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# **Pre-submission Meeting Outcomes**

| PRE-SUBMISSION MEETING OUTCOMES provide a succinct record of the pre-submission meeting discussion between the Department and applicants. Advice provided by the Department at pre-submission meetings is non-binding on the Department or applicants. The Procedure Guidance provides further information on the pre-submission meeting process.  PRE-SUBMISSION MEETING OUTCOMES are to be completed by applicants. Completed meeting outcomes are to be submitted to the [PBAC pre-submission meetings team](mailto:PBACpresubmissionmeetings@health.gov.au) in word format for acknowledgement within **10 business days** of the pre-submission meeting date. Please do not submit a scanned or pdf version of completed meeting outcomes. |
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## **Pre-submission meeting details**

| **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:** | Click or tap here to enter text. |

| Drug / Vaccine name: | Click or tap here to enter text. |
| --- | --- |
| Brand name(s): | Click or tap here to enter text. |
| PBS Indication/condition to be treated: | Click or tap here to enter text. |
| Applicant reference number: | Click or tap here to enter text. |

Reference number to be provided by the applicant (If applicable). This reference will be quoted in any correspondence with you regarding fees).

## **Pre-submission meeting outcomes**

This section should be a concise summary of the advice provided by the Department in response to the issues and/or key questions discussed in the meeting.

|  | | |
| --- | --- | --- |
| **Department acknowledgement** |  | The above summary reflects the pre-submission meeting outcomes; OR |
|  | The Department considers the issues and/or key points discussed were: |
|  | |

| **Attendees** |
| --- |

**Applicant attendees:**

| **Name** | **Position and Organisation** |
| --- | --- |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |

Please insert additional rows if required.

**Department attendees:**

| **Name** | **Role/Position** |
| --- | --- |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |

Please insert additional rows if required.

## **Pre-submission meeting feedback**

To assist with ongoing evaluation of pre-submission meeting processes please complete the section below.

**Applicant to complete**

The advice provided by the Department at the pre-submission meeting was constructive and useful?

| Please select | Please provide comments below in relation to the response provided. |
| --- | --- |
|  |

**Department to complete**

Was sufficient information provided in the briefing material for the Department to understand and advise on the issues and questions raised in the briefing paper and meeting?

| Please select | Please provide comments below in relation to the response provided. |
| --- | --- |
|  |

## **Applicant acknowledgement and declaration**

**I understand that:**

|  | Giving false or misleading information is a serious offence. |
| --- | --- |
|  | Any advice provided by the Department of Health at the requested pre-submission meeting is non-binding on the Department of Health and its contracted evaluation groups, the Pharmaceutical Benefits Advisory Committee (PBAC), its sub-committees, and the Applicant. | |

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

Complete PRE-SUBMISSION MEETING OUTCOMES must be submitted electronically in word format. Please do not submit a scanned or PDF version of the form.