Australian Government
Department of Health
Therapeutic Goods Administration

Application and submission user guide

Listed and assessed listed medicines

Version 5.1, July 2021

TGA Health Safety Regulation

Contents

Introduction

The TGA Business services (TBS) portal provides an electronic facility for the listing and registration of medicines on the Australian Register of Therapeutic Goods (ARTG). There are two pathways for listing a medicine in the ARTG:

- AUST L listed medicines are listed in the ARTG after self-certification by sponsors that all legislative requirements are met;
- AUST L(A) assessed listed medicines are listed in the ARTG after self-certification of quality and safety of the product and pre-market assessment for efficacy evidence to support the product indications.

The Act allows for cancellation of a product from the ARTG if a sponsor's certification is incorrect.

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

- Australian Regulatory Guidelines for Listed Medicines and Registered Complementary Medicines
- Permitted ingredients for listed medicines guidance
- Permitted indications for listed medicines guidance
- Assessed listed medicines evidence guidelines

Accessing the TGA Business Services (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.

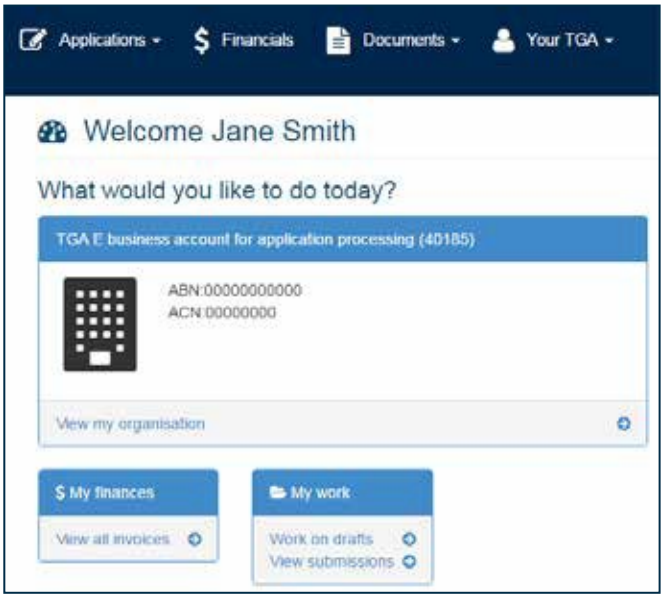
The TBS portal can be accessed through your web browser using either - Internet Explorer, Google, Chrome, Firefox or Safari.

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.

Note: 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).



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 new listed and assessed listed application

New applications

1. Select the application type from the drop down under the 'Applications menu'.
2. Under **Listed medicine** subheading the following options are displayed:
   - **General listed –** containing a single listed medicine made under section 26A of the Act;
   - **Assessed listed –** contains a single listed medicine made under section 26AB of the Act following assessment of efficacy;

- **General Composite pack** – allows for two or more medicine formulations to be included, forming a pack which is listed under section 26A of the Act;
- **Assessed composite pack –** allows for two or more medicine formulations to be included, forming a pack which is listed under section 26AB of the Act following assessment of efficacy;
- **Medicine kit** – enables two or more existing registered or listed medicines and an exempt good, to be grouped and sold together in a purpose built pack;
- **Change Multiple Current Listings –** allows for limited changes to be made to multiple general listed medicines.

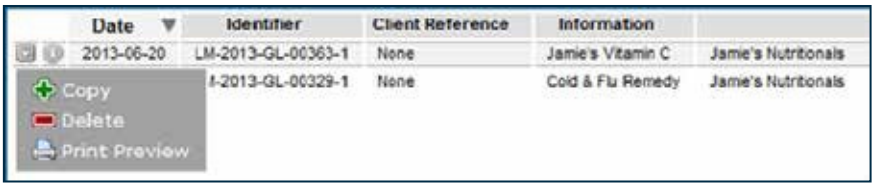
Select the appropriate application type from the list. The information required for each application type will vary slightly.

Draft applications

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

The Drafts window will open displaying a list of current draft applications. All types of listed medicines applications will be displayed in this window. 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.



NOTE: Draft applications are automatically deleted from the system if they have not been updated in the last twelve months. Once deleted, records are not retrievable.

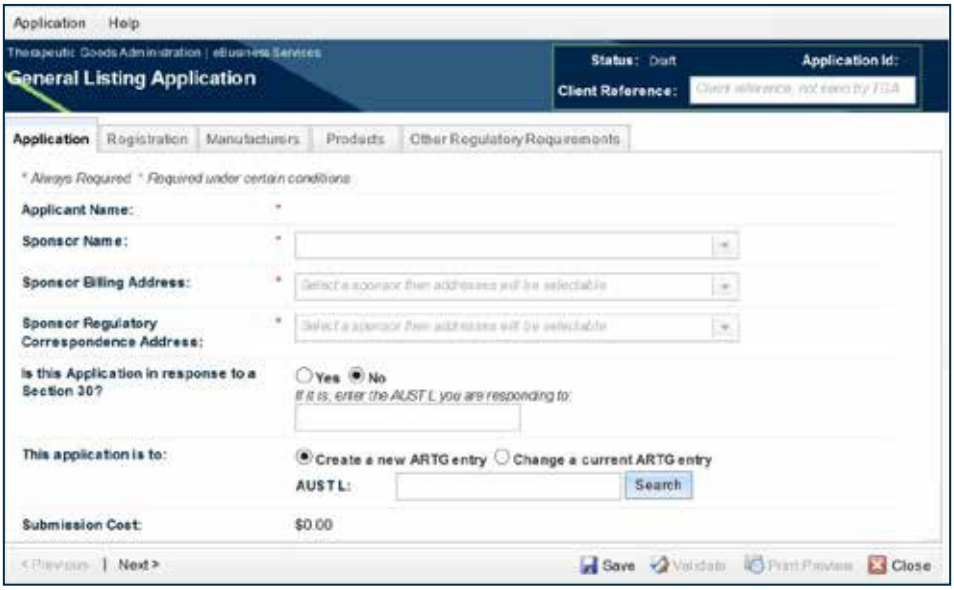
Navigating through an application

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

The Banner at the top of the application will display what type of application is being worked on. Types of listed medicine applications are:

- General Listed application;
- Assessed Listed application;
- General Composite Pack Application;
- Assessed Composite Pack Application;
- Medicine Kit Listing Application;
- Change Multiple Listings Application.

Each of the different applications will displayed fields that are appropriate for that application type.



Menu

There are two buttons above the Banner:

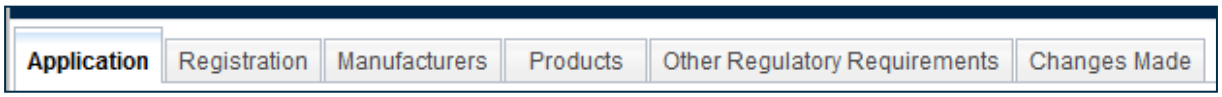
- Application: allows you to 'save' or 'close' an application. It also allows for validation once all necessary information has been entered;
- Help: provides definitions and information regarding each step of the application process.

The top right hand side in the Banner displays:

- Status: displays the current status of the application;
- Application ID: the unique application identification number for the application being displayed;
- Client Reference: name that can be entered by the application in order to identify the current application.

Tabs

There are a number of tabs below the Banner:

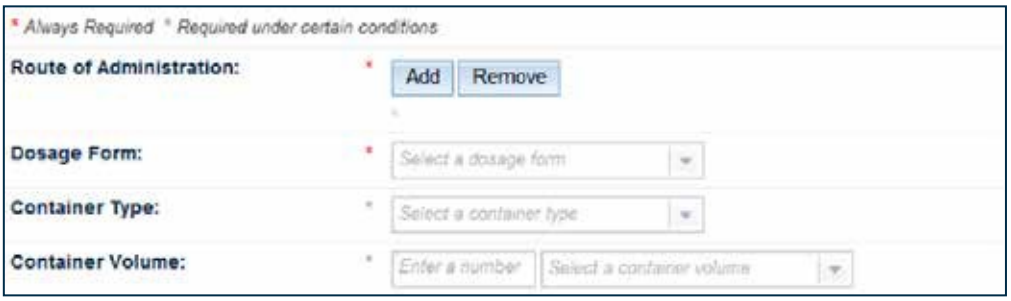


- Application: This tab contains general information relating to the application, including: applicant contact details and application type.
- Registration: This tab contains relating to general product information such as: product name, product code, and export names Manufacturers: This tab contains 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. It also includes subsection 26B(1) Notification (not required for assessed listed applications).
- Supporting Information: This tab is only displayed when the application type is an assessed listed medicine application type or a 9D(1) Variation to a general listed medicine. Supporting information can be uploaded here and in some cases is mandatory.
- 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).



Application tab

Field	Description
Applicant name	Displays your client name based on the log on ID used to access the TBS portal.
Sponsor name	This will be pre-populated unless you are an agent, then you can select the sponsor from the drop down list.
Sponsor Billing address	Select the preferred billing address for this product.
Sponsor Regulatory Correspondence Address	Select the sponsor address from the drop down list.
Who to contact for further information (Only appears if this application is for an assessed listed medicine or a 9D(1) variation to a general listed medicine)	Select the contact person from the drop down list. For agents, an additional radio button selection will be displayed. Select either the application or sponsor radio button and use the drop down list to select who TGA should contact in regard to this application.
Is this application in response to a Section 30	Select 'Yes' if this application is being submitted as a response to a Section 30 request. Enter the AUST L or AUST L(A)being responded to.
This application is to: Create a new ARTG entry or Change a current ARTG entry	Nominate whether this application is to change an existing ARTG listing or to create a new ARTG listing. Note: the default is 'Create a new ARTG entry'. For further information, refer to Varying or changing an existing product.
AUST L or AUST L(A)	Enter an AUST L or AUST L(A) for this application. If 'Create a new listing' is selected, this will create a copy of the existing medicine and will be listed with a new ARTG number.
Description of changes (Only appears if this application is for an assessed listed medicine or a 9D(1) variation to a general listed medicine)	Enter the details of the changes. Note: this should match the changes that are made to the details included on the Registration, Manufacturers and Products tab. For further information, refer to Varying or changing an existing product.
The following have the potential to impact efficacy, Are there any changes to these aspects? (Only appears if this application is to change an existing assessed listed product)	Select 'Yes' if the changes made will impact on the efficacy of the product. Select 'No' if the changes made will not impact on the efficacy of the product. For further information, refer to Varying or changing an existing product.

Field	Description
Are you submitting: (Only appears if this application is to change an existing assessed listed product)	From the drop down arrow, select either: Efficacy data Justification for not providing efficacy data No data/justification as the change does not have the potential to impact efficacy For further information, refer to Varying or changing an existing product
Is this a correction of an error under section 9D(1) of the *Therapeutic Goods Act 1989*? (Only appears if this application is to change an existing product)	Select 'Yes' if the variation to the product is due to incomplete or incorrect information at the time of listing. If you select 'Yes', you will be required to complete the 'Supporting information' tab. Note that you cannot submit other product changes (that are not product corrections) as part of the same application. You will need to wait until *after* the first application is finalised prior to preparing a second application. Select 'No' if the variation to the product is not due to incomplete or incorrect information. For further information, refer to Varying or changing an existing product.
Do you need to provide an updated label? (Only appears if this application is to change an existing assessed listed product)	Select 'Yes' if you need to supply an updated label. Select 'No' if you do not need to supply an updated label. For further information, refer to Varying or changing an existing product.
Submission cost	Displays the submission cost when the draft application has been validated.
Application Type	For general listed and general composite pack – the application type will be displayed when the draft application has been validated e.g. New, Grouping, Variation or ARTG correction. For assessed listed and assessed composite pack – you will need to select the application type from the drop down menu.
Payment exemption number	Enter a payment exemption number, if applicable, to notify TGA that payment is not required.

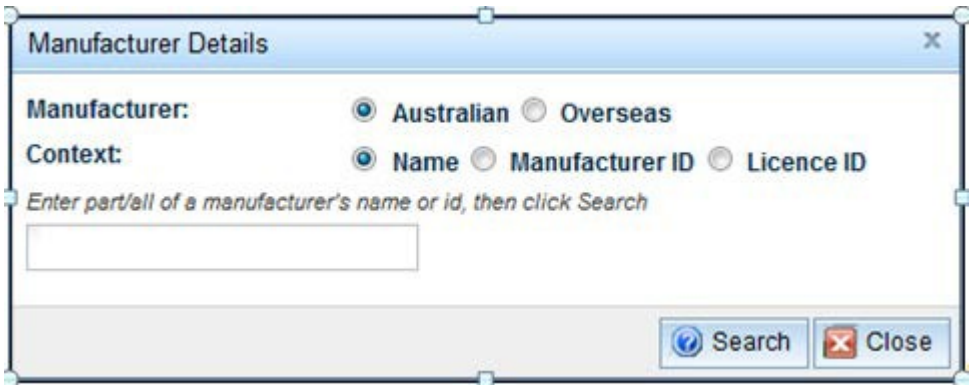
Registration tab

Field	Description
Product name	Enter the name of the product. This is the final product name that will be used if the product is listed on the ARTG.
Product code	Select the product code from the drop down list. For further information, see Preparing to make an application.
Export names	Select the 'Add' button to add export names. To remove export names, select the box beside the name you wish to remove and the 'Remove' button. Multiple export names can be added to a product.

Manufacturers tab

Adding a manufacturer

1. Select the **'Add'** button to open the **'Manufacturer Details'** form:



2. Select the location of the manufacturer; either **'Australian'** or **'Overseas'**.
3. Select either **'Name'**, **'Manufacturer ID'** or **'Licence ID'** for the search criteria.
4. Enter all, or part of the information and select the 'Search' button.

NOTE: If not enough information is entered, an error message stating **'Too many entries found. Please refine your search'** will appear.

5. Select the required **'Manufacturer name'** from the drop down list.
6. Select the **'Manufacturer location'** from the drop down list.
7. Select the steps performed by the manufacturer and **'Save'** to return to the manufacturing tab.

