Australian Government
Department of Health
Therapeutic Goods Administration

Applications for registered complementary medicines

Australian regulatory guidelines

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TGA Health Safety Regulation

Contents

Abbreviations in ARGCM

Refer to the TGA acronyms & glossary for terms, definitions and acronyms used in the ARGCM.

Registered complementary medicines

Information: This guidance replaces the archived document ARGCM V8.0 Part D Evaluation of registered complementary medicines.

Refer to Standards, guidelines & publications for a list of all guidance relevant to listed medicines and registered complementary medicines.

This guidance assists applicants who wish to either:

- register a complementary medicine in the Australian Register of Therapeutic Goods (ARTG)
- make a change to an existing registered complementary medicine

Overview of registered complementary medicines

Registered medicines are considered to be of higher risk than listed medicines based on their ingredients and/or the therapeutic indications they carry. Medicines must be registered on the ARTG where one or more of the following applies:

- they do not solely comprise of permitted ingredients for use in listed medicines
- they contain an ingredient or ingredient component that is subject to the conditions of a Schedule or relevant appendix to the Poisons Standard (other than Schedule 4, 8 and 9)
- they may be required to be sterile
- they have higher level indications that are not permitted for use in AUST L or AUST L(A) listed medicines - see Three-tiered risk-based hierarchy of indications in Overview of the Regulation of listed medicines and registered complementary medicines

Prior to being approved for entry in the ARTG, registered medicines are subject to critical assessment by the TGA to determine whether the proposed medicine meets the requirements for quality, safety and efficacy.

TGA assessed label claim for registered complementary medicines

AUST R registered complementary medicines are eligible to include a TGA assessed claim on their medicine label and other advertising material indicating that the TGA has assessed the evidence the sponsor holds for the medicine's indications. The use of the TGA assessed claim is optional for the product sponsor – refer to TGA assessed claim for assessed listed and registered complementary medicines.

Applying for evaluation of a registered complementary medicine

Route of evaluation for complementary medicines

Schedule 10 of the Therapeutic Goods Regulations 1990 (the Regulations) prescribes which area within the TGA conducts the evaluation of specific therapeutic goods. Part 2 of Schedule 10 states that complementary medicines that do not meet the criteria for inclusion in Schedule 4, 8 and 9 of the Poisons Standard are evaluated by the Complementary and OTC Medicines Branch.

Important: Where a medicine is/would be subject to Schedules 4, 8 and 9 of the Poisons Standard it will be evaluated as a prescription medicine - refer to Australian Regulatory Guidelines for Prescription Medicines.

In some circumstances, we may refer an application to the Prescription Medicines Authorisation Branch for evaluation to ensure an appropriate level of evaluation is applied to a medicine commensurate with its level of risk. These include medicines that meet one or more of the following criteria:

- the medicine is intended to treat serious medical conditions that require medical supervision
- the medicine is not suitable for self-selection by consumers
- the medicine may have significant adverse effects, contraindications or drug interactions

If an application is referred to an alternative registration pathway, we manage the application according to the requirements (for example: fees, process, data requirements and evaluation time lines) of the new evaluation process.

Scheduling of registered complementary medicines

Registered complementary medicines may be subject to the conditions of a schedule (not Schedules 4, 8 and 9) or an appendix of the Poisons Standard, for example:

- Schedule 2 – 'Pharmacy Medicine'
- Schedule 3 – 'Pharmacist Only Medicine'

It is important that you consider possible scheduling requirements before submitting an application for registration - refer to the Principles of Scheduling in the Poisons Standard and the AHMAC - Scheduling policy framework for medicines and chemicals. The decision to include a medicine in a schedule takes into consideration toxicity, the purpose of use, potential for abuse, safety in use and the need for the substance.

If you are unsure of potential scheduling of your proposed medicine you should seek advice from the TGA.

Application categories

Registered complementary medicine applications are categorised according to complexity. There are five levels for applications to register a complementary medicine (RCM 1 to RCM 5).

Each of these levels corresponds to an application category. Applications in lower levels require less supporting information and have lower fees and reduced timeframes compared to applications in higher levels.

Descriptions and examples of the five categories for registered complementary medicines applications are provided below.

Category 1 (RCM 1)

An RCM1 application is an application made under section 23 of the Act to register a complementary medicine that is identical to another registered complementary medicine (the parent medicine[1]) other than differences between presentation, colour, flavour or fragrance.

