



Australian Government
Department of Health
Therapeutic Goods Administration

General dossier requirements

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TGA Health Safety
Regulation

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Introduction

This guidance assists you as the applicant, to meet our requirements for the dossier¹ of information you send to us for evaluation in support of the following types of applications:



- Û To register a medicine (prescription, OTC or complementary) on the ARTG
- Û To include a biological on the ARTG that requires evaluation of information
- Û To include a medical device (including IVD) on the ARTG if you have been advised that it will be audited and requested to provide information for the audit
- Û To list an assessed listed medicine (where information is required for evaluation)
- Û For medical device (including IVD) conformity assessment certification
- Û For evaluation of new ingredients for use in listed medicines
- Û To vary the ARTG record which requires supporting information

This guidance does not apply to the following applications:

- Û To list a complementary or OTC medicine (where information is not required for evaluation)
- Û To include a medical device on the ARTG (other than those selected for audit)
- Û To vary the ARTG record if supporting information is not required.

Note: An application for a variation to a prescription medicine will be submitted as an eCTD sequence.

- Û For Good Manufacturing Practice (GMP) certification or GMP clearance of overseas manufacturers.



Make sure to follow parts A to D of this guidance. Only follow [Part E](#) for hard copy paper dossiers if you are unable to send your information electronically.

¹ A collection of files and documents containing data (including administrative, technical, clinical) relating to a therapeutic good

Part A: Requirements for all dossiers

Although the formatting of dossiers of information will vary depending on the type of therapeutic good you are applying for, the following general requirements apply irrespective of the type of therapeutic good or the media you use to submit your dossier - that is, online, electronic or paper.

English

Make sure that either all information is in English and readable.

For information that is not in English, include both:

- a copy of the information in the original language
- a full translation of the information in English

You are responsible for the accuracy of the translation.

If you need assistance, you can search for a qualified translator through the [National Accreditation Authority for Translating and Interpreting \(NAATI\) website](#).

Acronyms and abbreviations

Make sure all acronyms and abbreviations are defined.

Fonts and readability

Make sure tables and images are large enough and of a style to be easily read, even after photocopying, scanning or printing and that any shading does not impair readability.

We recommend that text is no smaller than:

- 12 point text
- 10 point text within tables
- 10 point text within footnotes.

Units of measurement

Use the Metric system.

Check that all the documents in your dossier refer to measurements in SI units² or units generally accepted in clinical practice in Australia - for example, mmHg or French gauge.



The [relevant standard for labels](#) applies to the labels submitted as part of the dossier.

² International system of metric units

Related information and guidance

The [Australian Measurement System](#) from the National Measurement Institute.

Cross references (for medicines)

Refer to the module, volume, tab index and page number when cross referencing within your dossier - for example: see Module 3, 3.2.P.4.3 Method validation, p 23.

Responses to requests for information (RFI)

If we request additional information during the evaluation of your dossier, make sure your response also meets the general dossier requirements.

We can accept emails of up to a maximum 40MB if you are requested to respond via email.

Commercially confidential information

Information provided to us, whether as part of an application or otherwise, may be commercially confidential or personal in nature.

We will treat such information appropriately. For further information visit the following information published on our website:

- [Treatment of information provided to the TGA](#)
- [TGA approach to disclosure of commercially confidential information \(CCI\)](#)
- [Privacy information](#)
- [Background information on Freedom of information.](#)

Part B: Electronic dossiers

This guidance is for dossiers you intend to send to us electronically and needs to be used in conjunction with the [Part A: Requirements for all dossiers](#).

If you cannot send the information to us electronically, please see guidance on [Part E: Hard copy \(paper\) dossiers](#).

Text-searchable content

Your electronic dossier should be text-searchable.

Generate PDF documents from electronically-sourced documents. The following diagrams demonstrate the difference between searchable and non-searchable text in a PDF.