NOTE: The following five manufacturing steps are compulsory:

- Manufacture of dosage form
- Packaging and labelling
- Release for supply
- Testing: chemical and physical testing
- Testing: microbial testing

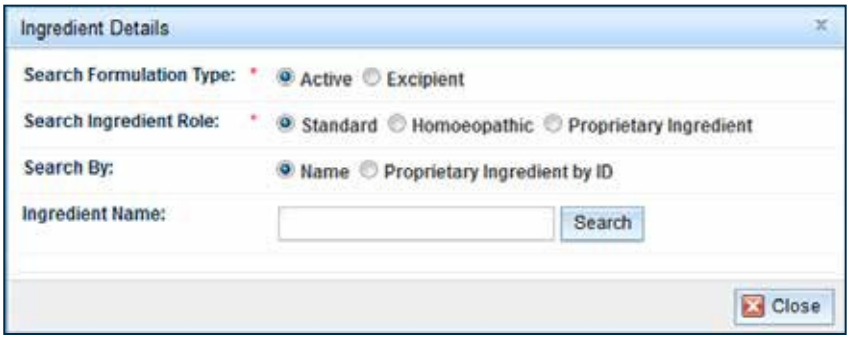
Each step can be undertaken by more than one manufacturer.

Products tab

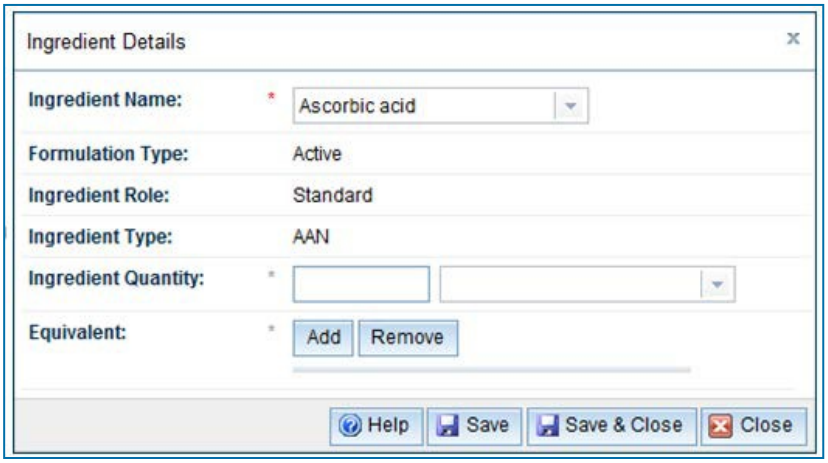
Field	Description
Route of administration	Select the 'Add' button to enter the route of administration. Multiple routes of administration can be entered.
Dosage Form	Select the dosage form from the drop down list.
Container type Container volume Container closure Container condition	Only required when the formulation contains ingredients which have been restricted to a 'container type', 'closure' or 'size limit'. Information can be entered into the correct field or selected from a drop down list.
Maximum single dose Maximum daily dose	Only required when restrictions apply. Enter the formulation's recommended maximum single or daily dose.
Minimum weight of divided dosage form	Only required when using a divided dosage form e.g. tablet and the formulation contains restricted ingredients.

Ingredients

1. Select the **'Add'** button to open the **'Ingredient details'** form:



2. Select the ingredient type, ingredient role, and enter the ingredient name. ProprietaryIngredients can be searched using their ID number.
3. Enter all, or part of the ingredient name and select the **'Search'** button.



4. The ingredient will be populated or you can select from the drop down list.
5. Enter the ingredient quantity and units from the drop down list.
6. Save and Close.

NOTE: Proprietary ingredients

Formulation details of **'Proprietary Ingredients'** are published on the 'ARTG public summary'. Active and Excipients are listed separately but in alphabetical order. and Active with quantities and equivalents..

'Active Proprietary Ingredients' require ingredient quantities to be entered. Some excipient **'Proprietary Ingredients'** such as flavours, fragrances and printing inks also require quantities to be entered, as the following limits apply to the final formulation:

- Flavour – 5%
- Fragrance – 1%
- Printing Ink – 0.1%

The following options are available in the ingredient details form. Note that only those fields applicable to the particular ingredient will be displayed.

Field	Description
Ingredient name	Select the ingredient from the drop down list.
Formulation type Ingredient role Ingredient type Proprietary ingredient ID	These fields are automatically populated based on the ingredients selected.
Ingredient quantity	Ingredient quantities are required for all active ingredients. Excipient ingredient quantities are currently not required unless they are AHNs or have restrictions. Enter the ingredient quantity and select the appropriate unit.
Equivalent	There are two instances where equivalents are used: Equivalent dry or fresh herbal material where the ingredient is a herbal preparation such as an extract, decoction or tincture. Mandatory components which are required to be declared in the application.

Field	Description
Homoeopathic ingredients	
Ingredient name	Select the ingredient from the drop down list.
Potency	Enter the potency of a homoeopathic ingredient.
Label name & potency	Enter the label name and potency values of a homoeopathic ingredient.
Diluent	Select the 'Add' button to add a diluent to the ingredient. Select appropriate diluents from the drop down list and enter the percentage. Multiple diluents can be added. Select the 'Diluents are not present in the final product' box if applicable.
Reference	Select the homoeopathic reference from the drop down list.
Essence ingredients	
Concentration of mother substance	Applicable when the ingredient role is 'Essence'. Enter the quantity and select the unit from the drop down list.
Manufacturer method	Applicable when the ingredient role is 'Essence'. Select the manufacturing methods from the drop down list.
Ingredients of human or animal origin	
Ingredient of human or animal origin	Applicable to AAN or ABN ingredients. A preclearance certificate issued by the TGA's Scientific Evaluation Branch may be required.
Animal origin	Select the country or countries of origin for the ingredient from the drop down list.
Animal type	Select the animal the ingredient is derived from the drop down list.
Animal part	Select the part of the animal from which the ingredient is derived from the drop down list.

Field	Description
Australian Herbal Name (AHN) ingredients only	
Plant part	Select the plant part from the drop down list.
Plant preparation	Select the plant preparation from the drop down list. Changing plant preparation may cause values in other fields to be automatically updated.
Equivalent preparation	Select the appropriate equivalent preparation from the radio buttons if required.
Equivalent quantity	Enter the amount of equivalent preparation to be used in the ingredient. Select the unit from the drop down list.
Final preparation ratio	Enter the final preparation ratio. The ratio will reverse depending on the preparation type selected.
New ratio	Applicable when the ingredient ratio requires updating. Enter the new ratio value then select the 'Update' button to the right of the ratio field.
Preparation steps	Select the 'Add' button to add a preparation to the ingredient. Multiple preparation steps can be added. Plant preparation: Select the plant preparation from the drop down list. This will automatically default to the plant preparation value previously selected on the parent ingredient page. Preparation ratio: Enter the ratio values if different to the original ratio entered on the parent ingredient. Plant preparation step: This is automatically generated by the system. Solvents: Select the 'Add' button to add a solvent. Multiple solvents can be added. Select appropriate solvents from the drop down list and enter the percentage. The total percentage must equal 100%. Select the 'Remainder water' box if applicable.
Remaining restricted solvent	Required if solvents are restricted. The solvent to be added must be the same as those used in preparation steps previously completed. Select the 'Add' button to add a 'Remaining restricted solvent' to the ingredient. Multiple solvents can be added. Residue Quantity: The upper limit (maximum amount) of solvent allowed in the specifications for the ingredient.
Carrier	A carrier is an excipient ingredient which may be included in an herbal ingredient. Select the 'Add' button to add a carrier to the ingredient. Multiple carriers can be added.

Indications

When creating a new general listing or composite pack you must select your indications from the list of **'permitted indications'** which is contained in the Therapeutic Goods (Permissible Indications) Determination. For more information, please see the Permitted indications in listed medicine guidance.

When creating a new assessed listed or assessed composite pack it is compulsory to enter a **specific indication**. Specific indications are intermediate level indications that exceed the permitted indications list but are not high level indications. Indications contained in the list of permitted indications can be entered but are not mandatory. For more information, please see the Assessed listed medicines evidence guidelines.

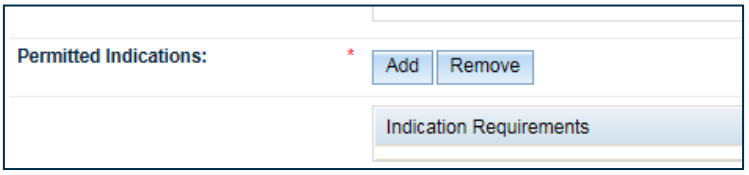
When creating a medicine kit listing, specific indications are compulsory. Permitted indications cannot be entered.

As a sponsor of a listed medicine, it is your responsibility to ensure that your product meets all the requirements for listing, including (but not limited to) holding evidence for all indications for your medicine. Similarly, you must hold evidence for all advertising claims you make, including the permitted indications for your advertised medicine.

Adding a permitted indication

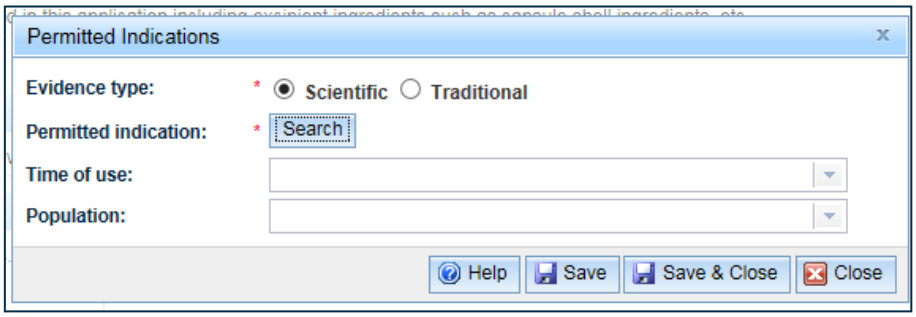
For more information on Permitted Indications, please see the Permitted indications in listed medicines guidance.

1. Select the **'Add'** button.



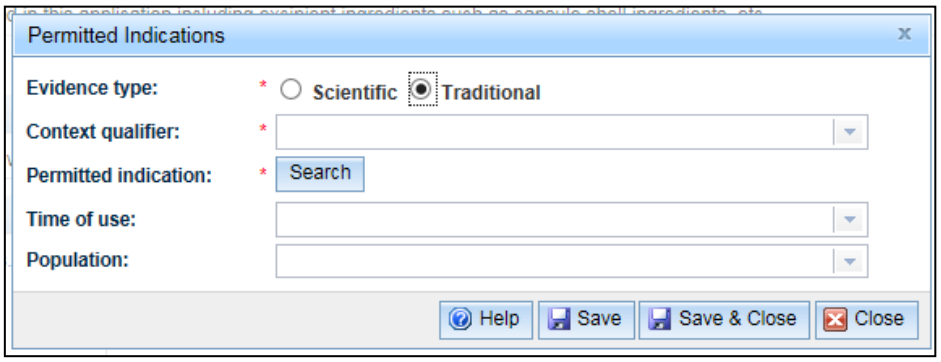
2. Select the **'Evidence type'** you hold to support your indications using the radio buttons. The results returned will be different depending on which evidence type you select.

   a. For '**Scientific evidence'** select the **'Scientific'** radio button and click '**Search**'.



   When **'Scientific evidence'** is selected, only indications which can supported by '**Scientific'** and '**Scientific and Traditional'** evidence will be returned in your search.

   b. For '**Traditional evidence**' select the '**Traditional**' radio button. A '**Context qualifier**' box will appear.



You need to enter a '**Context qualifier**' that specifies the traditional paradigm for the indication. Click the drop down arrow on the right hand side and make a selection from the drop down list and '**Save**'.

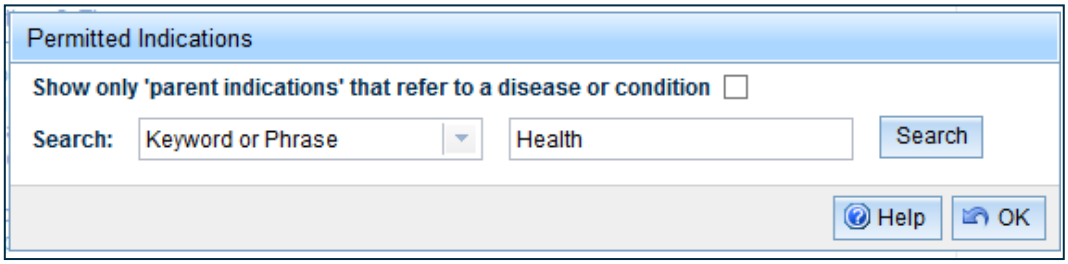
The search results are dependent on your '**Context Qualifier**' selection:

- For all traditional indication contexts qualifier, no indications which must be supported by '**Scientific**' evidence will be displayed.
- If you select the Ayurvedic medicine Context qualifier, only indications which can be supported by '**Ayurvedic**', '**Traditional**' or '**Scientific and Traditional**' evidence will be returned.
- If you select the Traditional Chinese medicine Context qualifier, only indications which can be supported by '**Traditional Chinese Medicine**', '**Traditional**' and '**Scientific or Traditional**' evidence will be returned.

Selecting the **Traditional Chinese medicine Context Qualifier** will also allow you to add a **TCM Pattern qualifier**. This is explained at **Step 7**.

- For all other traditional Context Qualifiers, only indications which can be supported by '**Traditional**' or '**Scientific and Traditional**' evidence will be returned.

3. Select the '**Search**' button and you will be taken to a new screen to search for permitted indications.



Note the permitted indications search field includes an option to '*Show only 'parent indications' that refer to a disease or condition'*. This is for use when you want to link symptom indications to a disease/condition. Refer to How to link indications.