Conditions for RCM 1 applications

- Parent medicines must be registered in the ARTG and have been fully evaluated for safety, quality and efficacy (that is, they cannot be a 'grandfathered' medicine). If in doubt, check the list of evaluated registered complementary medicines.
- The label, indications and formulation of the RCM 1 application must reflect the fully evaluated parent medicine.
- Parent medicines must comply with all applicable current requirements such as Required Advisory Statements for medicine Labels, the Poisons Standard and relevant Therapeutic Goods Orders and default pharmacopoeial standards.
- The sponsor of the parent medicine must authorise, for the purpose of the RCM 1 application, the TGA to access the information on the parent medicine files and ARTG record.

The guidance document for OTC new medicine N1 applications, 'Permitted differences for the parent medicine', is applicable for RCM1 applications.

For data requirements for RCM1 applications refer to Mandatory requirements for an effective registered complementary medicine application: Appendix A-Specific mandatory requirements.

Category 2 (RCM 2)

An RCM 2 is an application made under section 23 of the Act to register a complementary medicine for which the evaluation of the safety, quality and efficacy of the medicine is based on evaluation reports from a competent regulatory authority of a foreign country or foreign jurisdiction [comparable overseas body(COB)] determined under regulation 16GJ.

Important: COB evaluation reports that are provided for RCM 2 applications must be from a list of COBs that is determined by the TGA under Regulation 16GJ – see List of COBs for registered complementary medicines, assessed listed medicines and substances for use in listed medicines

[1] The parent medicine (sometimes referred to as the 'innovator' or 'originator' medicine) is one that has been approved for marketing in Australia following the evaluation of a full dossier.

For data requirements for RCM 2 applications refer to Mandatory requirements for an effective registered complementary medicine application: Appendix A-Specific mandatory requirements.

Category 3 (RCM 3)

An RCM 3 application is an application made under section 23 of the Act to register a complementary medicine, where:

- the application is for a generic product for which bioequivalence data is not needed for the purposes of evaluation of the medicine (refer to Medicines that do not require biopharmaceutic data); or
- the application has been evaluated by a COB and requires an independent evaluation of one of the following by the TGA:
  - the safety of the medicine
  - the quality of the medicine
  - the efficacy of the medicine

Conditions for RCM 3 generic complementary medicines

In comparison to the fully evaluated (not grandfathered) parent medicine, the proposed generic medicine must have the same:

- amount of active ingredient with similar quality
- safety and efficacy properties
- the safety and efficacy data provided with the parent medicine must not be 'protected' (refer to Section 25A of the Act)
- pharmaceutical form and be appropriately justified to be therapeutically equivalent

NOTE: Generic complementary medicines applications that require submission of bioequivalence data are category RCM 4.

For data requirements for RCM 3 applications refer to Mandatory requirements for an effective registered complementary medicine application: Appendix A-Specific mandatory requirements.

Category 4 (RCM 4)

An RCM 4 is an application made under section 23 of the Act to register a complementary medicine, where one of the following applies:

1. The application has been evaluated by a COB and requires an independent evaluation of two of the following by the TGA:

- the safety of the medicine
- the quality of the medicine
- the efficacy of the medicine

2. The application is for a generic product for which bioequivalence data is needed for the purposes of evaluation of the medicine (refer to Medicines that require biopharmaceutic data)
3. The application is for a medicine that is registered and is for one or more of the following:

- an extension of indications of the medicine

- new directions for use of the medicine
- an increase in the target population for the medicine

For data requirements for the different types of RCM 4 applications refer to Mandatory requirements for an effective registered complementary medicine application: Appendix A-Specific mandatory requirements.

Refer to Tables 1 and 2 for examples of RCM 4 applications.

