Australian Government
Department of Health
Therapeutic Goods Administration

Requesting variations to your manufacturing licence

A step-by-step guide

Version 1.2, June 2021

TGA Health Safety Regulation

Contents

This is a step-by-step guide for Australian manufacturers of therapeutic goods (other than medical devices) applying through TGA Business Services to vary an in-force manufacturing licence for an Australian manufacturing site under section 40B of the *Therapeutic Goods Act 1989*. If you have any questions, contact the Manufacturing Quality Branch.

This process should not be used for requesting:

- **licence transfers**
- **licence suspension or revocation**
- **a new licence**
- **a new licence when a primary manufacturing site has relocated**

You **cannot** request a variation to your **GMP certification for an overseas manufacturer** via TGA Business Services. You should email these requests to Manufacturing Quality Branch.

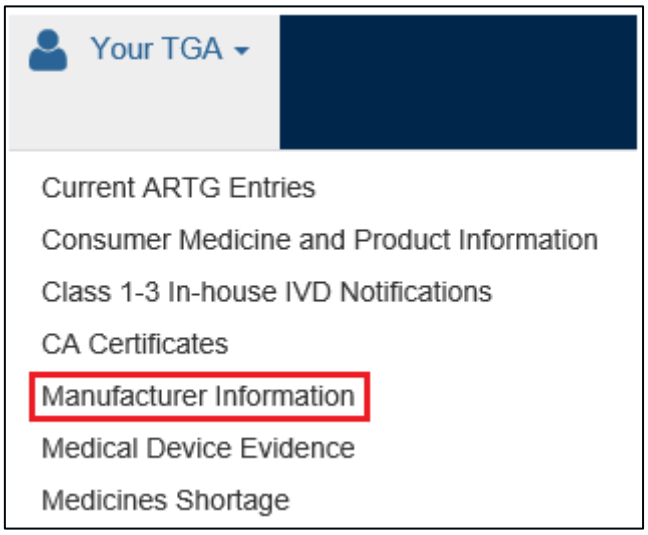
You can request to vary details of the manufacturing licence such as the licence nominees (Persons in control of Quality Control and Production) and manufacturing authorisations (e.g. dosage forms and manufacturing steps et cetera). See Section 40B of the *Therapeutic Goods Act 1989* for additional information.

Variations made to a manufacturing licence under Section 40B of the *Therapeutic Goods Act 1989* may incur a licence variation fee.

The application fees for manufacturing licence variations are published in the Summary of fees and charges, under Manufacturing medicines and OTGs.

Commencing a licence variation application

1. Log in to TGA Business Services.
2. Click on **Your TGA** to open the dropdown menu and select **Manufacturer Information**.



3. Search for your licence. One way to do this is to select **Licences** in the drop down menu in '**Approval Area**' field and '**filter on**' by **Identifier** to search for your licence number. You may search for your licence using other fields or filters too.

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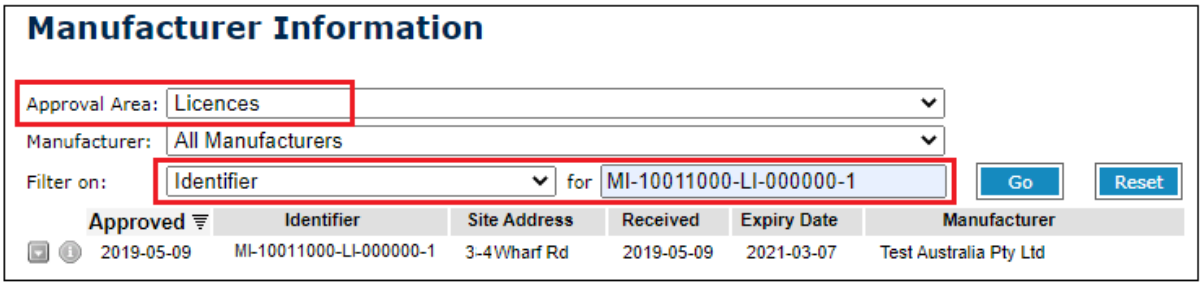
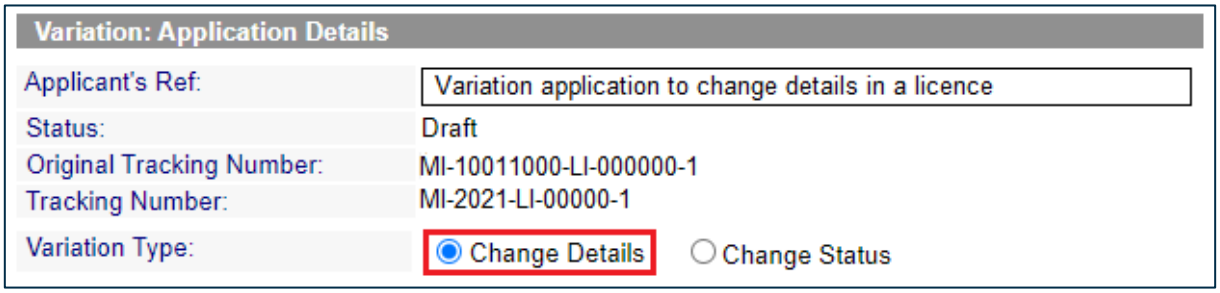


4. When you locate your licence, double-click on it. This will open your application.
5. Click on the **Vary Application** tab at the top of the screen.

6. Under **Variation: Application Details**, you will see:
   - the **original tracking number** – the tracking number of the current approved licence
   - the **tracking number** – the new tracking number for the replacement application
   - two radio buttons – **Change Details** and **Change Status**.

7. Select the **Change Details** radio button. (The **Change Status** button is used to request us to suspend or cancel the licence.)



