Australian Government
Department of Health
Therapeutic Goods Administration

CTD Module 1: Administrative information for registered complementary medicines

Australian regulatory guidance

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TGA Health Safety Regulation

Contents

Introduction

The Mandatory requirements for an effective registered complementary medicine application describes the information, consistent with the CTD format, that must be submitted to the TGA in order for an application to register a complementary medicine to be considered effective and proceed to evaluation.

The General dossier requirements provides guidance for applicants to meet the general information requirements for an application for evaluation of a new registered complementary medicine.

This document provides guidance for applicants on information required in dossiers for registered complementary medicines for Module 1 to be consistent with the Common Technical Document (CTD) format.

For information required in dossiers for registered complementary medicines for Module 2- 5 refer to:

- CTD modules 2, 3, 4 and 5 for registered complementary medicine applications- Guidance for applicants

For general information on registered complementary medicine applications refer to;

- Applications for registered complementary medicines
- Registered complementary and OTC medicines application and submissions: TGA Business Services (TBS) user guidance

CTD module 1: Registered complementary medicines

Module 1 of the Common Technical Document (CTD) has been tailored to accommodate the needs and requirements for complementary medicines.

It is a standardised format for collating and organising the administrative information component of the dossier to support an application to either:

- register a complementary medicine under section 23 of the *Therapeutic Goods Act 1989* by following the registered complementary medicine registration process
- change the details of an ARTG entry for a registered complementary medicine under section 9D of the *Therapeutic Goods Act 1989* - for more information refer to Changing a registered complementary medicine: Application levels and change tables.

Sections intentionally deleted

The following sections have been deleted from CTD Module 1 as they do not apply to complementary medicine applications:

- 1.6 Master files and certificates of suitability
- 1.8 Pharmacovigilance (NOTE: requirements of section 1.8.1 apply to all medicines listed on the ARTG but are not required to be supplied as part of the dossier)
- 1.10 Information relating to paediatrics

- 1.12 Antibiotic resistance data

CTD module 1.0 Correspondence

Use this section to include:

- Your application cover letter.
- Your responses to the requests we make for information during screening (Step 11) or evaluation (Step 12 of the registration process).
- Any other correspondence you may have received from us before submitting your application. For example, an email from us about:
  - data requirements for a registration application
  - using a particular code and application level for a change application
  - format for the application as agreed at the pre-submission meeting

CTD Module 1.0.1 Application cover letter

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

This guidance relates to steps 2, 3, 5, 7 and 10 in the complementary medicine registration process and is to be included in Module 1 of your dossier, which you will prepare in Step 7 of the registration process and submit to us in Step 9 for evaluation.

Cover letter basics

Ensure your cover letter is on company letterhead and includes:

- the purpose of the application
- the medicine name
- the proposed therapeutic 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 (for example: DVD/CD/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

Make sure the cover letter is signed by a person authorised to liaise with us on your behalf.

Cover letter additional information

The cover letter also needs to 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 registered medicine
- the medicine contains a new substance; state the date that you submitted the relevant application form for proposing a name
- 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 proposing to use a restricted representation on your medicine label
- you are requesting:
  - a reduction or waiver of the evaluation fees
  - any exemptions (for example: section 14 and 14A exemptions, advertising exemptions)

Cover letter justifications

Where data or literature-based evidence is required, but not available for a particular CTD heading, provide a scientific justification under that heading to explain why it hasn't been included.

We will assess the content and merit of a justification (i.e. whether the alternative approach is in fact valid) during the evaluation phase.

For some complementary medicine registration applications, certain parts of the CTD are not relevant. The Registered Complementary Medicines data requirements matrix (included in CTD modules 2, 3, 4 and 5 for registered complementary medicine applications) indicates documents that are not relevant; no justification is required in these instances.

Make sure the cover letter is on a company letterhead and:

- includes the information required of your application
- is signed by a person listed in your company details as authorised to conduct business with us. The 'AU eCTD specification: Module 1 and regional information contains information about electronic signatures

Include the cover letter in Module 1.0.1 for all applications.

