Australian Government
Department of Health
Therapeutic Goods Administration

Common Technical Document Module 1: OTC medicines

Administrative information to support OTC medicine applications in Australia

Version 1.2, June 2017

TGA Health Safety Regulation

Contents

Introduction

CTD Module 1 consists of the administrative information to support an OTC medicine application to either:

- register an OTC medicine under section 23 of the Act
- change the details of an ARTG entry for an OTC medicine under section 9D of the Act.

The information on these pages:

- explains the format and content for Module 1 of a dossier
- describes what must be included in Module 1.

Further information

OTC dossier document matrix - A summary of the CTD document requirements for each application level.

Module 1.0 - Correspondence

Use this section to include:

- Your application cover letter.
- Your responses to our requests we make for information during the screening/evaluation of your application.
- Any other correspondence you may have received from us before submitting your application. For example, an email from us about:
  - data requirements for a new registration application
  - using a particular code and application level for a change application.

Module 1.0.1 Cover letter (letter of application)

Follow the guidance on Preparing an OTC application cover letter.

Include the cover letter in Module 1.0.1 for all applications. Notification requests do not require a cover letter.

The cover letter must:

- be on a company letterhead
- be signed by a person authorised to conduct business on behalf of the applicant. The person must be listed on our client database and may be a company employee or an agent
- include the necessary information for a cover letter.

Module 1.0.3 Responses to request for information

Only use this section to include your responses to requests for information that we may send during screening or the evaluation of your application.

You will not need to include a document in this section when you first submit your dossier.

Preparing your response to a request for information

Prepare a letter or an email that includes:

- the submission ID
- the medicine name, active ingredient details and dosage form of the medicine
- a comprehensive response to each question in our request

Referencing CTD documents

When you reference CTD documents in your response, make sure you include detailed references to the CTD module, the tab identifier and the page number. For example, '*See Module 3, 3.2.P.4.3 Method validation, p 23*'.

Include the submission ID if you are referencing CTD documents submitted as part of a previous application.

Including new documents that belong elsewhere in the CTD

Include the document as an attachment to the letter or email or, if an eCTD submission, in the appropriate part of the CTD i.e. elsewhere in Module 1 or in Modules 2-5.

Include a reference to the location with the answer to the question in Module 1.0.3

For example: if the answer requires a revised version of the Finished Product Specification:

- include any comments with the answer in Module 1.0.3, making reference to the location of the document in the CTD format (i.e. module 3.2.P.5.1)
- include a new version of the Finished Product Specification as an attachment to the correspondence. If an eCTD submission, include a new version of the specification in Module 3.2.P.5.1.

The revised/new CTD documents are:

- to be sent to the TGA with Module 1.0.3
- addenda to the modules already provided as part of the dossier
- subject to CTD requirements outlined in this document and the General Dossier Requirements.

Module 1.1 – Comprehensive table of contents

Locate the main table of contents in the top level folder of the dossier as described in the section of the general dossier requirements specific for OTC medicines.

- Do not use Module 1.1 for the dossier's overall table of contents.

Module 1.2 – Administrative information

This section contains the patent certification documents for medicine applications.

Do not include the application forms for OTC medicines in Module 1. They are submitted online through business services.

Module 1.2.3 Patent certification

You will need to provide one of the following forms under section 26B of the Act for all new registrations including formulation changes, changes in trade name, extensions of indications and changes to the directions for use before a newly approved registration can be included in the ARTG.

- 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.

You can either:

- Include the form in Module 1.2.3 if you are able to provide it when you submit your dossier.
- Send the form to the TGA application entry team by email (otc.medicines@tga.gov.au) at any time after you lodge the application with the submission ID clearly visible and clearly identified as Module 1.2.3 Patent certification.

Module 1.3 – Medicine information and labelling

This section holds documents relating to the presentation and packaging of the medicine(s) including:

- product information and package insert
- consumer medicine information
- labels

You can also include labelling and product documentation of other medicines in Module 1.3. For example:

- labelling of 'parent' medicines (for N1 applications)
- labels of other medicines included in the dossier to assist the evaluator.

Note

Medicine information and labelling for:

- N1 level applications must comply with the requirements in the guideline for OTC new medicine N1 applications.
- N2 level applications must comply with the Requirements for OTC new medicines N2 applications.

Module 1.3.1 Product information and package insert

This module is for both the product information and the package inserts.

