



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Australian regulatory guidelines for prescription medicines

Appendix 5: Conduct of meetings between TGA and sponsors

June 2004

TGA Health Safety
Regulation



About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- TGA administers the Therapeutic Goods Act 1989 (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website.

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Appendix 5: Conduct of meetings between TGA and sponsors

Purpose/background

This guideline describes the policies and procedures for scheduling and conducting meetings, including pre-submission meetings, between Therapeutic Goods Administration (TGA) staff and sponsors. It is intended to provide a consistent and transparent approach to the scheduling and conduct of meetings.

Meetings will not be formally minuted.

Although pre-submission meetings are not a regulatory requirement, TGA would strongly encourage companies to consider using this facility.

This guideline applies to all meetings relating to different types of applications in all categories and to meetings not associated with applications.

It is recognised that meetings serve a beneficial purpose for both the TGA and intending sponsors to provide clarity and resolve issues related to the medicine development and review processes.

Definitions

Meeting: A planned meeting that occurs through a face-to-face interaction, videoconference or teleconference between relevant TGA staff and person/s from the pharmaceutical industry or their representatives. Meetings dictated by emergency situations shall be handled on a case-by-case basis, although action sheets should be prepared as described below.

Applicant: A person who has made an application, or is intending to make an application, pursuant to the *Therapeutic Goods Act 1989* (hereafter referred to as *applicant*). These guidelines apply to persons who have made or intend to make such an application and who can provide evidence of this on request. This term is interchangeable with *sponsor*.

TGA: The Therapeutic Goods Administration, specifically the Drug Safety and Evaluation Branch (DSEB) and the Laboratories Branch (TGAL).

General

All meetings should be conducted according to a pre-determined agenda appropriate to the purpose of the meeting, with specified objectives and accurate summarisation of key points and action items at the end of the meeting.

Letters described in this document may generally be sent or received by facsimile or email.

As knowledge evolves over time, advice may become out of date or be superseded. Sponsors are reminded of the importance of continued monitoring of international and Australian guidelines and

of the use of their products in trial and in the community to ensure they meet accepted standards of best practice concerning the ongoing development and evolution of the products.

Responsibilities

Sponsor

The sponsor should request a meeting by writing to: The Section Head of the relevant Evaluation Section, DSEB. The request should contain the following elements:

- a statement of the purpose of the meeting;
- a proposed agenda, including times needed for each agenda item;
- the expected outcomes of the meeting;
- a list of planned applicant participants;
- a list of requested representatives from the TGA (can be expressed in functional terms according to the organisational chart rather than as named persons). The TGA will arrange appropriate representation;
- relevant background information;
- the approximate time at which supporting documentation will be sent to the TGA;
- the applicant's requirements as to equipment; and
- listing of the preferred time and date and at least one alternative time and date.

Supporting documentation for the meeting should be received by TGA in hard copy as early as possible, and preferably, two weeks in advance of the scheduled meeting. The documentation should be forwarded to the Section Head of the relevant Evaluation Section, DSEB. Sufficient copies for all attendees should be provided. The supporting documentation should be brief, for example, 10 A4 pages and perhaps one or two reprints from the literature. Alternatively, the narrative from an expert report may be negotiated.

Regulatory consultants must have a letter from an Australian sponsor or a foreign principal confirming they will be the agent before discussions on particular products can occur.

Sponsors should be aware that at pre-submission meetings, the TGA may want to discuss:

- the availability of evaluation reports from other regulatory agencies;
- the possibility of negotiating shared evaluations;
- medicine specific issues.

Sponsors need to take the following into account:

- a clear purpose has to be identified in advance;
- the sponsor should not seek a guarantee that the data package will be adequate to ensure the likelihood of registration as suggestions or comments from the TGA cannot be taken as binding as circumstances may change and the eventual view of the Delegate or Australian Drug Evaluation Committee (ADEC) following the full evaluation cannot be pre-empted;
- the participants will be expected to be aware of relevant guidelines, including the ARGPM, adopted foreign guidelines and ICH guidelines and any other published DSEB guidelines;
- Pharmaceutical Benefit Scheme applications are not appropriate for discussion with the TGA.

TGA

The TGA will try to respond to requests for scheduling meetings from sponsors and will agree to such meetings unless they are clearly unnecessary, premature or inappropriate.

When the TGA requests a meeting with a sponsor, a written request will be sent to the sponsor, by facsimile or mail.

While meeting minutes will not be taken, official action sheets will be prepared by TGA after meetings with sponsors and distributed to attendees.

The TGA will work with sponsors, prior to the conclusion of the meeting, to identify and resolve any inconsistencies or discrepancies with respect to understandings of the outcome of the meeting. If any further inconsistencies are identified once the action sheet has been drafted, the entire sheet can be revised to more accurately reflect the agreed outcomes, or to reflect lack of agreement if relevant.

Advice given by TGA will of necessity be somewhat general at times, and is given in good faith but without prejudice.

Procedures

Meeting

A TGA official shall chair/facilitate the meeting and, at the beginning of the meeting, should state TGA's understanding of the purpose and goals of the meeting. It should be clear all remarks are *without prejudice*.

Pre-submission meetings should not be used for a promotional presentation of the dossier to be submitted, although it is expected that the content will be outlined.

It is expected that most meetings will not exceed one to two hours in duration.

Post-meeting (follow up)

TGA will endeavour to distribute a copy of the action sheet to all participants within two weeks of the meeting. Applicants are responsible for notifying TGA of any significant differences in their understanding of the meeting outcomes as reflected in the action sheets.

Attachments

Meeting Agenda (see Attachment A)

Meeting Action Sheet (see Attachment B)

Attachment A

Meeting Agenda

Meeting Date:

Location:

Time:

Details of Product to be discussed:

Generic Name :

Trade Name :

Dose Form/s :

Meeting Facilitator (TGA):

Applicant/External participants:

TGA participants:

Introductions - including TGA understanding of Meeting Objective/s:

Meeting Discussion Items:

Name of Presenter:

Discussion Item:

Time Allocated:

Summarise Points of Agreement/Unresolved issues:

Summarise action required:

Close meeting - Time:

Attachments/Handouts:

Attachment B

Meeting Action Sheet

Meeting Date:

Location:

Time Start:

Time Close:

Product Details

Generic

:

Trade Name

:

Dose Form/s

:

Meeting Facilitator:

Meeting Recorder:

Applicant/External Participants (including titles):

TGA Participants (including titles):

Meeting Objectives:

Discussion Points (bullet format):

- .
- .
- .
- .
- .

Outcomes:

- .
- .
- .
- .

Unresolved issues or issues requiring further discussion:

[NB: These should result in further correspondence]

Action Items:

Item:

Responsible person:

Due Date:

Attachments/Handouts:

Historical document

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Reference/Publication #