Table 1: Examples of application category RCM 4 requiring Module 4 and/or Module 5

Example of RCM 4	Further considerations	Conditions
New therapeutic indication	Only if grouping does not apply. If grouping applies, refer to Changing a registered complementary medicine: Application levels and change tables	Must not result in a change in the target population
Wider target population	A reduction in the class of person for whom the goods are suitable is considered a C1 change (change code GDS)	-
Decrease in the strength	Determined per dosage unit	-
New directions for use	For example, change in recommended daily dose	Only if grouping does not apply. If grouping applies, refer to Changing a registered complementary medicine: Application levels and change tables
Medicines requiring a PI and CMI	Applications requiring a PI and CMI are considered RCM 4 or RCM 5 applications; as a minimum Module 4 and Module 5 data are required	-

Table 2: Examples of application category RCM 4 requiring Module 3 and Module 5

Example of RCM 4	Further considerations
Generic medicine application requiring bioequivalence data	Excluding enteric-coated tablets and capsules.
Generic modified-release dose forms	Excluding enteric-coated tablets and capsules
Deletion of an active ingredient	-

Example of RCM 4	Further considerations
RCMs using active ingredients permitted for use in listed medicines with higher level indications	-

Category 5 (RCM 5)

A RCM 5 application is made under section 23 of the Act to register a complementary medicine where the application is not an RCM category (1 to 4) and one of the following applies:

- the application requires independent evaluation of the safety, quality and efficacy of the medicine by the TGA
- the application is for a medicine that is already registered, and the application is for:
  - a new dosage form (as defined in TGA approved terminology for medicines)
  - a new active ingredient
  - an increase in the strength of an active ingredient
  - the addition of an excipient not used in complementary medicines at the time the application is made

For data requirements for the different types of RCM 5 applications refer to Mandatory requirements for an effective registered complementary medicine application: Appendix A-Specific mandatory requirements.

Timeframes and fees for evaluation of registered complementary medicines

All applications for evaluation of a registered complementary medicine attract an application and evaluation fee – refer to current fees.

Regulation 16GH of the regulations provides for legislated timeframes for evaluation of registered complementary medicines. There are different evaluation timeframes for each of the five application categories. While the TGA is required to complete the assessment within the specified timeframes, applicants should not presuppose the outcome of an application. The timeframes for evaluation of registered complementary medicines are provided in Table 3.

Table 3: Timeframes for the evaluation of registered complementary medicines

Category	Description	Notification of preliminary assessment (working days)	Evaluation timeframe (working days)
RCM1	An identical medicine to another registered complementary medicine other than differences between presentation, colour, flavour or fragrance.	40	45
RCM2	Evaluation of the safety, quality and efficacy of the medicine is based on evaluation reports from a COB	40	90

Category	Description	Notification of preliminary assessment (working days)	Evaluation timeframe (working days)
RCM3	• A generic product that does not require bioequivalence data; OR • The application has been evaluated by a COB and only required TGA evaluation of one of the following: safety; or quality; or efficacy	40	150
RCM4	• The application has been evaluated by a COB and only requires TGA evaluation of 2 of the following: safety; quality; efficacy; OR • A generic product requiring bioequivalence data; OR • A registered medicine with a change of one of the following: Increased indications, new directions or increased population	40	180
RCM5	• Requires full independent evaluation by the TGA; OR • A registered medicine with a change to : new dosage form, new active ingredient, increased strength of active ingredient or additional excipient	40	210

Within 40 working days of receiving an application, the TGA delegate of the Secretary will notify the applicant in writing, whether the application has passed preliminary assessment.

The evaluation timeframes for registered complementary medicines:

- only commence once an application is accepted for evaluation and the evaluation fee has been paid
- apply to working days only and exclude public holidays and weekends
- exclude the time when the evaluation clock has stopped (for example: the time taken by the applicant to provide responses to formal requests for information; or when the applicant and TGA agree to a mutual stop clock)

If the Secretary does not make a recommendation within the evaluation timeframe, the TGA must refund 25% of the prescribed evaluation fee.

Information required for a registered complementary medicine application

General requirements for RCM applications

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.

Data requirements for RCM applications

The Common Technical Document (CTD) sets out the format for an application when applying to register a medicine in the ARTG. 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 CTD specifies the organisation of the information across 5 modules so they are grouped logically and can be easily located:

- Module 1: Administrative information and prescribing information for Australia (for RCM applications refer to the modified CTD module 1: registered complementary medicines)
- Module 2: Summaries of quality, safety and clinical data
- Module 3: Quality
- Module 4: Non-clinical data (safety)
- Module 5: Clinical data (efficacy)

The actual content of the dossier for a RCM application will vary according to the application category (RCM 1 to 5). Appendix A - Specific mandatory requirements of the Mandatory requirements for an effective registered complementary medicine application specifies the data requirements for each RCM application category.

