CTD Module 1
Administrative information for assessed listed medicines
Applicable to applications received by the TGA from March 2018

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Introduction

CTD Module 1 consists of the administrative information to support assessed listed medicine applications to either:

- List an assessed listed medicine in the ARTG under section 23B of the Therapeutic Goods Act 1989 (the Act)
- Change the details of an ARTG entry for an assessed listed 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.

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 listing application
- using a particular application level
- format for the application as agreed at a pre-submission meeting (if organised)

Module 1.0.1 Cover letter (letter of application)

A cover letter is part of your application to list or change the ARTG entry for your complementary medicine. In your cover letter, provide useful information regarding the nature and scope of the application.

Include the cover letter in Module 1.0.1 for all applications.

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 all the necessary information for a cover letter:
  - the purpose of the application
  - the medicine name
  - the proposed indications
– the contact person and sponsor name
– the date of submission and submission ID (if known)
– whether payment of fees has been forwarded directly to TGA finance
– the electronic format of the dossier (e.g. USB)
– the rationale for selecting the application category. Include information that is significant for determining the application category and technical data requirements
– other relevant background information, such as overseas regulatory status.

The cover letter must also notify us if:

• you are providing a detailed scientific justification for not complying with technical data requirements and/or not adhering to guidelines, and the location of each justification in your dossier

• the medicine is a reformulation of a currently listed or registered medicine

• you have submitted a request to extend or renew a GMP clearance including
  – the date of the request
  – whether your request is a clearance extension or renewal
  – any other relevant details

• you are requesting:
  – a reduction or waiver of the evaluation fees
  – any exemptions (e.g. S14 exemptions, advertising exemptions).

### 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.

If you are referring to any documents submitted as part of a previous application, include the submission ID.

#### 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 5, 5.3.5.1: Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication, p 44’.
Module 1.1 - 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. The table of contents can have hyperlinks that navigate to the headings in the dossier.

Module 1.2 - Administrative information

This section contains forms and certification documents for assessed listed medicine applications.

Module 1.2.1 Application forms

Complete the Assessed listed medicines application e-form using the TGA Business Services (TBS) and a Module 1.2.1: Assessed listed medicine general application information form. The information entered in these forms is the basis of the new/revised ARTG entry. It is critical that this information is an accurate reflection of the information provided in the dossier.

Submit both forms in Module 1.2.1.

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 listings including formulation changes, changes in trade name, extensions of indications, before a new approved listing 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 certification under section 26B(1) of the Therapeutic Goods Act 1989 is not required

You can either:

- Include the certification or notification in Module 1.2.3 if you are able to provide it when you submit your dossier; or

- Send the certification or notification to complementary.medicines@health.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 1.2.5 Form for approval to use a restricted representation

If you are proposing to use a restricted representation on your medicine label (e.g. if your indication refers to a restricted representation), complete and include the Application for approval to use a restricted representation in advertising in Module 1.2.5.
Module 1.3 - Medicine information and labelling

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

- Labels
- Package inserts.

Module 1.3.3 Label mock-ups and/or specimens

Include copies of all draft medicine labels with applications for:

- new assessed listed medicines
- changes to the labelling of existing assessed listed medicines.

When the quantity (e.g. number of tablets) is the only difference in labels for different pack sizes:

- you only need to submit one label; and
- include an assurance that this is the only difference between the pack sizes.

Application involving a change to the medicine label

If your application involves a change to the current medicine label, include both the current approved 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
- include the justification for the differences in a table in Module 1.3.3
- identify the location within the dossier of the evidence to support the differences.

Labels of other medicines

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

- is a L(A)1 application (include copies of the most recently approved originator labels)
- refers to labels of other medicines.

Module 1.4 - Information about the experts

Module 1.4 is optional for assessed listed medicines.

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.

If an expert report is provided it should be cross-referenced by page number or hyperlinked to the submission.

The author of an Expert Report should have appropriate qualifications and experience relevant to the subject matter. For example, the expert for a mineral or vitamin supplement application
should have qualifications and expertise in nutritional epidemiology. You may wish to include information about the clinical expert in Module 1.4.3, such as:

- A declaration form completed and signed by the expert that both:
  - declares the extent, if any, of their professional or other involvement with the dossier owner
  - confirms that the report has been prepared by them or if not, any assistance provided and by whom.
- A curriculum vitae (CV) outlining the expert’s educational background, training and occupational experience.

