Australian Government
Department of Health
Therapeutic Goods Administration

OTC new medicines registration process

Version 1.2, August 2020

TGA Health Safety Regulation

Contents

Introduction

This guidance is intended to assist applicants to register a non-prescription over-the-counter (OTC) medicine on the Australian Register of Therapeutic Goods (ARTG).

The following steps:

- identify the regulatory process you need to follow
- navigate you through the process step-by-step
- link to relevant guidance and forms.

Step 1 - Verifying your OTC medicine and access to Business Services

If you have already determined your medicine[1] is an OTC that requires registration on the ARTG and you have a client ID number and password to access TGA Business services go to Step 2.

Verifying you have an OTC medicine

To verify you have an OTC medicine that requires registration on the ARTG, go to the guidance:

- Pathway to evaluating your medicine

Client identification and access to Business services

Applications are created and lodged through 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.

[1] Goods represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the human body

Step 2 - Checking for new medicine ingredients

Before you prepare your application to register an OTC medicine, you need to check if the medicine contains a new ingredient or has ingredients that require assessment.

Checking for ingredients in our tables

Check whether the ingredients in the medicine are included in our relevant Tables under Public TGA Information on the business services homepage:

- Ingredients Table
- Proprietary Ingredients Table

For new proprietary ingredients

Submit the completed Notification of a Proprietary Ingredient form to obtain a proprietary ingredient ID number.

You will need the proprietary ingredient ID number to complete your application to register the medicine (Step 7).

For new substances (excipient or active ingredient)

There are two options to apply for approval of a new substance (excipient[2] or active ingredient[3]). You can either:

1. Apply as part of the OTC medicine application. If you choose this option, make sure to:
   - take this into account when you determine the application level (Step 3)
   - state this in your application cover letter
   - provide the data described in the Guidelines on OTC applications for new substances

or

2. Apply before submitting the OTC medicine application. This option is usually only used for new excipients or active ingredients in sunscreens. If you choose this option, make sure to:
   - use your login access to our business services to access the application form
   - complete a new substance application form
   - provide the data described in the Guidelines on OTC applications for new substances.

[2] Any component of a finished dosage form other than an active ingredient
[3] The therapeutically active component in a medicine's final formulation that is responsible for its physiological action

Proposing a name for new substances

You will also need to propose a name for the new substance.

To do this:

- select the relevant application forms for proposing names
- 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 OTC medicine application or new substance application.

Ingredients that require assessment

Ingredients included in the Ingredient Table may not have been approved for your proposed use or at the proposed concentration.

The Ingredient Table includes limited information on the restrictions for use (for example, for topical use only).

The absence of restrictions in the Ingredient Table does not mean that the ingredient has been approved for your proposed use or at the proposed concentration.

If the proposed use or concentration is not typical for your ingredient or you are not sure whether your ingredient has been assessed for your proposed use or at the proposed concentration you can contact OTC Medicines by email.

If your ingredient requires assessment of safety and efficacy data make sure to:

- take this into account when you determine the application level (see Step 3)
- state this in the cover letter of your OTC medicine application
- provide the required data, in accordance with the Guidelines on OTC applications for new substances.

Related information and guidance

- The Poisons Standard (SUSMP)
- Adventitious agent safety of medicines

Step 3 - Determining your application level

Applications to register an OTC medicine are categorised into five levels, based on risk and have different fees and target evaluation times.

Determining the correct application level

It is important that you determine the correct application level.

If your application does not include the required data, in accordance with the application level, it will not be accepted for evaluation under section 23(2)(b) of the *Therapeutic Goods Act 1989*.

Five application levels for new OTC medicines

1. N1 Generic medicines that meet the requirements for OTC new medicine N1 applications (clones or flavour/fragrance/colour variants of a currently registered medicine).
2. N2 Generic medicines that fully meet a specific OTC monograph and the general requirements for OTC New Medicine N2 applications.
3. N3 Generic medicines that are not an N1, N2 or N4 level application (N3 applications require CTD Modules 1 and 3).
4. N4 Generic medicines that are one or more of the following:
   - require supporting safety and/or efficacy data
   - have not been previously registered as an OTC medicine following down - scheduling
   - require a higher level assessment due to the umbrella segment of the product name.
5. N5 New medicines that are not generics, including either one or more new:
   - active ingredient (new chemical entity)
   - combination of active ingredients
   - indication
   - strength
   - dosage form – directions for use
   - patient population.