Module 1 of the CTD has been tailored to accommodate the needs and requirements for complementary medicines. Refer to CTD Module 1: Administrative information for registered complementary medicines - Guidance for applicants and CTD modules 2, 3, 4 and 5 for registered complementary medicine applications - Guidance for applicants' for more information. The Data requirements matrix for new RCM applications is a useful tool for sponsors that provides a summary of the CTD modules required for each new registered complementary medicines application category.

If you are unable to submit a full CTD dossier, the minimum structural requirement for registered complementary medicine dossiers consists of a single pdf document for each module. To maintain this structure, organise the document content using the CTD headings (combination of module number and module name).

Application process for a registered complementary medicine

Step by step guide for a complementary medicine registration process

There are 14 steps in the application process for evaluation of a registered complementary medicine application.

Step 1—Verify your complementary medicine and access to TGA Business Services

If you have already determined your product is a complementary medicine that you wish to register, and you have a client ID number and password to access TGA Business services, go to Step 2.

Verify you have a complementary medicine

To verify you have a complementary medicine for registration in the ARTG, go to the section entitled 'What are complementary medicines' in General guidance for listed medicines.

Related information and guidance

- Pathway to evaluating your medicine

Client identification and access to TGA Business services

Applications are created and lodged through TGA Business services.

You will need both of the following to make an application:

- a Client ID number
- password access to our Business services

If you do not have a Client ID number or access to our business services:

- go to our Business services: getting started with TGA

- complete and submit the online organisation details form

Step 2—Check ingredients and scheduling

Before you prepare your application to register a complementary medicine you need to make sure its active ingredients are designated active ingredients only (Schedule 14 to the Regulations provides a list of designated active ingredients for complementary medicines).

If the formulation contains at least one non-complementary medicine active ingredient your medicine will be evaluated via an alternate pathway and you will need to follow the appropriate registration (OTC medicines or prescription medicines).

Check for ingredient names in our tables

Check whether the ingredients in the medicine are included in the following tables under Public TGA Information on the business services homepage:

- Ingredients Table
- Proprietary Ingredients Table

Important: These code tables only provide the approved name or synonym for the ingredient. Inclusion of the name in the code tables does not mean we have approved the ingredient for use in therapeutic goods.

New proprietary ingredients

You will need the proprietary ingredient ID number to complete your application and to register the medicine in Step 9.

If the proprietary ingredients are new (not in the Code tables), submit the completed Notification of a Proprietary Ingredient form to obtain a proprietary ingredient ID number. You will be issued a proprietary ingredient ID number.

Proposing a name for new substances

If your registered complementary medicine contains a substance that is new, you will need to propose a name for it. To do this:

- Follow the guidance on how to propose a new substance name
- Select the relevant application form for proposing names:
  - Australian Approved Name (chemical substances)
  - Botanical name for a herb (an Approved Herbal Name)
  - Herbal component name
- Submit the relevant form via email to TGA Names
- Make sure that you state that you have submitted the form in the cover letter of your complementary medicine application

Scheduling ingredients

You also need to check if your complementary medicine is subject to the conditions of a schedule (excluding Schedules 4, 8 and 9) or an appendix of the Poisons Standard.

Medicines may be subject to the conditions of a schedule or an appendix of the Poisons Standard, for example:

- Schedule 2 – 'Pharmacy Medicine'
- Schedule 3 – 'Pharmacist Only Medicine'

Important: Consider possible scheduling requirements before submitting an application.

If you are unsure of potential scheduling of your medicine, you can contact Complementary medicines.

Step 3—Ensure a valid GMP evidence

You will need valid evidence that the manufacturer(s) of your complementary medicine have applied Good Manufacturing Practice (GMP) for each step of manufacture. To ensure this you will need:

- For Australian manufacturers: a copy of a GMP licence issued by the TGA.
- For overseas manufacturers**:** a GMP clearance issued by the TGA.

Duration of GMP for overseas manufacturers

We cannot finalise your application without current and valid GMP clearance (issued by the TGA) for each overseas manufacturer. You need to ensure that the GMP clearance will not expire during the evaluation timeframe.

GMP clearance that is due to expire

If the GMP clearance is due to expire within the minimum timeframe or is likely to expire before the application is finalised:

- Before you submit the application, you need to either:
  - apply to renew the GMP clearance
  - seek an extension to the GMP clearance expiry

We recommend renewing the GMP clearance for applications with a target evaluation time exceeding 6 months rather than seeking extension of the GMP clearance because extension to the expiry may not cover the full period, to completion, of the application.