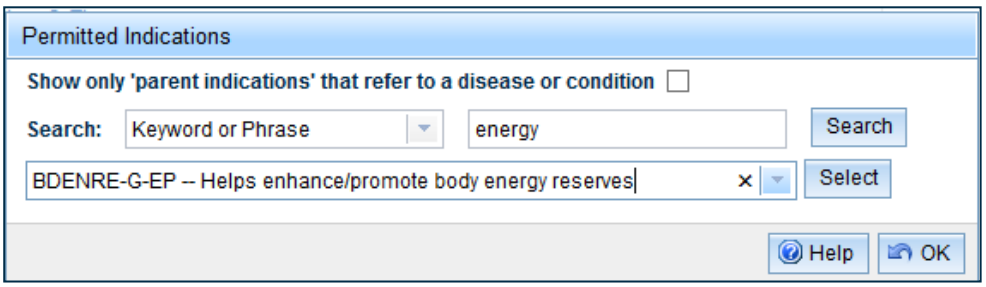
You can search for Permitted indications by:

- **Keyword** or **phrase**, e.g. 'energy';

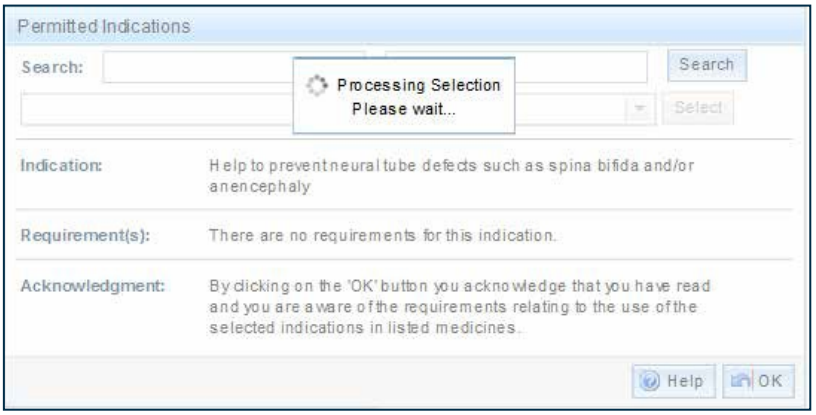
- **Body part/system**, e.g. 'heart';
- **Code**, e.g. 'CVHEHE-G-MS'.

Select a Search category, enter your search criteria in the second box and select '**Search**'.

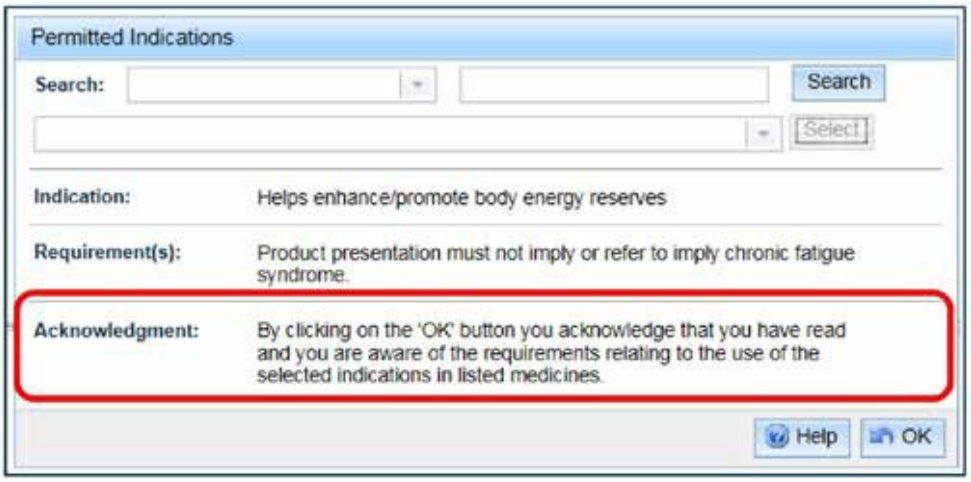
4. Select the drop down arrow beside the '**Permitted Indication**' box to display the permitted indications that meet your search criteria. Choose a Permitted indication from the drop down menu and '**Select**'.



5. The permitted indication and relevant requirements will be displayed below the search bar. The system will take a moment to search for any applicable indication requirements. During this time the following screen will appear.



If the indication has Requirements, an acknowledgement will also appear.



To add the indication, select '**OK**' and you will be taken back to the previous screen.

Note: that by selecting OK, you are acknowledging that you have read and are aware of the requirements relating to the use of the selected indications.

6. You can choose to add optional qualifiers from drop down lists to align with the evidence you hold. The three optional qualifiers are described in the table below. Note that the optional qualifiers can be selected before or after the indication has been chosen.

Optional qualifiers	Description
TCM pattern	This will only be available for selection if a Traditional Chinese medicine Context qualifier was selected.
Time of use	Indicates the time of therapeutic benefit for the medicine, e.g. 'after exercise'.
Population	Specifies the target population for the medicine, e.g. 'in healthy individuals'.

When you have selected your optional qualifiers from the drop down lists, select '**Save & Close**'.

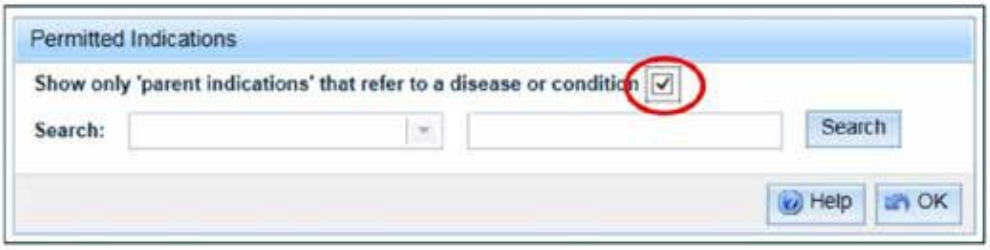
Linking permitted indications

You have the option to link certain indications to specify the symptoms of a condition/disease, to align with the evidence you hold.

Parent indications (that can have other indications linked to them) are usually those that include the term '*symptoms of*'. The indication code of a parent indication ends in '*-PR*'. When you select a parent indication, you will be given the option to link symptom indications to it. If an indication is selected that does not have a code that ends with 'PR' there is not an option to link it to another indication.

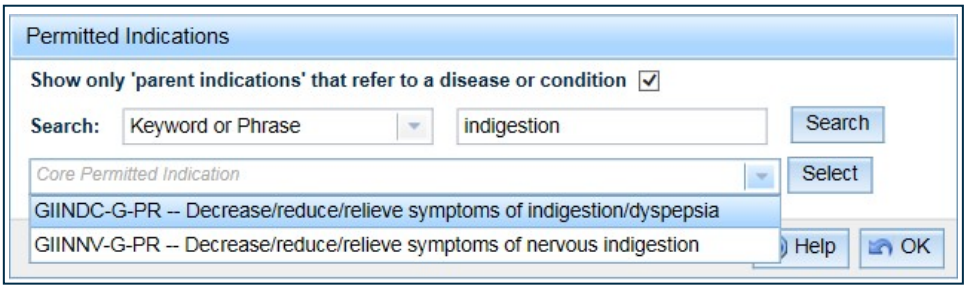
Note that parent indications and symptom indications can be included in your ARTG entry as standalone or as linked indications.

1. Follow steps 1 to 2 under How to add a permitted indication. At Step 3 your search can be filtered to show only those indications that can be used as parent indications. Select the box next to the words '*Show only 'parent indications' that refer to a disease or condition'*:

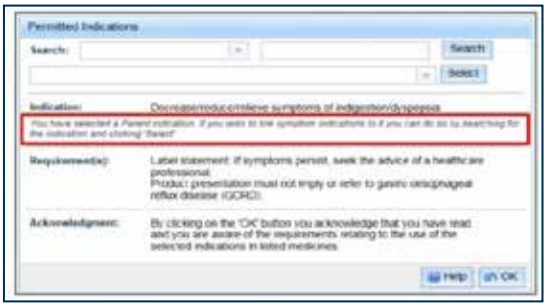


2. Enter your search criteria and **'Search'**.

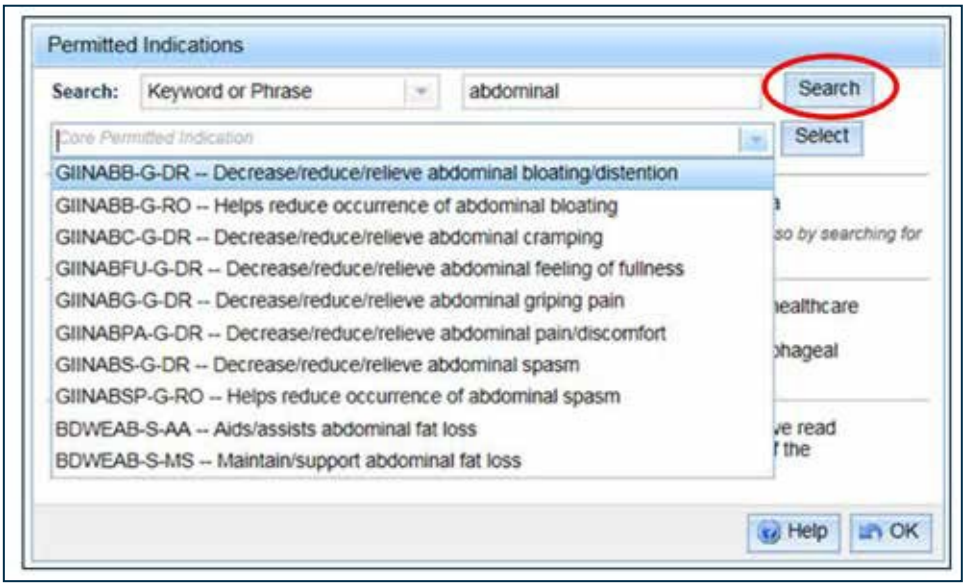
   Only indications with the letters 'PR' at the end of the code appear in the list.



3. When a parent indication is selected, a message will appear under the indication advising that if you can link a symptom indication.

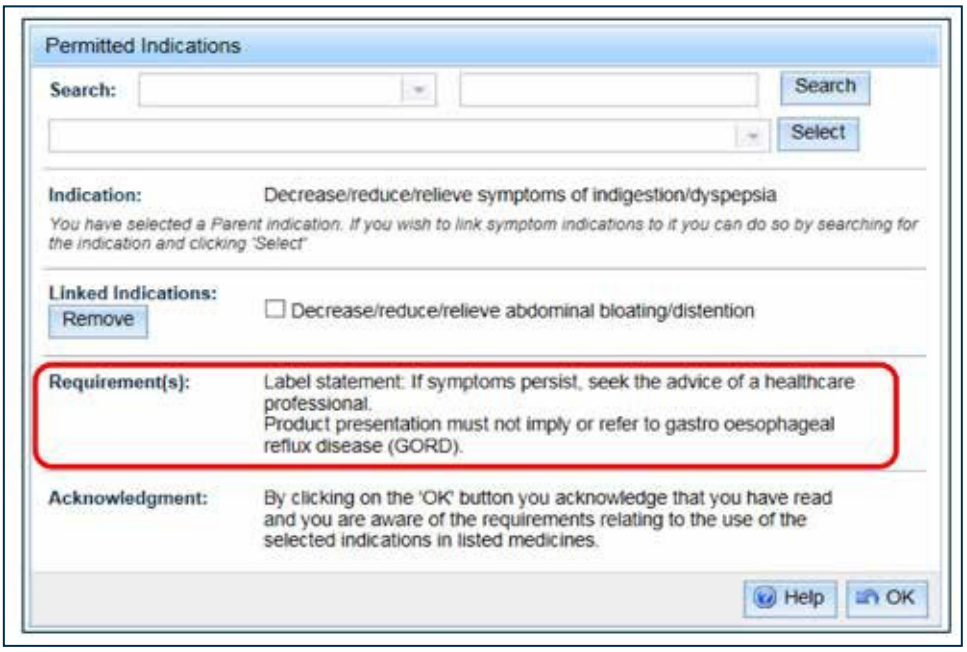


To search for an indication to link to the parent indication, select a **'Search category'**, enter the search criteria and **'Search'.** After selecting an indication from the drop down list, click '**Select'.**



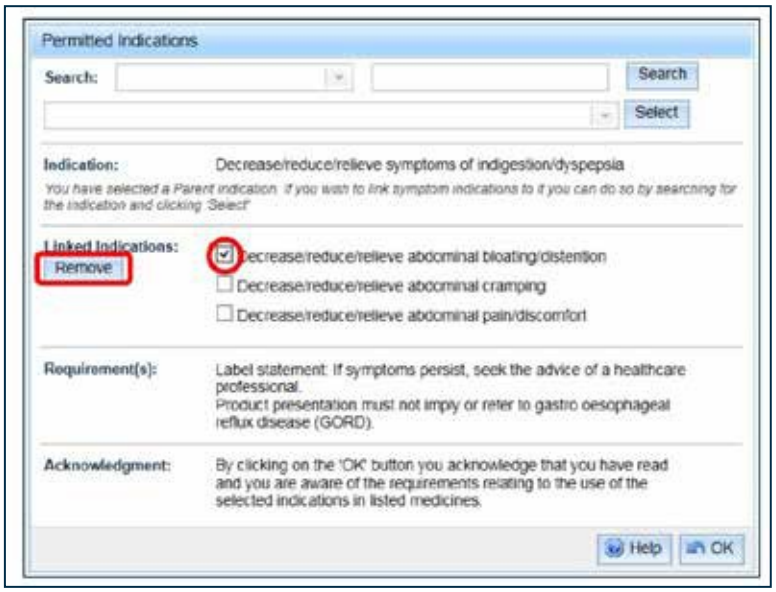
Note that the list of indications will not include any that have a code ending in 'PR' because a parent indication cannot be linked to another parent indication.

4. The **linked indication** will appear beneath the parent indication. If a linked indication has a requirement that is different to the requirements already listed for the other indications chosen, it is included in the '**Requirement(s)**' section. If a requirement is the same as one already listed, it will not be repeated in the list.



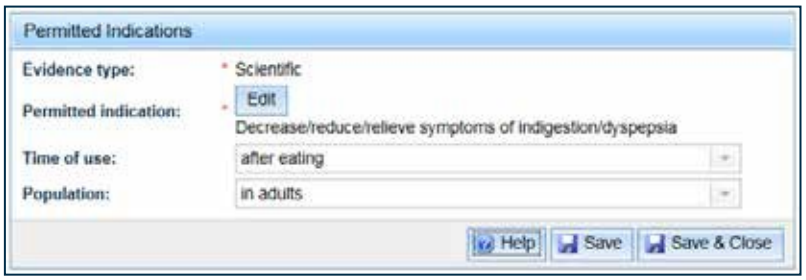
5. You can repeat the above steps to continue selecting indications to link to the parent indication until the list is completed.