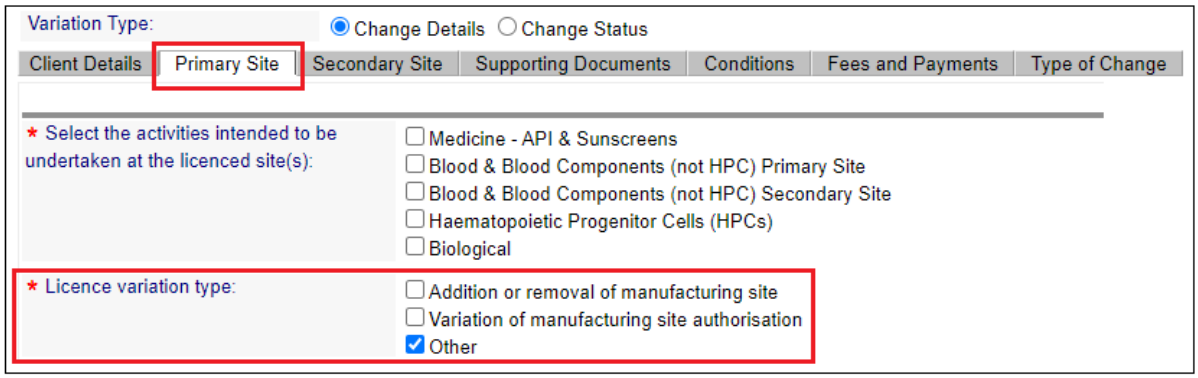
Variation application types

You can vary your application by editing a number of fields, including:

- the licence nominees (Persons in charge of Production and Quality Control)
- the manufacturing authorisations (Manufacturing Items table)
- the manufacturer name or address (Client Details tab)
- the secondary manufacturing site (Secondary Site tab)

Requesting a change to the licence nominees (Persons in charge of Production and Quality Control)

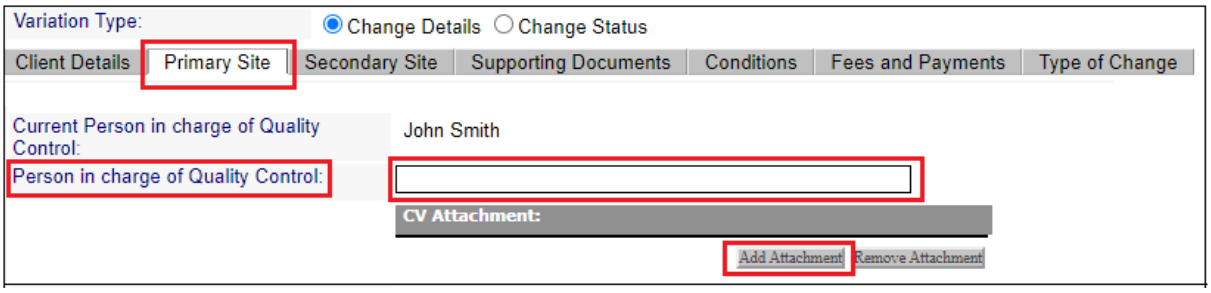
1. On the **Primary Site** tab, you will see a field for **Licence variation type**. For a change in the Person in charge of Quality Control or Production, select **Other**.



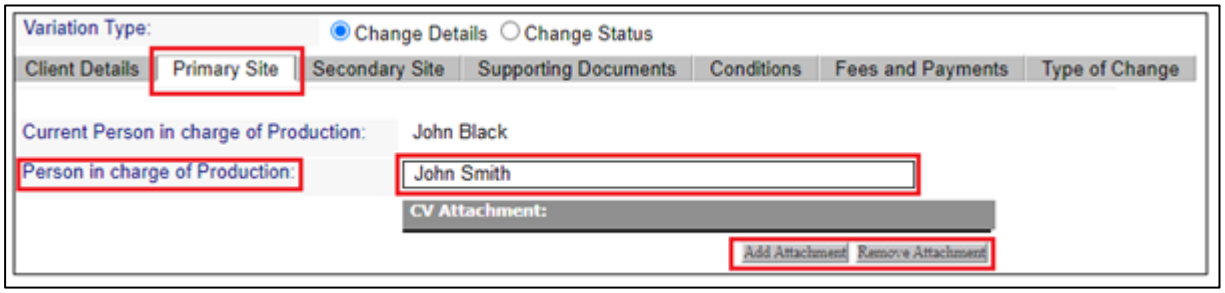
   Please ensure that you have selected '**Other**' to stop an invoice from generating, as this is an administrative change only.

   If you do not select '**Other**' and an invoice issues, the application cannot be process until the invoice is paid. Invoices may not be cancelled once generated.

2. On the **Primary site** tab, you will see the name of the current Person in charge of Quality Control and an editable field where you can enter the name(s) of the new nominee(s) and attach their CV (resume) if this a new person is now doing this role.

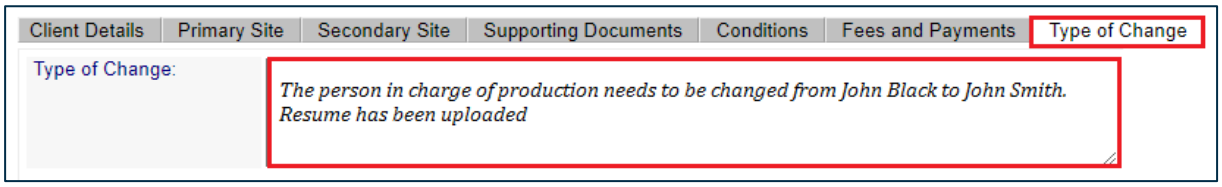


3. You can also enter the name(s) of the new nominee(s) for Person in charge of Production and attach their CV(resume) if this has changed.