Step 4 - Checking guidelines and mandatory requirements

When planning your OTC medicine application you will need to identify and understand the relevant mandatory requirements and guidelines.

Relevant guidelines

Check all of the relevant guidelines for any specific requirements or advice that apply to your application:

- OTC -specific guidelines
- European Union and ICH guidelines adopted in Australia - guidelines prepared by the European Committee for Medicinal Products for Human Use (CHMP) and/or those prepared within the ICH process that have been adopted by the TGA.

Mandatory requirements

The mandatory requirements explain what you need to do for your application to be effective, pass screening and be accepted for evaluation:

- Mandatory requirements for an effective OTC medicine application
- CTD Module 1: OTC medicines
  - Note the requirement in CTD Module 1.5.8 to submit your own umbrella brand assessment for applications that require a higher level assessment due to the umbrella segment of the product name.
- Common Technical Documentation (CTD)
- General dossier requirements
- Cover letter

Need assistance

If you have read the applicable guidance and need our assistance, you can contact OTC Medicines by email. We will usually respond in writing as meetings are not needed for most OTC medicine applications.

Step 5 - Ensuring valid GMP evidence

You will need valid evidence that the manufacturers of your OTC registrable medicines have been certified to perform each step in the manufacture of the goods.

If you do not have valid evidence of GMP for each manufacturer, your application will not validate when you submit your application (Step 7).

Evidence we accept

We accept:

- Australian manufacturers: a Licence to Manufacture (GMP licence) issued by the TGA.
- Overseas manufacturers: a GMP clearance issued by the TGA.

In both cases the evidence is valid only for the steps of manufacture and dosage forms nominated on the licence or clearance.

Duration of GMP clearance for overseas manufacturers

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

Check that the GMP clearance will not expire within the following minimum timeframe from when you submit your application in Step 7:

- 3 months for N1 applications
- 4 months for N2 applications
- 6 months for N3, N4, and N5 applications.

GMP clearance that is due to expire

If the GMP clearance is due to expire within the minimum timeframe (see previous section) 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.

Consider applying to renew the GMP clearance for applications with a target evaluation time that exceeds 6 months rather than seeking extension of the GMP clearance. 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 clearance, state this in the cover letter of your OTC medicine application.

Guidance to complete this process

- Guidance on manufacturing medicines
- Chapter 2 of the GMP clearance guidance

Step 6 - Compiling data for your application

You will need to prepare your OTC medicine dossier of administrative and technical documentation to submit for evaluation.

General requirements for your dossier

You must submit an electronic application dossier.

To compile your dossier, follow the General dossier requirements.

Organisation and structure of the dossier

Compile your electronic dossier according to the Common Technical Documentation (CTD).

To identify the CTD Modules you need for your application check:

- CTD Module 1: OTC medicines
- Mandatory requirements for an effective OTC medicine application.

Meeting the mandatory requirements

Ensure your application dossier contains all of the administrative and technical data required for the application level.

It is important that you check to ensure your dossier:

- is complete
- is in the required format
- includes the required information for an effective application detailed in:
  - CTD Module 1: OTC medicines
  - Mandatory requirements for an effective OTC medicine application
  - the guidance to prepare your cover letter

We will check whether the application meets the requirements for an effective application during screening (Step 9). If your application does not meet the requirements to be effective, we will not accept it for evaluation.

Step 7 - Completing and submitting your application

In this step, you will be completing the OTC medicine application form and submitting your application.

How to complete the application form

To complete and submit your application, follow these steps and save your information as you progress through each page.

