



**Australian Government**

**Department of Health**

Therapeutic Goods Administration

# CTD Module 1

## Administrative information and prescribing information for Australia

Applicable to applications received by the TGA from 1 July 2015

Version 3.0, July 2015

**TGA** Health Safety  
Regulation

# About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The 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 <<http://www.tga.gov.au>>.

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## Version history

<b>Version</b>	<b>Description of change</b>	<b>Author</b>	<b>Effective date</b>
V1.0	First version	Office of Medicines Authorisation	28/09/2007
V2.0	Second version to reflect outcomes from the public and stakeholder consultation and the revised prescription medicine registration process.	Office of Medicines Authorisation	16/05/2013
V2.1	Editorial amendments	Office of Medicines Authorisation	30/05/2013
V2.2	Alignment with revised PPF, editorial changes.	Office of Medicines Authorisation	30/04/2014
V2.9	Revisions to align with introduction of eCTD format	Office of Medicines Authorisation	05/09/2014
V3.0	Third version to reflect electronic dossiers	Medicines Authorisation Branch	01/07/2015

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# Introduction

## Terminology

### Regulatory activity category

Regulatory activity category is identified by a number, for example, category 1 and category 2 applications, and refers to the overall legislated time-frames for decisions about regulatory activities.

### Regulatory activity type

Regulatory activity type relates to the fees associated with an application and is identified by a letter, for example, A, B or C applications.

Examples include:

- new chemical entity
- new indication

### Sequence

A sequence is a package of information bundled together in an electronic structure providing information to the agency. The contents of a sequence will depend on the regulatory activity type and whether it is the initial sequence of the regulatory activity or a follow-up providing additional data or changes (see also [Module 1.0.2 Lifecycle tracking table](#)).

## Common technical document (CTD)

The Common Technical Document (CTD) is a set of specifications for a dossier for the registration of medicines. The CTD was developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and adopted by the TGA in 2004.

The CTD prescribes:

- the organisation of the dossier across 5 modules
- the order in which documents must appear so they are grouped logically and can be easily located.

Under the CTD format:

- Each dossier is a collection of documents grouped into 5 modules as detailed below.
- The actual content of the dossier will vary according to the regulatory activity: for example, category 1, 2 or 3; Type A (new chemical entity), Type D (new generic medicine) etc.
- The format of Modules 2, 3, 4 and 5 is described in the relevant adopted CTD guidelines.

There is no single document that explains the content of Module 2. The documents for Modules 3, 4, and 5 include a section on the information that must be provided in Module 2.

- [CTD for the registration of pharmaceuticals for human use—Quality overall summary of Module 2 and Module 3: quality](#)

- [CTD for the registration of pharmaceuticals for human use—Nonclinical overview and nonclinical summaries of Module 2 and organisation of Module 4](#)
- [CTD for the registration of pharmaceuticals for human use—clinical overview and clinical summary of Module 2 and Module 5: clinical study reports](#)
- See also: [CPMP/ICH/5552/02 ICH Topic M 4. Common Technical Document for the Registration of Pharmaceuticals for Human Use. Questions and Answers](#)
- The content of Modules 3, 4 and 5 (technical data requirements) will vary according to the regulatory activity and is described in the relevant TGA [standards & guidelines for prescription medicines](#).

The format and content of Module 1 (Administrative information and prescribing information for Australia) are described in this document.

The electronic Common Technical Document (eCTD) is the electronic version of the CTD and is described by the following documents:

- [Australian eCTD specification: Module 1 and regional information](#)
- [ICH Electronic Common Technical Document Specification, Version 3.2.2](#)
- [Australian eCTD regional specification and validation criteria](#)

# Module 1: Administrative information and prescribing information for Australia

Module 1 of the CTD describes the administrative information and prescribing information (for example, the application form, the proposed product information and labelling) for Australia to support:

- the registration of a prescription medicine under section 23 of the *Therapeutic Goods Act 1989* ('the Act')
- the variation of the details of an ARTG registration for a prescription medicine under section 9D of the Act.

This guidance:

- explains the format and content for Module 1 of a dossier
- describes each document in Module 1
- outlines when each document needs to be provided
- details any other requirements relating to the documents.

## Further information

### Dossier document matrix

- A summary of CTD document requirements for applications to the TGA is shown in the eSubmission *Document matrix*, available at [Australian eCTD regional specification and validation criteria](#).

### Regulatory requirements

The following documents provide further information about the regulatory requirements for applications for prescription medicines:

- [Prescription medicine registration process](#). This document provides an overview of the TGA's regulatory processes for category 1 and category 2 applications.
- [Mandatory requirements for an effective application](#)
- [Questions and answers about the prescription medicines registration process](#). These pages are updated on a regular basis in response to queries from applicants about the process. Subscribe to the [TGA Update email list](#) to receive notifications when the *Question and Answers* page is updated.
- [CTD Modules 2, 3, 4 and 5](#)
- [Standards & guidelines for prescription medicines](#).

## Module 1.0 Correspondence

### Overview

This section of Module 1 holds the cover sheet, the Cover letter, the Lifecycle management tracking table, and the applicant's response to request/s for information (answers to questions) from TGA.

### Summary of requirements

#### Documentation

Section	Description	Category 1/Category 2		Category 3	
		New registration	Variation	New registration	Variation
1.0.1	Cover letter	●	●	●	●
1.0.2	Lifecycle management tracking table	●	●	●	●
1.0.3	Response to request for information (if questions raised)	●	●	●	●

**Key:** ● = mandatory  
○ = requirement defined by the regulatory activity  
x = not required.

### Module 1.0.1 Cover letter

#### When to include the Cover letter

Include in Module 1.0.1 for all regulatory activities and for each sequence associated with that regulatory activity.

#### How to prepare the Cover letter

Prepare the letter on company letterhead and sign by an authorised officer of the company.

The *Cover letter* should not contain any evaluable information. Do not include responses to questions raised by TGA in the *Cover letter*, since they have been assigned a specific location in Module 1.0.3.

Include the signed *Cover letter* in Module 1.0.1.

Ensure the letter contains the following information:

---

## Initial cover letter

Include the following information in the initial *Cover letter* for a regulatory activity:

- a description of the submission, including appropriate regulatory information
- the submission number allocated at the time of lodging the *Pre-submission planning form* for category 1 and category 2 applications
- regulatory activity category and regulatory activity type(s)
- the trade name(s), active ingredient name(s), dosage forms and strengths of the medicine(s)
- the AUST R numbers of the existing registered medicines for applications seeking to vary those medicines
- the identity of any studies supplied in the dossier that have been previously evaluated by the TGA, including information relating to the initial lodgement of the data (submission ID and date). Not required for studies previously submitted in the eCTD format.
- for category 3 applications, a declaration that:  

‘No aspects of the quality information have been changed, including manufacturing procedures and equipment, raw material, finished product specifications, other than the changes nominated in this application.’

## All Cover letters

Include the following information in the *Cover letter* for all sequences:

- the eSubmission Identifier in the subject line
- the full name, phone number, facsimile number and email address for:
  - the regulatory point of contact
  - information technology points of contact
- a description of the electronic dossier provided for that sequence, including type and number of electronic media, approximate submission size, and if appropriate, characteristics relating to the media
- a statement that the electronic dossier is virus free with a description of the software used to check the files for viruses
- an indication of which validation tool and version was used as well as a statement addressing any issues found in the accompanying validation report.

## Note to evaluators

A *Note to evaluators* is not a requirement, but sponsors occasionally include them to provide further information to facilitate navigation (e.g. on hyperlinking) etc. To promote a consistent approach to naming them and placing them within the regulatory activity, a *Note to evaluators* should be filed as a leaf element under the *m1-0-1-cover* heading. The title of the leaf should be “Note to evaluator”.

## Module 1.0.2 Lifecycle management tracking table

### When to include the lifecycle management tracking table

The *Lifecycle management tracking table* will support transparency and ease tracking of sequences regardless of the format.

The sequence number is a four digit number referring to a package of information bundled together in an electronic structure for eCTD submissions to TGA. Sequence numbers, as defined for eCTD submissions, are not applicable for [non-eCTD electronic submissions \(Nees\) format dossiers](#); however, the use of a four digit number in the top level folder name is recommended.

The initial application should normally have a sequence number of 0000. As additional data are submitted, for example, in response to questions, the sequence number will advance, 0001, 0002, etc.

An updated *Lifecycle management tracking table* should be placed in Module 1.0.2 any time a new sequence is submitted.

### How to prepare a lifecycle management tracking table

Prepare a table listing sequences submitted to the TGA. An example is shown below.

Sequence	Sequence Type	Sequence Description	Related Sequence
0000	Baseline	Reformat	0000
0001	C-Extension of Indication of COPD	Initial	0001
0002	Supplementary information	Response to Request for Information	0001
0003	H-Minor Variation, Not Resulting in a New Register Entry	Initial	0003
0004	F-Major Variation—New Strength	Initial	0004

## Module 1.0.3 Response to request for information

### When to include a response to a request for information

Include only when responding to a TGA request for information after dossier lodgement.

