



Australian Government

Department of Health

Therapeutic Goods Administration

# Registered complementary and OTC medicines application and submissions

## TGA Business Services (TBS) user guidance

Version 1.0, May 2020

**TGA** Health Safety  
Regulation



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# Introduction

The [TGA Business services](#) (TBS) portal provides an electronic facility for an application to register a complementary medicine (RCM) or over the counter (OTC) medicine on the Australian Register of Therapeutic Goods (ARTG). In relation to the TBS portal, RCM and OTC medicines are known collectively as 'Non-prescription medicines'.

Sponsors should have an understanding of the regulation of registered medicines in Australia and their legal obligations prior to preparing an application. For more information, refer to:

- [Applications for registered complementary medicines](#)
- [Australian regulatory guidelines for OTC medicines \(ARGOM\)](#)

## TGA business service portal (TBS)

To apply for a TGA client ID and access to the TBS portal, please see [TGA Business Services: getting started with the TGA](#). Information regarding the various 'roles' within TBS, can be found at [TGA Business Services - how to use the site](#) under [Roles: what each user can do](#).

The TBS portal can be accessed through your web browser using either - Internet Explorer, Google Chrome, Firefox or Safari.

## How to login

Once you have received your login details, log on to the [TBS portal](#). You will be prompted to enter your login details on the right hand side of the screen.



### For information:

Note that the user name and password are case sensitive.

Once logged in, you will see a personalised work page or 'dashboard'. What you can see and do on the dashboard will depend on your [user role](#) (access level).

TGA E business account for application processing (40185)

ABN:000000000000  
ACN:00000000

View my organisation

\$ My finances

View all invoices

My work

Work on drafts

View submissions

Welcome Jane Smith

What would you like to do today?

At the top of the dashboard, the main menus: **Application**, **Documents** and **Your TGA** are displayed. If you also have financial access, the **Financials** menu will be displayed.

From this screen you can:

- Access the '**My work**' menu to work on drafts or view submissions;
- Access the '**\$ My finances**' to view invoices;
- Access the '**News Panel**' to view the latest TGA news;
- Access the '**Work on drafts**' and '**View submissions**' to view all draft and submitted applications;
- View the '**Applications menu**' – the drop down will display all application types available;
- View the '**Documents menu**' – the drop down will display manufacturers, Consumer Medicine information and Product information;
- Access the '**View my organisation**' to edit user details;
- View the '**Your TGA menu**' – the drop down will display your current ARTG entries and other useful information.

# Creating a new RCM or OTC application

Select **Applications** from the top menu.



**Applications** (circled in red)

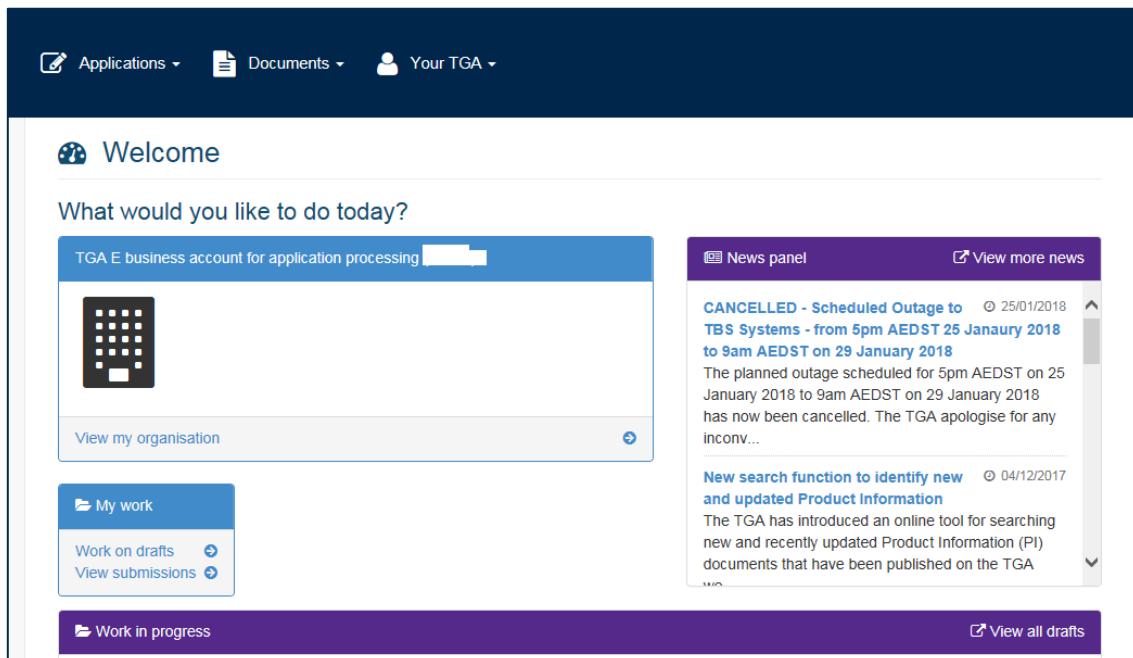
**Non-Prescription Medicines** (circled in red)

|  |  |   |   |  |
|--|--|---|---|--|
| <b>Adverse Event Reporting</b><br>Medicine Adverse Event<br>Medical Device Incident Reporting  | <b>Annual Charge Exemption</b><br>Manage my entries  | <b>Biologicals</b><br>Biological Application Submission   | <b>Listed Medicine</b><br>General Listed<br>Assessed Listed<br>General Composite Pack               | <b>Clinical Trials</b><br>Clinical Trial Notification Submission   |
| <b>Medicine Shortages</b><br>Notification Submission   | <b>Export Only Medicine</b><br>S.26 - Export Only<br>General Listing<br>Composite Pack<br>Change Multiple Current Listings                   | <b>Manufacturers</b><br>Certification Application<br>Clearance Application<br>Declaration<br>Licence Application  | Assessed Composite Pack<br>Substance Evaluation<br>Medicine Kit<br>Change Multiple Current Listings | <b>Medical Device</b><br>Device/OTG Application<br>Class III/AIMD Variation<br>Class 1-3 In-house IVD Notification<br>Manufacturer Evidence<br>Conformity Assessment<br>IVD Variation<br>Request Change<br>GMDN Help |
| <b>Non-Prescription Medicines</b><br>Non-Prescription Medicine<br>Non-Prescription Composite Pack<br>Change Multiple ARTC Entries<br>Substance Evaluation Submission<br>Welcome Page | Export Certificates<br>Listable Product (CLP)<br>Pharmaceutical Product (CPP)<br>Submission<br>Export Only<br>Solely for Export Certificates | <b>Prescription Medicine</b><br>Designation/Determination<br>Designation/Determination Extension<br>Pre-Submission<br>Single Medicine Application<br>Composite Pack Application Variation<br>Submission | Indication and Qualifier application<br>Label Information Submission<br>Welcome Page                | <b>Recalls</b><br>Recall/Non-Recall Submission   |
|  |  |   | <b>Regulatory Actions</b><br>ARTG entry Cancellation  |  |

Under Non-Prescription Medicine subheading, select either Non-Prescription medicine for a single medicine RCM or OTC application or Non-Prescription Composite Pack for a composite pack RCM or OTC application.