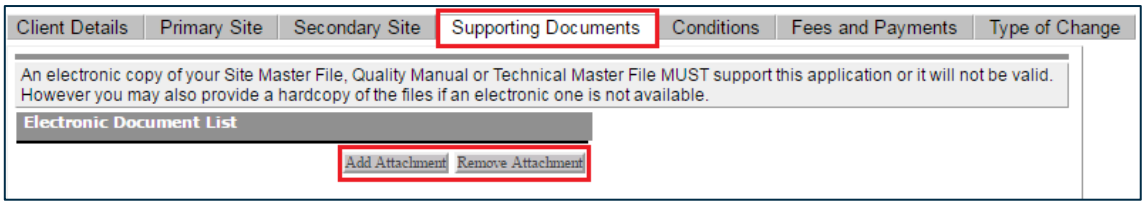
Under the **Type of Change** tab, please write a brief description of the requested change.

For example, '*The person in charge of production needs to be changed from John Black to John Smith. Resume has been uploaded*.' This is a free text box. The more information you provide, will assist us in processing your application in a timely manner.



Supporting documents

4. On the **Supporting Documents** tab you may attach a cover letter detailing the reason for the change and the date of its effect.

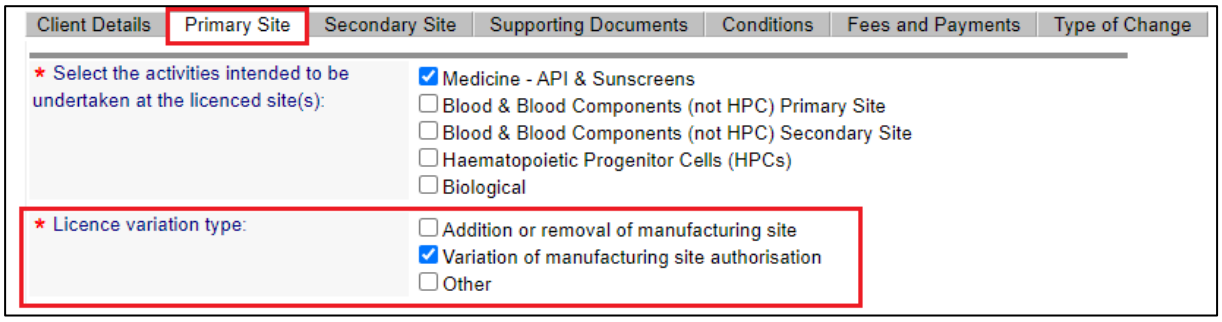


Under Regulation 21 of the *Therapeutic Good Regulations 1990*, the licence holder must inform the Secretary **as soon as practicable** when there is any change to those in charge of production and/or quality control and provide the name, qualifications and experience of the replacement person(s).

The licence remains in force and manufacturing operations can continue while we review your licence variation.

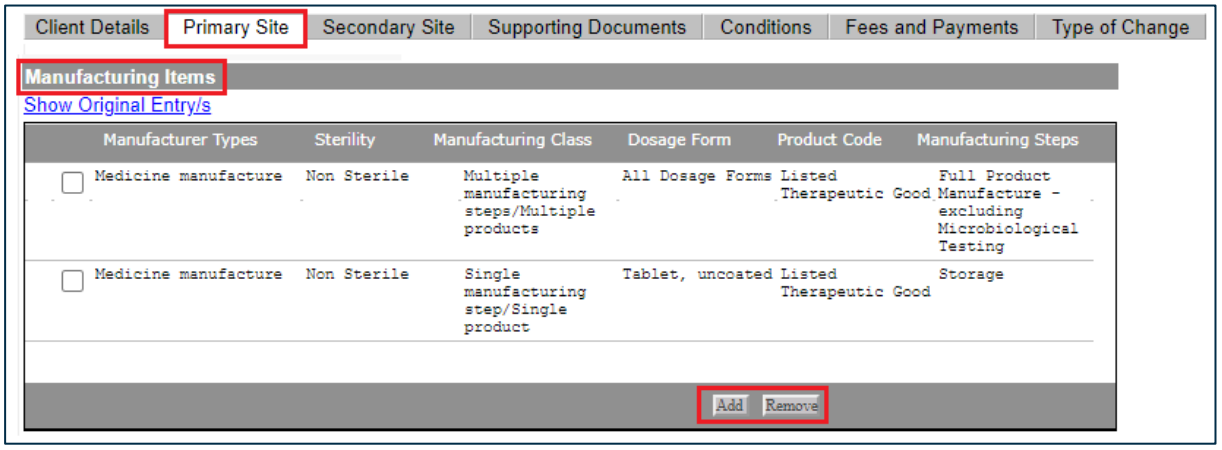
Requesting a change to manufacturing authorisations

1. On the **Primary Site** tab, you will see a field for **Licence variation type**. For a change in the manufacturing authorisations, select **Variation of manufacturing site authorisation**.



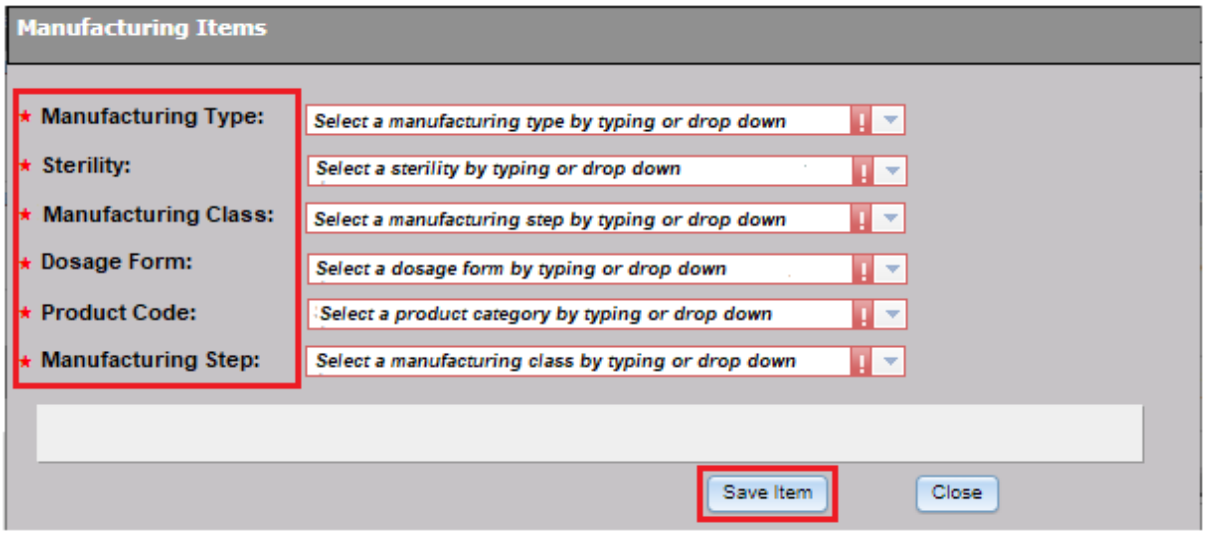
2. On the **Primary Site** tab, you can edit the **Manufacturing Items** table (e.g. dosage forms, manufacturing steps, et cetera) to add, remove or edit existing items.