Do not include this document in the dossier:

- when it is initially lodged
- to provide details on how the applicant has addressed any items raised by the TGA in the *Planning letter*. Information on the applicant's actions to address issues raised in the *Planning letter* must be provided at *Module 1.7.1 Details of compliance with pre-submission outcomes*.

## How to prepare a response to a request for information

- Assess the TGA's request for information and determine whether it will be necessary to provide revised or new CTD documents as part of the response
- Prepare a Cover letter (see [Module 1.0.1](#))
- Prepare a document that includes an appropriate response to each question in the TGA's request (see 'Appropriate response' below) and include in Module 1.0.3.

## Including new documents that belong elsewhere in the CTD

- Place new documents submitted as part of the responses to questions in the appropriate part of the CTD (elsewhere in Module 1 or in Modules 2-5).
- Include a reference/hyperlink to the location of these new documents with the answer to the question in Module 1.0.3.

For example, if the answer requires a revised version of the Product Information:

- include any comments with the answer in Module 1.0.3
- include copies of the new version of the Product Information in Module 1.3.1.1 (clean copy) and Module 1.3.1.2 (marked copy).

## Appropriate response to a request for information

An appropriate response to a request for information is one that:

- provides a comprehensive response that addresses all aspects of the question(s)
- may need to include updates, or addenda, to the relevant summaries and/or overview sections of Module 2 when a response includes extensive data/documents and/or analyses.

## Referencing documents

In an eCTD dossier, provide hyperlinks to references previously submitted in the eCTD format.

When referencing CTD documents that were provided previously to the TGA as part of a hard copy dossier or NeeS dossier, include detailed references to CTD documents:

- the submission ID
- the module
- tab identifier
- page number

For example: See PM-2012-12345-6-7, Module 3, 3.2.P.4.3 Method validation, p 23.

# Module 1.1 Comprehensive table of contents

## Overview

All dossiers **not in the eCTD format** must include a comprehensive table of contents for the complete dossier.

## Summary of requirements

### Documentation

Section	Description	Category 1/Category 2		Category 3	
		New registration	Variation	New registration	Variation
1.1	Comprehensive table of contents  (for dossiers <b>not in the eCTD format</b> )	●	●	●	●

**Key:** ● = mandatory  
○ = requirement defined by the regulatory activity  
x = not required.

### When to include a comprehensive table of contents

Include a comprehensive table of contents in all dossiers **not in the eCTD format**.

### How to prepare a comprehensive table of contents

The comprehensive table of contents is a complete list of all documents in the dossier, arranged by Module, and with location references for each document.

Specify the titles of studies in the table of contents, indicating the type of study and topic in the title. Study codes alone are not acceptable.

### Location reference

All documents in a Nees dossier should be referenced from a hyperlinked table of contents. Hyperlinks for each document should always be provided to the first page of the appropriate file.

Do not use page numbers for document location as page numbering is at the document level only.

## Module 1.2 Administrative information

### Overview

This section of Module 1 contains the application forms, pre-submission details, patent certification documents and change in sponsor information for prescription medicine applications.

### Summary of requirements

#### Documentation

Section	Description	Category 1/Category 2		Category 3	
		New registration	Variation	New registration	Variation
1.2.1	Application form	●	●	●	●
1.2.2	Pre-submission details	●	●	x	x
1.2.3	Patent certification	○	x	○	x
1.2.4	Change in sponsor (if change in sponsor)	●	●	●	●

**Key:** ● = mandatory  
○ = requirement defined by the regulatory activity  
x = not required.

### Module 1.2.1 Application form

#### How to prepare the application form

Download and complete the appropriate application form from the TGA website:

- New Registrations:
  - *Application form to register or vary the registration of prescription medicines* (Category 1 application)
  - [Section 23 Category 3 application that creates a separate and distinct good](#)
  - [Section 23 Self-assessable request \(SAR\) that creates a separate and distinct good](#)
  - [Additional trade names](#)

- Variations:
  - *Application form to register or vary the registration of prescription medicines (Category 1 application)*
  - [\*9D\(1\) Request to correct an ARTG entry\*](#)
  - [\*9D\(2\) Safety-related request \(SRR\) to vary an ARTG entry\*](#)
  - [\*9D\(3\) Category 3 application to vary an ARTG entry\*](#)
  - [\*9D\(3\) Self-assessable request \(SAR\) to vary an ARTG entry or minor editorial change to the PI\*](#)

If there is insufficient room in any field/section on the paper application form:

- enter 'see attached' in the field
- attach a separate page with the full details.

## **General application form information**

### ***ARTG information and provisional ARTG record***

The information entered in the application form is the basis of the new/revised ARTG entry. It is critical that this information is entered accurately and is an accurate reflection of the information provided in the dossier.

Before the application is approved, the information that forms the basis of the new/revised ARTG entry is called the provisional ARTG record (PAR). The information included on the PAR is updated as required during evaluation of the application.

At the conclusion of the evaluation, the final information becomes the ARTG entry for the product.

### ***Proposed indications***

The indications recorded on the application form for the registration of a new chemical entity, new biological entity or an extension of indications must be identical across:

- the application form
- Cover letter (if included in letter)
- the product information document (apart from the use of a trademark and copyright symbols).

### ***Manufacturing steps***

The manufacturing steps shown on a manufacturing licence or GMP clearance issued by the TGA are not necessarily identical to the manufacturing steps that need to be entered on the prescription medicine application form.

### ***Ingredient names***

The non-proprietary ingredients in the formulation must be specified using either:

- Australian approved names (AANs) or the proposed AANs
- Australian approved biological names (ABNs) or the proposed ABNs

A list of AANs and ABNs is available on the TGA website at: [TGA approved terminology for medicines](#).

For new ingredients and new proprietary ingredients, the completed [Application form for proposing a chemical/biological name](#) or [Notification of a New Proprietary Ingredient](#) form (respectively) must be lodged with the TGA before the *Pre-submission planning form* is lodged.

New medicines cannot be registered until all ingredients have either an AAN or ABN, or have been included as a proprietary ingredient in the ARTG.

## Module 1.2.2 Pre–submission details

### When to include the pre-submission details

When a [Pre-submission planning form \(PPF\)](#) has been lodged for a category 1 or a category 2 application, a copy of the PPF must be included at Module 1.2.2.

(A PPF is not required for category 3 applications.)

### How to prepare information about the pre-submission details

After lodging a PPF via TBS:

- go to the 'lodged submissions' view in TBS and locate the PPF
- include the document at Module 1.2.2.

It is not necessary to include the attachments to the PPF as these will be held by the TGA.

## Module 1.2.3 Patent certification

### When to include the patent certification

Before a newly approved registration can be included in the ARTG, one of the following forms is required to satisfy legislative requirements under section 26B of [the Act](#):

- [Certification in relation to patents required in relation to registration or listing under Sections 25, 26 and 26A of the Therapeutic Goods Act 1989](#)
- [Notification to the Secretary that a Certification under section 26B\(1\) of the Therapeutic Goods Act 1989 is not required.](#)

All regulatory activities for new registrations, including formulation changes, changes in trade name, and extensions of indication, require the applicant to provide one of the above forms before the registration process can be finalised.

Applications for a similar biological medicinal product or a generic medicine which result in a new registration must complete the [Certification in relation to patents required in relation to registration or listing under Sections 25, 26 and 26A of the Therapeutic Goods Act 1989](#).

### How to prepare the patent certification

- Locate and open the appropriate form
- complete and sign the form in accordance with the instructions provided on the form

- include the document at Module 1.2.3.



### Legislation

A certificate about relevant patents is required prior to registration under section 26B of the Act in relation to regulatory activities made under section 25 of the Act. If a certificate will not be provided, a notification must be lodged advising that a certificate is not relevant.

## Module 1.2.4 Change in sponsor

### When to include change in sponsor details

For Category 1 and 2 applications, the sponsorship of an application can be changed prior to the milestone 5 date indicated in the evaluation plan, regardless of whether or not evaluation reports have been received by the applicant.

For other regulatory activities or after milestone 5 of a category 1 or 2 application, the sponsor's name should only be changed after the regulatory activity has concluded.

### How to provide the change in sponsor details

For a transfer of sponsorship include:

- a copy of the [notification](#) of a change in sponsorship
- a letter from the original sponsor confirming that the new sponsor has access to all previously submitted data. If this is not the case, the original sponsor and the new sponsor must complete the Co-marketed medicines declarations ([Module 1.5.5](#)).