6. To remove a **linked indication** from the list, select the check box beside the indication and **'Remove'**. Any unique requirements for that indication will disappear from the 'Requirement(s)' list.



Select **'OK'** to finish and you will return to the previous window.

7. The parent indication is displayed in the window. You may choose to add optional indication qualifiers to your parent indication.



Note that the same qualifiers apply to the complete set of indications (i.e. the parent and linked indications).

8. Select **'Save & Close'** to finalise the selection.

The set of indications selected are displayed in the application form. The parent indication will appear with any qualifiers selected in Step 8. The linked indications are slightly indented.

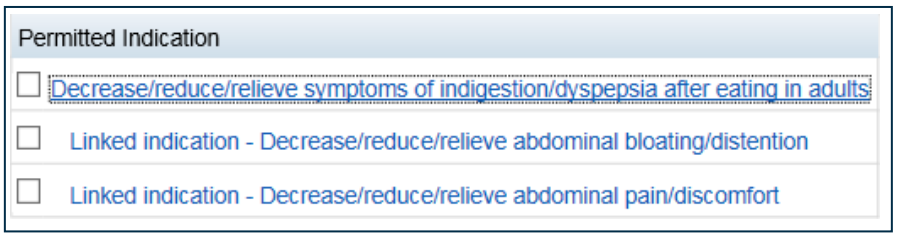
Removing a permitted indication

One or more linked indications can be removed from the application by checking the box next to them and selecting **'Remove'**.

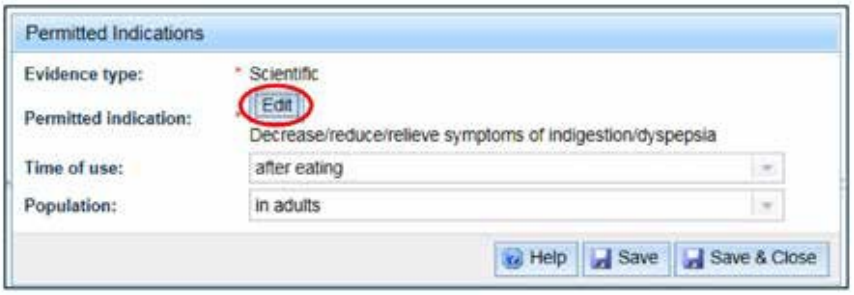
Note: if you remove a parent indication that has indications linked to it, the complete set is removed.

Editing a permitted indication

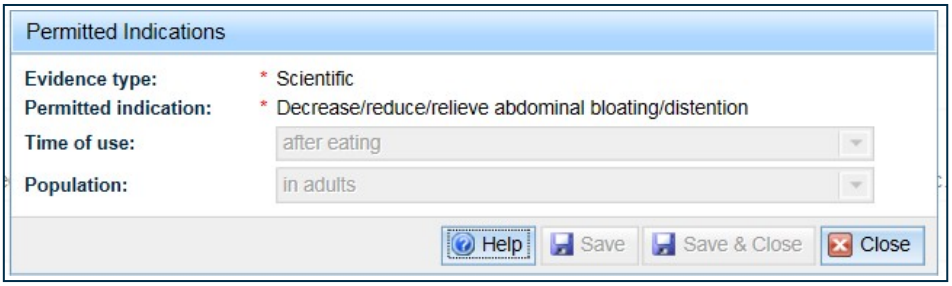
If you wish to edit a set of indications including adding more linked indications, click on the parent indication.



You can change the qualifiers for the set in this window or you can select **'Edit'** to link more indications to the parent indication.



Linked indications have the same qualifiers as the parent indication. If you select a linked indication the same window opens as for the parent indication, but the ability to edit the qualifiers is disabled.



Using permitted indications multiple times

An indication can be used multiple times in an application:

- A parent indication can be added to the application as a stand-alone indication, i.e. without linking other indications to it.
- An indication that cannot be used as a parent indication could be linked to multiple parent indications and/or used as a stand-alone indication.

Adding a Specific Indication (assessed listed medicines only)

1. Select the '**Add**' button.

2. Enter the specific indication and Save.

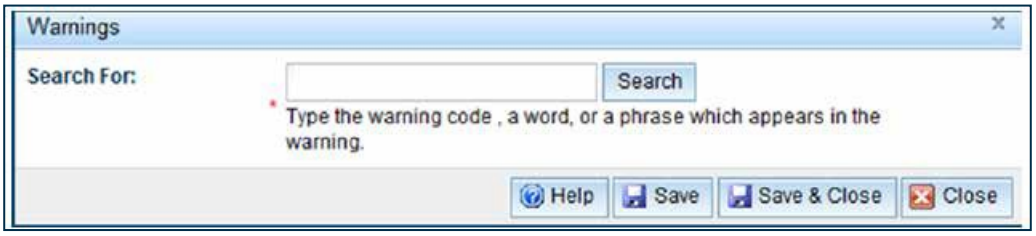
Multiple specific indications can be added by selecting the 'Add' button.

Warnings

Note: All requirements (including required label and warning statements) for permitted indications will be pre-populated. Sponsors are required to acknowledge these requirements before being able to validate.

To add a **Warning**:

1. Select the **'Add'** button to open the form.
2. Type in key words for the warning and **'Search'** or the **'Enter'**.



3. Select the required warnings and press the **'Save and close'** button.

NOTE: To add multiple warnings, select '**Save**' and keep the warning box open, allowing the selected warning to be added and a new warning search to be conducted.

Subsection 26B(1) Notification (general listed medicines only)

Applications for general listings must be accompanied by a notice, that a certificate under section 26B(1) is not required to the effect that the applicant is not marketing (does not propose to market) the therapeutic goods, in a manner that would infringe a valid claim of a patent in relation to the goods. For more information, see Australia-United States Free Trade Agreement.

Subsection 28B(1) Notification is mandatory for general listed and general composite pack applications and must be completed before an application can be validated and submitted.

This notification will not appear for an assessed listed or assessed composite pack application. You must complete a separate form about the certificate or a notice that a certificate under section 26B(1) is not required form and submit with your supporting information.

To add a Subsection 26B(1) Notification:

1. Select the **'Add'** button

Answer the questions by selecting either **'Yes'** or **'No'** radio buttons for the following questions:

- Are you required to submit evidence or information to establish the safety or efficacy of this listing application?

Usually, the answer to this question is **'No'.**

- For the purpose of subsection 26B(1) you are notifying the Secretary that a certificate under subsection 26B(1) is not required for this application.

Usually, the answer to this question is **'Yes'.**

2. Select the **'Save and Close'** button.

Supporting information tab

This tab will only be displayed for:

- assessed listed medicine and assessed composite pack applications
- 9D(1) variation requests for a general listed medicine and general composite pack applications.

Supporting data can be attached to the application or sent separately.

1. Select the Supporting information tab:

2. Select how the supporting data will be provided:

   a. Send separately

   i. Select the '**To be sent separately'** radio button.

   b. Attach to application

   i. Select the '**Attached**' radio button

   ii. Select the '**Add**' button

   iii. The Attachment Details window opens:

   iv. Enter a description.

   v. Select the '**Browse**' to search for the file.

   vi. Select the '**Save & close'** button.

The documentation will appear in the Supporting information window.

Note: Supporting documentation is mandatory for L(A)1, L(A)2, L(A)3, L(A)C1, L(A)C2 and general listed 9D(1) variation requests.

Only a single zipped file can be uploaded.

Removing an attachment

1. Select the box on the left hand side of the documentation.
2. Select the '**Remove**' button.

Other regulatory requirements tab

This window contains other general information and regulatory requirements applicable to the application. Information will be displayed ***after*** successful validation.

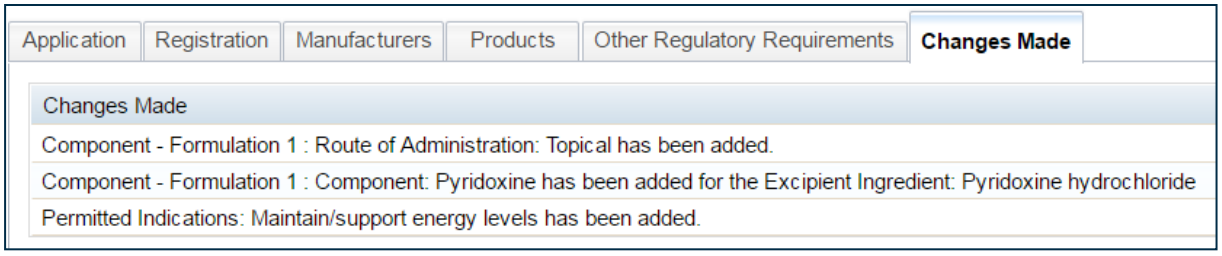
This tab contains important regulatory requirements that **must** be considered prior to submission.

Changes made tab

This window will display information relating to the changes that you have made in this application following validation of a change application.

You should review this tab prior to submitting to ensure that all intended changes have been made and are correct.

Example of changes made tab



Varying or changing an existing product

All changes can be made to your product through the TBS Portal. Multiple changes can be made to the same product within a single application, unless it is a 9D(1) variation request.

For general listed medicines, changes made to an existing entry may result in a number of validation outcomes

These types of changes are:

- ARTG Correction
- Variation
- Grouping
- New (with a new AUST L number).

For assessed listed medicines, the application type is determined by the user by selecting the application type from a drop-down menu.

For further information on product changes, please consult the Changing a listed or assessed listed medicine: application levels and change tables

Once you have logged in, select the relevant application type, for example 'General Listing' from the drop down menu within 'Applications'.

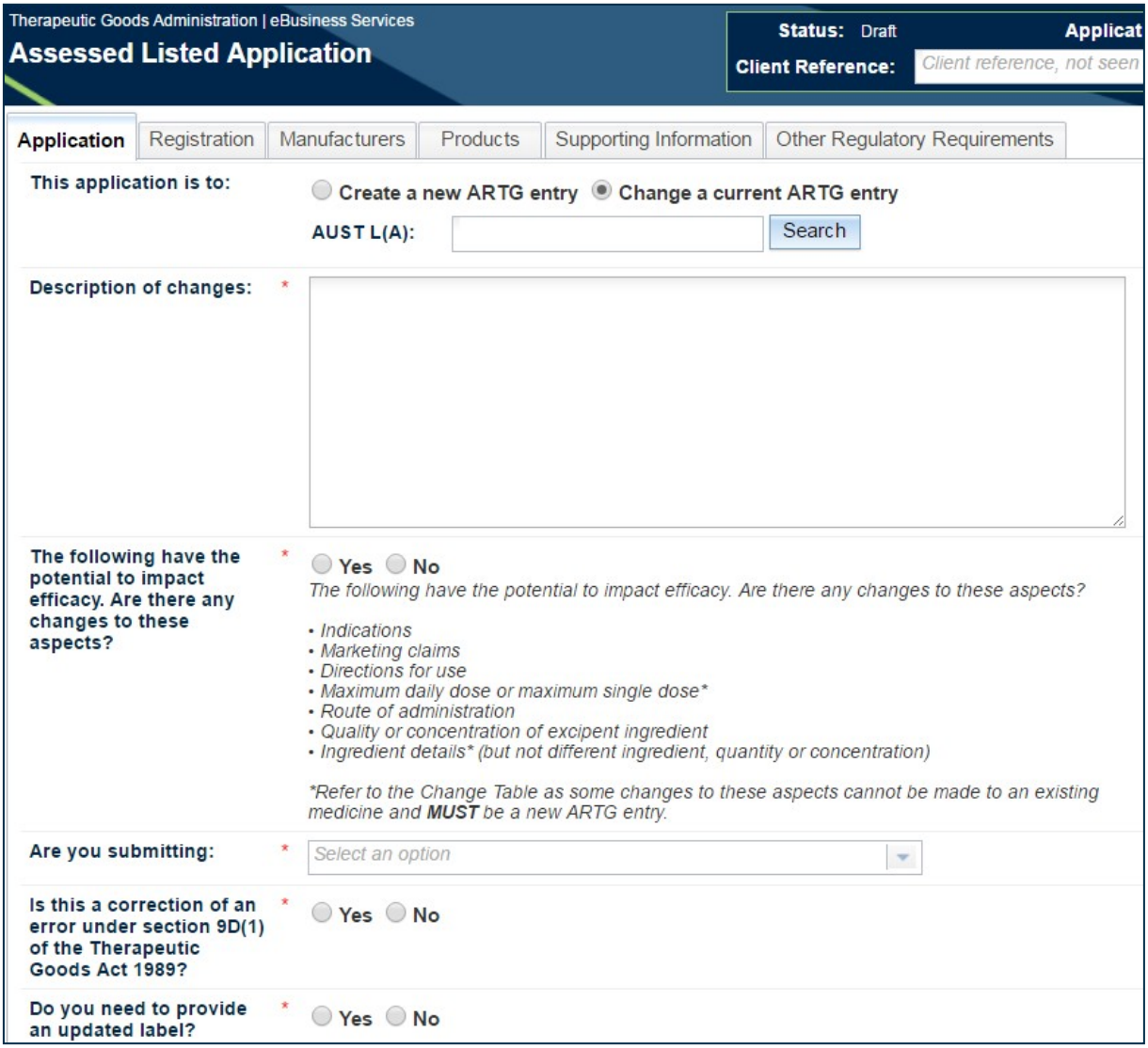
Changes can be made to all application types.