   To add or remove an item, select the **Add** or **Remove** button at the bottom of the table.



Radio buttons are only visible in window-based applications. They are not visible using mac products like iPads etc.

3. When adding an item, a pop-up dialogue window will open. Make the appropriate selection from the dropdown menu for each field.



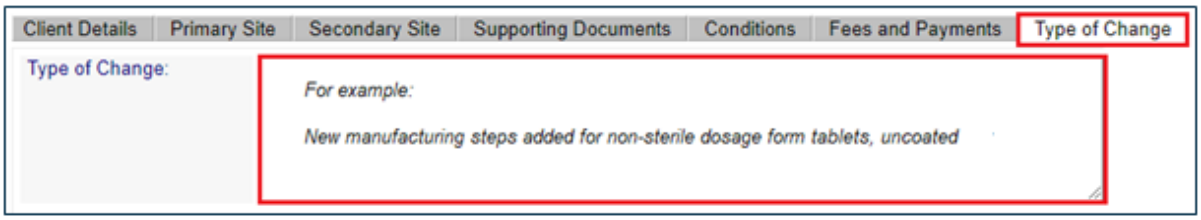
The dropdown menu is linked to **TGA code tables** for manufacturing type, sterility, manufacturing class, dosage form, product code and manufacturing steps.

A list of the current manufacturing steps and manufacturing steps groups can be found within the **Code Tables** heading under the '**Public TGA Information**' tab in the TGA Business Services (TBS) page

4. When you are finished, click on **Save Item** to add the new item.

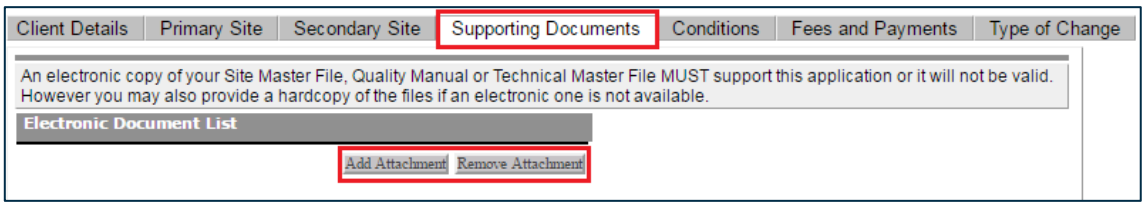
5. On the **Type of Change** tab, please write a brief description of the requested change.

For example, '*New manufacturing steps added for non-sterile dosage form tables, uncoated*'. This is a free text box. The more information you provide, will assist us in processing your application in a timely manner.



Supporting documents

6. On the **Supporting Documents** tab, attach a current Site Master File (SMF). Please also attach a cover letter detailing the requested change(s) and the proposed date of the change.



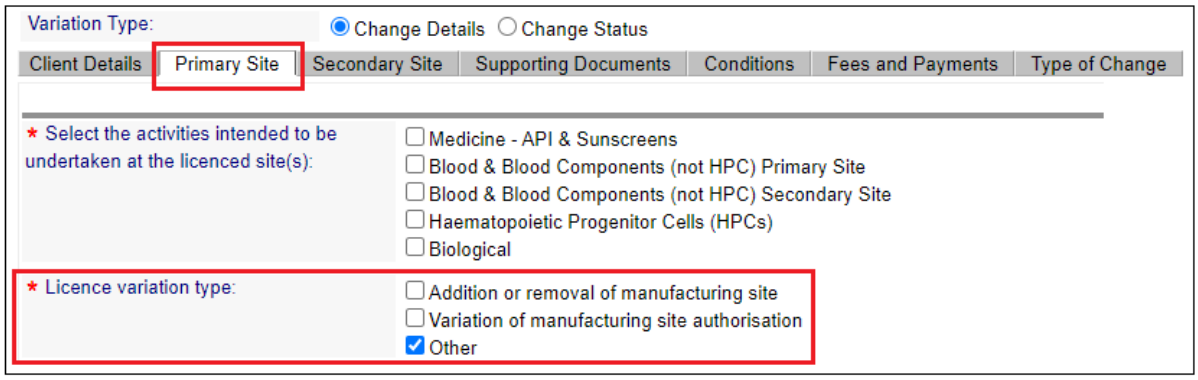
Changes to the items you are authorised to manufacture may require prior approval and an onsite inspection before the licence can be varied.

- **Do not commence additional manufacturing operations until an updated licence has been granted.**

Changing the manufacturer name or address

You can **change the manufacturer's name** on the **Client Details** tab.