### Note:

Also include the following documents:

- Letters of access for DMF, PMF and CEP holders regarding access to confidential parts of these documents ([Module 1.6.3](#))
- Revised medicine information and labelling where changes have been made:
  - Revised [Module 1.3.1.1](#) and [Module 1.3.1.2](#): Australian product information (clean and annotated copies)
  - Revised [Module 1.3.1.3](#): (package insert)
  - Revised [Module 1.3.2.1](#) and [Module 1.3.2.2](#): Australian consumer medicines information (clean and annotated copies)
  - Revised [Module 1.3.4](#): Label mock-ups and specimens.

For a change in sponsor name (same legal entity but change of name) include:

- a declaration in the Cover letter that, with the exception of a change to the sponsor name, the sponsor (company) has made no other changes that may reasonably be expected to impact on or affect the submission under evaluation.
- Revised medicine information and labelling where changes have been made:

- Revised [Module 1.3.1.1](#) and [Module 1.3.1.2](#): Australian product information (clean and annotated copies)
- Revised [Module 1.3.1.3](#): (package insert)
- Revised [Module 1.3.2.1](#) and [Module 1.3.2.2](#): Australian consumer medicines information (clean and annotated copies)
- Revised [Module 1.3.4](#): Label mock-ups and specimens.

## Module 1.3 Medicine information and labelling

### Overview

This section of Module 1 holds multiple documents relating to the presentation and packaging of the medicine(s).

### Summary of requirements

#### Documentation

Section	Description	Category 1/Category 2		Category 3	
		New registration	Variation	New registration	Variation
1.3.1.1	Product information - clean	●	●	●	○
1.3.1.2	Product information - annotated	○	●	●	○
1.3.1.3	Package insert	○	○	○	○
1.3.2.1	Consumer medicines information - clean	●	○	●	○
1.3.2.2	Consumer medicines information - annotated	○	○	●	○
1.3.3	Label mock-ups and specimens	●	○	●	○

**Key:** ● = mandatory  
○ = requirement defined by the regulatory activity  
x = not required.

### Module 1.3.1 Product information and package insert

#### When to include the product information and package insert

##### Product information (PI)

Include in all regulatory activities which:

- result in one or more new ARTG entries under section 16 of [the Act](#), for example:
  - new chemical entity

- change in formulation
- additional trade name
- change in trade name
- new container type
- relate to a variation that will result in a change to the PI, for example:
  - a category 1 application to update the clinical trials section of the PI
  - a category 3 application to change the storage conditions of the medicine which will be implemented immediately after approval.

## Package insert

Include a proposed package insert with all regulatory activities which:

- result in one or more new ARTG entries by reason of being a separate and distinct good under section 16 of [the Act](#) where a package insert is required (for example, injectables) or is proposed
- relate to a variation that will:
  - result in a change to an existing package insert
  - necessitate the inclusion of a package insert.

### Important information

The form for the product information has been approved by a delegate of the Secretary of the Department of Health and Ageing under subsection 7D(1) of the [Therapeutic Goods Act 1989](#) (the Act) for use by applicants for the registration of:

- a 'restricted medicine' to accompany the application in accordance with section 23(2) of the Act

other medicines for which the Secretary has given notice to the applicant that product information is to be provided to the Secretary (see section 25(1)(da) of the Act).



## How to prepare product information and the package insert

### Regulatory activities resulting in a new register entry/entries

- Include a draft PI in the dossier:
  - for regulatory activities to register a new medicine covered by the [Restricted Medicine Specification](#)
  - where the applicant has been given a notice that an Australian PI is to be included with the dossier.
- Draft the proposed Australian PI using the [form](#) and format specified by subsection 7D(1) of [the Act](#) and supporting [TGA Guidance on Product Information](#).

- If the PI for a new registration is based on an existing PI not in the form and format specified by subsection 7D(1) of the Act, the new PI must be in the form and format specified by subsection 7D(1) of the Act.

The information below is provided to assist applicants in producing an Australian PI and is to be read in conjunction with the [instructions on the form](#).

### **All other regulatory activities**

Ensure the Australian PI is updated and maintained based on the format and contents specified in [guidance for PI](#) and package inserts.

### **Product information**

- Ensure all information in the PI is supported by evidence provided in the dossier.
- If the PI is based on an existing PI, include:
  - a ‘clean’ Australian PI in Module 1.3.1.1. This clean copy incorporates all the changes proposed but removes the revision marks and comments.
  - the ‘marked-up’ (annotated) Australian PI in Module 1.3.1.2. This ‘marked-up’ copy clearly shows all additions, deletions or changes using ‘track changes’ when based on, or amending, an existing Australian PI.

### ***Regulatory activities resulting in a variation to an existing PI***

- Include the necessary information in the ‘marked-up’ document to direct evaluators to the evidence base in the dossier that supports the changes or new information being proposed in the PI, either as an explanatory comment box or as an attached table.

### ***Regulatory activities relating to multiple PIs***

- Provide both ‘marked-up’ and clean versions of each PI.

### ***Applications for additional trade name***

- Use the Australian PI of the original product as the basis for the ‘marked-up’ Australian PI.
- If the PI for an additional trade name is based on an existing PI not in the form and format specified by subsection 7D(1) of the Act, the new PI must be in the form and format specified by subsection 7D(1) of the Act.

### ***Applications for new generic medicine***

- Clearly identify and justify all differences between the Australian reference product PI and the generic PI, other than the trade name and the applicant’s name and address, on the ‘marked-up’ PI.
- If the PI for a new generic medicine is based on an existing PI not in the form and format specified by subsection 7D(1) of the Act, the new PI must be in the form and format specified by subsection 7D(1) of the Act.

### ***Applications requiring an amendment to an existing PI***

Where there is an amendment to an existing PI:

- Check the document to confirm it is current and incorporates any changes approved by the TGA before amending an existing Australian PI.

- The 'marked-up' document must include the necessary information to direct evaluators to the evidence base in the dossier that supports the changes or new information being proposed in the PI, either as an explanatory comment box or as an attached table.

### **Package inserts**

- must be consistent with:
  - the label
  - PI
  - consumer medicines information (CMI) documents and requirements
- are required when obligatory labelling information does not fit on the label and must be provided on a package insert
- must not be promotional. They can only contain information about the safe and appropriate use of the goods
- are included at Module 1.3.1.3.

#### ***For products for parenteral use***

- The PI must be supplied as a package insert.

#### ***For self-administered injections***

- The CMI and PI may be included as package inserts.

### **Related information and guidance**

- [Product information](#) and package inserts.

## **Module 1.3.2 Consumer medicines information**

### **When to include consumer medicine information**

Include in all regulatory activities which:

- result in a separate and distinct good under section 16 of the [Act](#)
- relate to a variation that will result in a change to the CMI

For example, an application to include important safety information in the PI and which needs to be reflected in the CMI.

### **How to prepare consumer medicine information**

The CMI:

- must conform with the format and contents specified in Schedule 12 (sub regulation 9A(1)) of the [Therapeutic Goods Regulations 1990](#)
- cannot be promotional.

If the CMI is based on an existing CMI, include:

- a 'clean' CMI in Module 1.3.2.1. This clean copy incorporates all the changes proposed but removes the revision marks and comments.
- the 'marked-up' (annotated) CMI in Module 1.3.2.2. This 'marked-up' copy clearly shows all additions, deletions or changes using 'track changes' when based on, or amending, an existing CMI.

### Note:

CMIs are referred to as 'patient information' in the legislation.

In addition to the requirements of the Regulations, the TGA strongly encourages applicants to follow [Writing about medicines for people: Usability guidelines for consumer medicine information](#) when developing a CMI. These guidelines outline the correct procedure for writing, testing, implementing and monitoring CMI.

It is the applicant's responsibility under the Regulations to ensure that the CMI remains consistent with the PI and the format specified in the Regulations.

#### Legislation

Schedule 12 of the Therapeutic Goods Regulations 1990 requires the CMI to be:



- clearly legible
- written in language that will easily be understood by patients
- consistent with product information (within the meaning of section 9D of the Act) about the product
- include the matters that are listed in Schedule 12.

## Module 1.3.3 Label mock-ups and specimens

### When to include labels

Include the proposed Australian labelling with all regulatory activities that:

- result in one or more new ARTG entries under section 16 of [the Act](#), for example:
  - new chemical entity
  - new strength
  - additional trade name
  - change in trade name
  - new container type
- seek a variation that will result in:
  - a change to the labelling

- the creation of a new label
- for example, a category 3 application to change the storage conditions or applicant details.

## How to prepare labels

- Ensure all Australian labels comply with the [Therapeutic Goods Order—General Requirements for Labels for Medicines](#) unless otherwise exempted.
- Prepare labelling in accordance with the [Best practice guidelines for prescription medicines labelling](#).
- Each label (for example, carton labels, container labels, package inserts) should be provided in Module 1.3.3 as individual PDF files. The samples should:
  - include all panels, if applicable
  - quote the scale and actual size dimensions; and
  - reflect the actual colour proposed for use.
- Ensure labels are provided for every separate and distinct good in the submission.