Application information

On the '**Application**' tab select 'Change a **Current ARTG entry'** radio button and enter the AUST L or AUST L(A) number and '**Search**'. This will populate your application with product details from the AUST L or AUST L(A) you have entered. A number of other fields will appear under this relating to the change application

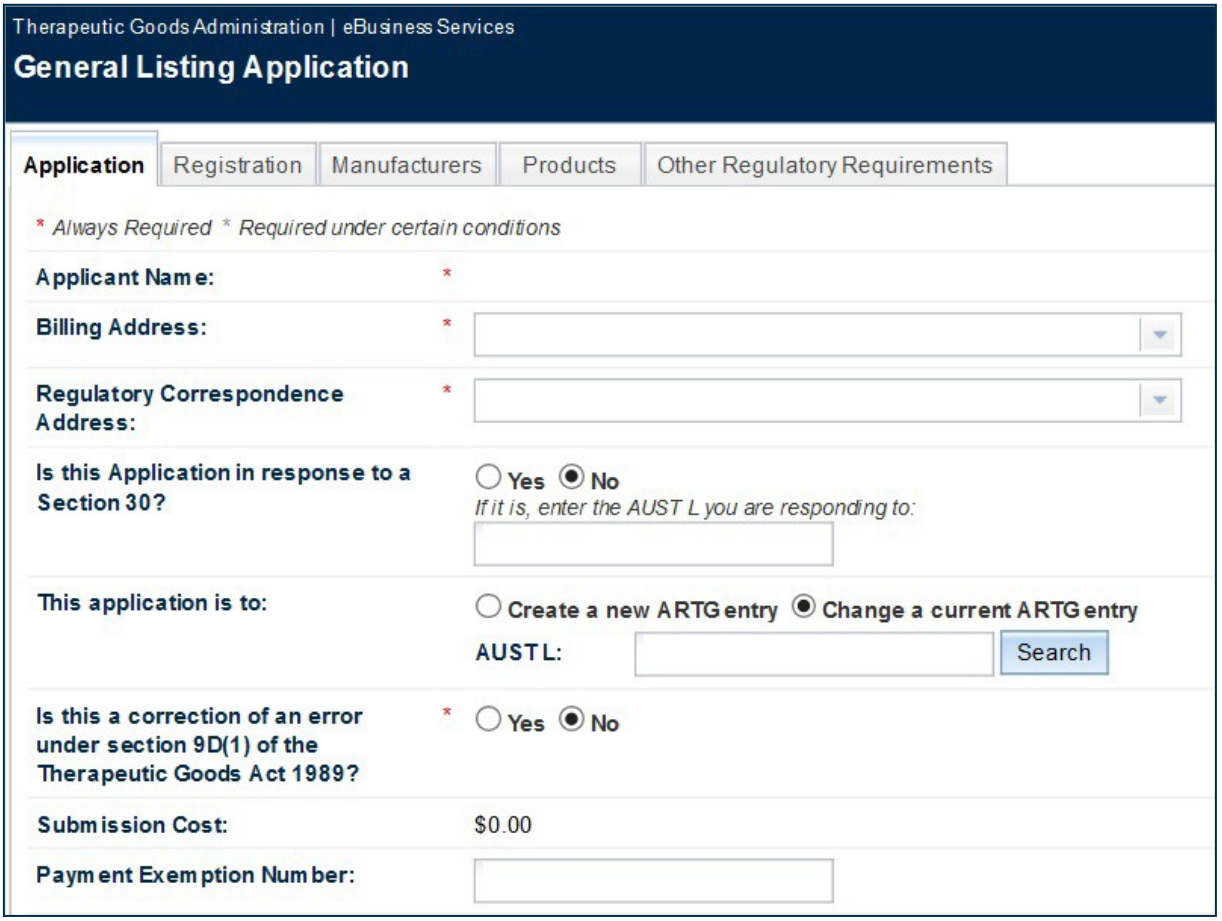
For assessed listed medicine and assessed composite pack applications, this includes:

- Description of changes
- The following have the potential to impact efficacy. Are there any changes to these aspects?
  - Aspects include: indications, marketing claims, directions for use, maximum daily dose or maximum single dose*, route of administration, quality or concentration of excipient ingredient or any other ingredient details* (but not different ingredient, quantity or concentration)
- Are you submitting:
  - Efficacy data, a justification for not providing efficacy data or no data/justification as the change does not have the potential to impact efficacy.
- Is this a correction of an error under section 9D(1) of the *Therapeutic Goods Act 1989* (the Act)?
- Do you need to provide an updated label?



For general listed medicine and general composite pack application this includes:

- Is this a correction of an error under section 9D(1) of the *Therapeutic Goods Act 1989*?
  - If you answer 'yes' to this question, you will be required to provide a 'Description of changes' and a 'Contact person' if we need further information.



Making changes

The application will be populated with the information on the Registration, Manufacturers and Product tabs from details in the ARTG. You will need to update this information where relevant to reflect the intended ARTG entry.

Once the necessary changes have been made, select the '**Validate**' button.

This will compare the information in the entire application against the previous entry and the system rules that reflects regulatory requirements. For example, requirements relating to the use of an ingredient such as a concentration limit. This may result in validation errors which need to be addressed prior to submitting the application.

Changing a manufacturer

Remove a manufacturer:

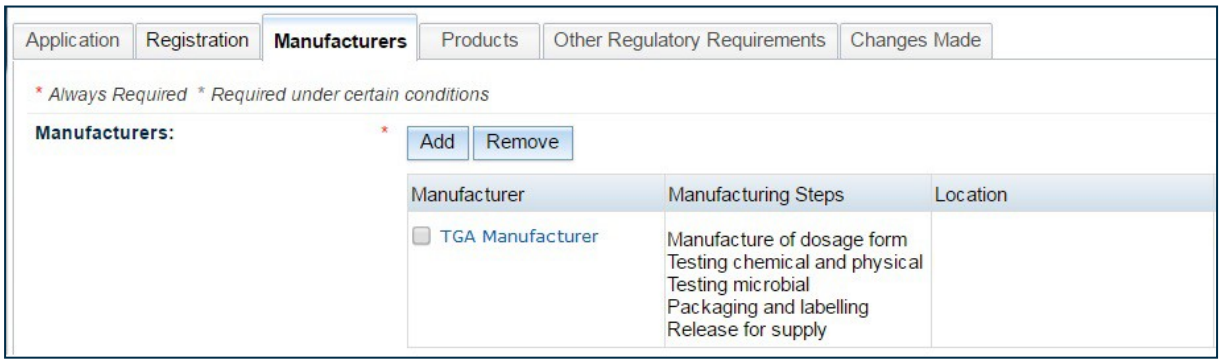
1. On the Manufacturers tab, select the box on the left hand side of the manufacturer name you intend to remove.
2. Select the '**Remove**' button.

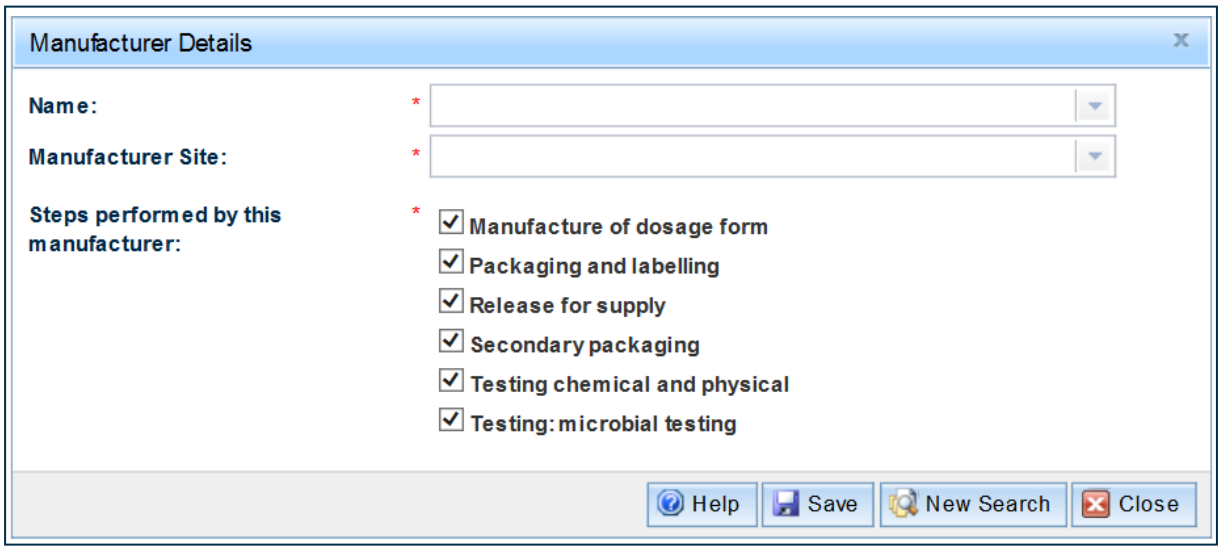
Add a manufacturer:

- Follow the steps outlined above under Navigating through an application – Manufacturers tab.

Change the steps of an existing manufacturer:

1. On the Manufacturers tab, select the name of the manufacturer you intend to change.
2. The Manufacturers Details box will open.
3. Select or unselect the steps you wish to add or remove.





Actioning a returned application

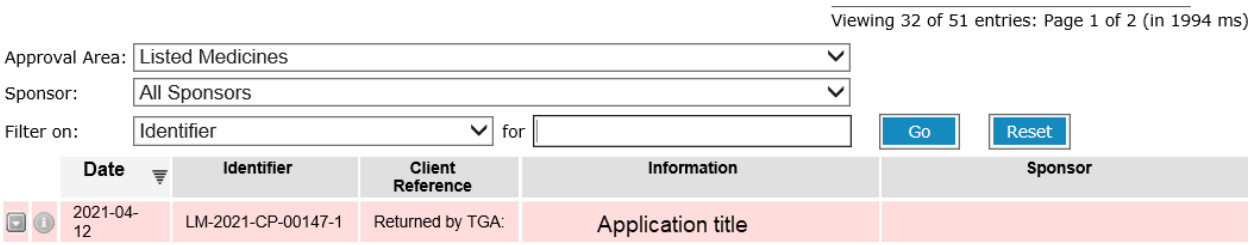
Submitted applications may be returned to the applicant if there is incorrect or missing information, in certain circumstances.

Application types which can be returned are:

- 9D(1) variation applications for both listed and assessed listed
- Assessed listed applications

When an application is returned to the applicant, the TGA will email to the applications contact officer to advise of the reason(s) the application has been returned.

The returned application will appear in the TBS portal in your 'Drafts' section and will be highlighted in red.



You can make the required changes, validate and submit your application.

Note: There is **no fee** for resubmitting a returned application. If when validating a returned application, the system states there is a fee to be paid, please contact Complementary Medicines, **before** submitting the application.

Note: A returned application cannot be copied or deleted.

Medicine kit applications

A medical kit is made up of individual components that are already listed, registered or excluded from the requirements to be in the ARTG. They are defined in the legislation under section 7B of the Act.

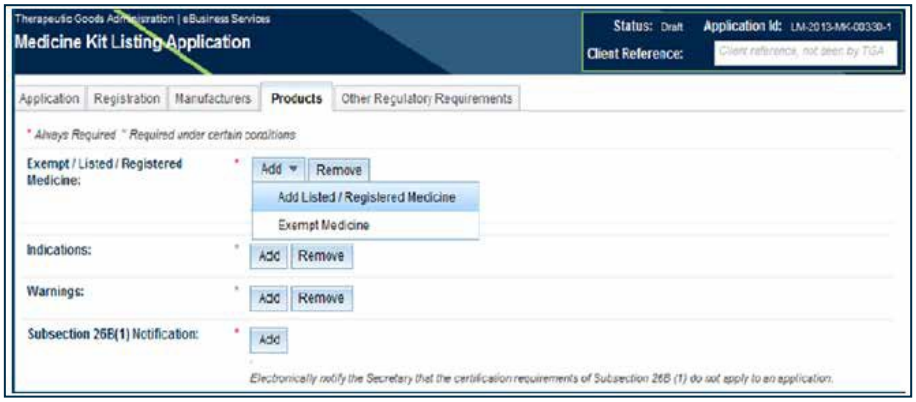
Completing a new medicine kit application

1. From the TBS portal, select **'Create applications and submissions'**, **'Listed medicines'**, **'Medicine kit'**.
2. Complete details in the **'Application tab', 'Registration tab'** and **'Manufacturers tab'**.
   a. The **'Product code'** will be populated with **'Drug kits'**.

Products tab

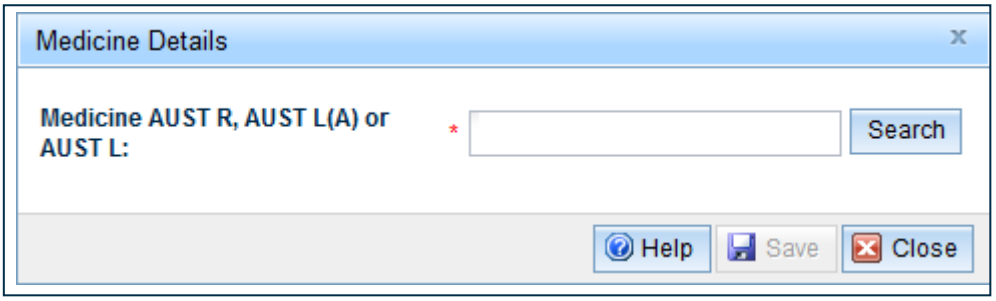
There are three types of medicines that can be added to a medicine kit:

- Exempt goods which are excluded from the requirements to be in the ARTG;
- Listed medicines –general listing and/or assessed listings;
- Registered medicines.



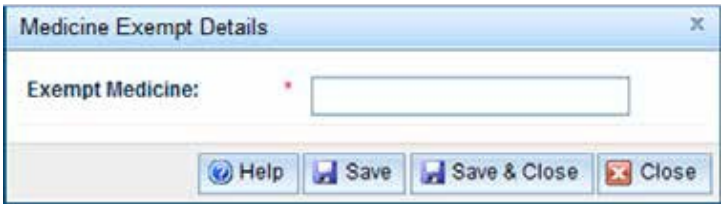
Add a listed, assessed listed or registered medicine

1. Select the **'Add'** button for the **'Exempt/Listed/Registered medicine'** field.
2. A drop down list will appear. Select **'Add Listed/Registered medicine'**.
3. The Medicine Details window will open. Enter the AUST R, AUST L(A) or AUST L number and **'Search'**.



To add an exempt medicine (such as a bandage)

1. Select the **'Add'** button for the **'Exempt/Listed/Registered medicine'** field.
2. A drop down list will appear. Select **'Exempt Medicine'**.
3. The Medicine Exempt Details window will appear.



4. Enter the name of the exempt medicine and **'Enter'** or **'Save and Close'** to return to the application.

To add multiple exempt medicines, you may select **'Save'** and keep the medicine Exempt Details window open, allowing you to enter additional exempt medicines.