1. Log in to Business services.
2. Select 'Applications'.
3. Select the appropriate application form under Over the Counter Medicine - for example, for single component medicines select 'Non-Prescription Medicine' and for composite packs select 'Non-Prescription Composite Pack'.
4. Complete the application form - ensure you select the correct application level.
5. Attach your application dossier (compiled in Step 6) to the application form or submit the dossier on CD/DVD/USB.
6. Select 'Submit' and agree to the declaration and relevant assurances.

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.

The application start date is the date that the fees are processed (see Step 8). When your fees have been processed the workflow status will change from 'Submitted' to 'Under Review', which means that the application is in screening (Step 9).

Withdrawing an application

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

To withdraw an application, inform us in writing of the intention to withdraw the application.

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

Note

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.

We do not refund the application fee.

Step 8 - Paying your fees

When you apply to register an OTC medicine, we will invoice you for both the application fee and the evaluation fee that corresponds with the application level.

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.

It is important to 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 will assess the fees during screening (see Step 9) and, if necessary, we will issue:

- an invoice for any additional fees if you have paid concurrent (reduced fees) and we determine that you are not eligible for these fees. For example, we may determine that the supporting information is not sufficiently similar to enable simultaneous evaluation.
- a refund, if we grant your request to waive or reduce the evaluation fee.

Concurrent fees

If you submit an application and you submit additional applications at the same time, you can apply concurrent (reduced) fees to the eligible additional applications which have:

- the same sponsor
- the same application level
- the same active ingredients
- sufficiently common supporting information to enable simultaneous evaluation.

If you are eligible for concurrent fees, select this option and enter the relevant details when you complete your application (Step 7).

The concurrent fees are listed in the Schedule of fees and charges.

Waive or reduce evaluation fees

- For applications that are not eligible for concurrent fees, in some circumstances we may be able to waive or reduce the evaluation fee (not the application fee) under Regulation 45(4) 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 think you may be eligible include a request and justification in the cover letter of your application. 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, **do**:

- ü indicate in the covering letter that payment has been forwarded to TGA Finance.
- ü forward payment, together with a copy of the relevant invoice, by *separate post* to:

  TGA Finance
  PO Box 100
  WODEN ACT 2606
  Australia

Do not:

- û include cheque or credit card details with the submission.

Paying additional evaluation fees

If we invoice you for additional evaluation fees these need to be paid 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 9 - Screening your application

We will screen your OTC medicine application to verify that it has been submitted at the correct application level and it meets the requirements to be effective.

Requirements for an effective application

Your application is effective if it meets the requirements under section 23(2) of the *Therapeutic Goods Act 1989*. This means:

- The prescribed application fee has been paid.
- The application includes all information required, for the correct application level, to enable us to make a decision.
- Applications for restricted medicines include a product information in the form approved under section 7D of the Act (section 23(2)(ba) of the Act).
- Samples of the medicine have been delivered to the TGA (only if requested).

We rely on information in your application cover letter to confirm the application level and corresponding data requirements.

If your application cover letter does not contain information critical to verify the application level, we may not detect an application submitted at the incorrect level until evaluation in Step 10. This can have implications for you as explained in Step 10.

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 that is mentioned in the cover letter, we will give you an opportunity to provide the attachment.

Effective applications

If your application is effective, we will:

- accept it
- undertake the evaluation
- send you both:
  - a notification email, advising the application has been accepted for evaluation
  - an invoice for the remaining evaluation fees, if applicable.

Not effective applications

If your application is not effective:

- we will:
  - not accept it for evaluation
  - remove your application from business services
  - write to you and explain why the application is not effective
  - refund the evaluation fee.
- you will forfeit the application fee.

If you reapply to register the medicine on the ARTG, 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.

Step 10 - Evaluating and requesting information

During this step in the process, to register an OTC medicine, we will undertake the evaluation and may request additional information.

Evaluating the OTC medicine application

During evaluation of your OTC medicine application, we will:

- assess the data and information
- review your responses to our requests for information
- document our findings.

Evaluation timeframes

Our aim is to complete the evaluations within the target times for OTC medicine applications.

These target times:

- differ for each application level
- apply to the TGA processing time
- do not include the time you take to respond to a request for information.

We stop the clock when we send you a request for information and restart the clock once we receive your response addressing the issues.