### *If batch number and expiry date are to be printed on the label during packaging*

- include a statement to this effect with the labels.

### *Label colours*

- Ensure label design takes into account the fact that dispensers and patients may have varying degrees of colour blindness and impaired vision.

### *Separate and distinct medicines with multiple pack sizes*

- Where a separate and distinct medicine has multiple pack sizes and the labelling is identical for each pack size (with the exception of the pack size identifier), provide one label with a declaration that the labelling for the other pack sizes is identical to the label provided.

### *New registrations where provisional AUST R is unknown*

- Show the proposed location for the AUST R number on the packaging using 'AUST R XXXXXX'.

### *New registrations and packaging modifications*

- Include a description of the proposed packaging(s) of the product and the pack size(s) in Module 3.2.P.7.



#### Legislation

Labels are evaluated under:

- Section 25(1) of the [Therapeutic Goods Act 1989](#) (the Act) requires that the Secretary must evaluate goods having regard to:
  - (e) whether the presentation of the goods is acceptable
  - (f) whether the goods conform to any standard applicable to the goods, or

any requirements relating to advertising applicable under part 5-1 or under the Regulations.

- Section 3 of the Act defines 'standards' to include:
  - 'a standard that is constituted by the matters specified in an order under section 10 that is applicable to the goods'.

Therapeutic Goods Order– General requirements for labels of medicines made under section 10 of the Act sets out requirements for labels for medicines. Labels are assessed against the requirements in this order.

## Module 1.4 Information about the experts

### Overview

This section of Module 1 holds multiple documents providing information about the experts who have reviewed the supporting data for the submission and prepared the summaries and overviews that constitute Module 2.

### Summary of requirements

#### Documentation

Section	Description	Category 1/Category 2		Category 3	
		New registration	Variation	New registration	Variation
1.4.1	Quality (if Module 2.3 included)	●	●	●	●
1.4.2	Nonclinical (if Module 2.4 included)	●	●	x	x
1.4.3	Clinical (if Module 2.5 included)	●	●	x	x

**Key:** ● = mandatory  
○ = requirement defined by the regulatory activity  
x = not required.

### Module 1.4.1 Quality

#### When to include information about the quality expert

Include where any subsection of Module 2.3 has been provided in the dossier.

#### How to prepare information about the quality expert

The expert responsible for compiling Module 2.3 must:

- complete and sign a declaration
- provide a curriculum vitae (CV) outlining his/her educational background, training and occupational experience.

The following table provides instruction on creating and completing the declaration.

### Creating and completing declaration - quality

Expert	Instruction
Australian expert	<p>Download the Module 1.4 form <i>Information about the experts</i> and complete the section for the 'Local (Australian) expert' as per the instructions on the form.</p> <p>The declaration must be signed by the expert who is the subject of the declaration.</p>
Expert from European Union	<p>Provide a copy of the expert's declaration from the application lodged with EMA.</p> <p>Alternatively, the 'Overseas expert' part of the Module 1.4 form can be completed.</p>
Other overseas expert	<p>Complete the 'Overseas expert' part of the Module 1.4 form.</p>

Module 1.4.1 must include, in the following order:

- the expert's signed declaration (as per the table above), and
- the expert's curriculum vitae

#### Note:

Module 2.3 is required for the following regulatory activity types:

- new chemical/biological entities, new similar biological medicinal products and new combinations
- new generics
- new dosage forms and new strengths
- any other category 1 or category 2 application containing Module 3 data.

## Module 1.4.2 Nonclinical

### When to include information about the nonclinical expert

Include where any subsection of Module 2.4 and/or Module 2.6 has been provided in the dossier.

### How to prepare information about the nonclinical expert

The expert(s) responsible for compiling Module 2.4 and Module 2.6 must:

- complete and sign a declaration

- provide a curriculum vitae outlining his/her educational background, training, and occupational experience.

The following table provides instruction on creating and completing the declaration.

### Creating and completing declaration - nonclinical

Expert	Instruction
Australian expert	Download the Module 1.4 <i>Information about the experts</i> form and complete the section for the 'Local (Australian) expert' as per the instructions on the form.  The declaration must be signed by the expert who is the subject of the declaration.
Expert from European Union	Provide a copy of the expert's declaration from the application lodged with EMA.  Alternatively, the 'Overseas expert' part of the Module 1.4 form can be completed.
Other overseas expert	Complete the 'Overseas expert' part of the Module 1.4 form.

Module 1.4.2 must include, in the following order:

- the expert's signed declaration (as per table above), and
- the expert's curriculum vitae.

#### Note:

Module 2.4 (nonclinical overview) is required when:

- nonclinical (Module 4) information will be submitted as part of the application
- the product includes a novel excipient or involves the novel use of an excipient
- the levels of impurities and degradants exceed guideline recommendations
- there is a deviation from adopted nonclinical guidelines
- there are changes to the nonclinical aspects of the Product Information
- a new generic medicinal product is a new salt, ester, or derivative of a registered active substance and the applicant claims the medicinal product to be essentially similar to the registered product.

Where the applicant claims essential similarity to a registered product, the nonclinical overview should focus on the grounds for claiming essential similarity and, if applicable, the additional data to demonstrate evidence of the equivalence of safety and efficacy properties of different salts, esters, or derivatives of an authorised active substance are to be provided.

Module 2.6 (nonclinical summary) is required for the following regulatory activity types:

- new chemical/biological entities, new similar biological medicinal products and new combinations

- regulatory activities where new nonclinical studies have been provided in the dossier.

## Module 1.4.3 Clinical

### When to include information about the clinical expert

Include where any subsection of Module 2.5 and/or Module 2.7 has been provided in the dossier.

### How to prepare information about the clinical expert

The expert(s) responsible for compiling Module 2.5 and Module 2.7 must:

- complete and sign a declaration
- provide a curriculum vitae outlining his/her educational background, training, and occupational experience.

The following table provides instruction on creating and completing the declaration.

#### Creating and completing declaration - clinical

Expert	Instruction
Australian expert	Download the Module 1.4 <i>Information about the experts</i> form and complete the section for the 'Local (Australian) expert' as per the instructions on the form.  The declaration must be signed by the expert who is the subject of the declaration.
Expert from European Union	Provide a copy of the expert's declaration from the application lodged with EMA.  Alternatively, the 'Overseas expert' part of the Module 1.4 form can be completed.
Other overseas expert	Complete the 'Overseas expert' part of the Module 1.4 form.

Module 1.4.3 must include, in the following order:

- the expert's signed declaration (as per table above), and
- the expert's curriculum vitae.

#### Note:

Module 2.5 and Module 2.7 are required for the following regulatory activity types:

- new chemical/biological entities, new similar biological medicinal products and/or new combinations
- extensions of indications
- changes to patient group or dosage and administration

- regulatory activities where new clinical studies have been provided in the dossier.

***Applications to register a new generic medicine***

For an application to register a new generic medicine:

- the clinical overview (Module 2.5) is mandatory
- clinical summaries (Module 2.7) can be provided, but they are mandatory if new clinical studies have been provided in the dossier
- where the applicant claims the medicinal product to be essentially similar to a registered product, the clinical overviews/summaries are to focus on the rationale for claiming essential similarity and, if applicable, the additional data to demonstrate evidence of the equivalence of safety and efficacy properties of different salts, esters, or derivatives of an authorised active substance are to be provided.

## Module 1.5 Specific requirements for different types of applications

### Overview

This section of Module 1 holds multiple documents required for specific types of regulatory activities.

### Summary of requirements

#### Documentation

Section	Description	Category 1/Category 2		Category 3	
		New registration	Variation	New registration	Variation
1.5.1	Literature-based submission documents (if literature-based submission)	●	●	x	x
1.5.2	Orphan drug designation (if orphan drug)	●	x	●	x
1.5.3	Genetically modified organisms consents	○	○	x	x
1.5.4	Not required				
1.5.5	Co-marketed medicines declarations (if applicable)	●	○	●	○
1.5.6	Combination medicine consent (if submission for a new combination)	●	x	x	x
1.5.7	OTC product assurances	Refer to OTC Guidance document. Not required for prescription medicine applications.			
1.5.8	Umbrella brand assessment	Refer to OTC Guidance document. Not required for prescription medicine applications.			

**Key:** ● = mandatory  
○ = requirement defined by the regulatory activity  
x = not required.

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## Module 1.5.1 Literature-based submission documents

### When to include information about literature based submissions

Include where the application partially or completely relies on a [literature-based data](#) set to support the application.

### How to prepare information about literature based submissions

For literature based submissions involving a systematic literature search, three items need to be prepared:

- Module 1.5.1.1—methodology of literature search, including complete details of database search strategies
- Module 1.5.1.2—a copy of the letter from the TGA in which approval for the search strategy is given
- Module 1.5.1.3—complete search output.

For literature based submissions NOT involving a systematic literature search, Module 1.5.1.1 and Module 1.5.1.3 only need to be prepared.