Product information

You must include product information (PI) with your application when:

- Your application, which results in a separate and distinct good under section 16 of the Act, is for a restricted medicine[1].
- Required by the Secretary under section 23 of the Act.
- Your application to change a registered medicine involves a change to the PI. For example, an update to the adverse events section of the PI.
- You submit an N1 application and the 'parent' medicine includes a PI. You will also need to:
  - Include a copy of the most recently approved PI of the parent medicine in Module 1.3.1.
  - Ensure the PI for the 'parent' medicine is in the approved form for providing product information if the parent medicine is either a restricted medicine or a medicine where the Secretary required a PI.
- You intend to supply a PI for the medicine.

Note

The PI must be in the form for providing product information if the medicine is a restricted medicine or a medicine where the secretary requires a PI.

Product information based on an approved PI

If your PI is based on an existing PI, you will need to include both the marked up and clean version.

The 'marked-up' PI

Include the marked-up version in module 1.3.1.2 and identify all additions, deletions or changes using 'track changes'. You will need to:

- Justify any differences between the existing and the proposed PI. You can include the justification for the differences either as comments within the document (i.e. as part of the tracked changed document) or in a table in the cover letter.
- Identify the location within the dossier of the evidence to support the differences.

[1] Restricted medicines include, but are not limited to, medicines in Schedule 3 of the current Poisons Standard

The clean version of the PI

Include the 'clean' PI in module 1.3.1.1. The 'clean' copy incorporates all the changes proposed but removes the version marks and comments.

Refer to the Product Information section in the Guidelines on presentation aspects of OTC applications for guidance on compiling a PI.

Package insert

Include a package insert in Module 1.3.1.3 with:

- Applications for medicines that need a package insert. For example, when labelling information does not fit on the label.
- Applications that involve changing the existing package insert.
- N1 level applications where the 'parent' medicine includes a package insert. In this case you need to include both:
  - the package insert for the proposed medicine
  - the most recently approved package insert of the 'parent' medicine in module 1.3.1.
- Applications where you intend to supply a package insert with the medicine.

If your application involves a change to the current package insert, include both the current package insert of the medicine and a draft copy of the new package insert. You will need to:

- Highlight the differences between the current and proposed package insert.
- Justify any differences between the current and proposed package insert – the justification for the differences could be included as comments within the document (i.e. as part of the tracked changed document) or included in a table in the cover letter.
- Identify the location within the dossier of the evidence to support the differences.

Further information and guidance

Package inserts section in the Guidelines on presentation aspects of OTC applications.

Product information and package inserts for other medicines

If your application refers to product information and/or package inserts of other relevant medicines, include these documents in module 1.3.1. For example, your product information is based on the PI of an originator medicine. Include the PI of the originator medicine in module 1.3.1.

Module 1.3.2 Consumer medicines information

Include a CMI when your application:

- Will result in a separate and distinct good under section 16 of the Act (e.g. registering a new generic medicine or applying to change the proprietary name of an existing medicine) AND where the medicine is included in Schedule 3 of the current Poisons Standard.
- Is for a change that affects the CMI. For example, an application to include important safety information in the PI which needs to be reflected in the CMI
- Is an N1 level application and the 'parent' medicine includes a CMI. Include the most recently approved CMI of the 'parent' medicine in module 1.3.2.

Further information and guidance

Consumer Medicine Information section in the Guidelines on presentation aspects of OTC applications.

Consumer medicine information based on an existing CMI

If the CMI is based on an existing CMI, include two versions of the CMI:

- Include the 'marked-up' CMI in module 1.3.2.2 and identify all additions, deletions or changes using 'track changes'. You will need to justify any differences between the existing and the proposed CMI.
- Include a 'clean' CMI in module 1.3.2.1. The 'clean' copy incorporates all the changes proposed but removes the version marks and comments.

Consumer medicine information for other medicines

If your application refers to the CMI of other relevant medicines, include those CMI documents in module 1.3.2.

Module 1.3.3 Label mock-ups and specimens

Include copies of all draft medicine labels with all applications to:

- register new OTC medicines
- change the labelling of existing OTC medicines.

Where the only difference in labelling between pack sizes is the quantity, only one set of labels needs to be submitted provided an assurance to that effect is submitted with the application.

If your application involves a change to the current medicine label include both the current label and a draft copy of the new label and:

- highlight the differences between the current and proposed labels
- justify any differences between the current and proposed labels – the justification for the differences could be included in a table in the cover letter
- identify the location within the dossier of the evidence to support the differences.

Further guidance

Product name and the Labelling in Guidelines on presentation aspects of OTC applications.

Labels for other medicines

Include labels of other relevant medicines in Module 1.3.3 when the application:

- is for an umbrella branded medicine that requires a higher level assessment (include the labels of all other medicines in the umbrella range)
- is at the N1 level (include copies of the most recently approved parent labels)
- refers to labels of other medicines.