If you have requested an extension, or applied to renew the GMP clearance, state this in the application cover letter.

Related information and guidance

- Guidance on manufacturing medicines
- Chapter 2 of the GMP clearance for overseas manufacturers.

Step 4—Determine your application category

There are 5 application categories to register a new complementary medicine based on complexity, with category 1 being the lowest and category 5 being the highest.

The data requirements and evaluation timeframes increase with the level of assessment and risk mitigation required, so it is important that you determine the application category correctly.

To help determine the correct application category, see Application categories for registered complementary medicines.

If your application does not include the data required for its application category, your application may not pass preliminary assessment and may be refused under section 23B of the *Therapeutic Goods Act 1989*.

Step 5—Check guidelines and requirements

When planning your application to register a complementary medicine, you will need to identify and understand the relevant technical and regulatory requirements and guidelines.

Guidance for effective applications

Use the following guidance to prepare your dossier of supporting information in Step 7. It will assist you to compile a complete application to pass preliminary assessment in Step 11 and progress to evaluation in Step 12.

- General dossier requirements (for all applications)
- Mandatory requirements for an effective registered complementary medicine application
- CTD Module 1—Registered complementary medicines including Cover letter (for all applications)
- Refer to the Data requirements matrices for the CTD modules required for each new registration

Related information and guidance

- Ensure you check:
- TGA assessed claim for assessed listed and registered complementary medicines
- Complementary medicine presentation
- The relevant European Union and ICH guidelines adopted in Australia for any specific requirements that apply to your application
- Therapeutic Goods Orders

Need assistance?

If you have read the guidance and need our assistance, please contact Complementary medicines.

Step 6—Request exemptions as part of your application

Exemption to use a restricted representation on the label

You will need an advertising exemption if you are using a restricted representation on your medicine label.

You can include your request for an exemption in your application to register your medicine.

To do this:

- Complete the Application for approval to use a restricted representation in advertising.

Include this application in Module 1.2.5 Form for approval to use a restricted representation.

Restricted representations

Please note that approval for the use of a restricted representation can only be considered once the complementary medicine is registered in the ARTG.

Step 7—Compile data for your application

General requirements for your dossiers

Compile your electronic dossiers (includes Module 1 and the technical modules) according to the general dossier requirements.

Dossier format

Compile the technical information consistent with the Mandatory requirements for an effective registered complementary medicine application.

Data requirements

Use the Mandatory requirements for an effective registered complementary medicine application: Appendix A-Specific mandatory requirements and the data requirements matrix tool in CTD modules 2, 3, 4 and 5 for registered complementary medicine applications to identify the data you will need for your application category.

Make sure you submit all relevant data in the modules you need for your application category. Provide justifications as to why any data is omitted and discuss with us at the pre-submission meeting in Step 8.

Guidance for applications to be effective

Check to ensure your dossier:

- is complete
- is in the required format
- includes the information required for an evaluation of quality, safety and efficacy
- includes an application cover letter (refer to CTD Module 1: Administrative information for registered complementary medicines) as part of CTD module 1

We will assess whether the application is effective during preliminary assessment in Step 11.

If your application is incomplete or deficient, we will refuse ineffective applications during preliminary assessment and it will not progress to evaluation.

Step 8—Arrange pre-submission meeting

We recommend you arrange a pre-submission meeting with us prior to submitting your application for a new registered complementary medicine. This will assist you to submit a high quality and complete dossier.

Discussion will focus on the structure of your proposed application, the identification of critical issues and the suitability of your proposed approach.

We do not:

- ✘ assess or evaluate as part of a pre-submission meeting
- ✘ charge a fee for a pre-submission meeting

To arrange a meeting, follow the guidance on pre-submission meeting with TGA.

Include the meeting record in CTD Module 1.7 Compliance with meetings and pre-submission processes.

Note that our guidance at the meeting is nonbinding and without prejudice. As knowledge evolves over time, the initial guidance we gave at the meeting may become out of date or be superseded.

Step 9—Complete and submit your application

In this step, you complete the application form and submit your application to register a complementary medicine.

How to complete the application form

To complete and submit your registered complementary medicine application, follow the instructions in: Registered complementary and OTC medicines application and submissions.

