Australian Government
Department of Health
Therapeutic Goods Administration

Suspending, revoking and TGA initiated variation of conditions of a manufacturing licence

Version 1.2, December 2021

TGA Health Safety Regulation

Contents

Suspending and revoking manufacturing licences

This guidance will assist Australian manufacturers understand how TGA manufacturing licences can be suspended or revoked.

It is not intended for:

- ✘ overseas manufacturers
- ✘ medical device manufacturers

We provide separate guidance on Revoking manufacturing licences for not paying the annual charge on our website.

If you wish to request a variation to the details of your licence, see our guidance on Varying a manufacturing licence.

When we revoke or suspend a licence we will:

- notify you of our decision in writing
- publish our decision in the Gazette or on our website [in line with subsection 41(6) of the *Therapeutic Goods Act 1989*].

Our decision is considered an 'initial decision' and you can request it be reconsidered under subsection 60(1) of the *Therapeutic Goods Act 1989*.

Manufacturer requests to suspend or revoke a licence

If you wish to stop manufacturing therapeutic goods, you need to ask us to suspend or revoke your manufacturing licence [as per section 41(1)(d) of the *Therapeutic Goods Act 1989*]. You can make this request via TGA Business Services.

You will be required attach notification letter to your application addressed to the **Assistant Secretary, Manufacturing Quality Branch.** Your letter should address but not be limited to:

For suspending your licence:

- your request to suspend your licence including the site address and licence number
- the reason why you wish to suspend your licence; and
- the time period for the suspension including the date that you intend to resume manufacture.

This letter must be signed by the Licence Holder [as per section 38 of the *Therapeutic Goods Act 1989*).

For revoking your licence:

- your request to revoke your licence including the site address and licence number
- the reason why you wish to revoke your licence
- How you will maintain your GMP responsibilities for any product manufactured at the site including the management of:
  - Manufacturing documentation including batch documents
  - Management of any retention samples
  - Information including the contact person/company if a recall were required
- the date of the revocation.

Please note: all outstanding fees are required to be paid prior to the revocation of your licence.

This letter must be signed by the Licence Holder [as per section 38 of the *Therapeutic Goods Act 1989*).

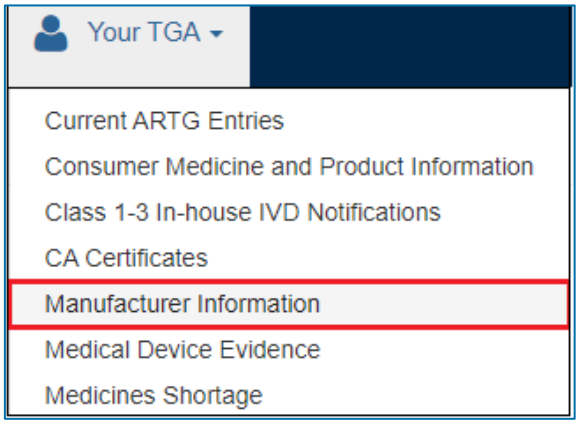
To request any other changes to your manufacturing licence, apply to vary your licence.

When we suspend or revoke a licence at your request we will not issue you a notice of intent. However, we may withdraw the revocation if you ask us to in writing within 90 days of the revocation date (as per section 41AAAA *Therapeutic Goods Act 1989*).

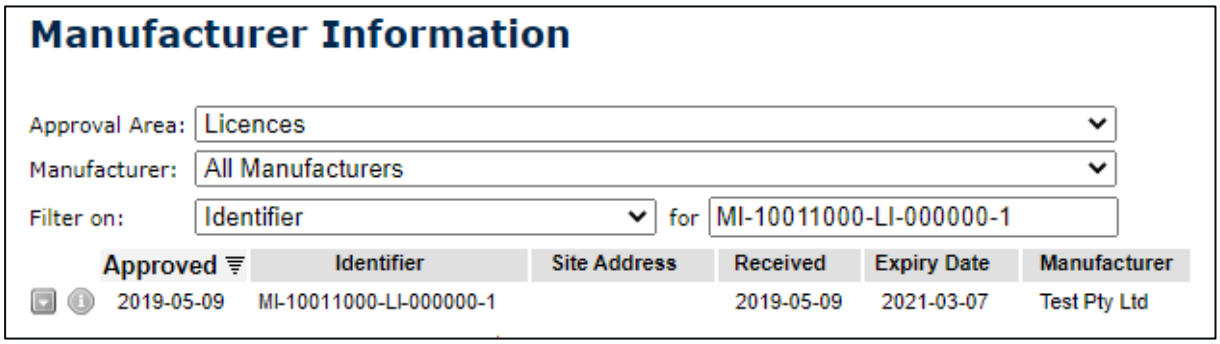
How to make a request to suspend or revoke a licence

You can ask us to suspend or revoke your manufacturing licence by applying through TGA Business Services.