## Draft applications

Previously initiated draft applications, which have not been submitted, can be accessed by selecting '**Work on drafts**' from the **My Work** menu:



**Welcome**

What would you like to do today?

TGA E business account for application processing [REDACTED]

**View my organisation**

**My work**

- Work on drafts (selected)
- View submissions

**Work in progress**

**News panel**

View more news

**CANCELLED - Scheduled Outage to 25/01/2018**  
TBS Systems - from 5pm AEDST 25 January 2018 to 9am AEDST on 29 January 2018  
The planned outage scheduled for 5pm AEDST on 25 January 2018 to 9am AEDST on 29 January 2018 has now been cancelled. The TGA apologise for any inconven...

**New search function to identify new and updated Product Information**  
The TGA has introduced an online tool for searching new and recently updated Product Information (PI) documents that have been published on the TGA website.

View all drafts

The drafts window will open displaying a list of current draft applications. Click on the draft application you wish to continue editing.

To access other functions such as 'copy', 'delete' or 'print preview', select the arrow to the left of the application.



**For information:**

Note that draft applications are automatically deleted from the Portal if they have not been updated in the last twelve months. Once deleted, records are not retrievable.

## Navigating through an application

Once a new application type or draft has been selected, the application will open.

### Menu

There are two buttons above the Banner:

- **Application:** allows you to 'save' or 'close' an application. It also allows for validation once all necessary information has been entered;
- **Help:** provides definitions and information regarding each step of the application process.

The top right hand side in the Banner displays:

- **Application ID:** the unique application identification number for the application being displayed (generated when the form is first saved);
- **Status:** displays the current status of the application;
- **Client Reference:** a name that can be entered by the application in order to identify the current application and is not visible to TGA.

The screenshot shows a web-based application form for a Non-Prescription Medicine. At the top, there's a dark blue banner with the TGA logo and the text 'Non-Prescription Medicine application'. Below the banner, a navigation bar has tabs for 'Application', 'Registration', 'Manufacturers', 'Products', 'Supporting Information', 'Other Regulatory Requirements', and 'Changes Made'. The 'Application' tab is highlighted. The main form area has fields for 'Applicant Name', 'Billing Address', and 'Regulatory Correspondence Address', each with a red asterisk indicating it's required. In the top right corner of the form area, there's a status box showing 'Status: Draft' and 'Application Id: OM-2015-GL'. Below that is a 'Client Reference' field containing the text 'Client reference, not seen by TGA'. A red circle is drawn around the status and application ID area.

### Tabs

There are a number of tabs below the Banner:

The screenshot shows a horizontal row of tabs below the banner. The tabs are labeled 'Application', 'Registration', 'Manufacturers', 'Products', 'Supporting Information', and 'Other Regulatory Requirements'. The 'Application' tab is highlighted with a blue border, while the others are in a lighter grey. This is consistent with the screenshot of the application form above, where the 'Application' tab is also highlighted.

- **Application:** This tab contains general information relating to the application, including: applicant contact details and application type;
- **Registration:** This tab contains general product information such as: product name, product code;
- **Manufacturers:** This tab contains manufacturer details and nominated manufacturing steps;

- Products:** This tab contains specific information relating to the product including: route of administration, dosage form, container specifications, ingredients, indications and warnings;
- Supporting Information:** Supporting information can be uploaded;
- Other Regulatory Requirements:** This tab displays regulatory information after validation;
- Changes made:** This tab appears after validation when the application is to change an existing ARTG entry. All changes that are made to the application will be displayed on this tab and should be reviewed before submitting.

## Required fields

A red asterisk next to a field indicates that it is mandatory.

A grey asterisk indicates a conditional mandatory field (the field must be completed if certain conditions are met).

\* Always Required \* Required under certain conditions

Route of Administration: \* Add Remove

Dosage Form: \* Select a dosage form

Container Type: \* Select a container type

Container Volume: \* Enter a number Select a container volume

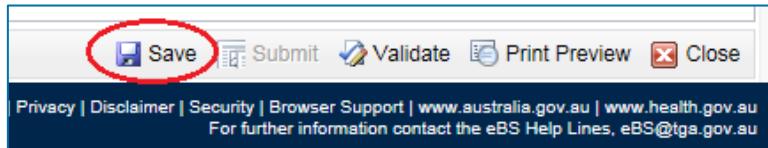
## Action toolbar

The action toolbar is located at the bottom right of the form.



## Saving a draft

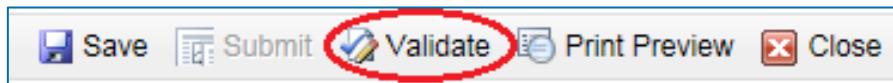
You can save a draft at any time by selecting **Save** in the action toolbar. It is recommended you save the application at regular intervals, to ensure no ongoing work is lost.



## Validation

The application must pass validation before it can be submitted.

Select **Validate**, located at the bottom right hand side of the form.



The validation process checks that all compulsory fields are completed, and that information is entered in the correct format.

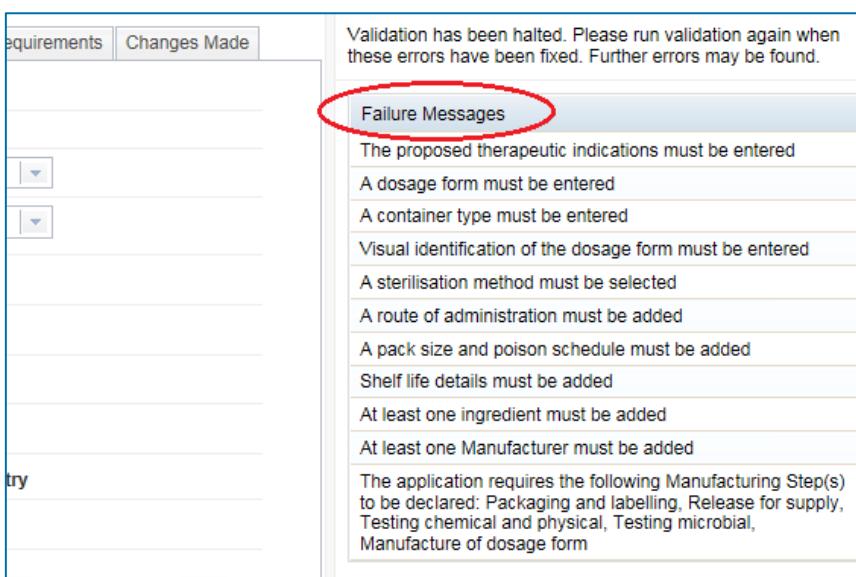
If there are no validation errors, the status of the form (top right of window) will change from **Draft** to **Passed Validation**.