Figure 1 - This image demonstrates how we can use the search function to find content in a PDF that is text searchable

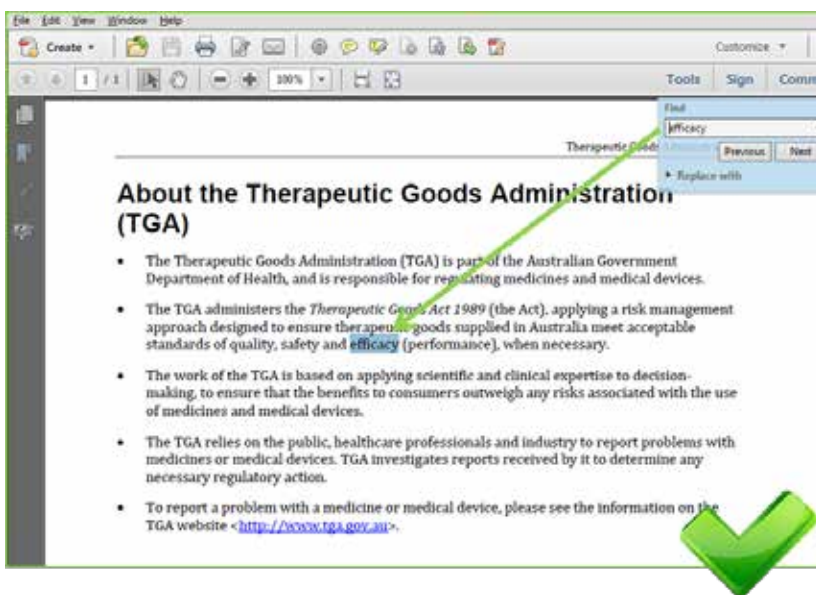
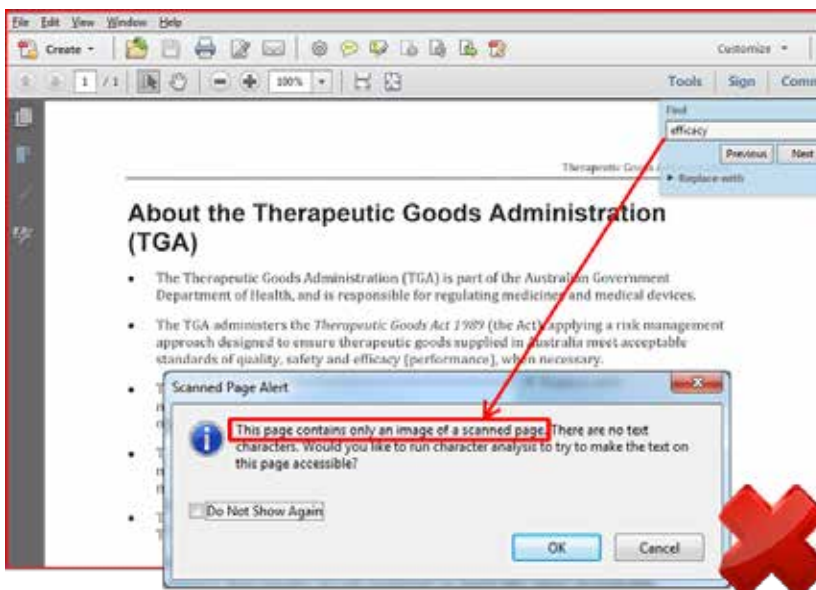


Figure 2 - This image shows the message received when trying to search for content when the text is not searchable in PDF documents. If you are not sure whether your text is searchable, try using this search function as a test.



Routine exceptions include:

- original certificates of analysis or certificates of suitability
- signed letters of authorisation
- labels and diagrams
- original GMP certificate or licence
- downloaded component documents of a literature search.

Folder and file names

Electronic folder and file names should indicate the content and allow documents to be easily identified within the structure of the electronic dossier.

Bookmarks and hyperlinks

Use specific settings when you create your PDF from a word document to ensure the hyperlinks will work in the PDF version.

This will greatly enhance our ability to find the relevant information and provide efficiencies with the evaluation process.

Use bookmarks to assist us to navigate around the document.

Organise the book marks like a table of contents and use them for sections, subsections figures, and appendices.

For example; use bookmarks for a summary document that has internal headings and subheadings.

For more information on creating bookmarks go to:

- [Electronic submissions](#)
 - eCTD AU Module 1 and regional information
 - AU NeeS specification: Module 1 and regional information.

'Not applicable' content

Do not create any of the following if a folder or document is not applicable to your dossier:

- ⊘ place holder(s)
- ⊘ 'empty' folder(s) or document(s)
- ⊘ blank 'not applicable' pages, within a document.

Security on electronic files

Security on electronic files inhibits our ability to access information. For this reason do not use:

- ⊘ application- or file-level security
- ⊘ one-time security settings

- password protection on any files
- security settings to lock files or folders, including passwords, certificate security, or adobe settings.