CTD 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'.

CTD module 1.1 Comprehensive table of contents

Locate the main table of contents in the top level folder of the dossier.

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 individual files (documents) in the dossier.

CTD module 1.2 Administrative information

✘ **Do not include:** application forms for complementary medicines in Module 1

For information: Using reports from Comparable Overseas Bodies

The TGA's Comparable Overseas Body (COB) report-based process allows technical evaluation reports from identified bodies to be used by TGA to assess applications against the Australian requirements. For the criteria to identify COBs, the current list of COBs and the process for using COB reports refer to Comparable Overseas Bodies (COBs) for complementary medicines.

If you are using a COB report, you must complete and submit the relevant Comparable Overseas Bodies (COB) checklist as part of Module 1.2 of your dossier submission. This checklist will enable the TGA to assess whether the application meets the requirements of the selected application category. If certain criteria are not met, the application must include appropriate justification.

CTD module 1.2.3 Patent certification

Provide either a patent certification or patent notification under section 26B(1) of the *Therapeutic Goods Act 1989* for all new registrations, including:

- formulation changes
- changes in trade name

- extensions of indications
- changes to the directions for use

Submit the relevant patent certification or notification:

- 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.
- 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.

CTD 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, note this in your cover letter.

Do not complete and submit the Application for approval to use a restricted representation in advertising form with your registration application.

Please note that approval for the use of a restricted representation in advertising can only be considered once the complementary medicine is registered in the ARTG. Any proposed restricted representation must be consistent with the product's accepted indications or intended purpose, as per its ARTG entry; and/or any mandatory warning or cautionary statements which are required to be included in the product packaging/labelling in order to satisfy other regulatory requirements.

CTD Module 1.2.6 Form for proposing a name for a new substance

Where a product formulation contains an ingredient that is not present in the list of Australian approved names, include an application form to apply for an Australian Approved Name. The TGA approved terminology for therapeutic goods provides guidance on requirements for approved names and links to the appropriate forms.

CTD module 1.3 Medicine information and labelling

This section holds documents relating to the presentation and packaging of the medicine 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 the originator medicine (RCM 1 applications)
- labels of other medicines included in the dossier to assist the evaluator

CTD module 1.3.1 Product Information and package insert

Module 1.3.1 is for both the Product Information (PI) and the package inserts.

Product Information

The PI contains technical information intended for healthcare practitioners and must not include promotional material.

For more information, go to:

- Product Information for information about what is required
- Guidance on Product Information

A PI is required for restricted medicines (Restricted Medicines Specification 2011), which are registered complementary medicines that are either:

- subject to Schedule 3 of the Poisons Standard
- contained in a therapeutic good mentioned in Part 1 of Schedule 10 to the Therapeutic Goods Regulations 1990 other than in items 1(b) and 14.

Include Product Information (PI) with your application when you:

- intend to supply a PI for the medicine
- submit an RCM 1 application and the originator medicine includes a PI. For these applications also:
  - include a copy of the most recently approved PI of the originator medicine in Module 1.3.1
- apply to change a registered complementary medicine that involves a change to the PI. For example, an update to the adverse events section of the PI

Even where a PI is not mandatory, you may choose to include one to provide more information on the medicine. However, the requirements for PI documents are the same.

Product information based on an approved PI

If your PI is based on an existing one, provide both the clean and marked-up versions.

The clean version of the PI

Include the 'clean' copy of the PI in Module 1.3.1.1.

This copy incorporates all the proposed changes, but has no version marks or comments.

The 'marked-up' PI

Include the marked-up version in Module 1.3.1.2.

This copy contains all the track changes including changes, additions and deletions.

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

Identify the location within the dossier of the evidence to support the differences.

Package insert

All package inserts for registered medicines are part of product labelling and require TGA approval.