The screenshot shows a software interface for an application form. At the top, there are two status indicators: 'Status: Passed Validation' and 'Application Id:'. Below these, a 'Client Reference' field is shown with the placeholder text 'Client reference, not seen by TGA'. A red oval highlights the 'Status: Passed Validation' text.

## Validation errors

If the form does not validate, the status will remain as **Draft**. The top right hand corner under Failure Messages, will display the fields you need to amend. You can double click on the message and the system will take you to the field where updating is required.



The screenshot shows the same software interface as above, but with validation errors. The 'Failure Messages' section is highlighted with a red oval. It lists several required fields that have not been entered: 'The proposed therapeutic indications must be entered', 'A dosage form must be entered', 'A container type must be entered', 'Visual identification of the dosage form must be entered', 'A sterilisation method must be selected', 'A route of administration must be added', 'A pack size and poison schedule must be added', 'Shelf life details must be added', 'At least one ingredient must be added', 'At least one Manufacturer must be added', and 'The application requires the following Manufacturing Step(s) to be declared: Packaging and labelling, Release for supply, Testing chemical and physical, Testing microbial, Manufacture of dosage form'. A message at the top right of the failure messages area states: 'Validation has been halted. Please run validation again when these errors have been fixed. Further errors may be found.'

Once you have corrected these fields, save the form and validate. Please note further validation errors may be displayed.

If you have issues with your application, please contact [Complementary medicines](#) for assistance.

## Printing, deleting, and copying

### Printing

You can print the application form at any time before or after submitting.

Prior to submitting the application, a copy can be found in the **Drafts** list, select the drop-down arrow located on the left hand side of the draft and **Print Preview**.

After submitting the application, a copy can be found in the **View Lodged Submissions** list, select the drop-down arrow and **Print Preview**.

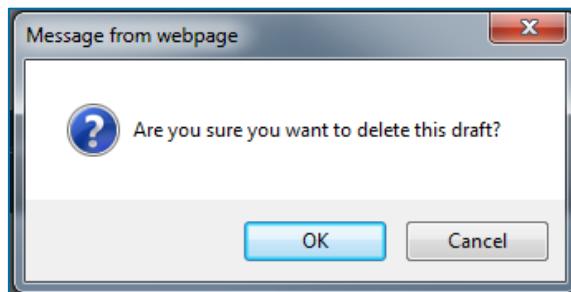
## Deleting

You can delete a draft application up until it has been submitted.

Select **View Drafts** in the navigation panel.

Select the drop-down arrow next to the draft application and **Delete**.

You will need to confirm that you want to delete the draft.



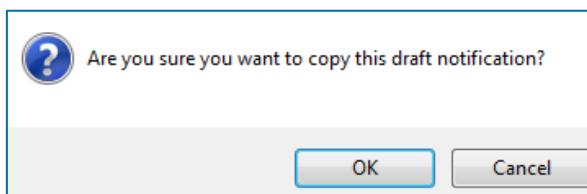
Select **OK** if you wish to proceed, or **Cancel** to go back to the **Drafts** list.

## Copying

You can copy any draft application to create an additional draft, which will retain all details previously entered.

Select **View Drafts** in the navigation panel.

Select the drop down arrow next to the draft application and **Copy**.



Select **OK** and a new draft application will be created. Selecting **Cancel** will take you back to the **Drafts** list.

## Submitting

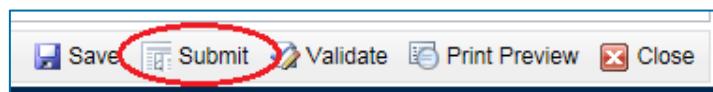


### For information:

It may be useful to make a [copy](#) of your application before submitting it.

This is for cases where you need to temporarily withdraw an application, as doing so removes all the originally submitted information.

Once validation has been successful, the **Submit** button will become available and can be accessed in the action toolbar.



## The Declaration

After selecting the **Submit button**, the Declaration page will be displayed. Read the declaration and either select the 'Agree' or 'Disagree' button.



Note: by selecting '**Agree**', you declare that the information given in the application is correct.

Therapeutic Goods Administration | Declaration

**Declaration**

The product names stated on the labels of the therapeutic goods which are the subject of this application are:

Product Name:

Sponsors Business Name:

Sponsors Business ID:

I (Your name) being a person authorised to make this application hereby certify that:

The information supplied in this application and all supporting data supplied to the TGA in connection with this application is true and accurate to the best of my knowledge and belief.

Any Category C ruminant ingredients included in this product have been 'self-assessed' in accordance with the TGA's self-assessment process.

I note the Therapeutic Goods Act 1989 provides penalties for making statements that are false and misleading in or about therapeutic goods.

**Assurances**

I hereby declare by clicking on the 'AGREE' button below that the information given in this application and the above statements are true and accurate.

Full name of signatory:

Date:

## Finalise the submission

Selecting **Agree** takes you to the submission step, which allows you to:

- confirm submission details;
- add comments in relation to other related submissions and special instructions;
- see the total fee (application + evaluation fee).

Therapeutic Goods Administration | eBusiness Services

**Submit Application**

**Submission**

Submission Selected:

Submission Number: 123456

Client Name: Example

Applicant Billing Address: \*

Application Fee: \$1,445

Evaluation Fee: \$9,665

Total Fee: \$11,110

Apply for concurrent application fee:  Yes  No

Parent submission relating to concurrent fee: No Submissions Available

Other related submissions:

Comments in relation to other related submissions:

Special Instruction:

Once completed, select **Submit** (bottom right-hand corner of the form). The **Checklist** will be displayed for you to review.

Therapeutic Goods Administration | eBusiness Services

**Application Information**

**Checklist**

The product names stated on the labels of the therapeutic goods which are the subject of this application are:

|                         |         |
|-------------------------|---------|
| Product Name:           | Example |
| Client Name:            | Example |
| Sponsors Business Name: |         |
| Sponsors Enterprise ID: | 00000   |

Applications in this Submission:

|      |
|------|
| Name |
|------|

Enquiries can be made to 02 6232

If the information is correct, select **Submit** at the bottom right-hand corner.

A notification page will be displayed which:

- confirms a successful submission;
- provides your submission number;
- gives instructions for accessing your invoice.