#### Note:

A literature-based submission uses literature references, rather than studies, for part or all of the supporting data required in the dossier to establish quality, safety, and efficacy.

Generally, the TGA will only accept literature-based submissions for medicines with an extensive registration history either in Australia or overseas.

A submission comprising a mix of conventional and literature-based data is treated in the same manner as a pure literature-based submission.

When completing the application form:

- confirm the search strategy used to generate the search output for the application is in full accordance with the search strategy approved by the TGA
- or
- document and include the reasons for all changes if not in full accordance with the search strategy approved by the TGA.

## Module 1.5.2 Orphan drug designation

### When to include information about orphan drug designation

Include when the medicine has been designated an orphan drug and the applicant wishes to request the fees be waived for an application under section 23 of the Act.

## How to prepare information about an orphan drug designation

Locate the TGA letter granting orphan drug designation and check the designation letter and the application to ensure:

- the applicant identified on the designation letter is identical to the applicant for the submission
- the active ingredient(s) specified on the designation letter is/are identical to those in the application
- the indications proposed in the application are identical to, or narrower than, those stated on the designation letter
- the dose form stated on the designation letter is identical to the dose form in the application

Include a copy of the TGA letter granting orphan drug designation in Module 1.5.2.

### Note:

#### *Variations*

Fees for variations to the registration of a medicine, that is, regulatory activities under section 9D of the Act, cannot be waived for an orphan drug.

#### *Broader indications than those designated for the orphan drug*

If the indications proposed in the application are wider than those stated in the orphan drug designation letter, then either:

- the full evaluation fee will be payable
- or
- a new orphan drug designation request must be lodged with the TGA and if designation is received, a new PPF lodged.

#### *Name of the applicant has changed*

A new orphan drug designation request must be lodged with the TGA.



#### **Legislation**

##### ***Orphan Drugs***

Orphan drug designation is granted under regulation 16J of the Therapeutic Goods Regulations 1990 where the applicant has made an application under regulation 16I that demonstrates why the drug satisfies the criteria set out in regulation 16H.

Regulation 45(12) allows for the waiving of a 'fee that would have been payable' for the Secretary considering the application under regulation 16J or 'as part of the registration of a designated orphan drug'.

Information about [how to apply for orphan drug designation](#) may be found on the TGA website.

## Module 1.5.3 Genetically modified organisms consents

### When to include information about genetically modified organisms

Include where the application seeks the registration of:

- a medicine that contains or consists of genetically modified organisms (GMOs)
- a medicine that is derived from a GMO manufactured in Australia and is subject to regulation by the Office of the Gene Technology Regulator (OGTR).

### How to prepare information about genetically modified organisms

- Consult the OGTR to determine requirements under the *Gene Technology Act 2000* before lodging the *Pre-submission planning form*.
- A licence or another form of consent may be required from the OGTR. Refer to Module 1.5.3 of [Information for applicants completing a pre-submission planning form](#) for more information.
- Include in Module 1.5.3 copies of any
  - licence
  - acknowledgement of receipt of application for a licence
  - other written consent from OGTR
  - declaration regarding an exemption for the medicine under part 1 of schedule 2 of the Gene Technology Regulations 2001.

### Related information and guidance

[TGA Guidance 21: Medicines produced by genetic manipulation.](#)

## Module 1.5.5 Co-marketed medicines declarations

### When to include a co-marketed medicine declaration

Include this document in Module 1.5.5 when:

- a cross-licensing agreement exists between the applicant of the current submission and a third-party sponsor
- the third party sponsor authorises the TGA to use information on its product (that is either on the ARTG or under evaluation) for the benefit of the first party's application
- the applicant's product will be identical or very similar to the third-party's product.

### How to prepare a co-marketing medicine declaration

#### Third party sponsor

The third party sponsor must provide the applicant lodging the submission with a letter that:

- authorises the TGA to use information in their registration file on behalf of the applicant of the new application

- 
- identifies the eSubmission Identifier, submission ID and file numbers relating to their data/information
  - identifies the following aspects of their medicine that are the subject of their data/information:
    - trade name(s)
    - active ingredient name(s)
    - dosage forms
    - strengths
  - states whether the applicant of the new application may view the information on file
  - advises of the extent of the authorisation encompassing:
    - the reason for the application (for example, permission to access data for the change in formulation)
    - any restrictions (for example, applies to tablets only, not capsules);
  - identifies which party is responsible for answering queries relating to the third party data/information
  - contains:
    - full name of the authorised officer
    - phone number
    - facsimile number
    - email address
    - signature of the authorised officer.
  - where the application concerns a copy of a medicine registered on the ARTG to a third party sponsor, the following must be provided:
    - a declaration confirming the completeness and accuracy of the ARTG record of the third party product for all data fields
    - or
    - evidence the TGA has been requested to correct the record (including the submission ID or eSubmission identifier and sequence for the correction), together with an assurance that all other aspects of the ARTG record are identical.

## **Applicant**

Where the application concerns a copy of medicine registered on the ARTG to a third party sponsor, the applicant of the submission must provide:

- a declaration that all quality (Module 3) aspects of the new product are identical to the third party product except for labelling

or

information on any differences together with a declaration that all other quality (Module 3) aspects are identical

- a declaration that the PI and CMI of the new product(s) are identical to those of the parent product(s) (except for the trade name and applicant's name and address)
- or
- a complete list of the differences.

**Note:**

Ensure the third party has lodged their data before lodging the application. Failure to provide a third party's data may result in an application being considered not effective.

To avoid delays in evaluating the application, requests to make corrections or variations to the ARTG entry for the third party's already registered product must be submitted to the TGA well in advance of lodging a submission for the co-marketed medicine.

## **Module 1.5.6      Combination medicines consent**

### **When to include information about combination medicines consent**

If the proposed product(s) is a new fixed combination, attach a copy of the TGA's letter advising that the justification for fixed combination is acceptable.

Fixed combination products may be presented as composite packs (i.e. with multiple dosage forms), multiple ingredients within a single dosage form, or a combination of both.

Module 1.5.6 does not apply to fixed combination regulatory activities for new generic medicines.

### **How to prepare information about combination medicines consent**

For a new fixed combination product the applicant must justify, prior to lodging a PPF, the particular combination and the type and extent of data to be provided in the dossier. This is done by preparing and lodging with the TGA a 'justification for fixed combination' as described in the TGA guidance on [Fixed combination prescription medicines](#). If your justification is accepted, attach a copy of the letter advising this in Module 1.5.6.

## **Module 1.5.7      OTC New product assurances**

Refer to OTC Guidance document. Not required for prescription medicine regulatory activities.

## **Module 1.5.8      Umbrella brand assessment**

Refer to OTC Guidance document. Not required for prescription medicine regulatory activities.

## Module 1.6 Master files and Certificates of suitability

### Overview

This section of Module 1 holds multiple documents relating to the use of drug master files (DMFs), plasma master files (PMFs) and Certificates of Suitability of Monographs of the European Pharmacopoeia (CEPs) to establish the quality of active substances in the medicine, novel excipients and excipients of animal and human origin.

### Summary of requirements

#### Documentation

Section	Description	Category 1/Category 2		Category 3	
		New registration	Variation	New registration	Variation
1.6.1	Relevant external sources	○	○	○	○
1.6.2	Applicant's declaration	○	○	○	○
1.6.3	Letters of access	○	○	○	○

**Key:** ● = mandatory  
○ = requirement defined by the regulatory activity  
x = not required.

### Module 1.6.1 Relevant external sources

#### When to include information about external sources

Include this document when the application makes reference to one or more:

- drug master files (DMFs)
- plasma master files (PMFs)
- Certificate(s) of Suitability of Monographs of the European Pharmacopoeia (CEPs).

#### How to prepare information about external sources

Obtain the relevant DMF/PMF/CEP details from the active substance manufacturer, including the eSubmission Identifier and any other TGA reference numbers.

Where a DMF, PMF or CEP is referenced, download and complete the relevant part/s of the [DMF/PMF/CEP details form](#). Include the completed form(s) in Module 1.6.1.

**Note:**

Declaration(s) and Letter(s) of access are required—see Module 1.6.2 and Module 1.6.3.

The applicant's (open) part of the DMF must be included in Module 3.2.S of the quality documentation in the dossier.

The active substance manufacturer's restricted (closed) part is supplied to the TGA directly by the active substance manufacturer.

Ensure that the active substance manufacturer's part of the DMF/PMF has been submitted to the TGA before lodging the application dossier.

**New registrations**

For medicines that contain either a raw material or an excipient that is derived from plasma a PMF must be included in Module 3 or have been previously approved by the TGA.

**Variation applications**

For variations to a registered medicine involving a modified DMF/PMF/CEP it is not necessary to provide this document again, unless a new DMF/PMF/CEP is to be provided.