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

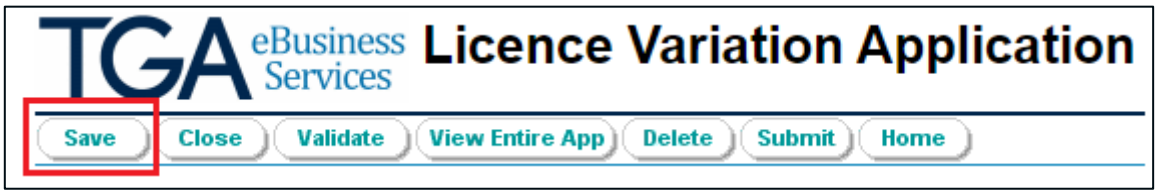


3. Search for your licence. One way to do this is to filter by **Identifier**, or you may search for your licence using other fields or filters.

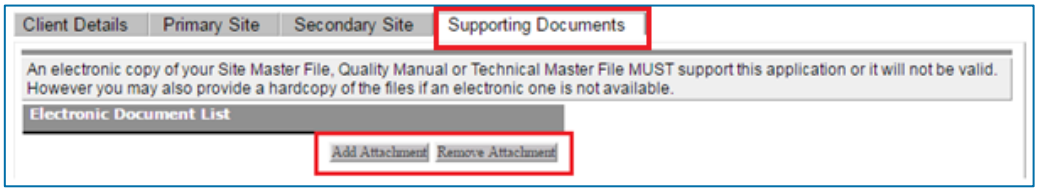


4. When you locate your licence, double-click on it to open the licence.
5. Click on the **Vary Application** button at the top of the screen.

6. Click on the **Save** button at the top of the screen



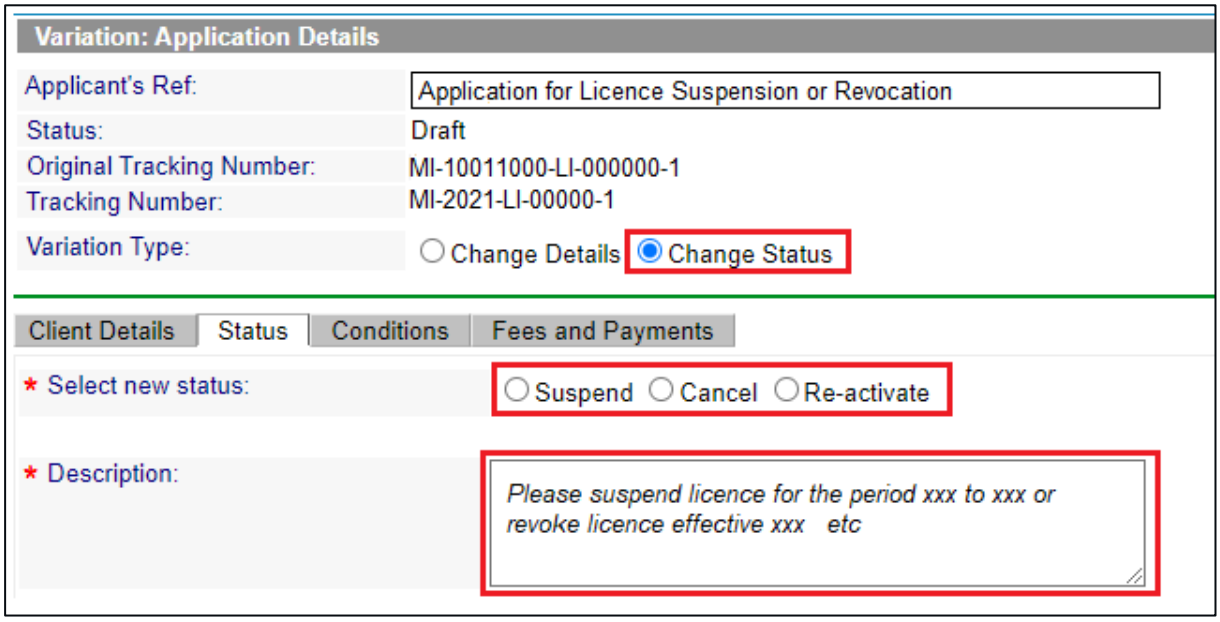
7. Click on the Supporting D**ocuments** tab and attach a notification letter to your application addressed to the **Assistant Secretary, Manufacturing Quality Branch**.