Submission ID number

You will be automatically issued a submission number, which uniquely identifies the application.

Use this submission number in all future communications about the application.

Monitoring the application progress

You can monitor the workflow status of your applications through Business Services.

Use the sponsor portal and the menu option 'View lodged submissions', under the column 'Workflow Status'.

The application start date is the date that the fees are processed.

Withdrawing an application

You can withdraw an application at any time up until the decision is made.

You can use Business Services to withdraw an application. Follow the instructions in Registered complementary and OTC medicines application and submissions.

Alternatively, you can advise us in writing of your intention to withdraw the application.

If the application is withdrawn due to safety issues, we may ask you to provide any adverse safety data.

Important: When an application is withdrawn, we may retain the application and any material submitted in connection with the application.

Refund when an application is withdrawn

We will:

- ✓ refund the evaluation fee if the application is withdrawn *before* it enters the *evaluation step* in the process
- ✘ not refund the application fee if the application is withdrawn during evaluation

Step 10—Pay your fees

When you apply to register a complementary medicine, we will invoice you for both the application fee and the evaluation fee together. The fees are based on the application category. If the application does not pass preliminary assessment, the full evaluation fee will be refunded.

For details of the current fees, go to Schedule of fees and charges.

Invoicing the fees

You will automatically receive an invoice when you submit the application.

Important: Pay the application and evaluation fees when you receive the invoice as we do not start screening the application until the fees are processed.

We may need to adjust the evaluation fee from that invoiced at the time of submission if:

- the application is considered to be a different application category—that is, different evaluation fee applies for different application categories
- we grant your request to waive or reduce the evaluation fee

We will assess the evaluation fee during preliminary assessment (see Step 11) and, if necessary, we will issue:

- an invoice, for any additional fees that apply
- a refund, if we waive or reduce the evaluation fee

Waive or reduce evaluation fees

- In some circumstances, we may be able to waive or reduce the evaluation fee (not the application fee) under Regulation 45 of the *Therapeutic Goods Regulations 1990*.
- Check these regulations to see if you are eligible for a waiver or reduction in evaluation fees.
- Once you have checked, if you then think you may be eligible, include a request and justification in the application cover letter (refer to CTD Module 1: Administrative information for registered complementary medicines).
- We will make a decision prior to accepting the application for evaluation.

Paying the fees

For information on fees and the available payment methods see:

- Fees & payments
- Payment options

Making payments by cheque

If you are paying the application fees by cheque:

- forward payment, together with a copy of the relevant invoice, by *separate post* to:

  TGA Finance
  PO Box 100
  WODEN ACT 2606
  Australia

- indicate in the covering letter of your application that payment has been forwarded to TGA Finance

Do not:

✘ include cheque or credit card details with the submission

Paying additional evaluation fees

You will need to pay any additional evaluation fees in full within 2 months of the date of the invoice or the following will occur:

- the application will lapse (section 24(2)(a) of the Therapeutic Goods Act 1989) and will not be evaluated
- you will forfeit the application fee

Step 11—Preliminary assessment of your application

We will conduct a preliminary assessment of your application to verify it meets both the administrative and technical eligibility requirements to proceed to evaluation.

Within 40 working days of receiving an application, the TGA delegate of the Secretary will notify the applicant in writing, whether the application has or has not passed preliminary assessment.

What makes an effective application

Your application will pass preliminary assessment (is effective) if it meets the requirements under section 23B of the Act. This means:

- The prescribed application fee has been paid.
- The application includes all **information required**, of the kind and form required, for the correct application category, to enable the TGA to evaluate the application.
- Applications for restricted medicines[2] include a form for providing product information that is approved under section 7D of the Act (section 23(2)(ba)).
- Samples of the medicine have been delivered to the TGA (only if requested).

We rely on information in your application cover letter (refer to CTD Module 1: Administrative information for registered complementary medicines) to confirm the application category and corresponding data requirements.

Effective applications

If your application passes preliminary assessment, we will notify you in writing:

- hat the application has been accepted for evaluation
- of any adjustment to the evaluation fee

[2] Defined in the *Restricted Medicine Specification 2011* and include prescription medicines (see Schedules 4 and 8 of the current Poisons Standard) and medicines that are only available from a pharmacist (Schedule 3 of the current Poisons Standard).

The evaluation process will not commence until you the evaluation fee is paid in full.