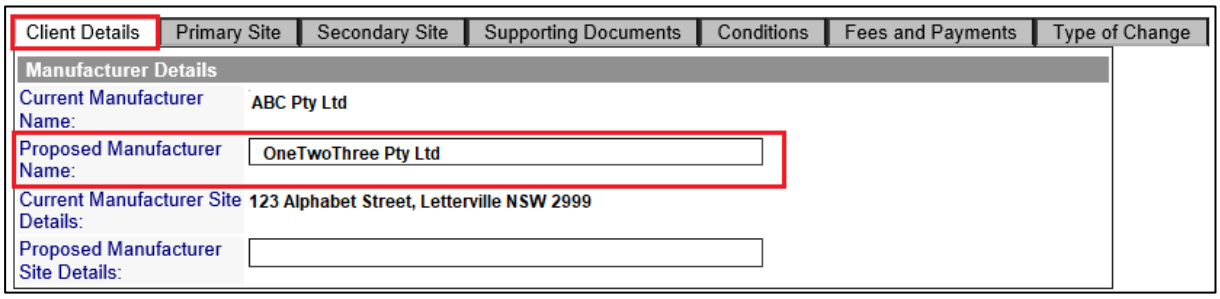
1. On the **Primary Site** tab, you will see a field for **Licence variation type**. For a change in the manufacturer name or address, select **Other**.



   Please ensure that you have selected **'Other'** to stop an invoice from generating, as this is an administrative change only.

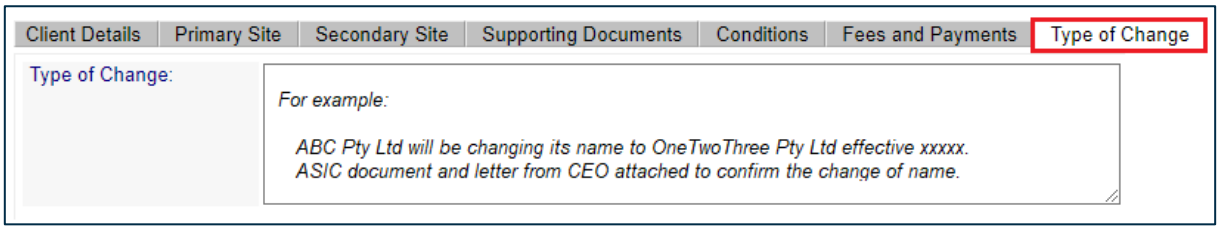
   If you do not select **'Other'** and an invoice issues, the application cannot be process until the invoice is paid. Once an invoice has been generated it may not be cancelled.

2. On the **Client Details** tab, under **Manufacturer Details,** type in the new proposed manufacturer name.



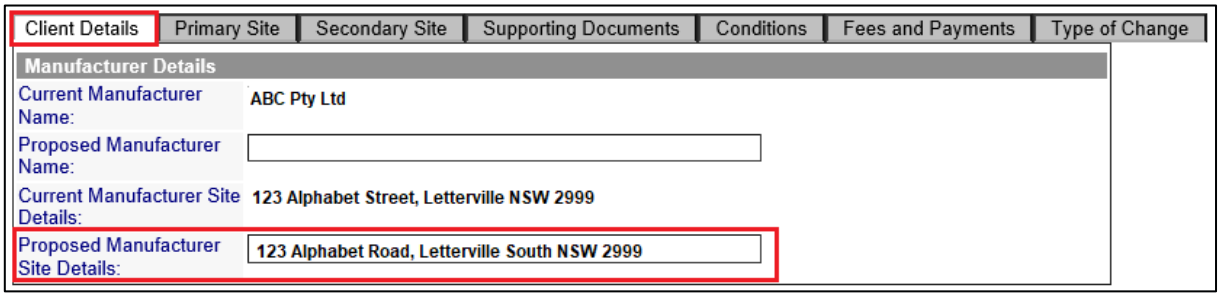
3. On the **Type of Change** tab, please write a brief description of the requested change.

   For example '*ABC Pty Ltd will be change its name to OneTwoThree Pty Ltd effective XX/XX/XXX* etc'. This is a free text box. The more information you provide, will assist us in processing your application in a timely manner.



4. If the primary manufacturing address has changed due to **council renaming or rezoning,** you can change the manufacturer's site address on the **Client Details** tab.

   On the **Client Details** tab, under **Manufacturer Details,** type in the new proposed **Manufacturer Site Details**.



Changes to primary manufacturing site address is only if a council has changed a street name or suburb etc.

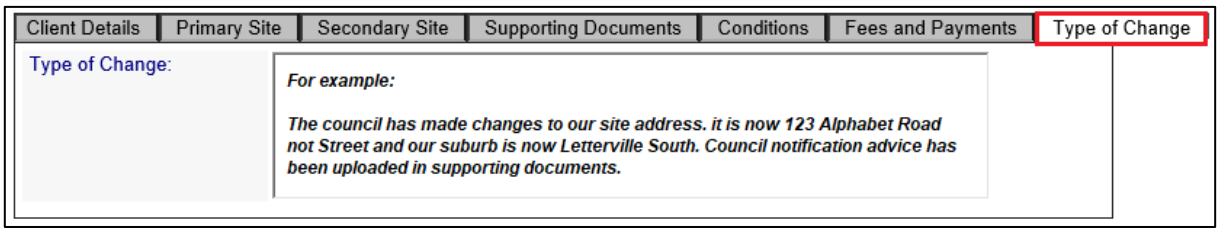
- **Do not use this process for primary manufacturing site relocations.**
- **Do not use this process for licence transfer requests.**

If there has been a change to an address because of a council change, the council notification advice must be provided.

5. On the **Type of Change** tab, please write a brief description of the requested change.

   For example '*The council has made changes to our site address. It is now 123 Alphabet Road not Street and out suburb is now Letterville South. Council notification advice has been uploaded in supporting documents*'.

   This is a free text box. The more information you provide, will assist us in processing your application in a timely manner.