## View lodged applications

From the TBS dashboard, there are two ways to access your submissions list:

- Select **View submissions** from the **My work** menu
- Select the **Submissions** tab in the **Work in progress** list, then select **View all submissions**

Applications ▾ Documents ▾ Your TGA ▾

**Welcome**

What would you like to do today?

Example Pharma



[View my organisation](#)

**My work**

[Work on drafts](#) [View submissions](#)

**Work in progress**

| Received        | Identifier      | Workflow status | Description | Product name | Sponsor        |
|-----------------|-----------------|-----------------|-------------|--------------|----------------|
| 01 January 2015 | OM-2015-00000-1 | Under Review    |             | Example med  | Example Pharma |

**News panel** [View more news](#)

**Login issues after nominating your password** 03/09/2015

Some TBS users are experiencing issues with logging in to the TBS portal after successfully nominating a new password. If after successfully nominating...

**Special 1 July edition of the TGA Update** 01/07/2015

New and updated information on ACE The TGA has published new and updated information on the annual charge exemption (ACE) scheme Clinical trials: New ...

**View all submissions**

From the navigation panel, select **View Lodged Submissions**:

You can view submitted application by selecting the drop-down arrow located on the left hand side of the application and select **Print Preview**.

## Complete an online non-prescription application form

The information below will assist you in providing the required information for completing (and submitting) an online application for an RCM or OTC medicine. The same application is used for both a new ARTG entry or changing an existing ARTG entry).



### For information:

This guide is set up to walk you through this application in sequence.

Ensure you complete **ALL fields**, indicating 'nil' or 'not applicable' if required.

## Application details tab

### Applicant name

Pre-populated based on the TBS logon ID used.

### Sponsor Name

If your organisation is authorised as an agent for other organisations in TBS, you will be able complete an application on behalf of a sponsor.

### Billing address

Select the address for the sponsor from a drop-down list.

### Regulatory correspondence address

Select the address for the sponsor from a drop-down list.

## Contact person

Enter the contact person for this application.

## This application is to:

This field defaults to '**Create a new ARTG entry**'. You will need to select change a current ARTG entry if you wish to update an existing ARTG entry. Selecting this will display additional fields that will need to be completed.

## Select application type: new non-prescription medicine

### Application types:

- Registered complementary medicine application types will be prefaced with 'RCM'. For example, RCM1 or RCM5.
- OTC medicine applications will be prefaced with 'N'. For example, N1 or N5.

Non-prescription medicine applications are categorised according to risk. For information on the levels for non-prescription medicine applications and examples, see:

### RCM1 and N1 Category type

If you select the application type RCM1 or N1, an additional field (**Parent**) will appear requiring you to select the AUST R number of the fully evaluated parent medicine.

|  |  |
|--|--|
| This application is to:                                    | <input type="radio"/> Change a current ARTG entry <input checked="" type="radio"/> Create a new ARTG entry   |
| Select application type:                                   | * RCM1   |
| Parent:  | * AUST R: <input type="text"/> <input type="button" value="Search"/>   |
| Application Type:  | RCM1<br><small>For complementary medicines that are identical to fully evaluated and registered complementary medicines other than its name, and/or colour and/or flavour and/or fragrance. Section 23</small> |
| Payment Exemption No.:                                     | <input type="text"/>   |
| Is the product intended to replace an existing ARTG entry? | <input type="radio"/> Yes <input checked="" type="radio"/> No  |

|  |   |
|--|---|
| This application is to:                                    | <input type="radio"/> Change a current ARTG entry <input checked="" type="radio"/> Create a new ARTG entry  |
| Select application type:                                   | * N1 <input type="button" value="Select N application types for Over-The-Counter Medicines and RCM application types for Registered Complementary Medicines"/>  |
| Parent:  | * AUST R: <input type="text"/> <input type="button" value="Search"/>  |
| Application Type:  | N1<br><small>HELP: Enter the AUST R number of the parent product. DO NOT press 'Search' if you are cloning another sponsor's product or if submitting an application for a flavour/fragrance/colour variant. Press the 'Search' button ONLY if the proposed product is a clone AND shares the same sponsor as the parent. APPLICATION TYPE: OTC Clone or Flavour/fragrance/colour variant. An application to register an OTC medicine that is classified as an NT application in accordance with the 'OTC Application Categorisation Framework' and 'OTC new medicine NT applications'. This is an application under Section 23</small> |
| Payment Exemption No.:                                     | <input type="text"/>  |
| Is the product intended to replace an existing ARTG entry? | <input type="radio"/> Yes <input checked="" type="radio"/> No   |

### For information:

The Parent AUST R number needs to be entered for all RCM1 or N1 applications. By selecting the Search button for the Parent the application will be auto populated.



Please note that the search button can only be used if the Parent is owned by the applicant. If not, you will need to manually enter the individual fields of the application.

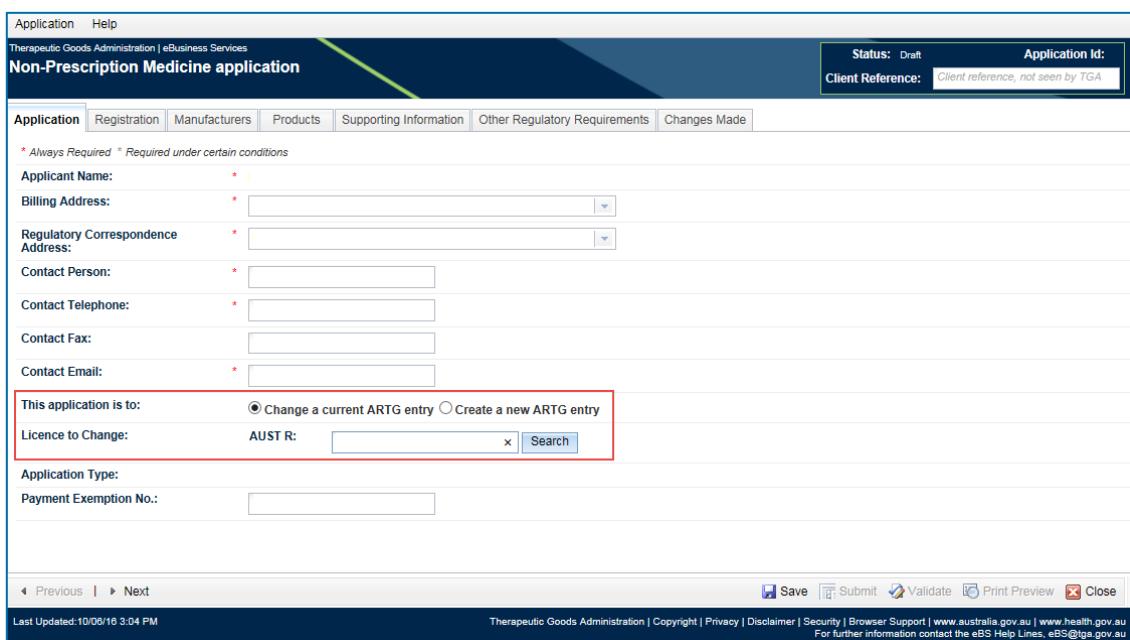
## Changes to registered complementary medicine

Applications to change an ARTG entry for a complementary medicine are categorised into five levels (CN to C4 for OTC medicines and RCM-CN to RCM-C4 for RCM) based on increasing risk. The application levels determine approval, data and assurance requirements as well as applicable fees.