**Where a PMF is referenced:**

- Prepare the PMF in accordance with EU guideline: [EMEA/CPMP/BWP/3794/03 Rev 1: Guideline for the scientific data requirements for a plasma master file](#) and its annex.
- Provide the epidemiological data for the previous calendar year in accordance with the EU guideline: [EMA/CHMP/BWP/548524/2008: Guideline on epidemiological data on blood transmissible infections](#).
- Ensure the PMF complies with the [Transmissible Spongiform Encephalopathies \(TSE\): TGA approach to minimising the risk of exposure](#).

**Related information and guidance**

[TGA Guidance 11: Drug Master Files and Certificates of Suitability of a Monograph of the European Pharmacopoeia for drug substances](#).

[European Union Guidelines](#) adopted in Australia.

## Module 1.6.2 Applicant's declaration

**When to include the applicant's declaration**

Include when the application makes reference to one or more:

- drug master files (DMFs)
- plasma master files (PMFs) from a third party
- Certificate (s) of Suitability of Monographs of the European Pharmacopoeia (CEPs).

## How to prepare the applicants declaration

Establish a formal agreement with the active pharmaceutical ingredient manufacturer to ensure the manufacturer communicates any changes to the applicant and the TGA before any significant change is made to the drug substance. This agreement is independent of the TGA.

Once the agreement has been established, download the [Applicant declaration form](#)

- complete and sign the form
- include the completed form(s) in Module 1.6.2.

### Note:

The declaration must be signed by an authorised officer of the company.

## Subsequent regulatory activities

For regulatory activities subsequent to the initial registration application involving the same DMF/PMF/CEP it is not necessary to provide the declaration again, unless a new DMF/PMF/CEP is to be provided or there has been a change in sponsor.

## Module 1.6.3 Letters of access

### When to include a Letter of access

Include when the application makes reference to one or more:

- drug master files (DMFs)
- plasma master files (PMFs) from a third party
- Certificate(s) of Suitability of Monographs of the European Pharmacopoeia (CEPs).

### How to prepare a Letter of access

#### Applicant

- establish a formal agreement with the active substance manufacturer.

#### Manufacturer

Each manufacturer providing a DMF/PMF for the application:

- completes the relevant part/s of the [Letter of access to DMF/PMF/CEP](#).

Each manufacturer providing a CEP for the application:

- completes the parts relevant to the CEP in the Letter of access to DMF/PMF/CEP, and
- authorises the TGA to access relevant European Directorate for the Quality of Medicines & HealthCare (EDQM) reports.

All manufacturers:

- provide the applicant with the completed and signed letter for inclusion in Module 1.6.3.

**Note:**

The finished product applicant must have written permission from the manufacturer to access their DMF/PMF/CEP to enable the TGA to proceed with the evaluation.

Where reference is made to a CEP, the finished product applicant must provide to the TGA a copy of the certificate and any annexes (see Module 3.2.R).

**Subsequent regulatory activities**

For regulatory activities subsequent to the initial registration application involving the same DMF/PMF/CEP it is not necessary to provide the declaration again, unless a new DMF/PMF/CEP is to be provided or there has been a change in sponsor.

**Legislation**

Applications are made under either section 23 (new registrations) or section 9D(3) (requests for variations) of the [Therapeutic Goods Act 1989](#) (the Act) and where the relevant legislative and business requirements are met, are approved under section 25 or section 9D(3), respectively.

Section 25(1)(d) of the Act requires that the TGA determine whether the quality, safety and efficacy of the goods for the purposes for which they are to be used have been satisfactorily established.

Section 9D(3)(c) requires that 'the Secretary is satisfied that the variation requested does not indicate any reduction in the quality, safety or efficacy of the goods for the purposes for which they are to be used'.

Assessing the quality of the goods includes establishing the quality of the active substance.

Where quality relating to the active substance cannot be established solely by the information provided by the applicant in Module 3.2.S, the applicant may make reference to external sources to establish the quality.

Acceptable external sources are a drug master file, plasma master file or an EDQM Certificate of Suitability of Monographs of the European Pharmacopoeia.

As a condition of registration it is a requirement that, apart from specified [minor variations](#), no changes are made to the active substance without the prior approval of the TGA.

To receive approval for some changes, revised and/or new DMFs, PMFs and/or CEPs need to be provided to the TGA and assessed, by reference to section 9D(3) of the Act.



## Module 1.7 Compliance with meetings and pre-submission processes

### Overview

This section of CTD Module 1 holds documents relating to pre-submission meetings held between the TGA and the applicant and identifies how any issues raised by the TGA in the *Planning letter* have been addressed in the dossier.

### Summary of requirements

#### Documentation

Section	Description	Category 1/Category 2		Category 3	
		New registration	Variation	New registration	Variation
1.7.1	Details of compliance with pre-submission meeting outcomes (if meeting held)	●	●	●	●
1.7.2	Details of any additional data to be submitted (if agreed)	●	●	x	x
1.7.3	Declaration of compliance with <i>Pre-submission planning form</i> and <i>Planning letter</i>	●	●	x	x

**Key:** ● = mandatory  
○ = requirement defined by the regulatory activity  
x = not required.

### Module 1.7.1 Details of compliance with pre-submission meeting outcomes

#### When to include details of compliance with pre-submission meeting outcomes

Include when one or more scientific advice meetings and/or pre-submission meetings with the TGA have resulted in outcomes that the applicant must address to comply with application requirements. See also [TGA Guidance 5: Pre-submission meetings with TGA](#).

## How to prepare details of compliance with pre-submission meeting outcomes

Identify:

- the date(s) of the meeting(s)
- the outcomes arising from the meeting(s) requiring applicant action
- how the outcomes from the meeting(s) have been addressed in the dossier
- any agreements reached at the meeting.

### Note:

Meetings include all relevant meetings requested by an applicant or TGA and include meetings conducted in any format (i.e. face to face, teleconference or videoconference). There may be multiple meetings before PPF or dossier lodgement.

Ensure the information provided in Module 1.7.1 is an accurate reflection of the meeting(s) and any outcomes that need to be addressed.

All meetings provide guidance only and outcomes are without prejudice and are not considered binding on the TGA.

## Module 1.7.2 Details of any additional data to be submitted

**The TGA will only agree to the lodgement of additional data where the medicine is of critical importance to the Australian community to address emergency or safety situations.**

**No additional data should be submitted during the course of the evaluation of an application, other than relevant safety data and data specifically requested by the TGA.**

### When to include details of any additional data

Include details of additional data to be submitted when discussions have resulted in the TGA agreeing to accept additional data during the course of evaluation.

### How to prepare information about any additional data

Include:

- a copy of the TGA's agreement that additional data could be lodged
- confirm the agreed date for lodgement
- provide details of the additional data that TGA agreed to accept.

### Note:

Additional data:

- are to be submitted to the TGA by a date mutually agreed between the TGA and the applicant
- must be well defined and relate to a particular and limited aspect of the application

- are not intended to facilitate inadequate or premature applications. The acceptance of additional data is at the discretion of the TGA
- may affect target timeframes.

## Module 1.7.3 Declaration of compliance with Pre-submission planning form and Planning letter

### When to include a declaration of compliance with Pre-submission planning form and Planning letter

Include when the application is one for which a *Pre-submission planning form* (PPF) was lodged with the TGA.

### How to prepare a declaration of compliance with Pre-submission planning form and Planning letter

After reviewing the PPF, TGA's *Planning letter* and the dossier to be submitted, prepare a declaration that:

- describes how each issue identified in the TGA's *Planning letter* has been addressed
  - states that the application is consistent with the PPF in both scope and scale
- or
- describes all differences with appropriate justifications for their inclusion or exclusion in the dossier.

### Related information and guidance

[Information for applicants completing a pre-submission planning form](#)



#### Important information on pre-submission and submission

The TGA will check the application for consistency with the PPF. Any differences between the information provided on the PPF and the resulting application may result in the TGA considering the application not effective. For example, the inclusion of an additional indication in the application at the submission phase increases the scope of the application and will not be accepted.

If an application will differ in scope and scale from that indicated in the PPF, contact the Medicines Authorisation Branch before lodging the dossier.

## Module 1.8 Information relating to pharmacovigilance

### Overview

This section of Module 1 holds documents relating to the pharmacovigilance activities for a new medicine, or significant changes to a registered medicine.