If there is pre-existing security on literature references, do not apply any further security.

Submitting your electronic dossier

You can submit your electronic dossier by one of the following two ways:

- [online submission](#)

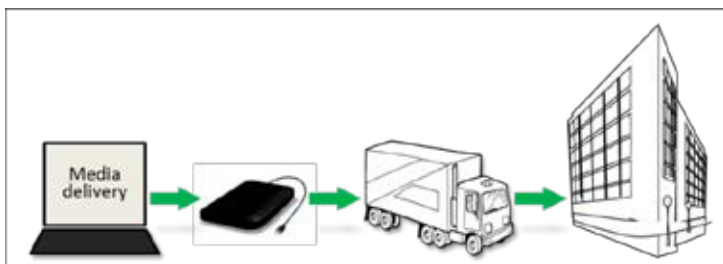
OTC medicines as an attachment to the electronic application. 'Zip' the entire dossier and upload it as a single attachment provided it is less than 100MB.

If the 'zipped' file is larger than 100MB, send to us electronically by following the guide on [electronic media delivery](#).
- [electronic media delivery](#)
- [email](#).

Figure 3 - Online submission: The preferred method of delivery where available.



Figure 4 - Electronic media delivery: Dossier copied to media; media transported; and delivered to the TGA. (NB: Media supplied to the TGA will not be returned.)



Online submission

Currently our online submissions are limited to OTC medicines, but will become our preferred option as our online services develop.

If you have not used our online services previously, follow our guidance - [online services getting started with TGA](#) - and complete an access request form.

Electronic media delivery

You can send one electronic copy of your dossier using one set of the following media:

- single-sided CD-R or DVD-R (single or dual layer)

- USB flash drive
- USB external hard drive.

Figure 5 - If more than one unit of media is required, ensure you use a single type of media.



Use the least number of media units possible - Figure 5 demonstrates the use of one USB external hard drive, making it unnecessary to use more than one unit of media.



Your electronic dossier forms part of our official record and we cannot return the media to you.

Do not use:

- ⊘ double-sided discs
- ⊘ more than one type of media - see Figure 5
- ⊘ zip files (unless requested)
- ⊘ email (unless requested).

If more than one unit of media is needed

Avoid spanning the content of a part, or a section, of the dossier over two units.

Labelling the media

Create and attach a label for each unit of media with the following information:

- TGA reference/application number(s) - if we have already provided one
- eSubmission Identifier (for NEES and eCTD format dossiers)
- applicant's name
- product name(s) (where relevant)
- proposed ingredient name (for listed medicine ingredient applications)
- approved name of the active substance(s) (AAN, ABN, etc. as applicable) (all medicines)
- total number of CDs or DVDs or USB flash drives or USB hard drives
- an indication of its place within the set - for example, 1/3, 2/3, 3/3. Choose electronic media that results in the minimum number of media units possible.

USB flash drives

Make sure the label is packaged with the USB flash drive to reduce the risk of separation.

Package all media to protect it during transport.

Email

For some prescription medicine application types, you can submit the dossier to eSubmissions@health.gov.au provided that:

- the email contains a **single** compressed (zipped) attachment that, in combination with the email, is less than 30 MB

AND

- the dossier is a **valid** eCTD or NeeS sequence

In the subject line of the email, include:

- eSubmission identifier
- sequence number
- sequence type
- regulatory activity number (if applicable)
- approved name or product name

Organisations can register for secure email (Transport Layer Security). Signing up for secure email ensures a more efficient and cost effective means of correspondence between TGA and applicants during the prescription medicines streamlined submission process.

For more information on how to use secure email when corresponding with TGA go to [TGA eBusiness Services](#) and select 'secure email' in the left column.

Part C: Formatting your dossier

This guidance on formatting your dossier needs to be used in conjunction with the [Part A: Requirements for all dossiers](#).

The formatting requirements differ depending on the type of therapeutic good and you need to follow the specific guidance for:

- [Complementary medicines](#)
- [Over-the-counter medicines](#)
- [Prescription medicines](#)
- [Biologicals](#)
- [Medical devices](#)
- [Conformity assessment](#)

Complementary medicines

Registered and assessed listed medicines

Prepare your dossier and submit electronically either using online submissions (preferred) or electronic media delivery.