**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**

This section applies to applications that partially or completely rely on literature based data. Include the following in Module 1.5.1:

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

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

- Section 4.3 of the Assessed listed medicines evidence guidelines
- the guidance on Literature-based submissions for complementary medicines.

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

This section holds documents that authorise TGA to:

- access information of a third party sponsor for the benefit of the applicant e.g. a cross-licensing agreement between the applicant and a third party sponsor
- use the proprietary information for the applicant’s medicine e.g. a third party sponsor authorises the use of their logo on the applicants medicine 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 an originator medicine.
What to include in a letter of authorisation

If your application is an L(A)1 level application, or refers to or relies on the data or information of an originator medicine, make sure the letter from the sponsor of the identical medicine:

- is on company letter head and includes the full name and signature of a person authorised to conduct business on behalf of the applicant. The person must be in our client database and may be a company employee or an agent;
- authorises TGA to use information in their registration file on behalf of the applicant of the new application; and
- identifies the medicine by stating its full ARTG name and AUST L(A) number.

Module 1.5.7 Assessed listed medicine assurances

This section holds specific assurances required for L(A)1 applications. You can also include assurances for any other application type.

For L(A)1 level applications, you must include an assurance stating that all aspects of the proposed medicine are identical to the originator medicine, other than specifically permitted differences listed in Table 3 of the Assessed listed medicines evidence guidelines.

Module 1.7 - Compliance with meetings and pre-submission processes

This section of Module 1 is for documents relating to pre-submission meetings and identifies how you have addressed any issues raised during the meeting in the dossier. Note that TGA minutes are the official record of the meeting.

Module 1.7.1 Pre-submission meeting outcomes

Only include information in this section if you had a pre-submission meeting with us and there were issues that you needed to address as part of your application.

Include a copy of the pre-submission meeting outcomes.

Provide the following details:

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

Ensure the information in Module 1.7.1 accurately reflects the meeting(s) and any outcomes you needed to address in your application.

All meetings provide guidance only and outcomes are without prejudice and are not considered binding on TGA.
Module 1.7.2 Details of any additional data

We usually only accept additional data if the medicine is critical to the Australian community to address emergency or safety situations.

You should only need to submit relevant safety data and data that we may request during the evaluation of an application.

If we agree to accept additional data during the evaluation, include:

- A copy of our agreement to accept the additional data
- The agreed date for sending the data
- Details of the additional data we agreed to accept.

The additional data:

- needs to be well defined and relate to a particular and limited aspect of the application
- may affect the evaluation timeframe
- is not intended to facilitate inadequate or premature 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 L(A)2 or L(A)3 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 form
- complete a separate form for each study
- include the form(s) in Module 1.9.1.

Related guidance

- See ‘Section 5.5: Biopharmaceutic and pharmacokinetic studies’ in the Assessed listed medicines evidence guidelines.
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 5.6 Justifications' in the Assessed listed medicines evidence guidelines).

Further guidance

Justification for not complying with technical requirements in the Mandatory requirements for an effective assessed listed 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 1.11 - Foreign regulatory information

This section holds documents relating to foreign regulatory information for a new medicine, or significant changes to a listed medicine. We may ask you to provide information on the foreign regulatory status during the screening or evaluation phase of an application.

The TGA is currently developing guidance for the use of evaluation reports from Comparable Overseas Regulators (CORs).

Module 1.11.1 Foreign regulatory status

Details of the foreign regulatory status may be included if the same or similar applications have been submitted in other countries or the medicine is marketed in other countries.

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 if the same or similar applications have been submitted in other countries or the medicine is marketed in other countries.
Module 1.11.3 Data similarities and differences

You may include data similarities if the same or similar applications submitted in other countries or the medicine is marketed in other countries.

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

For assessed listed medicines, you may include a foreign evaluation report for some L(A)2 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 and include a full un-redacted English copy of the evaluation report in this Module.

• If applicable, 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.
## Version history

<table>
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<th>Version</th>
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