### Summary of requirements

#### Documentation

Section	Description	Category 1/Category 2		Category 3	
		New registration	Variation	New registration	Variation
1.8.1	Pharmacovigilance systems	●	○	●	x
1.8.2	Risk management plan for Australia	○	○	x	x

**Key:** ● = mandatory  
○ = requirement defined by the regulatory activity  
x = not required.

### Module 1.8.1 Pharmacovigilance systems

#### When to include information about pharmacovigilance systems

Include in all regulatory activities which result in one or more new ARTG entries under section 16 of [the Act](#), for example:

- new chemical entity
- change in formulation
- additional trade name
- change in trade name
- new container type

#### How to prepare information about pharmacovigilance systems

The summary of the pharmacovigilance system should be provided in Module 1.8.1 of the application and includes the following elements:

- proof that the applicant has at his disposal a qualified person in Australia responsible for pharmacovigilance

- the contact details of the qualified person
- a statement signed by the applicant to the effect that the applicant has the necessary means to fulfil the tasks and responsibilities listed in [Australian requirements and recommendations for pharmacovigilance responsibilities of sponsors of medicines](#).
- a reference to the location where the pharmacovigilance system file for the medicinal product is kept.

## Module 1.8.2 Risk management plan for Australia

### When to include a risk management plan

Include in all regulatory activities for:

- a new chemical entity
- a similar biological medicinal product
- a generic medicinal product where a safety concern with the reference medicinal product requires additional risk minimisation activities.

Unless TGA has agreed that it is not required, include a risk management plan (RMP) for regulatory activities involving:

- a significant new registration (for example, new dosage form, new route of administration, significant change in indications, extension of paediatric population)
- a significant variation in a registration (for example, new manufacturing process of a biotechnologically-derived product).

In some circumstances products which do not fall into the above categories may require a RMP. These include:

- known active substances
- literature-based submissions
- fixed combination applications.

It is strongly recommended that discussions with the TGA on the need for, and content of, an RMP take place in advance of PPF lodgement, especially for situations where the submission of a RMP is not mandatory but may nevertheless be required.

Where a RMP waiver has been given by the Post-Market Surveillance Branch, include the relevant document from TGA in this module (see [Risk management plans for prescription medicines](#)).

### How to prepare a risk management plan

Provide a detailed description of a risk management system in the form of a RMP, as outlined in:

- TGA's [Risk management plans for prescription medicines](#)
- [Guideline on good pharmacovigilance practices: Module V - Risk management systems](#) (EMA/838713/2011 Rev 1), which TGA has adopted with annotation.

## Module 1.9 Biopharmaceutic studies

### Overview

This section of Module 1 holds documents relating to biopharmaceutic studies included in the dossier.

### Summary of requirements

#### Documentation

Section	Description	Category 1/Category 2		Category 3	
		New registration	Variation	New registration	Variation
1.9.1	Summary of bioavailability or bioequivalence study	○	○	x	x
1.9.2	Justification for not providing biopharmaceutic studies	○	○	○	○

**Key:** ● = mandatory  
○ = requirement defined by the regulatory activity  
x = not required.

### Module 1.9.1 Summary of bioavailability or bioequivalence study

#### When to include a summary of a bioavailability or bioequivalence study

Include for all regulatory activities which include a bioavailability or bioequivalence study in the dossier.

#### How to prepare a summary of a bioavailability or bioequivalence study

- download the [Summary of a bioavailability or bioequivalence study](#) form
- complete a separate form for each study
- include the forms in Module 1.9.1.

#### Note:

Australia's requirements for biopharmaceutic studies are aligned with the [CHMP Guideline on the investigation of bioequivalence \(CPMP/EWP/QWP/1401/98 Rev1/Corr\)](#) which has been formally adopted in Australia (with annotation).

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## Module 1.9.2 Justification for not providing biopharmaceutical studies

### When to include a justification for not providing appropriate biopharmaceutical studies

Include when biopharmaceutical studies are required as outlined in the TGA [guidance on Biopharmaceutical studies](#), but have not been provided.

For example, when:

- biopharmaceutical data for a generic medicine were not generated against a reference product obtained from Australia
- a BCS (Biopharmaceutics Classification System)-based biowaiver approach is used
- biopharmaceutical data do not cover all the different strengths for a new medicine.

### How to prepare a justification for not providing appropriate biopharmaceutical studies

The justification for not providing appropriate biopharmaceutical data, including the absence of biopharmaceutical data for all strengths of the product, must:

- address all the points in the [guidance on biopharmaceutical studies](#)
- include any references used to support the justification.

### Overseas reference product used for studies for a generic medicine

The justification for providing biopharmaceutical data for a generic medicine that was not generated against a reference product obtained from Australia needs to:

- address all the points in the [guidance on biopharmaceutical studies](#)
- include any references used to support the justification.

### BCS-based biowaiver

A BCS-based biowaiver approach should be justified in terms of the criteria listed in CHMP *Guideline on the investigation of bioequivalence* (CPMP/EWP/QWP/1401/98 Rev1 Corr) which has been formally adopted in Australia (with annotation).



## Legislation

### ***Applications for new registrations are made under section 23 of the Act.***

Section. 25(1) of the Act requires medicines to be assessed for safety, quality and efficacy.

For an application to register a new generic product, as defined in Schedule 9 of the Therapeutic Goods Regulations 1990, the applicant must be able to demonstrate that the proposed medicine is bioequivalent to a registered medicine.

### ***Applications requesting a variation to an existing registration are made under section 9D(3) of the Act.***

The Secretary must be 'satisfied that the variation requested does not indicate any reduction in the quality, safety or efficacy of the goods for the purposes for which they are to be used'.

Variations that have the potential to affect the quality of the goods may require the provision of Module 1.9.2, as described above.

## Module 1.10 Information relating to paediatrics

### Overview

This section of Module 1 holds information relating to the applicant's paediatric development program.

### Summary of requirements

#### Documentation

Section	Description	Category 1/Category 2		Category 3	
		New registration	Variation	New registration	Variation
1.10	Information relating to paediatrics	○	x	x	x

**Key:** ● = mandatory  
○ = requirement defined by the regulatory activity  
x = not required.

### When to include information relating to paediatrics

Include in all regulatory activities to register:

- a new chemical entity
- new combination
- extension of indication
- major variation.

### How to prepare information relating to paediatrics

Complete the form [Module 1.10 Information relating to paediatrics](#) and include the form in Module 1.10 of the dossier.

The form includes advice as to whether there is a paediatric development program for this medicine and provides TGA with information, relevant to the Australian application, about the data submitted, paediatric clinical study commitments given and waivers received in the European Union and United States of America.

#### Note:

##### European Union

A [paediatric investigation plan \(PIP\)](#) is a development plan aimed at ensuring that the necessary data are obtained through studies in children, when it is safe to do so, to support the authorisation of a medicine for children. All applications for marketing authorisation for new

medicines that were not authorised in the EU before 26 January 2007 have to include the results of studies carried out in children of different ages as described in the PIP. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorised and patented.

## United States of America

The [Pediatric Research Equity Act \(PREA\)](#) authorizes the FDA to require paediatric studies of drugs or biologics. Under PREA, a paediatric assessment is required for new applications, except when waived or deferred, and is designed to provide data needed to evaluate the safety and efficacy of a drug or biologic and to support dosing and administration for each paediatric subpopulation for which the product has been found safe and effective.

The [Best Pharmaceuticals for Children Act \(BPCA\)](#), enacted in 2002, encourages the manufacturers, or applicants, of drugs that still have marketing exclusivity, that is, are on-patent, to conduct paediatric drug studies, as requested by the Food and Drug Administration (FDA). If they do so, FDA may extend for 6 months the period during which no equivalent generic drugs can be marketed.

## Australia

The TGA has adopted internationally recognised [ICH/European guidelines](#) concerning paediatric data generation and facilitating the extrapolation of data from one patient population to another, including:

- Note for guidance on clinical investigation of medicinal products in the paediatric population (CPMP/ICH/2711/99)
- Guideline on the role of pharmacokinetics in the development of medicinal products in the paediatric population (EMA/CHMP/EWP/147013/2004Corr)
- Guideline on the investigation of medicinal products in the term and preterm neonate (EMA/536810/2008)
- Guideline on conduct of pharmacovigilance for medicines used by the pediatric population (EMA/CHMP/PhVWP/235910/2005/rev.1)
- Reflection paper: Formulations of choice for the paediatric population (EMA/CHMP/PEG/194810/2005)
- Paediatric addendum to CHMP guideline on clinical investigation of medicinal products in the treatment of lipid disorders (EMA/CHMP/494506/2012)
- Paediatric addendum to CHMP guideline on the clinical investigations of medicinal products for the treatment of pulmonary arterial hypertension (EMA/CHMP/213972/2010).

## Module 1.11 Foreign regulatory information

### Overview

This section of the Module 1 holds information regarding the foreign (overseas) regulatory status for the medicine and the supporting data for the dossier.

### Summary of requirements

#### Documentation

Section	Description	Category 1/Category 2		Category 3	
		New registration	Variation	New registration	Variation
1.11.1	Foreign regulatory status	●	●	x	x
1.11.2	Foreign product information	●	○	x	x
1.11.3	Data similarities and differences	●	○	x	x
1.11.4	Foreign evaluation reports:			○	x
	Category 1	○	○		
	Category 2	●	●		

**Key:** ● = mandatory  
○ = requirement defined by the regulatory activity  
x = not required.

### Module 1.11.1 Foreign regulatory status

#### When to include information about the foreign regulatory status

Include with all category 1 and category 2 regulatory activities.