The actual content of the dossier will vary according to the application category. Applicants are encouraged to organise each document in the CTD dossier within folders that correspond to the CTD modules appropriate to the application. Alternatively, applicants can supply a dossier that meets the following minimum requirements:

- CTD headings (combination of module number and module name).
- Single PDF document for each module.
- Text searchable and either bookmarked or hyperlinked PDFs (generated from electronic source documents and not from scanned material).

CTD headings can be found at: [Common Technical Document \(CTD\)](#).

New ingredients for use in listed medicines

We encourage you to present your dossier consistent with CTD format.

Related information and guidance

- [Information required for evaluation of a new complementary medicine](#)
- [Assessed listed medicines evidence guidelines](#)

Over-the-counter medicines

Prepare your dossier using [CTD](#) and submit electronically either using [online submissions](#) (preferred) or [electronic media delivery](#). Paper submissions are not accepted.

Folders

Organise each document in the CTD dossier within 'folders' that correspond to the CTD modules appropriate to the application.

We recommend you format your electronic dossier to be consistent with either:

- [International Conference on Harmonisation \(ICH\) eCTD specification and AU Module 1 specifications](#)
- [Non-eCTD electronic submission \(NeeS\)](#)

For module 1

We recommend you follow [CTD Module 1](#).

For modules 2, 3, 4 and 5

We recommend folder names detailed in Appendix 3 to the [ICH eCTD Specification](#).

Currently, we will accept other formats provided they follow the modular CTD structure and the guidelines below.

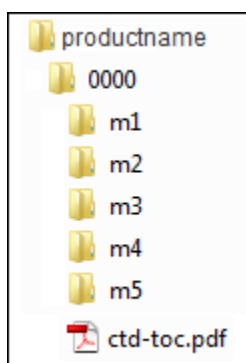
A sample empty eCTD folder structure is available to download from [eCTD Specification and Related Files](#). This may be a useful indicator of the folder structure for modules 2–5 (ignoring the folder "util" which is eCTD specific).

You can use it as a starting point to establish a folder structure for an electronic dossier. You would need to delete unused folders - see '[Not applicable](#)' content in Part B.

Table of contents

The main table of contents should be located in the top-level folder - see Figure 6.

Figure 6 - An example folder structure for locating the table of contents



The table(s) of contents should have hyperlinks that navigate to the individual files (documents) in the dossier.

The hyperlinks can direct either to the individual files or via individual 'module TOCs' as set out in the NeeS format.

Files (documents)

Files, or documents, included in an OTC dossier should be in (PDF) and generally be no larger than 100 megabytes (MB).

File names

File, or document, names should follow the ICH naming conventions.

The ICH file names are designed to be as short as possible while still corresponding to subordinate CTD titles and headings. That is, file names should be meaningful and be indicative of the position of the document within the CTD structure.

For modules 2, 3, 4 and 5, recommended file names are set out in Appendix 4 to the [ICH eCTD Specification](#).

Prescription medicines

Prepare your [electronic submission](#) using either:

- eCTD
- NeeS

We will contact you if there are any issues with uploading an electronic sequence.

Biologicals

Class-specific requirements and dossier structure for biologicals applications are outlined in Dossier requirements for Class 2, 3 and 4 biologicals.

Medical devices and IVDs

If you have been advised that your application has been selected for audit and requested to provide information, we suggest collating the information, and submit using either

- The [IMDRF format](#)
- The [table of contents structure \(for medical devices\)](#)
- Standard Technical Documentation (STED) for IVDs (see guidance on [application audit technical file review for IVD medical device applications](#)).

Table of contents structure- medical devices

If you are not using IMDRF format, structure the table of contents, for information requested in relation to an application audit for ARTG inclusion, in the following way:

Table of contents

1. Covering letter

Device information

2. Manufacturer's declaration of conformity
3. Manufacturer's certification/ declaration of conformity for systems and procedure packs and/or explanation how the kind of device is covered under the scope of the certificate (if required)
4. Copy of the product labels

5. Pictorial images of the device
6. Packaging - inner and outer packaging
7. Instructions for use
8. Product, user or operator manual
9. Advertising material including brochures, extracts from web pages
10. Technical documentation describing mechanism of action of the device (if required)

Additional information for level 2 application audits

11. Clinical evidence
12. Risk management report

Additional information for devices that sterilise/ disinfect

13. Efficacy and performance data for devices intended to disinfect/ sterilise other medical device.

Any other information we may request in the selection notice

Conformity assessments

We will accept your dossiers submitted in the following [IMDRF format](#) provided that the document contains the requested information:

- Non-In Vitro Diagnostic Device Market Authorization Table of Contents
- Vitro Diagnostic Medical Device Market Authorization Table of Contents

Part D: How and where to send your dossier

For dossiers that cannot be submitted via our online business services, we recommend you choose a service that provides both tracking information and proof of delivery - ensure you request and pay for these services.

