the National Health (Pharmaceuticals and Vaccines–Cost Recovery Regulations 2009. [↑](#footnote-ref-1)