TGA use only

This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Request for pre-submission meeting

Our guidance at the meeting is nonbinding and without prejudice. As knowledge evolves over time, the initial guidance we gave at the meeting may become out of date or be superseded.

Applicant

Company	
Address	

Contact person

Name	
Position	
Mailing address	
Phone	
Email	

Proposed scheduling information

Proposed date	
Proposed time	
Proposed meeting length	(1 to 1.5 hours maximum, unless agreed otherwise)

Once TGA receives your initial completed meeting request, we will consider your request and then advise if it is appropriate for a meeting to proceed or whether the issues can be appropriately addressed via email.

Proposed meeting type (tick preferred option):

☐ **Face to face meeting**

Face to face meeting at TGA (Symonston) or in the location of Delegate e.g. Melbourne.

If an alternate location to TGA (Symonston) is required, the applicant must organise a location convenient to TGA and provide a toll free dial in number to use on the day. Presentation slides need to have been made available with the full briefing package (at least 2 weeks prior to the meeting).

Additional facilities required:

☐ Computer ☐ Projector ☐ Other (please specify)

If required, TGA is able to provide a meeting specific dial in number and code for the purpose of conducting a meeting. However be aware that the security and IT connectivity of the number provided by the TGA cannot be guaranteed.

☐ **Teleconference/videoconference only**

A Teleconference/videoconference must be arranged by the applicant at a time that is mutually convenient.

Subject matter for discussion

☐ Prescription medicine registration

☐ Orphan drug designation

☐ Priority review prescription medicine designation

☐ Over-the-counter medicine

☐ Registered complementary medicine

☐ Assessed listed complementary medicine

☐ Ingredient for use in listed medicines

☐ Medical device (manufacturer)

☐ Medical device (sponsor)

☐ In vitro diagnostic medical device (manufacturer or sponsor)

☐ Biological (cell and tissue-based products)

☐ Disinfectant (manufacturer or sponsor)

☐ Other (please specify)

Medicine

Generic name	
Trade name	
Substance name	
Dosage form(s)	
Indications	
Patient population	
Other relevant information	

Medical device

Device name or Unique Product Identifier (UPI)	
GMDN Code	
Device Classification	
Device Description	
Intended Purpose	
Other relevant information	

Biological

Product name	
Trade name	
Biological ingredient name	
Dosage form(s)	
Other relevant information	

Name			
Signature		Date	

Please ensure that all information set out below is provided with the initial request.

Background information

1. Proposed agenda

2. Overview of the product and its development program (quality, nonclinical, and clinical)

Include a brief background to the disease that the product is supposed to treat, the place of this product in the treatment algorithm and any relevant regulatory history.

For medical devices include a brief background of the device description, mode of action, relevant regulatory history (including any approval overseas) and the intended purpose.

3. Purpose and objectives of the meeting

Include a:

a. brief statement of the purpose and objectives of the meeting

b. description of the issues underlying the agenda, and

c. summary of:

   i. completed or planned studies

   ii. clinical trials or data that the sponsor/applicant intends to discuss at the meeting

   iii. the general nature of the critical questions to be asked, and

   iv. where the meeting fits in overall development plans

Although the statement should not provide detailed documentation of trial designs or completed studies and clinical trials, it should provide enough information to facilitate understanding of the issues, such as a small table that summarises major results.

4. List of questions

Include a list of proposed questions, grouped by discipline (quality, non-clinical, clinical), with a brief explanation of the context and purpose of each question.

5. List of participants

Include a list of individuals, including titles and affiliations, from the sponsors /applicant's organisation or consultants who will attend the proposed meeting.

Include any requests for particular TGA staff or disciplines to participate in the proposed meeting. These people may not attend but are represented.

6. Full Briefing Package

To be provided electronically **2 weeks** prior to the scheduled meeting

Checklist

☐ Final agenda

☐ Overview of the product and its development program (quality, non-clinical and clinical)

Include a brief background to the disease that the product is supposed to treat, the place of this product in the treatment algorithm and any relevant regulatory history

For medical devices include a brief background of the device description, mode of action, relevant regulatory history (including any approval overseas) and the intended purpose

☐ Purpose and objectives of the meeting

Although the statement should not provide detailed documentation of trial designs or completed studies and clinical trials, it should provide enough information to facilitate understanding of the issues, such as a small table that summarises major results

☐ List of final questions

☐ List of confirmed participants

☐ Meeting presentation (or as agreed)

This is to be provided no later than 2 days before the scheduled meeting. However, if provided closer to the scheduled meeting **no new/additional** information is to be included to that which has been provided in the “full Briefing Package” otherwise this may result in the meeting being postponed