Opportunity for minor corrections

You will have an opportunity to make minor corrections, detected during the screening process, if the issue can be rectified promptly. For example, if we cannot locate an attachment mentioned in the application we will give you an opportunity to provide the attachment.

Ineffective applications

If your application does not pass preliminary assessment (is ineffective), we will:

- not accept it for evaluation
- remove your application from Business services
- write to you and explain why the application is ineffective
- refund the evaluation fee

You will forfeit the application fee.

Note that this notice is an administrative action and not an 'initial decision' within the meaning of Section 60 of the Act i.e. this decision cannot be appealed.

If you reapply to register the medicine, ensure your application meets the requirements for an effective application. You cannot lawfully import, supply or export the medicine until you have an ARTG registration.

Lapsing applications

Your application will lapse if evaluation fees are not paid within two months of becoming payable. We will notify you that your application has lapsed.

You will need to submit a new application and pay the application fee to register the medicine.

Step 12—Evaluation of your application and requests for information

Once your application has passed preliminary assessment and the evaluation fee has been paid, your application will progress to the evaluation phase. We will undertake the evaluation and may request information under Section 31 of the Act. The timeframe for evaluation is based on the application type - refer to Timeframes and fees for evaluation of registered complementary medicines.

During evaluation of your application, we will:

- evaluate the data and information on the quality, safety and efficacy and presentation of the medicine
- review your responses to our requests for information
- document our findings

Quality data

We evaluate the quality of the medicine, including the identity, impurities and stability of all ingredients and take into account information about:

- the manufacturing processes and the compliance with GMP
- quality-controls to determine if the quality of the medicine will be consistent
- stability data to confirm the medicine is of appropriate quality over its proposed shelf–life

Safety data

Our assessment of safety data includes:

- history of use
- pharmacology and pharmacokinetics
- drug interactions
- toxicology
- clinical trials
- reports of adverse reactions

Efficacy data

We assess efficacy data to determine whether it supports the indication(s)/claim(s) including:

- a detailed evaluation of the proposed indication(s)
- any claims that you intend to make for the medicine

Presentation of the medicine

We assess all aspects of the medicine presentation, including for compliance with the various legislative requirements (including advertising requirements) and to ensure clarity for consumers in relation to the medicine and its proposed use. This includes:

- proposed labelling
- inclusion of a TGA assessed label claim (where applicable)
- Product Information and Consumer Medicine Information (when provided)

Requesting information

We may request you to provide information to clarify or address issues that we identify during the evaluation. During this time, the evaluation clock will stop.

We make these requests for information under section 31 of the Act and include a timeframe for you to respond. The time between the RFI being issued and receipt by the TGA of the applicant's response will not be counted as part of the evaluation timeframe (i.e. the 'evaluation clock' will stop).

Evaluators may also seek clarification of minor issues on an informal basis. The clock will not stop in these circumstances.

Responding to requests for information

It is important that you provide complete and accurate information.

Preparing your response

If the request for information relates to the content of a module of the submission dossier:

✓ Provide an electronic copy of the response in the format described in step 7.

✘ Do not provide additional data (Unsolicited information) unless we request it.

Due date for responding to requests for information

✘ Do not wait until the response is due to request an extension of time.

✘ We will not extend the due date unless you can demonstrate that the time allowed is not reasonable.

If we do not receive your response within the timeframe or you only send a partial response, we will proceed with the evaluation based on the information we have available.

If you do not provide all of the information requested and the outstanding issues are significant, the decision maker may decide **not to** register the medicine (in Step 13) based on available information.

Unsolicited information

We do not evaluate unsolicited information or data, unless it is:

- New safety data that might negatively influence the benefit-risk assessment of the medicine. You are obligated to inform us about this as soon as it becomes available.
- Updated TGA manufacturing licences or clearances for the sites listed in the application.

Expert advisory committee advice

We may decide to seek advice from an expert advisory committee, such as the Advisory committee for complementary medicines (ACCM). We will inform you about:

- the committee meeting and give you an opportunity to provide comment for the committee's consideration
- any relevant advice from the committee

The advisory committee process will typically extend the evaluation timeframe.

Related information

- Statutory expert committees

Step 13— The decision

Before the delegate makes a decision on whether to register a complementary medicine, you may need to verify the details of the application, including any changes during the evaluation.