8. **Under Variation: Application Details**, you will see to see two radio buttons; Change Details and Change Status.

9. Select the **Change Status** radio button, then select the **Status** tab.

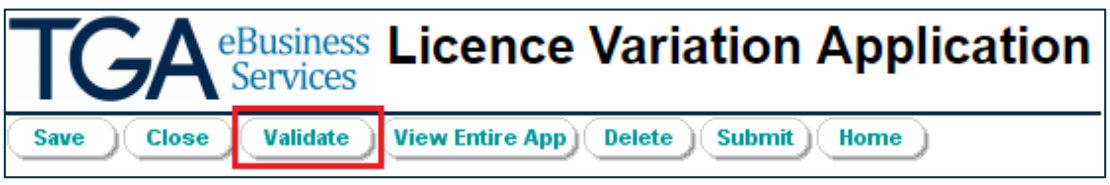
10. On the **Status** tab you will see a **Select new status** field and three radio buttons.



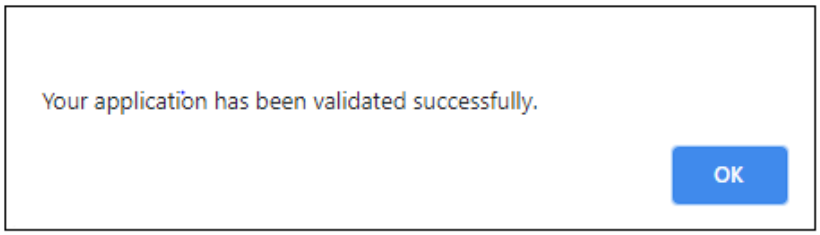
11. Select the **Suspend** radio button if you wish to suspend your licence. Select the **Cancel** radio button if you wish to request us to revoke your licence.

    You must provide details of the action to be taken in the Description text box.

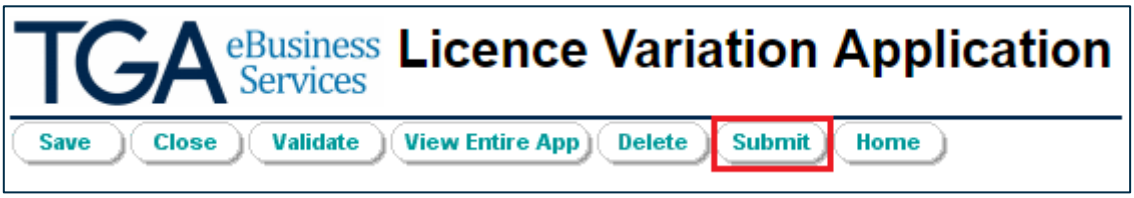
12. Click on the **Validate** button to validate your application. If validation fails, the system will advise you which areas you need to complete.



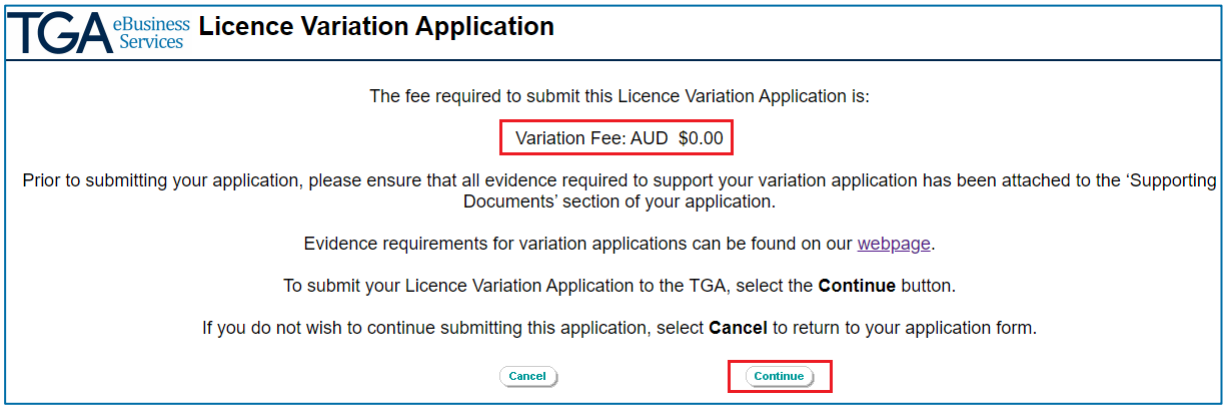
You will receive a pop-up message to advise you your application has been successfully validated.