When addressing your dossier include, with the name 'Dossiers', the type of therapeutic good. For example, **Dossiers*** (Complementary medicines).

This will assist our records management (our central mail service) to direct your dossier to the relevant area for evaluation.

**Shading provided to highlight content requirements and where they apply.*

Addresses

Postal address

Dossiers (type of therapeutic good)
Records Management
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Australia

Courier (street address)

Dossiers (type of therapeutic good)
Records Management
Therapeutic Goods Administration
136 Narrabundah Lane
Symonston ACT 2609
Australia

Part E: Hard copy (paper) dossiers

This 'Hard copy (paper) dossiers' guidance is provided as an interim only, as we move towards [electronic submissions](#) as the method for submitting all applications.

This guidance:

- applies only if you cannot submit your dossier either by [online submission](#) or by [electronic media delivery](#) - for example, CD, USB drive or external hard drive
- needs to be used in conjunction with the Part A: Requirements for all dossiers.

Number of copies

We only need a single hard copy, and you can print the pages on both sides.

Headers and footers (all dossiers)

Page numbering

Do ensure:

- ü each document is numbered sequentially and divided from other documents by a tab
- ü page numbering at the document level not at the volume (binder) level
- ü all documents have page numbers.

Do not number:

- ü the application consecutively, by page
- ü documents with more than one set of page numbers.

Paper size, margins and printing (all dossiers)

Figure 7 - Example of 2-ring binder, opened and laid out flat



Use standard A4 paper for all dossiers (hard copy and electronic).

Prepare text and tables using margins so that you do not lose content when printing on A4 paper and make sure:

- the left-hand margins are wide enough for ring-binder holes
- binders can be opened and laid flat - see Figure 7

When you print double-sided documents make sure:

- margin spaces are wide enough so that information is not obscured when the page is placed in a binder
- both sides of each page are numbered

Binding (all dossiers)

Present the information in binders (referred to as volumes) when the content exceeds 20 sheets of paper - includes responses to our [requests for information](#).

The binders need to have durable covers and enable us to disassemble and reassemble the content.

Ensure the external dimensions of binders do not exceed:

- 270 mm in width
- 320 mm in height
- 80 mm in thickness.

Do not submit information that is either:

- stapled
- contained in plastic sleeves.

Identifying volumes

Label each volume on the front, back and spine of the binder and include the following information for each volume:

- name of sponsor
- name of medicine or subject of other application types (e.g. name of proposed listed medicine ingredient)
- application number (when provided by the TGA)
- module and volume number
- content of volume - expressed as CTD document(s), if this format is used.

Packing your paper dossier

Submission of an electronic dossier is always preferred. Do **not** submit a paper dossier if you are able to submit an [electronic dossier](#).

When you prepare a paper dossier to send to us:

- Use boxes to pack dossiers consisting of more than two binders.
- Make sure:
 - the binders fit into boxes
 - the boxes are strong enough to protect the contents during transport.
- Pack the binder with the spines to the sides or bottom of the box to prevent the binders coming open.
- Use bubble, plastic or shrink wrap around the sides of the box to protect the folders.
- Number each box sequentially, with box 1 containing Volume 1 of Module 1 and write the contents (including type of dossier) for each box on both the box label and module.
- See guidance on [where to send your dossier](#) for the postal and delivery address.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	TGA	01/07/2015
V1.1	Minor updates	TGA	24 July 2015
V1.2	Part E deleted section: <i>Paper dossier from Nees or eCTD format</i> Added email submission of electronic dossiers Other minor updates	TGA	November 2017
V1.3	Amendments to Part C to update dossier requirements for Registered Complementary and Assessed Listed Medicines	TGA	March 2018
V1.4	Amendments to Part C to update the reference for dossier requirements for biologicals	TGA	July 2018

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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