Composite pack

A 'Composite pack application' is used for medicines that are to be sold together in one package, where the medicines are either combined before use or administered in a particular sequence, for a single treatment or course of treatment. They are defined in the legislation under section 7B of the Act. 'General Composite pack' and 'Assessed Composite Pack' applications differ from 'General listed' and 'Assessed Listed' applications, only in that they require the addition of multiple formulations in the same application. To complete a 'General Composite Pack' and 'Assessed Composite Pack' application:

1. From the TBS portal, select **'Create applications and submissions'**, **'Listed medicines'**, **'General Composite Pack'** or **'Assessed Composite Pack'**.
2. Complete the **'Application'**, **'Registration'** and **'Manufacturers'** tabs as explained previously.
3. For Assessed Composite Pack you will need to also complete the **'Supporting Information'** tab.

Products tab

This tab will allow you to add multiple formulations which will make up a composite pack. A minimum of two formulations are required. This section can be completed as previously described. The only difference is in the **'Component name'**, which will be the name used to distinguish each portion of the composite pack.

Change multiple current listings application

The '**Change multiple listings**' application allows for the same change to be made across a number of currently listed medicines in very limited circumstances. The information required under each tab varies from a'**General listing**' application.

This option is not available to assessed listed ARTG entries.

Application tab

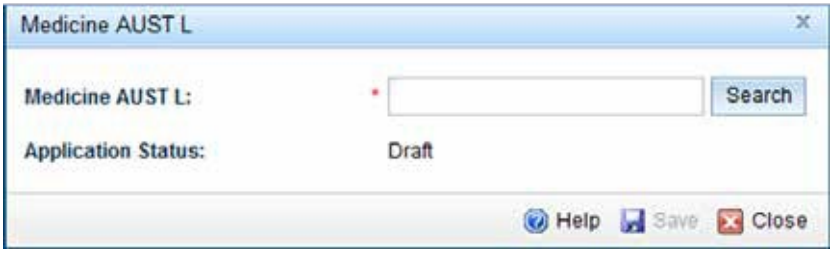
The application tab in the '**Change multiple listings**' application requires a **'Change multi listing name'** to be included.

Registration tab

To make a change to several ARTG listings, enter the AUST L numbers of the products to be changed:

To add an AUST L:

1. Select **'Add'**, to open the search function.

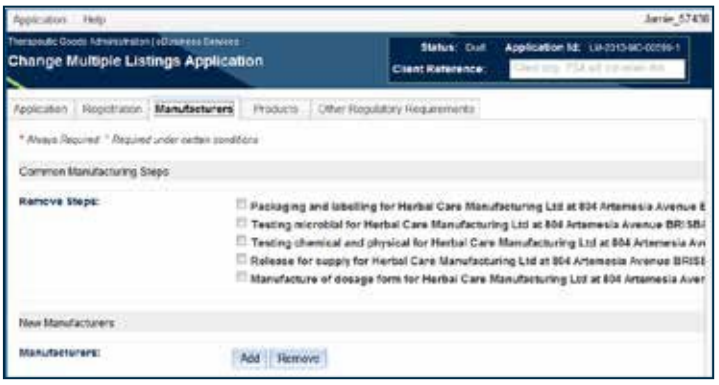


2. Enter the AUST L number and select '**Search**'.
3. Confirm that the details of the AUST L are correct and '**Save**.'

Manufacturers tab

The following changes can be made:

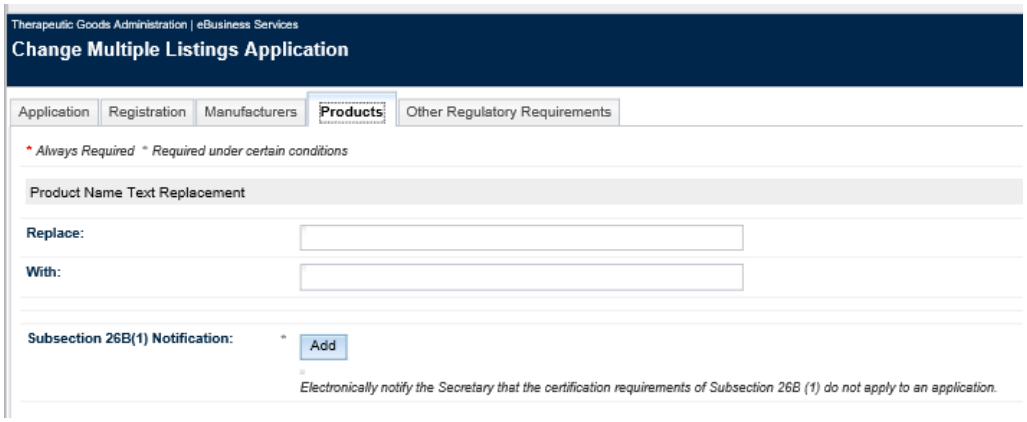
- Common manufacturing steps.
  - Based on information generated from the selected AUST Ls, common manufacturing steps will be displayed and can be changed.
- New manufacturers can also be added by selecting the **'Add'** button in the New Manufacturers field:



Products tab

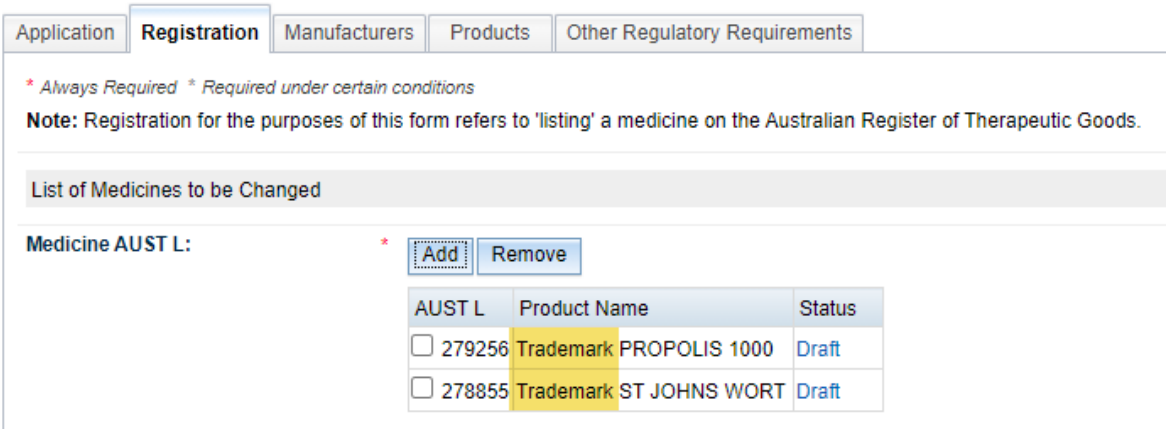
Common word/s (e.g. trade name) in a product name can be updated in a multiple change application. However only in specific situations:

- A word/s can only be replaced by another word/s but it cannot be replaced with 'blank'
- A word/s can only be replaced if it is common among all products entered in the application



An example for name change

1. Under the 'Registration' tab, add multiple products with a common word/s



2. Under the 'Products' tab make the required changes noting that you cannot replace a word with 'blank'

3. Complete the 26B(1) notification, validate and submit

Note: When submitting a multiple change application, the applicable fee will be applied to each product in the application. For example if there are three products and the product names are being updated, you will receive a grouping fee for each product.

Validating an application

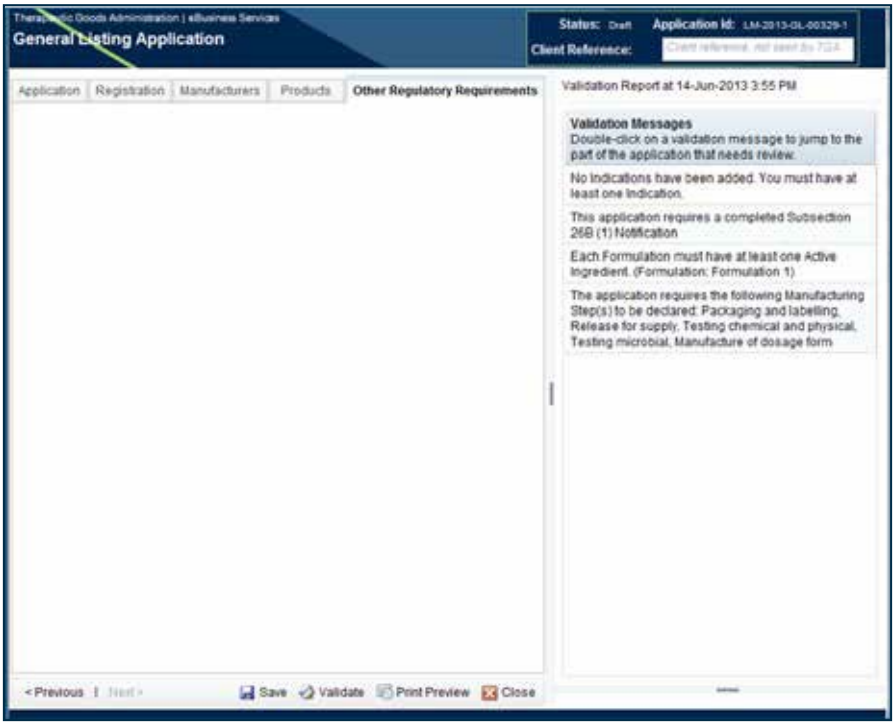
Once an application has been completed, it must be validated prior to submission.

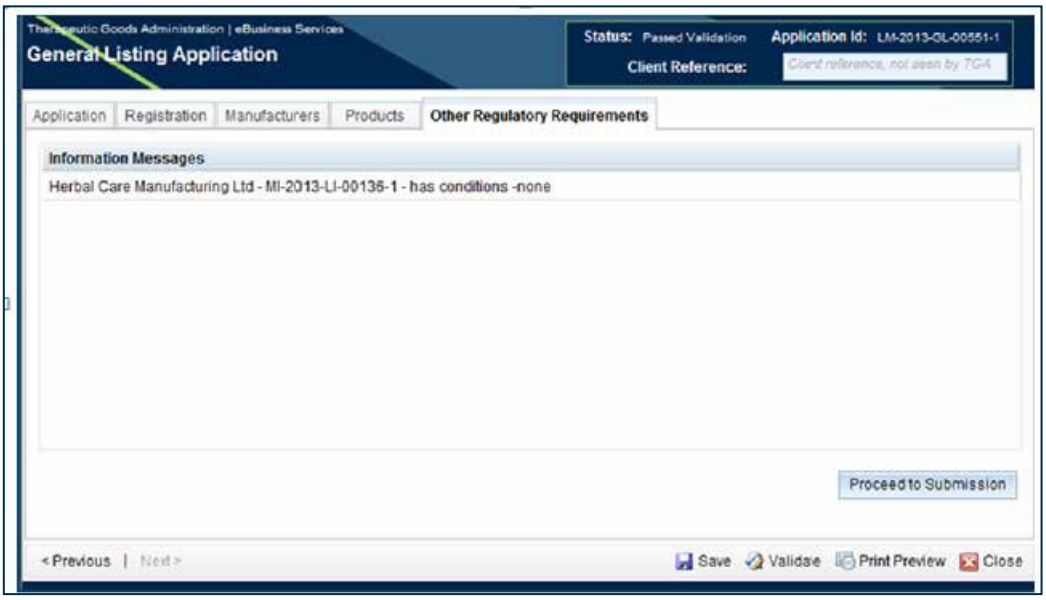
To validate an application

Select the **'Validate'** button which appears in the lower right hand corner of the application.

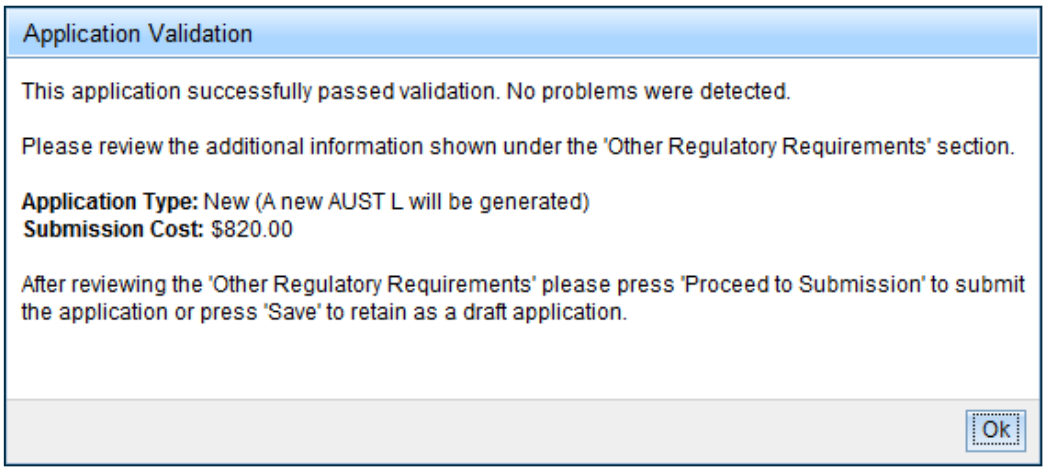
During validation, the application and all related sub-documents are checked against the listed medicine business rules. If issues are found, validation results will be displayed on the right hand side of the screen in the validation messages window.

Double-click on the validation message to open the section of the form the validation message relates to and make the required corrections.





