



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
<<http://www.tga.gov.au/treatment-information-provided-tga>>.

Pre-submission meeting record

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 As knowledge evolves over time, the initial guidance we gave at the meeting may become out-of-date or be superseded.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

Meeting information

Meeting date

Location

Start time

Closing time

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)

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Medicine

Generic name	
Trade name	
Substance name	
Dosage form(s)	
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

Meeting participants

Facilitator or Chair	Secretariat or minute taker

External participants	Company position

TGA participants	Position

Meeting objectives

Discussion points (keep brief in bullet format)

[NB: comments made by TGA participants may be recorded as '*TGA advised.....*' rather than naming individuals]

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Outcomes (bullet format)

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Unresolved issues, or issues requiring further discussion

[NB: These should result in further correspondence]

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Action items

Item #	Item to be actioned	Responsible person	Due date
1.			
2.			
3.			

Attachments/handouts