Matters considered before making a decision

When making the decision under section 25 of the Act on whether to register the medicine in the ARTG, the decision maker (the delegate of the Secretary of the Department of Health) will:

- review all documentation associated with the application, including:
  - the application and submission dossier
  - the evaluation reports
  - responses to requests for information
  - advice from expert advisory committees
  - other relevant advice or information
- consider the matters detailed under section 25 of the Act, including whether the quality, safety and efficacy of the medicine have been established.

We will send you a written notification of the decision.

Step 14— Finalise your registration

This step involves finalising the registration once a decision has been made on whether to register the medicine.

Decision to register the medicine

If the decision is to register the medicine, we will send you the decision letter. This letter will include standard and specific conditions on the registration of your medicine under Section 28 of the Act. It is important that you read, understand and comply with these conditions. If you do not comply with any one of these conditions of registration, your medicine may be cancelled from the ARTG under section 30(1)(da) of the Act.

The decision letter will also request you to provide assurance that all details of the medicine are correct before we create the ARTG entry.

Related information and guidance

- Appendix 4 of DR4—Conditions-standard and specific
- TGA assessed claim for assessed listed and registered complementary medicines

Patent certification under the Australia/USA free trade agreement

You need to provide a patent certificate under subsection 26B(1) of the Act, or notification that this is not required before the medicine can be registered in the ARTG. If you have not already provided the patent certificate or notification form with your application, complete either the:

- approved form for notification that 26B(1) certificate is not required
- relevant approved subsection 26B(1)(a) or (b) certificate.

Send the completed and signed notification form or certificate by email to complementary.medicines@health.gov.au quoting the application submission number.

Registering the medicine and your ARTG certificate

Once we receive the completed and signed notification form or patent certificate:

- We will register the medicine in the ARTG.
- You can download your certificate of registration from Business Services. To do this, follow the guidance on printing your ARTG certificate.

Date of effect of the registration

The registration of your medicine will commence on the day specified in the certificate of registration. The medicine cannot be lawfully imported, exported or supplied by the applicant prior to this date.

Annual charges

Annual charges will apply once the medicine starts generating turnover.

Related information and guidance

- Annual Charge Exemption Scheme

Decision not to register the medicine

If the decision is not to register the medicine, the decision letter will include a statement of the reasons for the decision and information on your rights to seek a review of the decision.

For information: Applicants for a new registered complementary medicine can appeal the Secretary's decision about that application under section 60 of the Act. Refer to Guidance for requesting reconsideration of an initial decision.

After registration of complementary medicines

Conditions of registration

Section 28 of the Act provides a number of conditions of registration that automatically apply when a medicine is registered in the ARTG. Failure to comply with a condition of registration may result in the cancellation of the medicine from the ARTG. Statutory conditions of listing are displayed in a medicine's ARTG certificate.

Section 28 of the Act provides legislative powers for the Secretary to impose, vary or remove additional conditions on all registered therapeutic goods at the time the medicine is registered, or any time thereafter.

How to apply for a change for a registered complementary medicine's ARTG entry

To apply for approval to make a change to your medicine, use the online application form for registered complementary medicines. Refer to Registered complementary and OTC medicines application user guide.

Where the same change is made across a number of products an individual application form is required for each product entry sought to be varied. Applicable fees are required to be paid for each product varied.

Refer to

- Notifications process: requests to vary registered medicines where quality, safety and efficacy are not affected
- Registered complementary and OTC medicines applications and submissions.

Version history

Version	Description of change	Author	Effective date
V1.0	This document, 'Applications for registered complementary medicines' has been extracted from the archived document ARGCM v.8 April 2018 pages 99 -238 (previously named 'ARGCM Part D). The sequence of information, headings and formatting have been amended from the original content for consistency, accuracy and easier navigation. References to outdated forms have been removed. Technical content has been extracted to the following standalone guidance document: • CTD Module 1: Administrative information for registered complementary medicines – Guidance for applicants • CTD modules 2, 3, 4 and 5 for registered complementary medicine applications - Guidance for applicants • Changing a registered complementary medicine (RCM): RCM application levels and changes tables New guidance has been included on changes to the regulatory framework for listed medicines, including: • the TGA assessed label claim • new application categories • legislated application timeframes • comparable overseas bodies • mandatory requirements for an effective registered complementary medicine application	TGA	May 2020

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