Requesting additional information

We may request you to provide information to clarify or address issues that we identify. The maximum number of requests for information we usually make are:

- one for N1 and N2 applications
- two for N3, N4 and N5 applications.

We make these requests for information under section 31 of the Act and include a timeframe for you to respond. We apply standard response timeframes to requests for information.

Responding to requests for information

It is important that you respond to our requests for information within the given timeframes and provide complete and accurate information.

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 11) based on available information.

Preparing your response

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

- ü Provide an electronic copy of the response in CTD format.
- û Do not provide additional data unless we have specifically requested it (see Unsolicited information)

Due date for responding to requests for information

- û 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.

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.

Ensure the application dossier is complete and that the mandatory requirements are met when you submit your application.

Expert advisory committee advice

We may decide to seek advice from an expert advisory committee, such as the Advisory Committee on Non-prescription Medicines (ACNM), on specific issues relating to the application.

This is more likely to occur for higher level applications, particularly when the application is the first of that type. For most applications, we do not seek the advice of an expert advisory committee.

The OTC medicines advisory committee process will typically extend the evaluation phase by three to six months.

Related information

- Statutory advisory committees

Applications submitted at the incorrect level

If, during evaluation, we determine that your application passed screening at the incorrect application level because your application cover letter did not contain adequate information relating to the application level and data requirements, we will:

- inform you that the application will be restricted to the application level that was accepted during screening
- only evaluate data required for the accepted application level
- advise you of the changes you need to make to meet the relevant criteria for the application level, detailed in determining the application level for an OTC medicine.

If you cannot make the changes, the decision maker may decide not to register the medicine in Step 11.

In this case, you will need to reapply and include all of the required data for the correct application level if you wish to register the medicine.

Example

An application submitted at level N3 passes screening and is accepted for evaluation.

During evaluation we note the medicine labels include an extension of target population, directions for use and a new claim, which were not raised in the cover letter and therefore not detected during screening.

Applications for medicines for use in an extended target population, with new claims and directions for use, do not meet the criteria for an N3 level application and require supporting safety and efficacy data.

We inform you (the applicant) that the target population, directions for use and claims will be restricted to those that meet the criteria for an N3 level application.

Step 11 - Making the OTC registration decision

Before making a decision on whether to register an OTC medicine, you may need to verify the details of the application, including any changes that may have been made during the evaluation.

Matters considered before making a decision

When making the decision, under section 25 of the *Therapeutic Goods Act 1989* on whether to register the medicine on 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.

Once the decision is made we will send you a written notification of the decision (Step 12).

Step 12 - Finalising your OTC registration

This step involves finalising the registration once a decision has been made on whether to register an OTC 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 decisions made by the delegate of the Secretary to impose standard and specific conditions on the registration of your medicine in the register, under Section 28 of the *Therapeutic Goods Act 1989*.

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.

Related information and guidance

- Appendix 4 of DR4 - Conditions - standard and specific

Patent certification under the Australia/USA free trade agreement

You need to provide a patent certificate under subsection 26B(1) of the *Therapeutic Goods Act 1989* or notification that this is not required before the medicine can be registered on 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
- The relevant approved subsection 26B(1)(a) or (b) certificate

Send us the completed and signed notification form or certificate by email, quoting the application submission number.

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

- We will register the medicine on 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.

Decision not to register the medicine

If the decision is not to register the medicine, the decision letter will include both:

- A statement of the reasons for the decision
- Information on your rights to seek a review of the decision

Uploading PI/CMI documentation

Only some OTC medicines have approved PI/CMI documents. Sponsors may choose to publish these on the PI/CMI search facility on the TGA website.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication Replaces ARGOM Guidelines on pre - market application and evaluation process for OTC medicines v1.3 09/04/2014	OTC Medicines Regulatory Guidance	November 2015
V1.1	Update to step 3 and step 8 of the process to reflect the new OTC fee structure commencing on 1 January 2016	COMB – OTC Medicines Evaluation Section	December 2015
V1.2	Update to Step 12 of the process to include information on publishing PI/CMIs on the TGA website	Complementary and OTC Medicines Branch	August 2020

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