#### How to prepare information about the foreign regulatory status

- Provide a list of countries in which a similar application has been submitted including:
  - dates of submission (if available)
  - the status of these regulatory activities
- List must include the status of similar regulatory activities in the following countries:

- European Union (if centralised procedure)
- the Netherlands, Sweden, and United Kingdom (if mutual recognition, decentralised, or national applications)
- United States of America
- Canada
- Switzerland
- New Zealand
- Singapore
- Include details of:
  - approvals (with indications)
  - deferrals (with reasons)
  - withdrawals (with reasons)
  - rejections (with reasons)
- For applications submitted to agencies in the European Union include:
  - the type of application (centralised, mutual recognition, decentralised, or national)
  - for centralised applications, the rapporteur and co-rapporteur
  - for mutual recognition and decentralised applications, the reference member state.

**Note:**

If an application is rejected by overseas authorities during the Australian evaluation process, the applicant must immediately inform the TGA.

The format for providing information to the TGA on foreign regulatory status should be consistent whenever an update to the information is provided for a given submission.

***Suggested format***

Information on the foreign regulatory status of similar applications may be provided in tabular form, as shown below:

**Medicine 1:**

Country/region	Submission date	Status	Indications (approved or requested)	Other relevant information
EU – centralised procedure	1 June 20xx	Pending	[details]	
USA	1 June 20xx	Approved Day, month year	[details]	

## **Applications referred to ACPM**

Provide an update on the overseas status of the application in the pre-ACPM response.

## **Applications not referred to ACPM**

Provide an update on the overseas status of the application to the TGA Delegate at the decision phase as defined in the *Planning letter*.

## **Module 1.11.2 Foreign product information**

### **When to include foreign product information**

Include with all category 1 and category 2 regulatory activities where a similar application has been lodged in:

- New Zealand, Canada and/or United States of America
- European Union via centralised procedure
- the Netherlands, Sweden, and/or United Kingdom via mutual recognition procedure, decentralised procedure, or national marketing authorisation.

### **How to prepare information about foreign product information**

Prepare copies of each of the following documents from the similar overseas application(s):

- product monograph from Canada
- summary of product characteristics (SmPC) from the Netherlands, Sweden and/or United Kingdom (if approved via mutual recognition procedure, decentralised procedure, or national marketing authorisation)
- United Kingdom SmPC (if via centralised procedure)
- data sheet from New Zealand
- prescribing information from United States of America.

### **Note:**

A draft document may be included in this part of the dossier if the overseas SmPC, monograph, or prescribing information has not been approved at the time the application is lodged in Australia.

If the overseas SmPC, monograph, data sheet, or prescribing information is approved after dossier submission in Australia, the documents should be submitted as they become available.

## **Applications to be referred to ACPM**

Provide updated overseas prescribing information documents or SmPC documents as part of a pre-ACPM response.

## **Applications not referred to ACPM**

Provide updated overseas prescribing information documents or SmPC documents to the TGA Delegate at the decision phase as defined in the *Planning letter*.

## Module 1.11.3 Data similarities and differences

### When to include information about data similarities and differences

Include with all category 1 and category 2 regulatory activities for which a similar application has been lodged in:

- New Zealand, Canada and/or United States of America
- European Union (if centralised procedure)
- the Netherlands, Sweden, and/or United Kingdom via mutual recognition or decentralised procedure, or national marketing authorisation.

### How to prepare information about data similarities and differences

Prepare a summary of the similarities/differences between the data in the Australian submission and the data packages submitted in:

- New Zealand, Canada and/or United States of America
- European Union (if centralised procedure)
- the Netherlands, Sweden, and/or United Kingdom (if mutual recognition, decentralised procedure, or national marketing authorisation).

Identify and account for any significant differences.

#### Note:

Category 2 regulatory activities may be rejected if any significant or substantial undisclosed differences are found by the TGA.

## Module 1.11.4 Foreign evaluation reports

### When to include foreign evaluation reports

Include for:

- all category 2 regulatory activities
- category 1 regulatory activities for which an overseas evaluation report is available.

### How to prepare foreign evaluation reports

#### Category 1 application:

- obtain copies of independent evaluation reports that are available from the list of acceptable countries where a similar application has been approved
- include complete copies of each evaluation report in Module 1.11.4.

#### Category 2 application:

- obtain copies of the complete evaluation reports from two acceptable countries where a similar application has been approved

- acceptable countries for the purposes of providing evaluation reports are:
  - Canada
  - Sweden
  - the Netherlands
  - United Kingdom
  - United States of America
- the two overseas evaluation reports must be independent reports
- the formulation, directions for use and indications for the medicine in the dossier must be identical to those evaluated and approved for marketing in the two countries from which the evaluation reports are provided
- any differences between the data set supplied in the dossier to the TGA and the two acceptable countries must be clearly identified in Module 1.11.3
- include complete copies of all evaluation reports in Module 1.11.4.



### Legislation

Regulations 16C and 16D of the Therapeutic Goods Regulations 1990 provide for shorter evaluation timeframes if

- the medicine or variation to the medicine has been approved in two other acceptable countries, and
- the applicant is able to provide the evaluation reports from these countries. These regulatory activities are described as category 2 applications.

## Module 1.12 Antibiotic resistance data

### Overview

Module 1.12 holds the antibiotic resistance data for new antibacterial medicines, extensions of indication to currently registered antibacterial medicines, and updated data for currently registered antibacterial medicines.

### Summary of requirements

#### Documentation

Section	Description	Category 1/Category 2		Category 3	
		New registration	Variation	New registration	Variation
1.12	Antibiotic resistance data	○	○		

**Key:** ● = mandatory  
○ = requirement defined by the regulatory activity  
x = not required.

### When to include antibiotic resistance data

Module 1.12 applies to:

- both topical and systemic antibacterial medicines
- combination products containing antibacterial medicines
- composite packs that contain one or more antibacterial medicines.

It is recommended applicants review the adequacy of data relating to the potential of an antibacterial medicine to promote resistance and cross-resistance for applications:

- for new antibacterial medicinal products
- that will extend use of currently registered antibacterial medicinal products
- to change the Australian product information to include updated antibiotic resistance data.

### How to prepare antibiotic resistance data

The risk assessment of microbial resistance consists of the following steps:

- hazard characterization
- exposure characterization
- impact characterization

- risk characterization.

The risk assessment may be qualitative in part, although quantitative data should be provided where possible.

It is acceptable for this document to refer to data supplied elsewhere in the dossier. References need to include module, tab identifier, and page number.

**Note:**

Include any Australian human antibiotic-resistance prevalence data in the pharmacology section of the Australian product information document.

**Related information and guidance**

- [Joint Expert Technical Advisory Committee on Antibiotic Resistance \(JETACAR\) Report](#) (released in October 1999)
- *Interim TGA Guidelines on antibacterial resistance risk data* available on request from the TGA.

## Module 2.3.R & 3.2.R Regional information

Any additional drug substance/active substance and/or drug product information specific to Australia should be provided in section R of the application. Applicants should consult the appropriate TGA guidelines for additional guidance.

### 2.3.R Regional information

A brief description of the information specific to the region, as provided under 3.2.R should be included, where appropriate.

### 3.2.R Regional information

Any additional drug substance and/or drug product information specific to Australia should be provided in section 3.2.R of the application.

Where similar or relevant information has been provided in another section of Module 3 or where there is supporting or related information from other modules of the application, the applicant is encouraged to clearly cross-reference to the location of that information. Cross-referencing should be sufficiently detailed, so as to allow the appropriate information to be easily located within the dossier.

Applicants should include the following information in Module 3.2.R, where appropriate:

- Process validation scheme for the drug product
- Certificates of suitability (including any annexes)  
*Reference: [Guidance 11: Drug Master Files and Certificates of Suitability of a Monograph of the European Pharmacopoeia for drug substances](#).*
- Risk of transmitting animal spongiform encephalopathy agents  
*Reference: Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products [EMA/410/01 Rev 3](#) and the [Transmissible Spongiform Encephalopathies \(TSE\): TGA approach to minimising the risk of exposure](#)*
- Certified product details  
*Reference: [Guidance 7: Certified product details](#)*
- Supplier's declarations regarding compliance with packaging standards and colouring standards.

### When to include certificates of suitability

Include when:

- the initial registration of the active ingredient for the sponsor makes reference to one or more Certificate of Suitability of Monographs of the European Pharmacopoeia (CEPs).
- subsequent regulatory activities for a new registration or a variation to an existing registration requires a new or amended CEP.

### How to prepare information about certificates of suitability

- Include a copy of each certificate of suitability (including any annexes) referenced in the application in Module 3.2.R.

## **Therapeutic Goods Administration**

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Reference/Publication #