For information on determining the change types for your medicine, refer to:

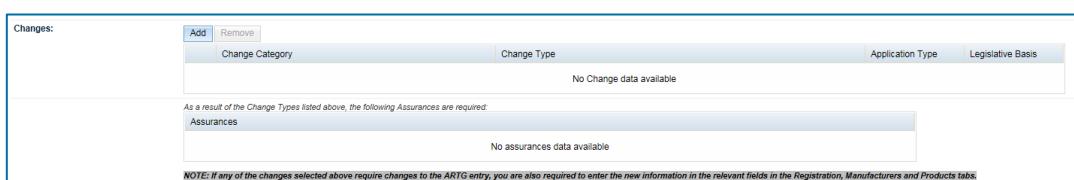
- [Changing a registered complementary medicine: Application levels and change tables](#)
- [Changes tables for OTC medicines](#)

After you select **Change a current ARTG entry**, enter the ARTG number of the entry you want to change in the **Licence to Change** field and select **Search**.



The screenshot shows the 'Non-Prescription Medicine application' interface. The 'Changes Made' tab is selected. The 'Licence to Change' field contains 'AUST R:' and has a red box around it, with a 'Search' button next to it. The 'Changes' box is also highlighted with a red box. Other fields visible include 'Applicant Name', 'Billing Address', 'Regulatory Correspondence Address', 'Contact Person', 'Contact Telephone', 'Contact Fax', and 'Contact Email'. At the bottom, there are buttons for 'Save', 'Submit', 'Validate', 'Print Preview', and 'Close'.

The **Changes** box will be displayed.



The screenshot shows the 'Changes' window with an empty table. The columns are 'Change Category', 'Change Type', 'Application Type', and 'Legislative Basis'. A note at the bottom states: 'As a result of the Change Types listed above, the following Assurances are required: Assurances'.

Select **Add** and the **Change Detail** window will open.

Select the relevant **Change Category** from the drop-down list.

Change Detail

\* Always Required

Change Category:

Change Type:

Change Type Description:

Change Type Assurances:

Comments relating to this change:

Help Save Save & Close Close

Select the **Change Type** from the drop-down list.



Note: This list will only contain the change types relevant to the change category you have selected.

Change Detail

\* Always Required

Change Category:

Change Type:

Change Type Description:

Change Type Assurances:

Comments relating to this change:

Help Save Save & Close Close

Once the relevant **Change Type** have been select, the **Description** and **Assurances** fields will be pre-populated with the relevant information. You will be able to add comments.

Change Detail

\* Always Required

Change Category: \* Labelling (including package insert) and product detail changes

Change Type: \* LSC: Changes on label (signal headings, warning statements) in compliance with new SUSMP requirements, where the change in scheduling is to a lower SUSMP schedule where no such products have previously been approved as a complementary medicine.

Change Type Description: LSC: Changes on label (signal headings, warning statements) in compliance with new SUSMP requirements, where the change in scheduling is to a lower SUSMP schedule where no such products have previously been approved as a complementary medicine.

Change Type Assurances:

Assurances

05) No aspects of the labelling, PI, CMI, pharmaceutical data or other product details (including manufacturing process) have been changed or are to be changed, other than changes nominated in this application and those made in conformity with the 'Changes table'.

08) The change is in compliance with a requirement introduced in the most recent version or amendment of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

Comments relating to this change:

Help Save Save & Close Close

Select Save and Close.

Multiple change types can be added.

Changes:

| Change Category   | Change Type  | Application Type | Legislative Basis |
|---|--|------------------|-------------------|
| Labelling (including package insert) and product detail changes | LSC: Changes on label (signal headings, warning statements) in compliance with new SUSMP requirements, where the change in scheduling is to a lower SUSMP schedule where no such products have previously been approved as a complementary medicine. | C3-RCM           | Section 90(3)     |

As a result of the Change Types listed above, the following Assurances are required:

Assurances

05) No aspects of the labelling, PI, CMI, pharmaceutical data or other product details (including manufacturing process) have been changed or are to be changed, other than changes nominated in this application and those made in conformity with the 'Changes table'.

08) The change is in compliance with a requirement introduced in the most recent version or amendment of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

*NOTE: If any of the changes selected above require changes to the ARTG entry, you are also required to enter the new information in the relevant fields in the Registration, Manufacturers and Products tabs.*

Application Type: C3-RCM  
Payment Exemption No.:



### For information

After entering the changes codes you need to ensure that you make the actual change in your application.

## Payment exemption number

Exemption from payment is allowed in exceptional circumstance and only available upon written authorisation for TGA.

## Registration details tab

### Product name

For a new registration application, enter the product name as it is to appear on the ARTG, as follows:

#### For medicines with single active ingredients:

LABEL NAME + generic name of active + strength of active + dosage form + container type

### For products with multiple active ingredients:

LABEL NAME + dosage form + container type

For a change application, only amend this field if proposing a change to the proprietary name.

## Export names

To add export names, select **Add**. A free text box is displayed and the export name(s) can be entered. Multiple export names can be entered.

The screenshot shows the 'Non-Prescription Medicine application' interface. In the 'Export Names' section, there is a table with a single row. The first column is 'Export Name' and the second column is 'Action'. The 'Action' column contains 'Add' and 'Remove' buttons. The 'Add' button is highlighted with a red circle and a red arrow points from it to a modal dialog titled 'Export Name Detail'. The dialog has a single input field for 'Export name' and standard buttons for 'Help', 'Save', 'Save & Close', and 'Close'.

## Manufacturer details tab

For change applications, this tab will be pre-populated with the details of the existing ARTG entry.

## Manufacturers

To add manufacturers, select **Add**. The manufacturer details box will be displayed.

The screenshot shows the 'Non-Prescription Medicine application' interface. In the 'Manufacturers' section, there is a table with a single row. The first column is 'Manufacturer' and the second column is 'Manufacturing Steps'. The third column is 'Location'. The 'Manufacturer' column contains 'Add' and 'Remove' buttons. The 'Add' button is highlighted with a red circle and a red arrow points from it to a modal dialog titled 'Manufacturer Details'. The dialog has fields for 'Manufacturer' (with radio buttons for 'Australian' and 'Overseas'), 'Context' (with radio buttons for 'Name', 'Manufacturer ID', and 'Licence ID'), and a search input field with 'Search' and 'Close' buttons.