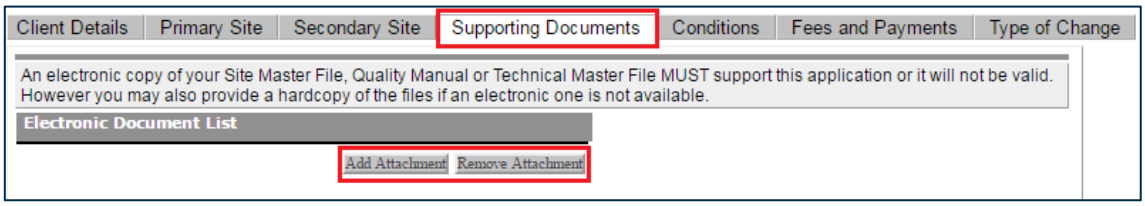


Supporting documents

6. On the **Supporting Documents** tab, attach a current Site Master File (SMF).

   For a **change of name**, please attach a copy of the ASIC document that supports the change of name as well as a letter from the Chief Executive Officer (CEO)/Managing Director (MD) confirming the change of name and the proposed date of the change.

   For a **change of address** due to a council decision, please attach a copy of the council notification advice.



Adding / removing a secondary site

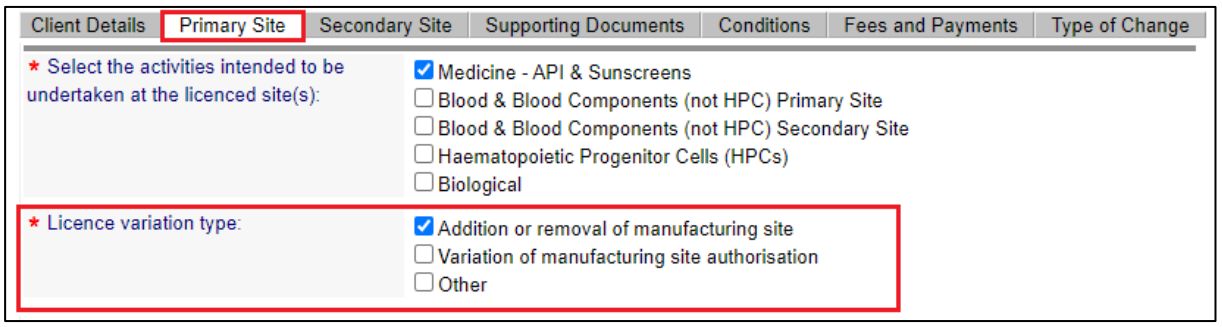
You can request to add a secondary manufacturing site to your licence.

You need prior approval to add a secondary site. The site must be inspected before we can grant an updated licence.

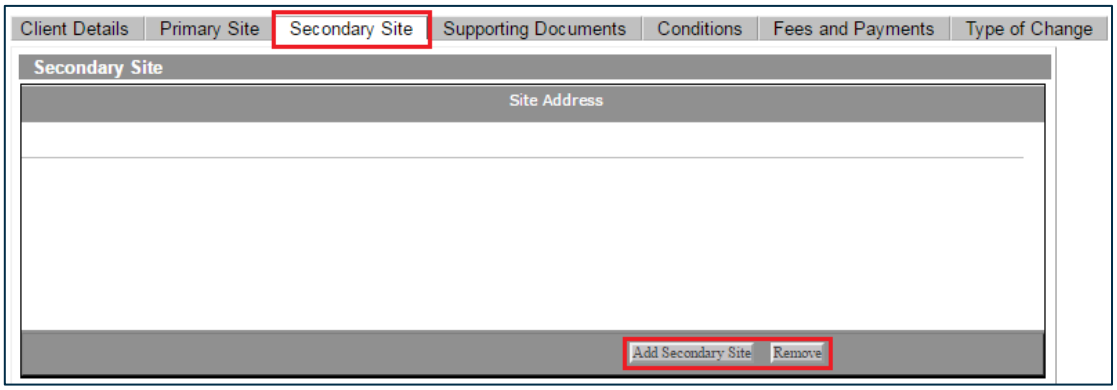
Secondary sites must meet the requirements outlined under section 38A of the *Therapeutic Goods Act 1989* in the Therapeutic Goods (Multi-Site Manufacturing Licences) Guidelines of 2010.

✖ **Do not commence additional manufacturing operations until an updated licence has been granted.**

1. On the **Primary Site** tab, you will see a field for **Licence variation type**. For the addition or removal of a secondary site, select **Addition or removal of manufacturing site**.



2. On the **Secondary Site** tab, click on the **Add Secondary Site** button at the bottom of the window. To remove a secondary site, select the site address and click on the **Remove** button at the bottom of the window.



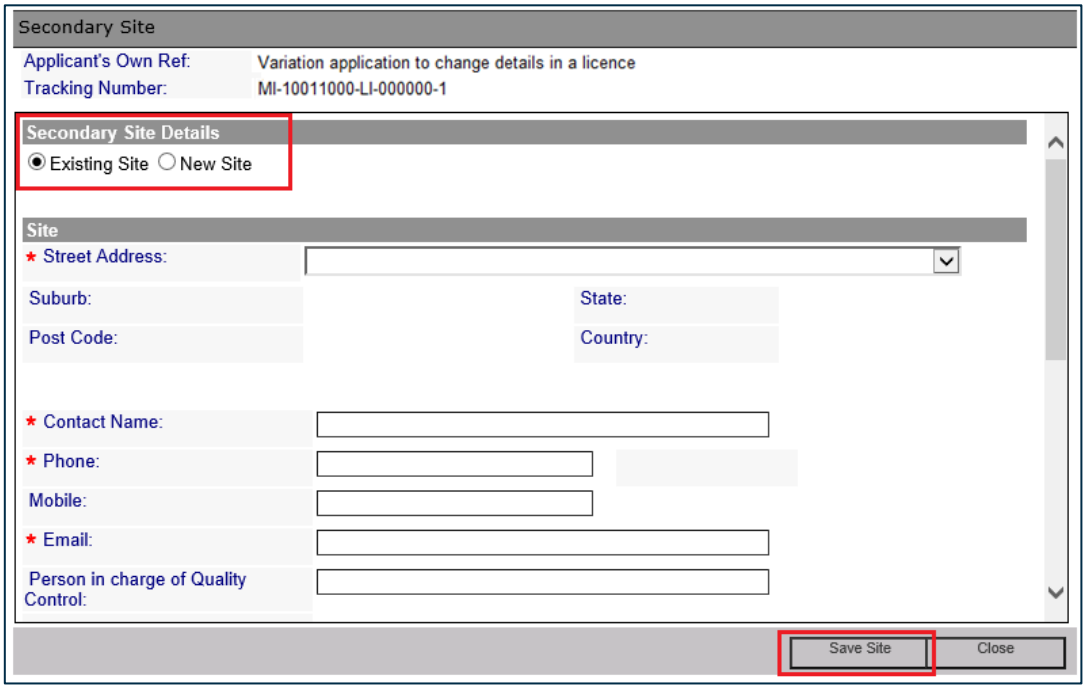
3. Where adding a secondary site, a pop-up dialogue window will open. You will see two radio buttons for **Existing Site** and **New Site**.

