Australian Government
Department of Health
Therapeutic Goods Administration

Process to change a registered OTC medicine

Version 1.3, August 2020

TGA Health Safety Regulation

Contents

Introduction

This guidance is intended for sponsors applying to change the entry in the ARTG for a registered non-prescription over-the-counter (OTC) medicine.

The following steps:

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

Step 1 - Verifying your changes require prior approval

Most changes to an ARTG entry for a registered OTC medicine require our approval prior to making the change to the medicine.

To determine whether your change requires prior approval check changes code tables.

If your change is identified as:

- 'SRR', 'SAR', 'N' or 'A', you will need to apply for approval prior to making the change to the medicine. Go to Step 2.
- 'New'. Go to OTC medicines registration process as you will need to apply for a new ARTG entry.
- 'O', you do not need to apply for approval to make the change.

Step 2 - Determining your application level and change codes

Applications to change an ARTG entry for a registered OTC medicine are categorised into four levels (C1-C4) based on risk and have different fees and target evaluation times.

It is important that you select the correct change codes in the changes code tables in Step 1 as these will determine the application level for you.

If you are applying to make more than one change, the change code with the highest application level determines the overall application level.

You will need the change codes to complete your application (Step 7).

The change code tables will also identify which section of the *Therapeutic Goods Act 1989* you are applying under.

Related guidance

- Determining the correct OTC application level

Step 3 - Checking relevant guidelines and requirements

Your application to change an ARTG entry for a registered OTC medicine needs to clearly describe each proposed change and include information to support the change so that it will pass screening and be accepted for evaluation. Notification applications do not undergo a screening process.

To determine the information necessary to support the change, you need to identify and understand the relevant requirements and guidelines:

- CTD Module 1: OTC medicines
  - relevant for all applications to change an OTC medicine.
- Mandatory requirements for an effective OTC medicine application
  - relevant for change applications:
    - made under s23 of the Act. For example, changing the indications or directions for use (change codes GID and GDD)
    - when supplying CTD Modules 3, 4 or 5.
- OTC-specific guidelines, in particular:
  - for quality related changes see Guidelines on quality aspects of OTC applications
  - for safety and efficacy related changes see Guidelines on safety and efficacy aspects of OTC applications
  - for changes to the presentation see Guidelines on presentation aspects of OTC applications.
- 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.

Need assistance

If you have read the applicable guidance and need our assistance email OTC medicines with your enquiry.

We will usually provide written advice. Meetings are not needed for most OTC medicine applications.

Step 4 - Obtaining an ID number for new proprietary ingredients

Skip this step if you are not including a new proprietary flavour, fragrance, ink or colour in the medicine.

- If you are adding a proprietary flavour, fragrance, ink or colour to the medicine, check whether the proprietary ingredient is included in the 'Proprietary Ingredients Table' under Public TGA Information on the Business Services homepage.

If the proprietary ingredient is not in the Table, before you submit your application:

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

You will need the proprietary ingredient ID number to complete your application to change the medicine (Step 8).

Step 5 - Ensuring GMP evidence is valid

You will need valid evidence that the manufacturers of your OTC medicine 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 8).

Evidence we accept

Ensure you have:

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

The duration of GMP clearance for overseas manufacturers

We cannot finalise your application without current and valid GMP 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 8:

- 2 months for C1 applications
- 4 months for C2 applications
- 6 months for C3 and C4 applications.

For notification applications, GMP must be current at the time of lodgement and payment.

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.

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 for overseas manufacturers

Step 6 - Compiling data for your application

Your application dossier needs to identify all proposed changes and include relevant supporting information.

Ensure that your application cover letter includes the information described in the guidance on preparing an OTC application cover letter.

You do not need to provide a cover letter for a notification application.

General requirements for your dossier

When compiling your electronic dossier, follow Parts A to D of the General dossier requirements.

Organisation and structure of the dossier

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

Checking the application dossier

Check that your application dossier contains all of the administrative and necessary technical data required for the application level and to support the proposed changes so that it will be accepted for evaluation after screening (Step 10). A notification application is not subject to screening.

Ensure your application:

- includes all relevant change codes
- is complete
- is in the required format
- includes the necessary supporting information.

Step 7 - Changing more than one medicine

Skip this step if you only want to change one OTC medicine.

If you want to change more than one medicine you will usually need to submit a separate application for each medicine that you want to change (Step 8).