Include a package insert with:

- Applications for medicines that either:
  - need a package insert, for example: when labelling information does not fit on the label
  - involve changing the existing package insert. Include both the current package insert of the medicine and a draft copy of the new package insert
- RCM 1 applications where the originator 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 originator medicine
- Applications where you intend to supply a package insert with the medicine.

Highlight the differences between the current and proposed package insert.

Justify any differences between the current and proposed package insert – include the justification either:

- as comments within the document (i.e. as part of the tracked-changed document)
- in a table in the cover letter

Identify the location within the dossier of the evidence to support the differences.

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, if your Product Information is based on the PI of another medicine, include the PI of that medicine in Module 1.3.1.

CTD module 1.3.2 Consumer Medicines Information

The CMI:

- contains general information about the medicine
- is written in plain English (for the consumer)

- must be consistent with the PI
- must comply with the requirements specified in Schedule 13 of the Therapeutic Goods Regulations 1990 (although the information does not have to be set out in the same order as the Schedule)
- cannot include promotional material

Include a CMI when your application is for a:

- medicine that falls under Schedule 3 of the Poisons Standard (or meets the criteria for mention in Schedule 3)
- 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)
- RCM 1 application and the originator medicine includes a CMI. Include the most recently approved CMI of the originator medicine in Module 1.3.2
- separate and distinct good[1] (for example: changing the proprietary name of an existing medicine that is in Schedule 3 of the Poisons Standard)

Consumer medicine information based on an existing CMI

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

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

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.

CTD module 1.3.3 Label mock-ups and/or specimens

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

- register new complementary medicines
- change the labelling of a registered complementary medicine

When the quantity is the only difference in labels for different pack sizes:

- submit one set of labels
- include an assurance that this is the only difference between the pack sizes

[1] A separate and distinct good is defined under section 16 of the *Therapeutic Goods Act 1989* as:
a different formulation, composition or design specification; strength or size, dosage form or model; name; indications; directions for use; or container type (disregarding container size).

If you wish to include a TGA assessed claim on your medicine, you must use the TGA approved label statement with/or without the TGA approved symbol. For more information refer to TGA assessed claim.

Application involving a change to the 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
- include the justification for the differences in a table in the cover letter
- 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 an RCM 1 (include copies of the most recently approved originator labels)
- refers to labels of other medicines

CTD 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 applications that include any subsection of Module 2.3 in the dossier
- safety nonclinical expert in Module 1.4.2 for applications that include any subsection of Module 2.4 and/or 2.6 in the dossier
- clinical expert in Module 1.4.3 for applications that include any subsection of Module 2.5 and/or 2.7 in the dossier

Expert reports

Include expert reports that:

- are cross-referenced by page number or hyperlinked to the submission
- provide separate critical appraisals of both the:
  - quality and manufacturing
  - nonclinical and clinical efficacy and safety of the medicine

Related guidance:

- Module 2 of the CTD

Authors of expert reports

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.

For each expert responsible for compiling Module 1, provide:

- a declaration 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

You may find the Module 1.4 form useful for this purpose.

CTD module 1.5 Specific requirements for different types of applications

This section holds documents required for specific types of applications.

You can include the optional OTC analytical validation summary form and request for section 14 exemptions in Module 1.5.

We have intentionally omitted subsections 1.5.2, 1.5.3 and 1.5.4.

CTD module 1.5.1 Literature-based submission documents

This section applies to applications that partially or completely rely on literature-based data.

Follow the guidance on Literature-based submissions for listed medicines and registered complementary medicines.

Prepare and include the following in Module 1.5.1:

- methodology of the literature search, including complete details of database search strategies
- the complete search output

Include the overview summary reports in Module 2.5.

CTD module 1.5.5 Co-marketed medicines (letters of authorisation)

This section holds documents that authorise TGA to both:

- 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
- use the proprietary information for the applicant's medicine, for example: a third-party sponsor authorises the use of their logo on the applicant's medicine label

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 for an RCM 1, 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 a 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 listed 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
- identifies the medicine by stating its full ARTG name and AUST R number

CTD Module 1.5.7 RCM New product assurances

This section holds specific assurances required for RCM 1 applications. You can also include assurances for any other RCM application type.