Once all validation messages have been corrected, select the **'Validate'** button. If no issues arise, a successful **'Application Validation'** message will be displayed:



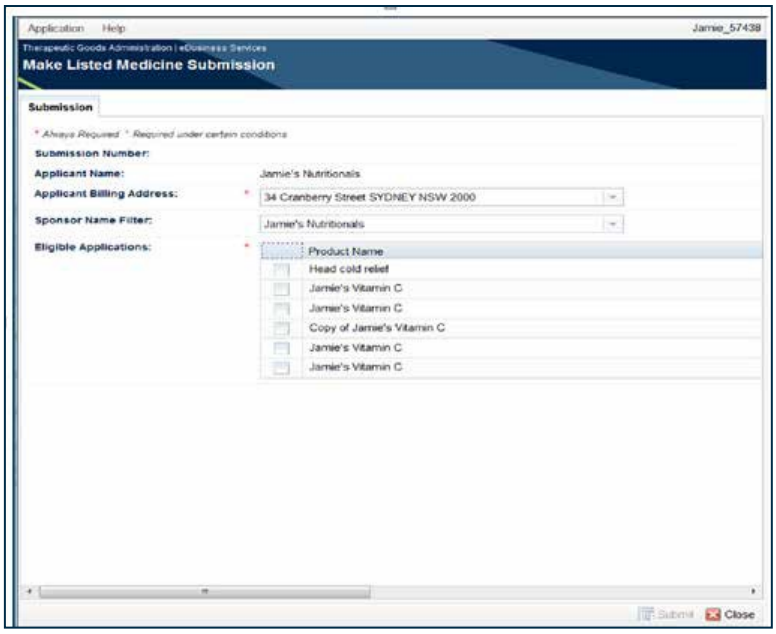
This message includes the **'Application type'** and **'Submission cost'**. Select the **'Ok'** button to review the **'Other Regulatory Requirements'**. Once reviewed, select the **'Proceed to Submission'** button. If you do not wish to submit the application select **'Save'** and the application will remain in the **'drafts'** window of the TBS portal.

Note: If the application validates in an unexpected manner, please contact Complementary Medicines, and do not submit the application. Carefully review all information within the application, including pop-up boxes, prior to proceeding.

Applications are NOT submitted automatically after successful validation.

Submission

Pressing the **'Proceed to submission'** button after validation, will take you to the submissions window:



Eligible applications must have successfully passed validation in order to appear in this window. All application types are displayed including their product name, application ID, date/time of validation, application type and associated fee.

Submissions can also be made from the TBS portal under **'Listed medicines, Create applications and submissions, Submissions'**.

Submitting your application

1. Select the checkbox next to the application you wish to submit. The **'Certification/Declaration'** will open:

2. Read the Certification/Declaration. Select either the **'Agree'** or **'Disagree'** button.

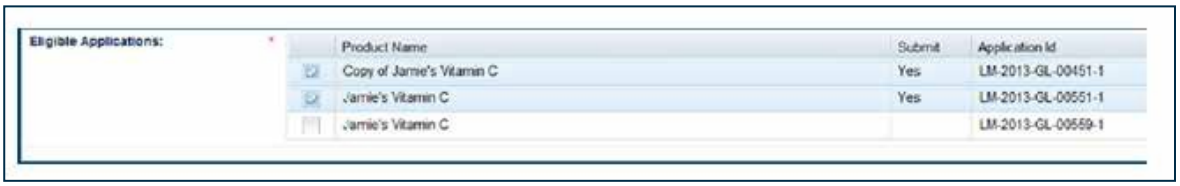
Note: by clicking on **'Agree'**, you declare that the information given in the application is correct.

The Certification/Declaration will be different for assessed listed and general listed medicine applications.

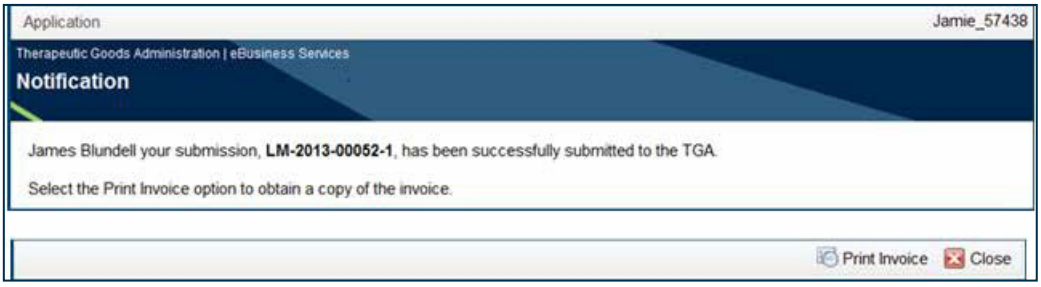
3. Once you have agreed, the selected application will be highlighted. Repeat steps 1 and 2 to add subsequent applications to your submission. All selected applications will be submitted in a single submission.

Note: Only one application for assessed listed, assessed composite pack and 9D(1) variation for a general listed medicine can be submitted at a time.

4. Each of the applications selected for submission will display **'Yes'** in the submit column under **'Eligible applications'**:



5. Select the **'Submit'** button in the bottom right hand corner. Successful submission will take the submitter to the **'Notification page'**.



6. Select the **'Print invoice'** button in the bottom right hand corner to print an invoice for this submission:

Australian Government
Department of Health
Therapeutic Goods Administration

ABN: 40 939 406 804

Tax Invoice

Jamie's Nutritionals
34 Cranberry Street
SYDNEY NSW. 2000

Tax Invoice	ONL099059
Date of Issue	09/07/2013
Invoice Total	$680.00

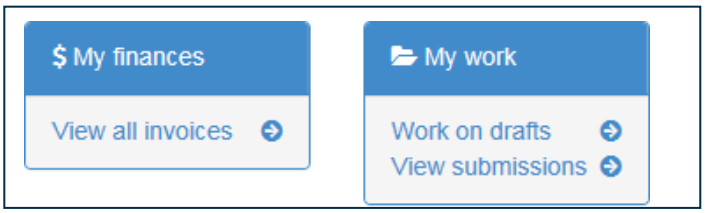
Client ID	Enquiries	Phone	Fax	Contact Email Address
57438	TGA Accounts Receivable	(02) 6232 8228	(02) 6232 8222	accountsrec@tga.gov.au

Identifier	Description	Unit Price	GST	Total
LM-2013-GL-00429-1	New (A new AUST L will be generated)	$680.00	$0.00	$680.00
LM-2013-GL-00429-1	New (A new AUST L will be generated)	$.00	$0.00	$.00
LM-2013-GL-00429-1	New (A new AUST L will be generated)	$.00	$0.00	$.00

Application fees are exempt from GST under Division 81 of A New Tax System (Goods & Services Tax) Act 1999

Subtotal	$680.00
GST	$0.00
Total	**$680.00**

7. The invoice can also be accessed from TBS portal, in the **'$My Finances'** window:



Accessing help

Help is available from within the TBS portal and can be accessed by clicking the **'Help'** link in the top left corner on each page of the application. This will open help in a new window.

Email

For listed medicine applications and submission enquiries, please email complementary.medicines@health.gov.au with as much information as possible, such as the application ID and screenshots of any validation messages.

For questions about TBS related issues and access you can contact the TBS helpdesk on ebs@health.gov.au.

Phone

You can phone Complementary medicines on 1800 020 653 or 02 6289 4627.

You can phone the TBS helpdesk on 1800 010 624.

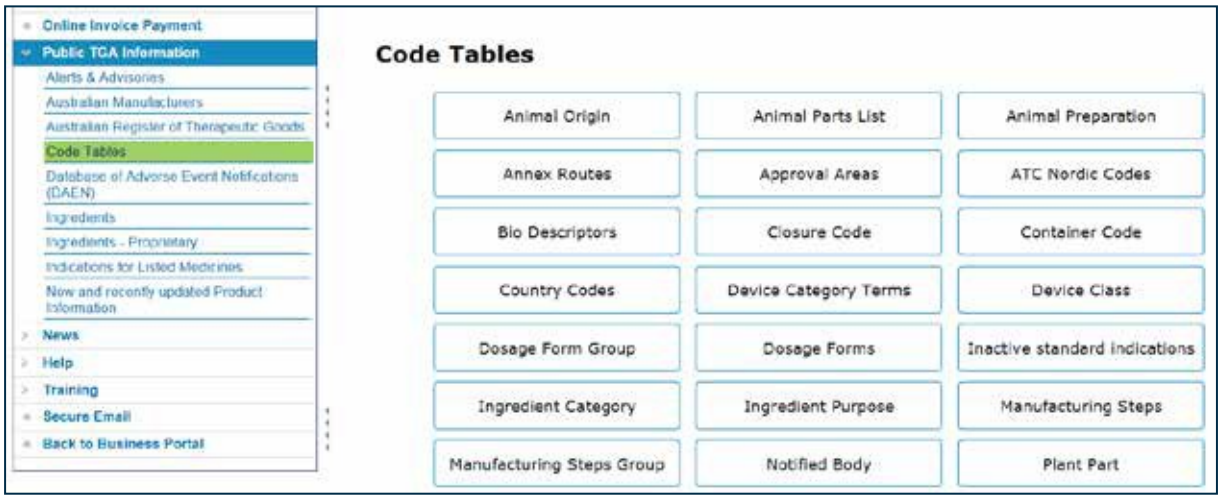
Preparing to make an application

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

- Code Tables
- Ingredients
- Ingredients – Proprietary
- Indications for Listed Medicines

Code tables

The code tables provide terminology for use in product applications. Data in certain drop-down lists in a listed 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.



Codes Tables that are most useful for preparing a listed medicine application are:

- Product Code
- Dosage Form Group
- Dosage Forms
- Manufacturing Steps
- Manufacturing Steps Group

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 Listed Medicine application.

Product code

Select the product code that best describes the type of product being submitted from the drop down list. Product codes that can be used in a listed medicine application are:

Type	Description	Requirements
Other Products	The most commonly used product code which is subject to all the standard requirements under section 26A and 26AB of the Act. There are no specific exemptions. Used to list products that only contain standard active ingredients, standard excipients and proprietary ingredients.	Must not contain homoeopathic ingredients.
Sunscreens Only		Must only contain active ingredients which are specifically permitted for use in sunscreen preparations. Must comply with the sunscreen standard
Homoeopathic Products Only	There are no specific exemptions. Used to list products that only contain homoeopathic ingredients.	Must not contain standard active ingredients.
Homoeopathic / Other Combination Products	There are no specific exemptions. Used to list products that contain both homoeopathic and standard active ingredients.	Permitted to contain both homoeopathic and standard active ingredients.
Medicated Soap - Bar	As per Item 16 of Schedule 7 of the Regulations, medicated soaps other than liquid medicated soaps	Exempt from the operation of Part 3 3 of the Act unless supplied as pharmaceutical benefits Homoeopathic ingredients are not permitted
Medicated Space Spray	As per Item 16 of Schedule 7 of the Regulations, medicated space sprays where the medication consists only of volatile oils and their constituents	Exempt from the operation of Part 3-3 of the Act unless supplied as pharmaceutical benefits Only permitted for use when dosage form is 'Nasal Drops – Solution' and route of administration is 'nasal' Homoeopathic ingredients are not permitted

Type	Description	Requirements
Medicated Throat Lozenge	As per Item 15 of Schedule 7 of the Regulations, medicated throat lozenges, where the medication consists only of volatile oils and their constituents either alone or in combination with ascorbic acid or its salts	Exempt from the operation of Part 3-3 of the Act unless supplied as pharmaceutical benefits Only permitted for use when dosage form 'lozenge' and route of administration 'buccal, oral, or sublingual' Homoeopathic ingredients are not permitted
Uncompounded BP Substances	When used as a standard active ingredient, can only be supplied as an uncompounded medicine substance packed for retail sale, and must comply with an uncompounded substance monograph of the British Pharmacopoeia as in force or existing from time to time.	Cannot be combined with other ingredients and must comply with a monograph of the British Pharmacopoeia that does not related to a compounded substance.

Manufacturers

Listed 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 six manufacturing steps that can be undertaken for a listed medicine application. Five of these steps are mandatory. Each step can be undertaken by more than one manufacturer but all five 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

The system will not validate and consequently not allow the medicine to be listed 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.

The following product codes are exempt from including manufacturers in the entry on the Register under Schedule 7 of the *Therapeutic Goods Regulations 1990*:

- Medicated space spray;
- Medicated throat lozenge;
- Medicated soap bar.

Manufacturer's licence or clearance – Product details

The product details of the manufacturer's licence/clearance will designate the dosage form, product category and manufacturing step.

For listed medicines and assessed listed medicines:

- The product category can be either Registered Therapeutic Good or Listed Therapeutic Good;
- The manufacturing step must be one of the six described in the above manufacturing step table or be a manufacturing step group that includes one of the six 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';
- The Dosage Form must be one of the Dosage forms described in the below Dosage forms table or it can be a dosage form group which includes the dosage form that you intend to use in your listed 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.

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 listed medicine application are:

Short description	Long description
Application	A liquid or semi-liquid preparation containing one or more active ingredients intended for application to the skin.
Bar, soap	A solid preparation derived from the action of a solution of alkali on fats or oils of animal or vegetable origin and containing one or more active ingredients in bar form.

Short description	Long description
Block	A solid (food) substance usually chocolate, serving as a vehicle for one or more active ingredients.
Capsule, enteric	A capsule prepared in such a manner that the shell, or the pelletised contents, resists the action of the gastric fluid but is attacked by the intestinal fluid to release the contents.
Capsule, hard	A capsule with a hard shell consisting of two prefabricated cylindrical sections one of which fits over the other. The active ingredients are usually in solid form.
Capsule, modified release	A capsule in which the rate or place of release of the active ingredients in the gastrointestinal tract has been modified.
Capsule soft enteric	A capsule, the contents of which are liquid or semi-liquid. The shells are usually thicker than those of hard capsules and consist of a single part with an enteric coating.
Capsule, soft	A capsule, the contents of which are liquid or semi-liquid. The shells are usually thicker than those of hard capsules and consist of a single part.
Cream	A homogeneous, viscous or semi-solid preparation, usually an emulsion, consisting of a solution or dispersion of one or more active ingredients in low proportions in a suitable base.
Collodion	A liquid preparation usually containing pyroxylin and one or more active substances in a mixture of volatile solvents, usually ether and ethanol, intended for application to the skin. When allowed to dry, a flexible film is formed at the site of application.
Ear Drops, emulsion	A dispersion of an oily liquid in an aqueous liquid either of which may contain dissolved solids, in which the aqueous liquid forms the continuous phase. Solids may be suspended in the emulsion.
Ear Drops, powder for	One or more active ingredients in a dry form to be reconstituted for use as ear drops
Ear Drops, solution	A liquid preparation composed of or containing one or more active ingredients dissolved in a suitable vehicle.
Ear Drops, suspension	A liquid preparation containing one or more active ingredients dispersed as solid particles throughout a liquid phase. In addition it may contain other active ingredients which are dissolved.
Enema	A liquid preparation composed of, or containing, one or more active ingredients for rectal administration.