Making identical changes to more than one medicine

You can submit a single application to make identical changes to more than one OTC medicine only when **all** of the following apply:

- The change codes correspond only to applications made under section 9D of the Act (determined in step 2).
- The specific details of the change are identical and common to each medicine in the application.
  - Take into account both the currently registered details and the proposed details for each medicine when you assess whether the change is identical.
  - If one or more of the medicines include a unique change you will need to submit separate applications.
- The changes **do not** require separate evaluation in the context of each medicine.
  - Most C2 to C4 level changes require separate evaluation for each medicine.

Information for identical changes to more than one medicine

To submit a single application to make identical changes to more than one medicine:

- Provide separate copies of the relevant supporting documents for each medicine that the changes apply to.
- Select the application form in Business Services (Step 8) titled *Change Multiple ARTG Entries*.

Examples

Adding the same manufacturer to four medicines and changing font size on the label for only one medicine

You would need to submit two applications:

- one application to add the manufacturer to three of the medicines, as this is an identical change to all three medicines
- a second separate application to add the manufacture and make the changes to the label of the fourth medicine.

Adding an overseas manufacturer to several medicines

Although the relevant change code (MOS) is common to all of the medicines, the specific additional overseas manufacturing site differs for each medicine. As the additional manufacturing sites are not identical for each medicine the sponsor cannot submit these changes on a single application form.

Adding a new 'fast' claim to the labels of several medicines with different formulations

The appropriateness of this claim needs to be evaluated separately for each medicine and you would need a separate application for each medicine.

Step 8 - Completing and submitting your application

To complete and submit your application to change an ARTG entry for an OTC medicine, follow these steps and save your information as you progress through each page.

Accessing the application form in business services

Log in to Business Services.

1. Select ‘Applications’.
2. Select the appropriate application form under the heading Over the Counter Medicine - for example,
   - for single component medicines select ‘Non-Prescription Medicine’
   - for composite packs select ‘Non-Prescription Composite Pack’.
3. Complete the application form - ensure you select all of the correct change codes.
4. Attach your application dossier (compiled in Step 6) to the application form or submit the dossier on CD/DVD/USB.
5. 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**.

Simultaneous applications

Avoid submitting an application to make changes to a medicine whilst another application to change the medicine is in process, as approved changes from the first application may be deleted from the ARTG when the subsequent application is finalised.

If you cannot delay submitting the application:

- Notify us of the submission ID numbers for the application(s) already in process.

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 (Step 9).

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 10). For changes processed as notifications, the workflow status will temporarily display as 'Under Review' as the system automatically processes the change.

Withdrawal of applications

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.

Refund when an application is withdrawn

We will refund the portion of the fees corresponding to evaluation if the application is withdrawn **before** the application enters the evaluation step in the process.

We do not refund the full fees.

Step 9 - Paying your fees

When you apply to change a registered OTC medicine we will invoice you for the fees that correspond with the application level.

For details of the current fees to change the ARTG entry for a registered OTC medicine 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 fees when you receive the invoice as the application will not be screened (or in the case of notifications, automatically approved) until the fees are processed.

The fees will be assessed during screening (Step 10) and if necessary we will issue a refund, if a waiver or reduction has been requested and granted.

Waiver or reduction of evaluation fees

In some circumstances, a waiver or reduction of the fees for evaluation may be possible under Regulation 45(4) of the Therapeutic Goods Regulations. If you are eligible:

- include a request and justification in the cover letter of your application and we will make a decision prior to accepting the application for evaluation.

Paying the fees

For information on the available payment methods see the following:

- Fees & payments
- Payment options.

If you are paying the application fees by cheque:

- indicate in the covering letter that payment has been forwarded to TGA Finance
- do not include cheque/credit card details with the submission
- forward payment together with a copy of the relevant invoice by separate post to:

  TGA Finance
  PO Box 100
  WODEN ACT 2606
  Australia

Step 10 - Screening your application

For most change requests, we will screen your application to change your ARTG entry for your OTC medicine to verify that it can be accepted for evaluation. Requests processed as notifications are not screened.

During screening, we check that your application:

- includes the correct change codes
- has been submitted at the correct application level
- is complete
- is in the required format
- includes the necessary supporting information.

We also assess the fees and, if necessary, issue an invoice for additional fees or a refund.

We rely on information in your application cover letter to confirm the correct selection of change codes and corresponding data requirements.