Enter part, or all of a manufacturer's names or ID and select Search.

Details of the manufacturer will be displayed.

\* Always Required \* Required under certain conditions

Manufacturers: \*

Add Remove

| Manufacturer | Manufacturing Steps | Location |
|--------------|---------------------|----------|
|--------------|---------------------|----------|

**Manufacturer Details**

\* Always Required \* Required under certain conditions

Name: \* Manufacturer name

Manufacturer Site: \* Manufacturer site

Clearance/Licence ID: MI-2016-CL-example-1

Steps performed by this manufacturer:

- \*  API - Active pre-mix
- Manufacture of dosage form
- Packaging and labelling
- Release for supply
- Secondary packaging
- Sterilisation
- Testing chemical and physical
- Testing microbial

Help Save & Close New Search Close

Select the 'Steps performed by this manufacturer' and **Save & Close**.

To remove manufacturers, select the check box next to the entry you wish to delete, and **Remove**.

## Product details tab

For change applications, the fields in this tab will be pre-populated with the information from the existing ARTG entry.

## Proposed therapeutic indications

Enter the proposed indications for the medicine.

## Additional appliance

Include details if your product contains an additional appliance, e.g. a measuring device.

## Dosage form

A dosage form can be selected from the drop-down list or begin entering your proposed dosage form, which will then display a filtered list of possible options from the available list.

## Visual identification of dosage form

Enter the medicine's visual appearance (visual ID), as specified in the medicine's Finished Product Specifications document, for example:

- white, circular, biconvex tablets.

## Route of administration

A route of administration can be added by selecting **Add**.

You can either select a route from the drop-down list or begin entering your proposed route, which will then display a filtered list of possible options from the available list. Multiple routes of administration can be selected.

## Is the product supplied sterile?

For 'is the product supplied sterile?', select **Yes** or **No**.

If **Yes**, select the relevant 'method(s) of sterilisation' from the drop down list. You can also begin entering the sterilisation method, which will then display a filtered list of possible options.

If you have selected **No**, the 'method(s) of sterilisation' will be hidden.

Is this product supplied sterile? \*  Yes  No

Method(s) of Sterilisation: \*

Ingredients: \*

## Ingredients

To add ingredients, select **Add** to open the **Ingredient** search box.

Ingredients:

Container Type:

Product Container and Shelf life details:

Pack Size and Poison Schedule:

No Ingredient data available

Ingredient

Search Formulation Type: \*  Active  Excipient  Starting Material not present in Final Product

Search Ingredient Role: \*  Standard  Proprietary Ingredient

Search By:  Name  Proprietary Ingredient by ID

Ingredient Name: \*

Or,

Enter a proposed Ingredient Name:

In the **Ingredient** search box, select the appropriate **Formulation Type** and **Ingredient Role**.

- Select search by **name** or **proprietary ingredient by ID**
- Enter either:
  - **Ingredient Name**
  - **proposed ingredient name**
- If you are searching for an ingredient name, enter your search term and select **Search**. This will open the **Ingredient** details box, and enter required fields.

Always Required \* Required under certain conditions

Ingredient Name: \*

Formulation Type: Active

Ingredient Role: Active

Specification: \*

Ingredient Quantity: \*

Is this Ingredient of human or animal origin? \*  Yes  No

Component:

| Substance Name              | Ingredient Qty |
|-----------------------------|----------------|
| No Component data available |                |

If a component needs to be added, select **Add** in the **Component** section. This will open the **Add Equivalent** search box to either search for a component, or enter a proposed component name.

When searching for a component (for example, pollen), you can enter either a full or partial term to search.

Once your component name is selected, enter the quantity of the component and Save.

Additional components can be entered. When completed **Save & Close**.

## Container type

Container types can be selected from the drop-down list.

## Product container and shelf life details

Select **Add** to open the **Product Container and Shelf life details** box.

The following details can be added:

- Container material
- Container closure

- Container condition
- Product shelf life
- Product storage conditions
- Additional shelf life information

When completed select **Save & Close**.

## Pack size and poison schedule

Select **Add** to open the **Pack Size and Poison Schedule details** box.

**Pack size:** Select the **Help** button for information on pack sizes.

**Poison schedule:** Select from the drop-down list.

When completed select **Save& Close**.

## Supporting information tab

Supporting information should be attached as a single zipped file or sent separately. The size of an attached file is limited to 100 megabytes.

The screenshot shows the 'Supporting Information' tab selected in a software interface. Below it, a sub-dialog box titled 'Attachment Details' is open. The dialog contains fields for 'Description' and 'Supporting Document', both marked with a red asterisk as required fields. A note at the top of the dialog states: '\* Always Required. NB: There is an individual file size limit of 100 MB.' At the bottom of the dialog are 'Help', 'Save & Close', and 'Close' buttons.

### Description

Title of the document is entered.

### Supporting document

Selecting the **Browse** button will open a window that will allow you to search and select the relevant file to upload.

Select **Save & Close** to attach the file to your application.

## Invoice and payment

Once you have submitted your application, an invoice will be created that comprises of:

- an application fee (non-refundable)
- a pre-determined base evaluation fee (refer to [Summary of fees and charges](#)).

Options on how to make your payment, refer to [Payment options](#).



#### Important:

Your application will not proceed until both the application fee and base evaluation fees have been paid and the supporting information has been received.

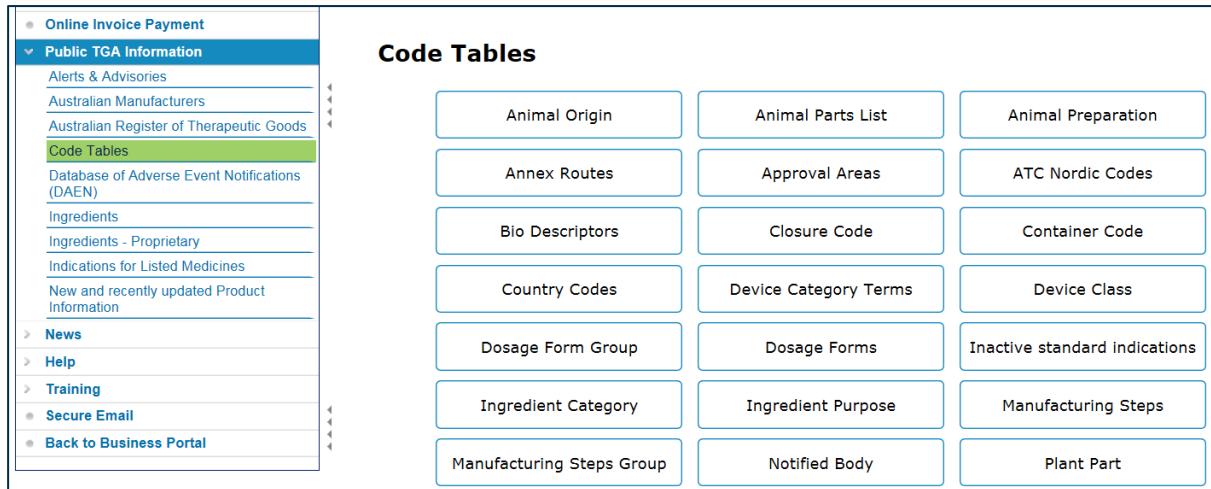
## Preparing to make an application

Useful information for preparing your application can be found in the TBS portal under '**Public TGA information**'. These include:

- Code Tables
- Ingredients
- Ingredients – Proprietary

## Code tables

The code tables provide terminology for use in product applications. Data in certain drop-down lists in a RCM or OTC medicine application is populated from Code Tables. Sponsors can view this information prior to creating an application by selecting the '**Code Tables**' in the TBS navigation panel.



The screenshot shows the TBS navigation panel on the left and a grid of code tables on the right. The navigation panel has a sidebar with links like 'Online Invoice Payment', 'Public TGA Information' (which is expanded), 'Alerts & Advisories', 'Australian Manufacturers', 'Australian Register of Therapeutic Goods', 'Code Tables' (which is selected and highlighted in green), 'Database of Adverse Event Notifications (DAEN)', 'Ingredients', 'Ingredients - Proprietary', 'Indications for Listed Medicines', 'New and recently updated Product Information', 'News', 'Help', 'Training', 'Secure Email', and 'Back to Business Portal'. The main content area is titled 'Code Tables' and contains a 4x3 grid of boxes, each representing a code table: Animal Origin, Animal Parts List, Animal Preparation; Annex Routes, Approval Areas, ATC Nordic Codes; Bio Descriptors, Closure Code, Container Code; Country Codes, Device Category Terms, Device Class; Dosage Form Group, Dosage Forms, Inactive standard indications; Ingredient Category, Ingredient Purpose, Manufacturing Steps; Manufacturing Steps Group, Notified Body, Plant Part.

Code Tables that are most useful for preparing a registered non-prescription medicine application are:

- Dosage Forms
- Dosage Form Group
- Manufacturing Steps
- Manufacturing Steps Group



### For information

Note the Code Tables display information for all type of applications e.g. Listed medicines, Non-Prescription Medicines and Prescription Medicines. Therefore, some of the information found in the Code Tables is not applicable to a RCM or OTC medicine application.

## Manufacturers

RCM and OTC medicines must be manufactured in accordance with [Good Manufacturing Practice \(GMP\)](#) (unless they are [exempt from manufacturing requirements](#)).

You must ensure that your manufacturer has a licence or clearance for the steps of manufacture required for your type of medicine and dosage form.

## Manufacturing steps

There are eight manufacturing steps that can be included in a registered non-prescription medicine application. Five of these steps are mandatory in all applications. The other steps must be included in the medicine application in certain situations. Each step can be undertaken by more than one manufacturer but all mandatory steps must be covered by a manufacturer.

| Manufacturing step            | Mandatory                               |
|-------------------------------|---|
| Manufacture of dosage form    | Yes                                     |
| Packaging and labelling       | Yes                                     |
| Release for supply            | Yes                                     |
| Secondary packaging           | No                                      |
| Testing chemical and physical | Yes                                     |
| Testing microbial             | Yes                                     |
| API – Active pre-mix          | No (except when using an active premix) |
| Sterilisation                 | No (except when the product is sterile) |

The system will not validate and consequently not allow the medicine to be registered if the manufacturer does not hold a valid licence/certificate with the exact manufacturing step match, unless they have been licenced for a manufacturing step group which contains the specific step.

Further information about what is covered by a particular manufacturing step group or dosage form group can be found in the relevant [TBS Code Table](#).

## Manufacturer's GMP Licence or Clearance – Product Details

The product details of the manufacturer's licence/clearance will specify the dosage form, product category and manufacturing step that the manufacturer is able to conduct.

For RCM and OTC medicines:

- The product category must be 'Registered Therapeutic Good'.
- The manufacturing step must be one of the eight described in the above manufacturing step table or be a manufacturing step group that includes one of the seven described steps.

For example, the 'Finished Product Manufacturer' group includes the following individual manufacturing steps: 'Release for supply', 'Secondary packaging', 'Manufacturer of dosage form', 'Testing chemical and physical', 'Testing microbial' and 'Packaging and labelling'.

'Active material manufacture' is not a manufacturing step group and it is an individual manufacturing step that does not work in non-prescription medicine application form.

- The Dosage Form in your GMP licence or clearance must be one of the Dosage forms described in the below Dosage forms table or in a dosage form group which includes the dosage form that you intend to use in your medicine application.

## Dosage Forms

The dosage form is the pharmaceutical form in which a product is presented for therapeutic administration, e.g. tablet or cream. Select the dosage form that best suits the application being submitted from the drop down list. Descriptions of the dosage forms can be found in the Code Table for dosage forms.

In an application for a GMP licence or GMP clearance, single or group items can be selected. For example, the single dosage form 'Liquids' or the group dosage form 'Liquids Group'.

Dosage forms that can be used in a registered non-prescription medicine application are:

| Dosage form                       | Dosage form           |
|-----------------------------------|-----------------------|
| Application                       | Ear Drops, suspension |
| Bar, soap                         | Enema                 |
| Block                             | Essential Oil         |
| Capsule, enteric                  | Extract               |
| Capsule, hard                     | Extract, concentrated |
| Capsule, modified release         | Extract, dry          |
| Capsule soft enteric              | Extract, liquid       |
| Capsule, soft                     | Extract, soft         |
| Cream                             | Eye Drops             |
| Collodion                         | Eye Drops, emulsion   |
| Drug delivery system              | Eye Drops, powder     |
| Drug delivery system, ocular      | Eye Drops, solution   |
| Drug delivery system, transdermal | Eye Drops, suspension |
| Diluent, not applicable           | Eye Ointment          |
| Dressing, medicated               | Eye and Ear Drops     |
| Ear Drops                         | Eye and Ear Ointment  |
| Ear Drops, emulsion               | Gel                   |
| Ear Drops, powder for             | Gel, eye              |
| Ear Drops, solution               | Gel, modified release |