   – If you are changing the details of an existing site, select the **Existing Site** radio button and fill in the site details fields.

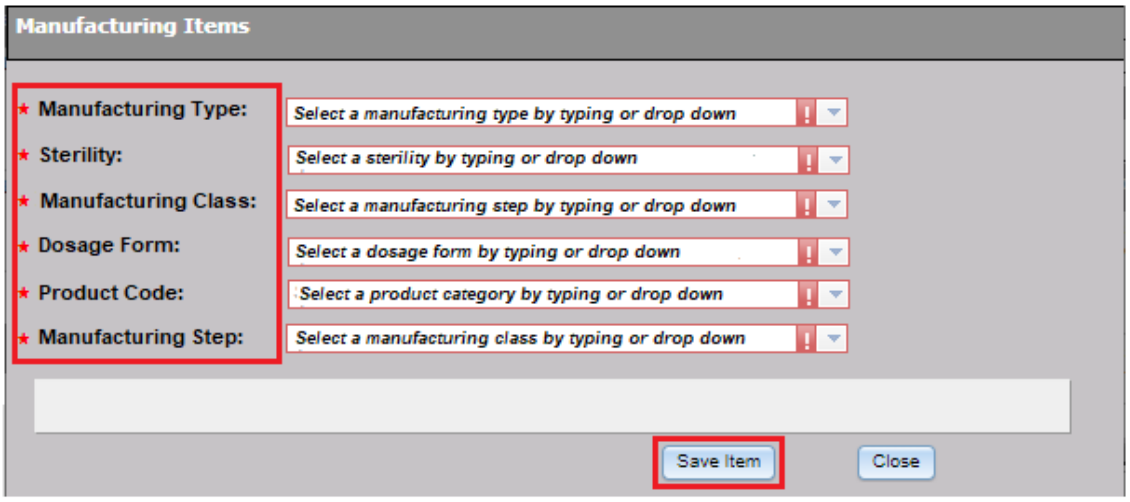
   – If you are entering a new site, choose the **New Site** radio button and fill in the site details fields.

   – Information must be added in fields denoted with an *

4. When you have entered all the necessary details, click on the **Save Site** button to save them.

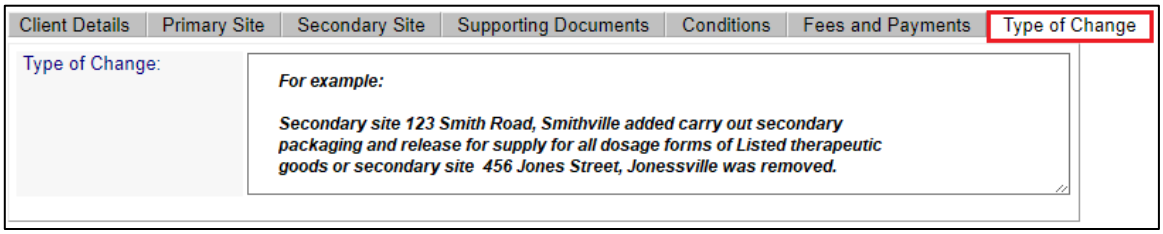


5. A pop-up dialogue window will open. Make the appropriate selection from the dropdown menu for each field. When you have made all the selections, click **Save Item**.



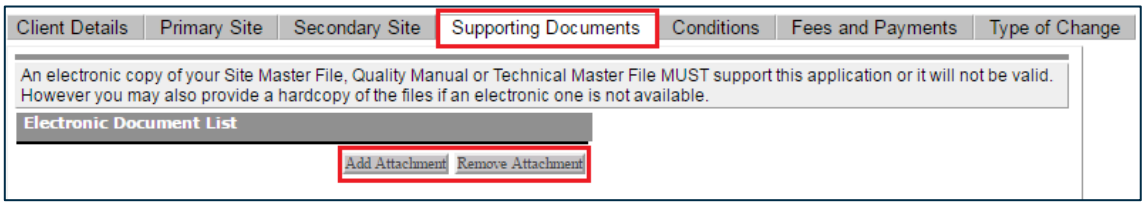
6. The **Type of Change** tab will appear after saving the application. On the **Type of Change** tab, please write a brief description of the requested change.

   For example *'Secondary site 123 Smith Road, Smithville added to carry out secondary packaging and release for supply for all dosage forms of listed therapeutic goods'* or '*Secondary site 456 Jones Street Jonesville was removed'*. This is a free text box, so the more information you provide, will assist us in processing the application in a timely manner.



Supporting documents

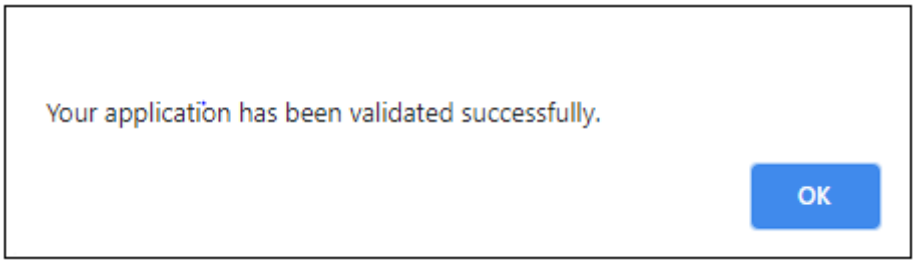
7. On the **Supporting Documents** tab, attach a current Site Master File (SMF). Please also attach a cover letter detailing the requested change and the proposed date of the change.