Module 1.4 – Information about the experts

This section holds documents about the experts who reviewed the supporting data for the application, and prepared the summaries and overviews that constitute Module 2.

Include information about the:

- quality expert in Module 1.4.1 for any N5 level application where any subsection of Module 2.3 has been provided in the dossier
- nonclinical expert in Module 1.4.2 for any N4, N5, C3 or C4 level application where any subsection of Module 2.4 and/or 2.6 has been provided in the dossier
- clinical expert in Module 1.4.3 for any N4, N5, C3 or C4 level application where any subsection of Module 2.5 and/or 2.7 has been provided in the dossier.

Information required

For each expert responsible for compiling a Module you must provide both:

- a declaration completed and signed by the expert as detailed in Table 1, below
- a curriculum vitae (CV) outlining the expert's educational background, training and occupational experience.

For the Australian expert

Download the form for the expert's declaration and complete as per the instructions on the form.

Ensure the declaration is signed by the expert making the declaration.

Expert from the European Union

Provide a copy of the expert's declaration from the application lodged with the EMA.

Alternatively, you can use the form for the Australian expert.

Other overseas expert

Complete the form for the Australian experts.

Module 1.5 – Specific requirements for different types of applications

This section holds documents required for specific types of applications.

Module 1.5.1 Literature-based submission documents

Include information about literature based submissions for any N4, N5, C3 or C4 level application where the application partially or completely relies on a literature-based data set to support the application.

You will need to refer to the following guidance when preparing the documentation:

- Section 4 of the OTC Medicines – Safety and efficacy data guidelines describes the OTC requirements for literature based submissions.
- literature based submissions.

Include the following in Module 1.5.1:

- Methodology of the literature search, including complete details of database search strategies.
- The complete search output.

Note

The overview and summary of reports, which includes a critical appraisal of all the papers submitted, is included in Module 2.5.

Module 1.5.5 – Co-marketed medicines declarations (letters of authorisation)

This section holds documents that authorise:

- The TGA to access information of a third party sponsor for the benefit of the applicant. For example, a cross-licensing agreement between the applicant and a third party sponsor.
- The use of proprietary information of a third party on the product documentation of the applicant. For example, a third party sponsor authorises the use of their logo on the applicants product labelling.

You must include a letter of authorisation in Module 1.5.5 when your application refers to or relies on the data or information held on file of a 'parent' medicine (either a currently registered medicine or simultaneously with an application for a medicine under evaluation).

What to include in a letter of authorisation

If your application is for an N1 level, or refers to or relies on the data or information of a 'parent' medicine, the letter from the third party sponsor (the sponsor of the parent medicine) must:

- be on company letter head and include the full name and signature of a person authorised to conduct business on behalf of the applicant; the person must be listed in our client database and may be a company employee or an agent

- authorise the TGA to use information in their registration file on behalf of the applicant of the new application
- identify the medicine by stating its full ARTG name and AUST R number.

Module 1.5.7 – OTC medicine assurances

This section holds specific assurances required for particular OTC application levels (N1 and N2). You can also include assurances for any other OTC application type.

For N1 level applications, you must include the Assurances to accompany N1 application form completed in accordance with the requirements in the guideline for N1 applications.

For N2 level applications, you must include the Assurances to accompany N2 application form completed in accordance with the Requirements for N2 applications.

Module 1.5.8 – Umbrella brand assessment

This section holds the sponsor's assessment of the medicine name and umbrella segment against the ARGOM guideline on umbrella/family brand names.

You must include your assessment of the proposed medicine name and umbrella segment addressing each of the points identified in the umbrella/family brand names guideline for any new registration application or a change application involving a new product name when:

- your application is restricted to application level N4 / C3 and above because the umbrella segment requires higher level assessment.

Note

Use the flowchart in the application route for umbrella branded medicines to determine the assessment level for a medicine that has an umbrella segment in the medicine name.

Module 1.6 – Master files and certificates of suitability

This section of Module 1 holds documents relating to drug master files (DMFs) and Certificates of Suitability of Monographs of the European Pharmacopoeia (CEPs) to establish the quality of a new chemical entity (NCE) in a medicine which is an active ingredient.

This section is relevant only to some N5 level applications that include a new active ingredient.

Note, module 1.6.4 is no longer used for certificates of suitability – complete copies of the certificates of suitability are included in module 3.2.R.

Module 1.6.1 Relevant external sources

Include this document for any N5 level application that includes a new active ingredient when the application refers to one or more:

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

Preparing information about external sources

Obtain the relevant DMF/CEP details from the active substance manufacturer, including any TGA reference numbers where available.

If you are referencing a DMF or CEP, download and complete the DMF/CEP details form.

Include the completed form(s) in Module 1.6.1.

