Australian Government
Department of Health
Therapeutic Goods Administration

Pre-submission meetings with TGA

Version 2.3, December 2020

TGA Health Safety Regulation

Contents

Pre-submission meetings with TGA

This guidance is for applicants (sponsors, manufacturers and agents) preparing for pre-submission meetings related to applications:

- to enter therapeutic goods on the Australian Register of Therapeutic Goods (ARTG). This includes all medicines, biologicals (cell and tissue-based products), medical devices and other listed and registered therapeutic goods
- for designation of prescription medicines, e.g. orphan drugs, priority review
- for TGA Conformity Assessment Certification (for the manufacture of medical devices)
- for priority applicant determination (medical devices).

It does **not** apply to applications for a manufacturing licence or Good Manufacturing Practice certification or clearance.

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As knowledge evolves over time, the initial guidance we gave at the meeting may become out of date or be superseded.

Alternatives to meetings

Consider whether or not a meeting is needed. You may be able to resolve the issues more effectively by:

- viewing our website and the EU guidelines we have adopted for relevant guidance materials
- phoning or emailing us for guidance
- seeking assistance from a regulatory affairs consultant

Purpose of pre-submission meetings

A pre-submission meeting can help both the applicant and TGA to:

- obtain a common understanding of the therapeutic good and:
  - what supporting documentation is needed to evaluate the application
  - any issues to resolve before submitting applications
- plan for the submission and to manage both timeframes and resources

Please note:

✓ we provide advice to clarify any issues you have relating to existing studies or the proposed data package

✘ we do **not** address issues that require evaluation of data

✘ we do **not** generally give advice on developing a data package or the number of studies required to support an application

When meetings are most beneficial

Pre-submission meetings are most beneficial for:

- complex therapeutic goods
- new or emerging technologies (including 'first in class' medicines, novel medical devices)
- combination goods (e.g. a medicine device combination product)
- medicines with a companion in vitro diagnostic (IVD) (details of both to be included in the meeting)
- specific regulatory issues for therapeutic goods with multiple applications

When meetings are highly recommended

We highly recommend pre-submission meetings for the following:

- prescription medicines:
  - novel biological medicines including new vaccines
  - biosimilars (especially a first biosimilar and biosimilars of botulinum toxin, monoclonal antibodies or low molecular weight heparins)
  - where the development program has substantially diverted from applicable TGA-adopted EU guidelines
  - new generics of non-biological complex drugs (such as glatiramer, sevelamer)
  - levothyroxine, used to treat thyroid hormone deficiency and carbimazole, used to treat hyperthyroidism
  - new generics of medicines for inhalation
- registered and assessed listed complementary medicines
- all Class 3 & 4 biologicals (including CTA applications)
- medical devices (dependent upon route of application):
  - novel medical devices (including IVD and HIV self-tests)
  - those used in urogynaecological procedures

Before the meeting

Request a meeting

To request a meeting, complete the meeting request form.

1. Include sufficient information in the form for us to:
   - determine if a meeting is the best option for your situation
   - arrange for our staff with the relevant expertise to participate in the meeting
2. Propose whether to conduct a teleconference, videoconference or meet in person at TGA
3. Attach the form to an email and send at least 4 weeks (but no more than 2 months) before the proposed meeting date to one of the following:
   - For prescription medicines - TGA case manager at streamlinedsubmission@tga.gov.au
   - For other therapeutic goods, the relevant office in TGA for OTC medicines, complementary medicines, medical devices, biologicals
4. Finalise the meeting (i.e. arrange your travel, teleconference or videoconference). If you are meeting TGA staff outside Canberra, you need to organise the meeting venue

Meeting attendees

Advise TGA of who will be attending the pre-submission meeting, including any consultants, and their titles and affiliations in the meeting request form.

Duration of meeting

You will generally be allocated **1 to 1.5 hours** maximum for the meeting, unless agreed otherwise.

Responding to meeting requests

We respond to requests and, if we decide a meeting is the best option, we will schedule a mutually acceptable time and date. Sometimes meetings are premature or the issues can be easily resolved without a meeting.

We do not generally reschedule or cancel unless there are extenuating circumstances such as:

- not receiving the full briefing package and agenda in time (at least 2 weeks prior) to review
- the full briefing package does not contain sufficient information for us to provide guidance

Prepare a briefing package

Prepare a briefing package to ensure we all gain the maximum benefit from the meeting.

Please include:

- an agenda
- a summary of relevant information for the therapeutic good
- any supplementary information relevant to the objectives of the meeting (highlight any questions that you have for TGA)
- summaries describing:
  - results of relevant studies
  - clinical trials with a sufficient degree of quantification
  - any development plan that deviates from current guidelines or practices
- any issues with the design or evidence for the therapeutic good (e.g. the use of a surrogate end point, reliance on a single study use of a non-inferiority design, adaptive designs)
- meeting presentation with full set of slides scheduled to be presented at the meeting

Do not include:

- ✘ detailed data or full study and trial reports
- ✘ promotional material for the company or the therapeutic good

Organise the briefing package

Organise the briefing package content according to the proposed agenda, and:

- number the pages sequentially (individual sections can be numbered separately)
- include a table of contents, appendices, cross-references and tabs differentiating sections, if necessary
- use the checklist in the meeting request form

Send the briefing package

Email the full briefing package at least 2 weeks prior to the scheduled meeting to email address used to request a meeting.

Rescheduling or cancelling the meeting

Unless you no longer need the meeting, avoid rescheduling or cancelling wherever possible.

If you need to cancel or reschedule, tell us as soon as possible so we can notify any interstate participants.

During the meeting

Keep your presentation concise. Relevant TGA officers will have already read the briefing package prior to the meeting.

A TGA officer opens the meeting and will usually begin with clarifying:

- the purpose of the meeting is to focus only on the issues identified
- no new material should be presented that was not included in the full briefing package (if important new information becomes available within the preceding 2 week period, send an updated presentation to the TGA at least 48 hrs prior to the meeting, identifying the new information)
- the meeting is not to promote the therapeutic good or company history
- the meeting is not to be audio or video recorded in any capacity

All participants should summarise the important points, agreements, clarifications and action items.

After the meeting

- Complete a meeting record (use the meeting record form, if desired), which provides a summary that clarifies the agreed outcomes, and any actions arising.
- Send a copy of the meeting record to all participants within 2 weeks.
- Include a copy of the final meeting record in:
  - Module 1 of the application dossier for medicines
  - the application dossier for a TGA Conformity Assessment Certificate submission.

We will acknowledge the meeting record within 2 weeks of receipt.

Version history

Version	Description of change	Author	Effective date
V1.0	Guidance 5: Pre-submission meetings with TGA Previously ARGPM Appendix 5: Conduct of meetings between TGA and sponsors	Office of Medicines Authorisation Office	12/07/2013
V2.0	New title Expanded scope to include applications for designation and conformity assessment for medical devices Removed pre-submission dossier information and form Restructured and reordered information Reduced wording to enhance readability and clarity Shortened headings for increased scanability Updated contact details	Prescription Medicines Authorisation Branch and Regulatory Guidance Section	August 2017
V2.1	Pre-submission meeting record to include assessed listed complementary medicines	Prescription Medicines Authorisation Branch and Regulatory Guidance Section	March 2018
V2.2	Minor updates to reflect CTA name change	Biological Science Section	November 2020
V2.3	Minor update to include priority applicant determination (medical devices) in introduction.	Devices Clinical Section	December 2020

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

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