For RCM 1 applications you must include an assurance that all quality aspects of the proposed medicine are identical to the originator medicine, other than differences that are specifically permitted (as listed in the permitted differences guidance).

CTD Module 1.5.8 Umbrella brand assessment

This section holds the sponsor's assessment of the medicine name and umbrella segment against 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 RCM 4 / C3 and above because the umbrella segment requires higher level assessment.

Note

You can use the flowchart in the application route for umbrella branded medicines to assist in determining the assessment level for your registered complementary medicine that has an umbrella segment in the medicine name.

CTD 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 ratified minutes are the official record of the meeting.

CTD module 1.7.1 Details of compliance with pre-submission meeting outcomes

Only include information in this section if you had a pre-submission meeting with us (Step 8 of the registration process) and there were issues that you needed to address as part of your application.

Include a copy of the pre-submission meeting outcomes.

In preparing the details of how you have addressed any issues that arose from the pre-submission meeting, you need to 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

Meetings include all relevant meetings in any format (i.e. face to face, teleconference or videoconference) requested by either an applicant or the TGA.

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

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

CTD module 1.7.2 Details of any additional data to be submitted

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 in Step 12 of the registration process, 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:

- need to be well defined and relate to a particular and limited aspect of the application
- are not intended to facilitate inadequate or premature applications

CTD module 1.9 Summary of biopharmaceutic studies

CTD module 1.9.1 Summary of bioavailability or bioequivalence study

Include the summary of a bioavailability or a bioequivalence study for RCM 4 and RCM 5 applications that include 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

Justifications when you do not have data

You can submit a scientific justification when biopharmaceutic studies are required but not provided under the Module 5 Reports of biopharmaceutic studies (5.3.1).

Ensure that you:

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

CTD 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. Foreign regulatory information may be relevant in certain circumstances, for example: an application for a new medicine with a new active ingredient (a category RCM 5 application) where simultaneous applications are being submitted in other countries.

The TGA's Comparable Overseas Body (COB) report-based process allows technical evaluation reports from identified bodies to be used by TGA to assess applications against the Australian requirements. For the criteria to identify COBs, the current list of COBs and the process for using COB reports refer to Comparable Overseas Bodies (COBs) for complementary medicines.

CTD 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.

Include:

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

CTD module 1.11.2 Foreign product information

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

Include a copy of the overseas document that is equivalent to the Australian Product Information. For example, a data sheet from New Zealand or the prescribing information from USA.

CTD module 1.11.3 Data similarities and differences

You may include data similarities for some category applications 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.

CTD module 1.11.4 Foreign evaluation reports

You may include a foreign evaluation report for some applications or RCM 3 or RCM 4 applications if another 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.
- 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. Justify how the foreign evaluation report meets TGA technical requirements and provide a gap analysis if required.

CTD module 1 data requirements matrix for new registered complementary medicine applications

How to use the matrix

Determine the appropriate application category in the Applications for registered complementary medicines and use the matrix to obtain an indication of which documents you need to provide. The information included in CTD Module 1: Administrative information for registered complementary medicines will also provide assistance in determining what documents are required. For full folder names, refer to The Common Technical Document.

The codes in the matrix are provided in Table 1.

Description of codes used in data matrix

Code	Description
R (red)	The document(s) and/or appropriate scientific justification for not providing document(s) are required for a valid application.
D (green)	The document(s) are dependent on the kind of application in a particular category for the particular dossier. For example: 'D' is listed for Product information in Module 1.
O (blue)	The document(s) are optional. There is no requirement for the document(s) to be submitted with the application. However, the document(s) can be provided if the applicant considers the information is relevant to the application.
Blank:	The document(s) are not relevant and should not be submitted.