Module 1.6.2 Applicant's declaration

Include an applicant's declaration for any N5 level application that includes a new active ingredient when the application refers to one or more:

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

Preparing the applicant's 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 making any significant change to the drug substance. This agreement is independent of the TGA.

Once the agreement has been established:

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

Module 1.6.3 Letters of access

Include letters of access for any N5 level application that includes a new active ingredient when the application refers to one or more:

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

Preparing a Letter of access

Applicant

Establish a formal agreement with the active substance manufacturer.

Manufacturer

Each manufacturer providing a DMF for the application needs to complete the Letter of access.

Each manufacturer providing a CEP for the application needs to complete the Letter of access to CEP and authorise 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.

Module 1.7 – Compliance with meetings and pre-submission processes

Module 1.7 is not applicable to OTC medicine applications. It relates to a process relevant to prescription medicine applications only.

Module 1.8 – Information relating to pharmacovigilance

Information in module 1.8 is not expected for OTC medicine applications.

Module 1.9 – Summary of biopharmaceutic studies

Module 1.9.1 Summary of a bioavailability or bioequivalence study

You must include the summary of a bioavailability or a bioequivalence study for any N4, N5, C3 or C4 level application that includes a bioavailability or bioequivalence study in the dossier.

To prepare a summary of a bioavailability or bioequivalence study:

- download the Summary of a Bioavailability or Bioequivalence Study
- complete a separate form for each study
- include the form(s) in Module 1.9.1.

Related guidance

Section 2 Safety and efficacy of OTC medicines.

Module 1.9.2 Justification for not providing biopharmaceutic studies

You must include a justification for not providing biopharmaceutic studies when biopharmaceutic studies are required (as outlined in Section 2 Safety and efficacy of OTC medicines).

Further guidance

Justification for not complying with technical requirements in the Mandatory requirements for an effective over-the-counter medicines application.

The justification for not providing biopharmaceutic studies must:

- address all the relevant points in justification for not submitting biopharmaceutic data
- include any other relevant information
- include any references used to support the justification in Module 5.

Module 1.10 – Information relating to paediatrics

Information in module 1.10 is not expected for OTC medicine applications.

Module 1.11 – Foreign regulatory information

This section holds documents relating to foreign regulatory information for a new medicine, or significant changes to a registered medicine.

You will not usually need to include information in Module 1.11 for a new OTC medicine application or a change to an existing OTC application but it may be relevant in certain circumstances. For example:

- an application for a new medicine with a new active ingredient (a level N5 application) where simultaneous applications are being submitted in other countries
- a new combination medicine (a level N5 application) where the combination is registered in another country.

We may ask you to provide information on the foreign regulatory status during the screening or evaluation phase of an application.

Module 1.11.1 Foreign regulatory status

Details of the foreign regulatory status may be included for some N4, N5, C3 or C4 level applications where the same or similar applications have been submitted in other countries or where the medicine in question is marketed in other countries.

What to include

Relevant information for inclusion in this module would include:

- A list of countries in which a similar application has been submitted
- A list of countries in which the proposed medicine or a similar medicine(s) is marketed
- Details of approvals, deferrals, withdrawals or rejections of the application in other countries.

Module 1.11.2 Foreign product information

You may include foreign product information for some N4, N5, C3 or C4 level applications if the same or similar applications have been submitted in other countries or the medicine is marketed in other countries.

What to include

Include a copy of the equivalent overseas document to the Australian product information. For example, a data sheet from New Zealand or the prescribing information from United States of America.

Module 1.11.3 Data similarities and differences

You may include data similarities for some N4, N5, C3 or C4 level applications if the same or similar applications have been submitted in other countries or where the medicine is marketed in other countries.

What to include

Prepare a summary of the similarities/differences between the data in this application and the data packages submitted in the overseas country.

Identify and account for any significant differences.

Module 1.11.4 Foreign evaluation reports

You may include a foreign evaluation report for some N4, N5, C3 or C4 level applications if a regulatory authority in another country has evaluated the same or similar applications and the evaluation report is available.

What to include

Obtain a copy of the relevant evaluation report and include a complete copy of the report in this Module.

Module 1.12 – Antibiotic resistance data

Information in module 1.12 is not expected for OTC medicine applications.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	OTC Medicines and Regulatory Guidance Team TGA	Published 30 November 2015. Effective 1 March 2016
V1.1	Minor changes to clarify original publication and effective dates	Complementary and OTC Medicines Branch	1 March 2016
V1.2	Minor change to module 1.0.1 to reflect the process around the new notification process commencing 1 July 2017	OTC Medicines Evaluation Section / Scientific Operations Management Section	June 2017

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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