| Dosage form                | Dosage form               |
|----------------------------|---------------------------|
| Granules, effervescent     | Oral Liquid, powder for   |
| Granules, enteric-coated   | Oral Liquid, solution     |
| Granules, modified release | Oral Liquid, suspension   |
| Granules                   | Oral Liquid               |
| Gum, chewing               | Oral Liquid, syrup        |
| Herb, dried                | Pad, impregnated          |
| Inhalation, conventional   | Paint, concentrated       |
| Inhalation, powder for     | Paint, powder for         |
| Inhalation, pressurised    | Paint                     |
| Inhalation                 | Paste                     |
| Insufflation               | Pastille                  |
| Liquid, multipurpose       | Patch, dermal             |
| Liquids, tinctures         | Pessary, compressed       |
| Liniment                   | Pessary, modified release |
| Lotion                     | Pessary, moulded          |
| Lozenge                    | Pessary, shell            |
| Mouthwash                  | Pessary                   |
| Nasal Drops                | Pill                      |
| Nasal Drops, emulsion      | Powder, dusting           |
| Nasal Drops, powder for    | Powder, dusting, sterile  |
| Nasal Drops, solution      | Powder, oral              |
| Nasal Drops, suspension    | Powder                    |
| Ointment                   | Solution, irrigation      |

| Dosage form             | Dosage form                   |
|-------------------------|-------------------------------|
| Solution, powder for    | Tablet, chewable              |
| Solution                | Tablet, dispersible           |
| Soluble Film            | Tablet, effervescent          |
| Spray, nasal            | Tablet, enteric coated        |
| Spray, pressurised      | Tablet, film coated           |
| Spray, solution         | Tablet, gelatin coated        |
| Spray, suspension       | Tablet, modified release      |
| Spray                   | Tablet, multilayer            |
| Stick, lip              | Tablet, orally disintegrating |
| Stick                   | Tablet, soluble               |
| Suppository, compressed | Tablet, sugar coated          |
| Suppository, moulded    | Tablet, uncoated              |
| Suppository, shell      | Tea                           |
| Suppository             | Tincture                      |
| Suspension, powder for  | Wafer                         |
| Suspension              | Wipe, medicated               |

## Ingredients of animal origin

All therapeutic goods containing products of animal origin must comply with the *Ph. Eur* general monograph 1483: Products with risk of transmitting agents of animal spongiform encephalopathies. The assessment for animal derived material must be against the principle and requirements detailed in the *Ph. Eur* monograph, and can be conducted:

- For low risk materials, by self-assessment; and
- For all other materials, by TGA evaluation.

Additional information can be found [Transmissible Spongiform Encephalopathies \(TSE\): TGA approach to minimising the risk of exposure](#).

You may need a pre-clearance prior to starting your application.

## Trouble shooting in the TBS portal

The TBS portal successfully processes a large number of applications each year; however, occasionally there are system errors that may occur from time to time.

If an application is not behaving in a manner you expect, please DO NOT submit the application. Instead, use this trouble shooting guide below to investigate the issues.

If you are unable to rectify the issue, contact [Complementary medicines](#) In your correspondence please include the following:

- application ID (located in the top right corner of your application)
- screen shot of the validation messages and relevant sections of the form
- details of the changes required (applicable to change applications only).

## Common IT issues

| Issue   | Suggestion   |
|---|--|
| When validating, there is an instant validation error.  | Stop the validation process and re-validate.   |
| The system is responding slowly or a jumbled screen has appeared.   | Clear the cache in the web browser.<br><br>Internet Explorer: Press CTRL-SHIFT and click on the refresh button in the address bar at the same time.<br><br>Firefox: Press Shift and click on the refresh button in the address bar at the same time.                                   |
| Your application fails validation.  | Read Validation error message carefully and correct the application as per instructions in the Validation message.<br><br>Double click on the validation error to be directed to the field that is affected.<br><br>You may need to check the requirements if the error is unexpected. |
| The following system error message appears<br>- “www.ebs.tga.gov.au says: An error occurred while updating some of the page...” | Try re-validating the application until the message disappears. If not contact the TGA via the above email.  |

| Issue  | Suggestion  |
|--|---|
| When validating an application the following error message appears stating information is required in a particular field, even though the information has been added to the application. | Remove the information, save and validate the application. Re-add the information, save and validate the application.   |
| The validation message appears – Manufacturer is not valid for dosage form.  | <p>Check the manufacturer's GMP licence or clearance and compare with the dosage form in the medicine application.</p> <p>The product dosage form must be an exact match with the Manufacturer's licence or clearance or be covered by a dosage form group.</p> <p>For example, tablet film-coated is covered by the dosage form group Solid Unit Dosage Forms – Tablets.</p> |
| Your application has validated successfully but when you select 'Submit' – the application field is blank.   | Ensure that the correct billing address and sponsor name has been selected on any filters.  |
| Your application does not appear in the submission window.   | After proceeding to Submission, if a window does not appear advising you of the cost and type of application, your application has not been submitted correctly. You should attempt to re-submit.   |
| Your draft application has disappeared from the system.  | <p>Draft application will remain in the system for 365 days. If the application has not been edited in that time, the system will automatically delete it.</p> <p>To prevent this, open the draft and select save.</p>  |

| Issue   | Suggestion  |
|---|---|
| Cannot find my medicine in the 'Change Multiple ARTG entries' form                                      | <p>Registered complementary medicines cannot be changed in the 'Change Multiple ARTG entries' form.</p> <p>Check that all medicines being changed are OTC medicines.</p> <p>There are limited changes that can be applied for through the 'Change Multiple ARTG entries' form:</p> <ul style="list-style-type: none"> <li>• manufacturing details</li> <li>• shelf life</li> <li>• visual identifier</li> <li>• labelling changes under section 9D<sup>1</sup> (where there is no change to the fields in the application form).</li> </ul> |
| One or more of the selected medicine did not pass validation in the 'Change Multiple ARTG entries' form | <p>All medicines must be current and pass validation before using the 'Change Multiple ARTG entries' form.</p> <p>You may need to submit separate applications for the medicines that did not pass and address the validation issues separately.</p>  |

<sup>1</sup> Changes under section 23 of the Act (known as 'grouping' changes) cannot be made through the 'Change Multiple ARTG entries' form. For further information, see [Changing an OTC medicine: using the Changes Tables](#).

## Version history

| Version | Description of change   | Author  | Effective date |
|---------|---|---|----------------|
| V1.0    | <p>Information extracted from ARGCM pages 122-147 to create standalone user guide. The guidance has also been amended to include references to OTC medicine applications as these medicines use the same on line application portal as RCM applications.</p> <p>Additional information provided on Code tables and common IT issues</p> | Complementary and over the counter medicines branch | May 2020       |

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D18-10618784