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

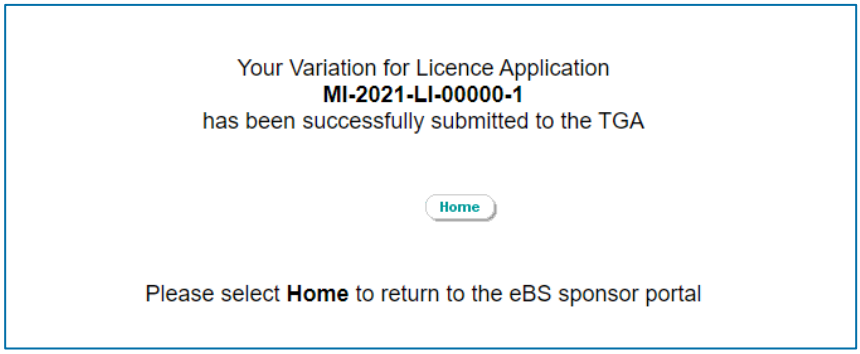


14. When you click on **Submit** you will be shown the following screen to ensure that all the evidence required to support a suspension or cancellation application has been submitted and offers you the option to cancel your application or continue with your submission.



There is currently no fee for submitting a request to suspend or revoke a TGA manufacturing licence.

15. Click on **Continue** to submit your application. You will receive the follow message confirming your application has been successfully submitted to the TGA.



TGA-initiated suspension or revocation

Why we suspend or revoke licences

We may suspend or revoke a licence for any of the reasons listed in section 41(1) of the *Therapeutic Goods Act 1989*. Where we propose to revoke or suspend a licence, other than at the request of the licence holder, we would issue a notice of intent to revoke or suspend, unless we consider there is imminent risk.

Imminent risk

If we consider there is imminent risk of death, serious illness or serious injury, we may immediately suspend or revoke a manufacturing licence without notice of intent, as prescribed in section 41(2) of the *Therapeutic Goods Act 1989*.

We may also take other regulatory actions depending on the nature of the risk.

Process

This section describes the typical process for how TGA initiates and actions the suspension or revocation of a manufacturing licence.

1: Notification of intent

When we intend to suspend or revoke a manufacturing licence, we will usually advise you in writing of our intention to suspend or revoke the manufacturing licence.

We are not required to issue a notice of intent if we consider there is an imminent risk of death, serious illness or serious injury, as prescribed in section 41(2) of the *Therapeutic Goods Act 1989*.

2: Delegate's decision

The Secretary's delegate will decide whether to suspend or revoke your manufacturing licence under subsection 41(1) of the *Therapeutic Goods Act 1989*, and will take into account any information submitted in response to our notification of intent before making a decision.

3: Publishing our decision

When we decide to suspend or revoke your manufacturing licence, we will:

- notify you of our decision
- publish the decision in the Gazette or on our website [subsection 41(6) of the *Therapeutic Goods Act 1989*].

4: Your ongoing obligations

If your manufacturing licence has been suspended or revoked:

- it becomes an offence to manufacture, supply or export a therapeutic good from the manufacturing site, in accordance with section 35(4) of the *Therapeutic Goods Act 1989*.

TGA initiated variations to your licensing conditions

We may impose new conditions, or vary or remove existing conditions of your licence, in accordance with section 40(2) of the *Therapeutic Goods Act 1989*. We will notify you of any such decision in writing.

In accordance with section 40(3) of the *Therapeutic Goods Act 1989*, any changes to conditions (whether to vary or remove conditions or impose new conditions) take effect:

- **on the day the notice is given** if there is an imminent risk of death, serious illness or injury
- **on the day specified in the notice** in any other case. This must be at least 28 days after notice is given unless the person has agreed to an earlier day.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication following consultation with industry in January 2017	Manufacturing Quality Branch	August 2017
V1.1	Minor editorial changes	Manufacturing Quality Branch	March 2019
V1.2	Minor editorial changes	Manufacturing Quality Branch	December 2021

Therapeutic Goods Administration

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Reference/Publication #