Short description	Long description
Essential Oil	Essential oil
Gel	A semi-solid preparation usually consisting of a solution or dispersion in a suitable base, prepared with the aid of a suitable gelling agent.
Granules, effervescent	Granules which evolve carbon dioxide when added to water. They are intended to be dissolved or dispersed in water before administration.
Granules, enteric-coated	Granules which resist the action of gastric fluid but are attacked by intestinal fluid to release the active ingredients.
Granules, modified release	Granules in which the rate or place of release of active ingredients in the gastrointestinal tract has been modified.
Granules	A preparation of one or more active ingredients usually in the form of irregular particles 2mm to 4mm in diameter. Some granules are intended to be dissolved or dispersed in water before issuing or before taking; others are chewed or placed on the tongue and swallowed with a draught of water.
Gum, chewing	A preparation containing one or more active ingredients in a gum base, to be chewed and subsequently discarded.
Herb, dried	Dried plant or parts of plants including mixtures of such, used for the extemporaneous preparation of infusions, decoctions or similar preparations for therapeutic use by oral administration.
Inhalation, conventional	A preparation composed of, or containing, active ingredient(s) which when vaporised or dispersed in a suitable manner (eg. hand actuated pump, nebuliser etc.) is intended to release the constituents for inhalation.
Inhalation, powder for	A powder preparation composed of, or containing, active ingredients which when dispersed in a suitable manner is intended to be self-administered by inhalation via the nasal or the oral route for local or systemic effect. It is usually inhaled in controlled amounts.
Inhalation, pressurised	A metered dose preparation usually consisting of a solution, suspension or emulsion of one or more active ingredients held under pressure with a suitable propellant or a suitable mixture of propellants. They are intended to be inhaled in controlled amounts and are delivered by the actuation of an appropriate metering valve.

Short description	Long description
Inhalation	A preparation composed of, or containing, active ingredients which, when vaporised or dispersed in a suitable manner, is intended to be administered into the lungs or into the nasal, paranasal or ethmoid sinuses via the nasal or oral respiratory route. Inhalations may be intended for local or systemic effect.
Insufflation	A powder containing one or more active ingredients usually diluted with a suitable inert powder. It is intended for introduction into the ear, nose, throat, body cavities or wounds.
Liquid, multipurpose	A liquid (or oily) preparation composed of, or containing one or more active ingredients intended for multipurpose use, e.g. aroma therapy oils can be used for inhalation, topically or orally.
Liquids	liquids
Liniment	A liquid or semi-liquid preparation composed of or containing one or more active ingredients intended to be applied to the unbroken skin with friction.
Lotion	A liquid or semi-liquid preparation composed of or containing one or more active ingredients usually intended to be applied to the unbroken skin without friction.
Lozenge	Lozenge: a hard, solid, single-dose preparation intended to dissolve or disintegrate slowly in the mouth when sucked. They contain one or more active substances usually in a flavoured base containing sweeteners.
Mouthwash	An aqueous solution of one or more active ingredients intended, usually after dilution with warm water, for use in contact with the mucous membranes of the oral cavity, including gargling.
Nasal Drops, emulsion	A dispersion of an oily liquid in an aqueous liquid either of which may contain dissolved solids, in which the aqueous liquid forms the continuous phase. Solids may be suspended in the emulsion.
Nasal Drops, powder for	One or more active ingredients in a dry form to be reconstituted for use as nasal drops
Nasal Drops, solution	A liquid preparation composed of or containing one or more active ingredients dissolved in a suitable vehicle.
Nasal Drops, suspension	A liquid preparation containing one or more active ingredients dispersed as solid particles throughout a liquid phase. In addition it may contain other active ingredients which are dissolved.

Short description	Long description
Ointment	A semi-solid preparation intended for topical use, usually consisting of a solution or dispersion of one or more active ingredients in low proportions in a suitable base, usually non-aqueous.
Oral Liquid, powder for	One or more active ingredients in a dry form to be reconstituted for use as an oral liquid.
Oral Liquid, solution	A liquid preparation composed of or containing one or more active ingredients dissolved in a suitable vehicle.
Oral Liquid, suspension	A liquid preparation containing one or more active ingredients dispersed as solid particles throughout a liquid phase. In addition it may contain other active ingredients which are dissolved.
Oral Liquid	A preparation usually consisting of a solution, a suspension or an emulsion of one or more active ingredients in a suitable vehicle. They are intended to be swallowed either undiluted or after dilution.
Paint, concentrated	A liquid which must be diluted with another liquid in order to prepare a paint.
Paint, powder for	One or more active ingredients in a dry form to be reconstituted for use as a paint.
Paint	A liquid preparation containing one or more active ingredients for application to broken skin or mucous surfaces.
Paste	A semi-solid preparation for external application usually containing a high proportion of finely powdered active ingredients mixed with soft or liquid paraffin or with a non-greasy base made with glycerol, mucilage or soap.
Pastille	Pastille: a soft, flexible, solid, single-dose preparation intended to dissolve slowly in the mouth when sucked. It contains one or more active substances in a flavoured base containing natural or synthetic polymers or gums and sweeteners.
Patch, dermal	A system containing active ingredients which is affixed to the skin and is intended to produce a local effect by diffusion of the active ingredients to the skin.
Pessary, compressed	A solid preparation, generally similar to an uncoated tablet, but intended for vaginal administration. Also known as vaginal tablet.
Pessary, modified release	A pessary in which the rate of release of active ingredients in the vagina has been modified.

Short description	Long description
Pessary, moulded	A solid preparation, prepared by allowing a liquefied mass to cool in a mould of suitable size and shape. It contains one or more active ingredients and is intended for vaginal administration.
Pessary, shell	A solid preparation, similar to a soft capsule, but intended for vaginal administration. Also known as vaginal capsule.
Pessary	A solid preparation containing one or more active ingredients intended for vaginal administration.
Pill	A spherical or ovoid solid preparation containing a unit dose of one or more active ingredients for oral administration.
Powder, dusting	A finely divided powder composed of or containing one or more active ingredients intended for application to the skin, mucous membranes or wounds.
Powder, oral	A finely divided powder composed of, or containing one or more active ingredients for oral or nasogastric administration, generally with water. The dose is obtained either by measuring a volume of the powder or from an individual container e.g. sachet, paper tube or vial.
Powder	A mixture of solid, finely divided substances containing one or more active ingredients intended for internal or external use.
Slice	A thin piece cut from a larger portion of bulk raw material, usually of herbal or biological origin.
Solution, powder for	One or more active ingredients in a dry form to be reconstituted in a suitable liquid for use as a solution.
Solution	A liquid preparation composed of, or containing, one or more active substances dissolved in a suitable vehicle.
Spray, nasal	Spray, nasal
Spray, pressurised	A liquid preparation usually consisting of a solution, suspension or emulsion containing one or more active ingredients held under pressure with a suitable propellant or a suitable mixture of propellants. They are intended for local application and are delivered by the actuation of an appropriate valve.
Spray, solution	A liquid preparation for application after dispersion with a suitable device other than aerosol.

Short description	Long description
Spray, suspension	A liquid preparation containing one or more active ingredients dispersed as solid particles throughout a liquid phase. In addition it may contain other active ingredients which are dissolved.
Spray	A liquid preparation for application after dispersion with a spraying device.
Stick, lip	A solid preparation containing one or more active ingredients in stick form for application to the lips.
Stick	A solid preparation containing one or more active ingredients in stick form.
Suppository, compressed	A solid preparation generally similar to an uncoated tablet, but intended for rectal administration.
Suppository, moulded	A solid preparation, prepared by allowing a liquefied mass to cool in a mould of suitable size and shape. It contains one or more active ingredients and is intended for rectal administration, usually as a single dose.
Suppository, shell	A solid preparation, similar to a soft capsule, but intended for rectal administration, also known as a rectal capsule.
Suppository	A solid preparation containing one or more active ingredients intended for rectal administration, usually as a single dose.
Suspension, powder for	A finely divided powder composed of, or containing, one or more active ingredients to be reconstituted in a suitable liquid for use as a suspension.
Suspension	A liquid preparation composed of, or containing one or more active substances suspended in a suitable vehicle. It may also contain dissolved active substances.
Tablet, chewable	A tablet with a palatable formulation designed to be chewed rather than swallowed whole.
Tablet, dispersible	A tablet which rapidly produces a uniform dispersion in water and is intended to be dispersed prior to administration.
Tablet, effervescent	A tablet generally containing acid substances and carbonates or bicarbonates which react rapidly in the presence of water to release carbon dioxide. It is intended to be dissolved or dispersed in water before administration.

Short description	Long description
Tablet, enteric coated	A tablet covered with one or more layers of coatings intended to resist the gastric fluid but permit disintegration in the intestinal fluid.
Tablet, film coated	A tablet surrounded by a thin layer of various substances usually polymeric in nature.
Tablet, gelatin coated	A tablet surrounded by a layer of gelatin with or without other substances.
Tablet, modified release	A coated or uncoated tablet in which the rate or place of release of the active ingredients in the gastrointestinal tract has been modified.
Tablet, multilayer	A compressed tablet comprising two or more layers of different composition. The layers may be concentric (compressed coated) or parallel.
Tablet, orally disintegrating	A tablet that is intended to disintegrate rapidly on contact with siliva in the mouth. Tablet, orally disintegration approved as a new dosage form in AAN OOS 20/2002 meeting - 18 July 2002.
Tablet, soluble	An uncoated tablet that is intended to be dissolved in water prior to administration. The solution produced may be slightly opalescent due to excipients used in the manufacture of the tablet.
Tablet, sugar coated	A tablet surrounded by a layer of sugar with or without other substances.
Tablet, uncoated	A compressed solid preparation containing a unit dose of one or more active ingredients for oral administration. The tablet is not coated and not multilayer.

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.

9D(1) Variations

Subsection 9D(1) of the Act provides for variations to be made to an entry on a set of limited and prescribed circumstances. These circumstances include where information included in the register is incomplete or incorrect as a result of a mistake at the time of listing.

Before you apply, you should review the Changing a listed or assessed listed medicine: application levels and change tables to identify the relevant change type. If the change type is a 'variation' or 'correction' for a general listed medicine, you should consider submitting the change as a standard variation application (rather than a 9D(1) Variation) as this will be approved automatically by the system and the feewill be equal to or less than the fee for a 9D(1) Variation.

Where a listing has been incomplete or incorrect at time of listing, you can apply online through the TBS portal for a 9D(1) variation. Please ensure that all 9D(1) changes are made to your product within this application via the portal.

As part of this application, you will need to provide the following information:

- A copy of the original signed and dated product specifications showing the formulation of the medicine at the time of listing
- Evidence of how the mistake happened
- Advice of whether the product has already been manufactured and sold in Australia.

Once payment has been received, a delegate will review the changes made in the application, the description of changes and the supporting documentation. If your application is approved these changes will be written to the register.

Please note that your application will be assessed to ensure that your changes will not compromise the safety, quality or efficacy of your product. The delegate will also need to be satisfied that the changes do not mean that the good is separate and distinct to the manufactured medicine (as per subsection 16(1A) of the Act).

What if I have other changes to make?

The delegate will only consider changes that meet the definition of subsection 9D(1) of the Act in this application. If you have other changes to make, please submit them separately either:

- **before** creating the draft application for the 9D(1) Variation; or
- **after** the decision has been finalised for the 9D(1) Variation and has written to the ARTG entry.

Please note: if a second draft variation application is created before the first application has written to the ARTG entry, the second application will overwrite changes in the first application.

Trouble shooting in the TBS portal

The online listed medicine application and 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 (for example, a variation application generates a new AUST L), 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@health.gov.au. In your correspondence please include the following:

- application ID (located in the top right corner of your application)
- screen shot of the validation messages
- details of the change(s) required.

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. Internet Explorer: Press CTRL-SHIFT and click on the refresh button in the address bar at the same time. 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. Double click on the validation error to be directed to the field that is affected. You may need to check the requirements if the error is unexpected, for example the Permissible Ingredients Determination.
The following system error message appears - “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.
When validating an application the following error message appears stating ‘Warning X’ required, even though it has been added to the application.	Delete ‘Warning X’, save and validate the application. Re-add ‘Warning X’, save and validate the application.

Issue	Suggestion
You receive an automated email with a new AUST L or AUST L(A) but if this number does not appear on the Register.	Wait 24-48 hours for new AUST L or AUST L(A) number to appear on the Register. After this time, contact Complementary.medicines@health.gov.au.
The validation message appears – Manufacturer is not valid for dosage form.	The product dosage form must be an exact match with the Manufacturer's licence or clearance or be covered by a dosage form group. For example, tablet film-coated is covered by the dosage form group Solid Unit Dosage Forms – Tablets. For additional information refer to TBS Code Tables or contact Complementary.medicines@health.gov.au.
Your variation application generated a new AUST L or AUST L(A) number.	In the Application tab check that the radio button 'Change a current ARTG Entry' been selected & the AUST L or AUST L(A) number entered. Select the 'Search' button to pre-populate the application. If you have not changed anything it will automatically validate as a 'New' application. Check the Guidance on product changes to ensure the changes you have made do not warrant a 'New' AUST L or AUST L(A). If you make two or more Grouping type changes in the one application it is likely that a 'New' AUST L or AUST L(A) will be generated. For additional information refer to Guidance on Product Changes.
Your application has validated successfully but when you click on 'Proceed to Submission' – the 'eligible application' field is blank.	Ensure that the correct billing address and sponsor name has been selected.
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.	Unedited draft application will remain in the system for 365 days. The system will automatically delete it after this time. To prevent this, open the draft and select save.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	TGA	August 2013
V2.0	Updated publication	Complementary and OTC Medicines Branch	March 2018
V3.0	Updated to include guidance on linking permitted indications	Complementary and OTC Medicines Branch	June 2018
V4.0	Major rewrite and included assessed listed applications	Complementary and OTC Medicines Branch	March 2019
V5.0	Updated to remove all reference to code stock applications	Complementary and OTC Medicines Branch	July 2019
V5.1	Update to add 'Actioning a returned application', redefining how ingredients are displayed on documents, and removed references to specific and standard indications	Complementary and OTC Medicines Branch	July 2021

Therapeutic Goods Administration

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