If your application cover letter does not contain information critical to verifying the change codes, we may not detect an application submitted at the incorrect level in Step 11.

Opportunity to correct minor errors

You will have an opportunity to correct minor errors that may be detected during screening, if the error can be rectified promptly. For example, if the cover letter refers to an attachment that we cannot locate, you will be given the opportunity to promptly provide the attachment.

Passing screening

For C2 to C4 level applications, when your application passes screening we will notify you that it has been accepted for evaluation.

Step 11 - Evaluating and requesting information

This step is evaluating an application to change the ARTG entry for a registered OTC medicine.

Evaluating the application

Evaluating an application to change a registered OTC medicine involves us:

- assessing the data and information
- reviewing your responses to our requests for information
- documenting the findings
- aiming to complete the evaluation within target times.

Requests processed as notifications are not evaluated.

Requesting information

We may send you a request for information (RFI) seeking clarification, or to any address issues identified. The maximum number of requests we make are:

- one for C1 and C2 applications
- two for C3 and C4 applications.

We make these requests 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 RFIs within the given timeframes and provide complete and accurate information. Do not provide additional data unless we have specifically requested it - see Unsolicited information.

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 approve the application (Step 13).

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.

How to prepare 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 CTD format.

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 when you submit your application.

Seeking advice from expert advisory committees

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.

Seeking advice from the ACNM will typically extend the evaluation phase by three to six months.

Related information

- OTC medicine advisory committee process

Applications submitted at the incorrect level

If during evaluation, we determine that your application passed screening at the incorrect application level because you did not select the correct change codes and 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 approve the application (Step 13).

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 C2 passes screening and is accepted for evaluation.

During evaluation we note the medicine labels included a new indication, which was not identified in the application form or raised in the cover letter and therefore not detected during screening.

Applications to introduce a new indication do not meet the criteria for a C2 level application and require supporting safety and efficacy data and are made under a different section of the *Therapeutic Goods Act 1989*.

We inform the applicant that the change to the indications needs to be removed from the labels, consistent with the changes identified in the application form and the criteria for a C2 level application.

Timeframes for the evaluation

Our aim is to complete the evaluation 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.

Step 12 - Making the decision

When we complete the evaluation of your application to change an ARTG entry for your registered OTC medicine and prior to the decision:

- You may need to verify the accuracy of the details of the application, including any changes that may have been made during the evaluation.

The decision maker (the delegate of the Secretary) reviews all documentation associated with the application, including:

- the application and submission dossier
- any evaluation reports
- responses to any requests for information
- advice from expert advisory committees
- other relevant advice or information.

The delegate considers the matters detailed in the relevant section of the *Therapeutic Goods Act 1989*:

- Safety related requests (SRR); subsection 9D(2).
- Self-assessable requests (SAR); subsection 9D(1) or subsection 9D(3).
- Approvable changes (A); subsection 9D(3) or section 25 for applications made under section 23.

Once the decision is made we will send you a written notification of the decision (Step 13).

Changes processed as notifications

After a notification application is successfully submitted and the fees are processed, a computer program automatically makes the approval for the Secretary.

An acknowledgement email is then sent that informs the sponsor that a decision has been made to vary the medicine as requested.

Step 13 - Finalising your application

Decision to vary the entry on the ARTG

If the decision is to change the entry in the ARTG for your OTC medicine, under section 9D of the *Therapeutic Goods Act 1989*, you will receive the decision letter. For changes processed as notifications, this decision letter will be automatically generated once payment has been processed.

Decision not to vary the entry on the ARTG

If the decision is not to vary the entry in the ARTG, the decision letter will include both:

- a statement of the reasons for the decision
- information on your rights to appeal the decision. See TGA internal review guideline.

Applications made under section 23 of the Act

If your application included a change code corresponding to section 23 of the Act, go to Step 12 of the OTC medicine registration process for information on finalising your application.

Related information and guidance

- Standard and specific conditions of registered and listed therapeutic goods (Appendix 4 DR4)

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	OTC Medicines Regulatory Guidance	November 2015
V1.1	Update to steps 2, 8 and 9 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 steps to reflect the new notification process commencing 1 July 2017.	OTC Medicines Evaluation Section / Scientific Operations Management Section	June 2017
V1.3	Update step 13 of the process to include information on publishing PI/CMIs on the TGA website	Complementary and OTC Medicines Branch	August 2020

Therapeutic Goods Administration

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Reference/Publication #