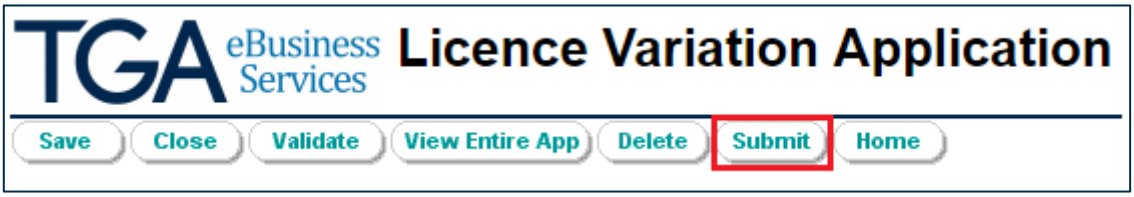
Completing & submitting your licence variation application

1. When you have entered all the variations you wish to request, click on the **Validate** button to validate your application. If validation fails, the system will advise you which areas you need to complete.

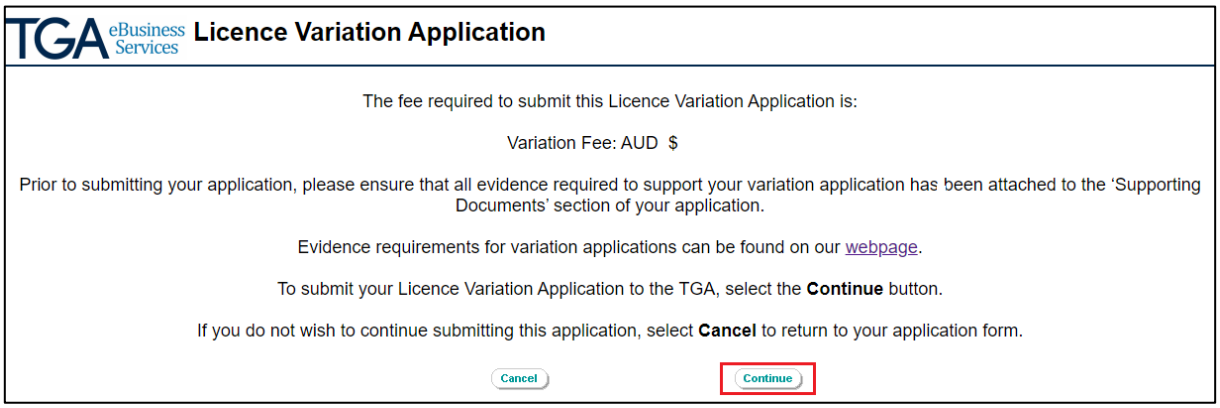
2. You will receive a pop-up message to advise you your application has been successfully validated.



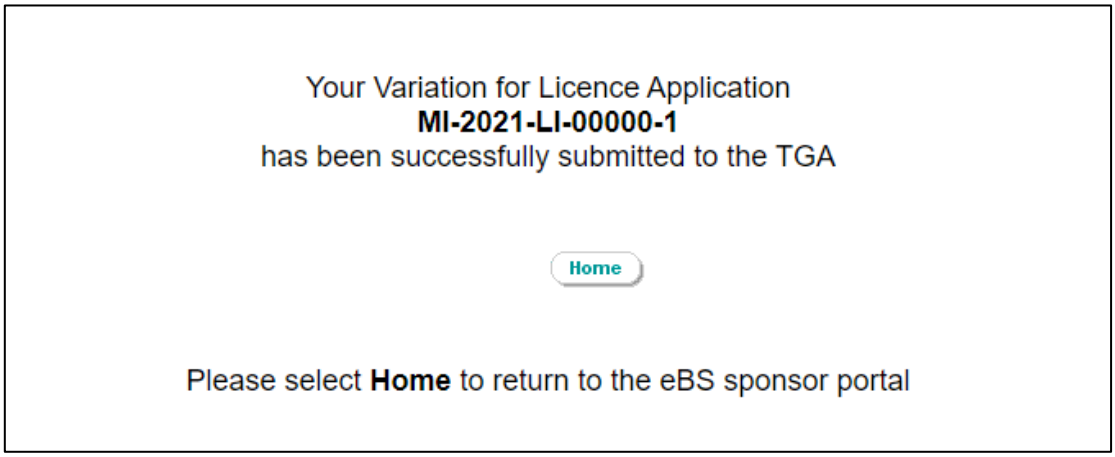
3. Click on the **Submit** button to submit your validated application.



4. When you click on **Submit** you will be shown the following screen, which advises you the associated cost for submitting the licence variation application and to ensure that all the evidence required to support a variation application has been submitted and offers you the option to **Cancel** your application or **Continue** with your submission.



5. Click on **Continue** to submit your application or **Cancel** to return to the application. If you choose **Continue**, you will receive the follow message confirming your application has been successfully submitted to the TGA.



Reviewing your variation application

We will review your variation application to determine whether an inspection is required. We may ask you for additional information to assist with our review.

If inspection is not required, we will let you know whether the variation is approved.

If an inspection is required, we will determine whether:

- this should be conducted as part of the next routine inspection, or
- a special inspection covering the scope of the variation is required.

The TGA works towards timeframes. Our target scheduled timeframes can be found on the TGA website under Target timeframes for manufacturing inspections.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication following consultation with industry in January 2017	Manufacturing Quality Branch	June 2017
V1.1	Added instructions for selecting manufacturer name and site details, and the manufacturing activities and variation type in the application form. Minor editorial changes.	Manufacturing Quality Branch	March 2019
V1.2	Minor editorial changes	Manufacturing Quality Branch	June 2021

Therapeutic Goods Administration

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