CTD module 1 data requirements matrix for new registered complementary medicine applications

Module	Name	RCM 1	RCM 2	RCM 3	RCM 4	RCM 5	File or folder name
1.0	**Correspondence**	R	R	R	R	R	100-correspondence
1.0.1	Application cover letter	R	R	R	R	R	1001-cover
1.0.3	Responses to request for information (including screening questions)	D	D	D	D	D	1003-response
1.1	**Comprehensive table of contents**	R	R	R	R	R	101-toc

Module	Name	RCM 1	RCM 2	RCM 3	RCM 4	RCM 5	File or folder name
1.2	**Administrative information**	D	D	D	D	D	102-admin-info
1.2.3	Patent certification	D	D	D	D	D	1023-pat-cert
1.2.6	Form for proposing a name for a new substance	O	O	O	O	O	1026-new-sub
1.3	**Medicine information and labelling**	D	D	D	D	D	103-med-info
1.3.1	Product Information and package insert	D	D	D	D	D	1031-pi
1.3.1.1	Product information – clean	D	D	D	D	D	10311-pi-clean
1.3.1.2	Product information – annotated	D	D	D	D	D	10312-pi-annotated
1.3.1.4	Package insert	D	D	D	D	D	10314-pack-ins
1.3.2	Consumer medicines information (CMI)	D	D	D	D	D	1032-cmi
1.3.2.1	CMI – clean	D	D	D	D	D	10321-cmi-clean
1.3.2.2	CMI – annotated	D	D	D	D	D	10322-cmi-annotated
1.3.3	Label mock-ups and specimens	R	R	R	R	R	1033-mock-ups
1.4	**Information about the experts**			R	R	R	104-experts
1.4.1	Quality			R	D	R	1041-quality
1.4.2	Nonclinical				D	R	1042-nonclinical
1.4.3	Clinical				D	R	1043-clinical

Module	Name	RCM 1	RCM 2	RCM 3	RCM 4	RCM 5	File or folder name
1.5	**Specific requirements for different types of applications**	D	D	D	D	D	105-specific
1.5.1	Literature-based submission documents				D	D	1051-lit-based
1.5.5	Co-marketed medicines declarations	D					1055-co-marketed
1.5.7	RCM New product assurances	R	R	D	D	D	1057-assurance
1.5.8	Umbrella brand assessment				D	D	1058-umbrella-br-assess
1.7	**Compliance with meetings and pre-submission processes**	D	D	D	D	D	107-compliance
1.7.1	Details of compliance with pre-submission meeting outcomes	D	D	D	D	D	1071-pre-sub-outcomes
1.7.2	Details of any additional data to be submitted	D	D	D	D	D	1072-additional-data
1.9	**Summary of biopharmaceutic studies**				D	D	109-biopharm
1.9.1	Summary of bioavailability or bioequivalence study			D	D	D	1091-ba-be
1.11	**Foreign regulatory information**	D	D	D	D	D	111-foreign
1.11.1	Foreign regulatory status	D	D	D	D	D	1111-status
1.11.2	Foreign product information	O	O	D	D	D	1112-pi

Module	Name	RCM 1	RCM 2	RCM 3	RCM 4	RCM 5	File or folder name
1.11.3	Data similarities and differences	O	O	D	D	D	1113-similarities
1.11.4	Foreign evaluation reports	O	O	D	D	D	1114-eval-reports

Version history

Version	Description of change	Author	Effective date
V1.0	Information for original publication extracted from pages 156 - 159 and 175 - 184 of ARGCM V8.0. New introductory paragraph. Module 1.0.3 'Responses to request for information' added. Information on comparable overseas bodies included under Module 1.2. CTD module 1.2.5 modified to include information on the new electronic online submission and process change for applying for restricted representation approvals. Explanatory text added for Modules 1.2.6, 1.5.7 and 1.5.8. Data matrix moved to back of document. Module 1.2.5 removed from matrix as the form for a restricted representation is no longer submitted with a RCM application.	Complementary & OTC Medicines Branch	May 2020

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