Australian Government
Department of Health
Therapeutic Goods Administration

Completing a determination or designation application form in TGA Business Services

A step-by-step guide for prescription medicines

Version 1.1, March 2018

TGA Health Safety Regulation

Copyright
© Commonwealth of Australia 2018
This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to <tga.copyright@tga.gov.au>.

Contents

Before you apply ____ 4

Completing your application ____ 4

Saving your draft application ____ 5

The Applicant Details tab ____ 6

The Application Scope tab ____ 8

Priority Review Determination ---- 8

Provisional Determination ---- 8

Orphan Drug Designation ---- 9

The Product Details tab ____ 12

The Administration tab ____ 15

Validating your application ____ 17

Submitting your application ____ 18

Application assessment ____ 18

This is a step-by-step guide for agents and sponsors who wish to apply for Priority review or, Provisional determination and / or Orphan drug designation of a prescription medicine.

If you are logging in as a sponsor, some fields that are visible to agents will not be visible to you. This is because we already hold certain information about you and you do not need to re-enter it.

Before you apply

To make an application you will need:

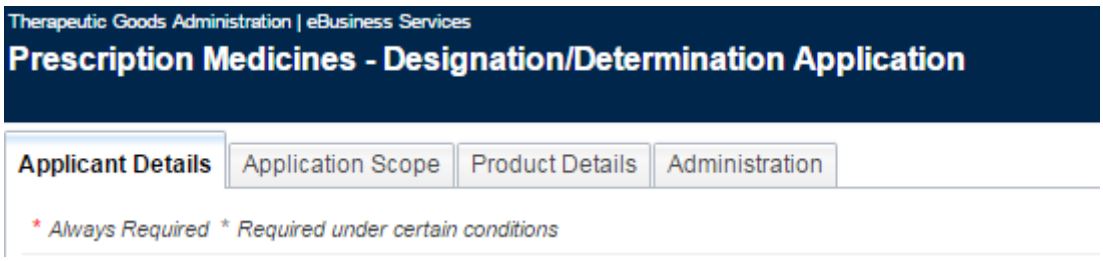
- a TGA client ID number
- access to the TGA Business Services (TBS) portal

If you do not have a client ID number or access to the TGA Business Services portal, go to TGA Business Services: getting started with TGA and submit the online organisation details form.

Completing your application

1. Log in to TGA Business Services.
2. From the **Applications** dropdown menu, go to Prescription Medicine and select **Designation/Determination**.

3. An application window will open. This window offers four tabs:
   - Applicant Details
   - Application Scope
   - Product Details
   - Administration



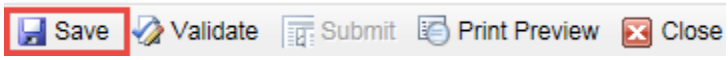
On each tab there are a number of fields to fill in.

Fields marked with a red asterisk (*) are always mandatory. Fields marked with a grey asterisk (*) are mandatory in some circumstances.

Saving your draft application

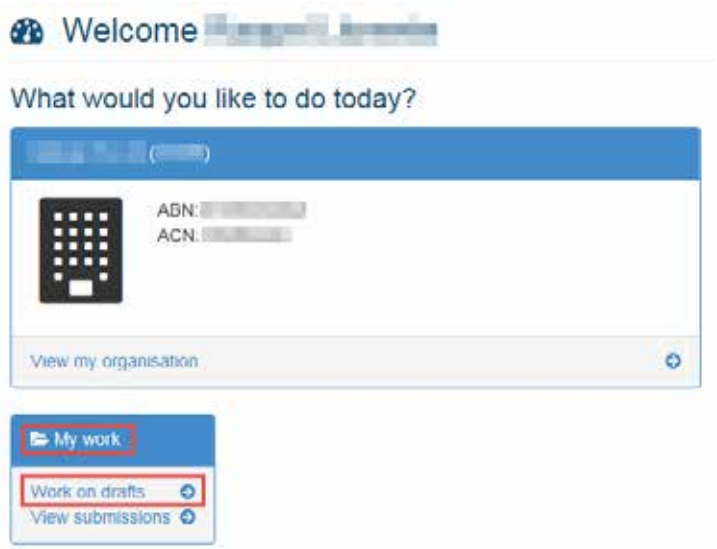
If you need to exit your application before it is complete, you can save it as a draft.

1. From within the application screen, click on the **Save** button at the bottom right of your browser window.

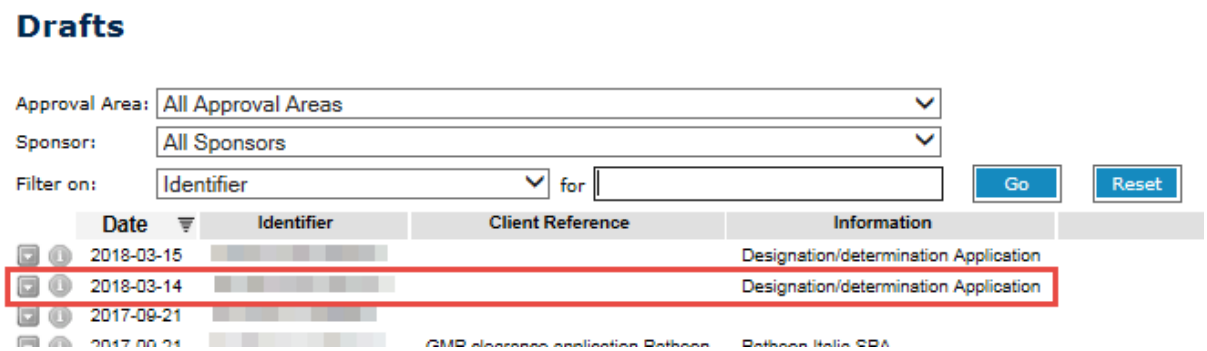


   Your changes will be saved as a draft. You can now close your application.

2. When you next log in to your Business Portal, go to the **My work** menu and click on the arrow beside **Work on drafts**.



3. This will open a list of your drafts. Choose your draft determination/designation application from this list.



4. Double-click on the Designation/determination Application to reopen your draft and continue.

The Applicant Details tab

Enter the applicant details on the **Applicant Details** tab.

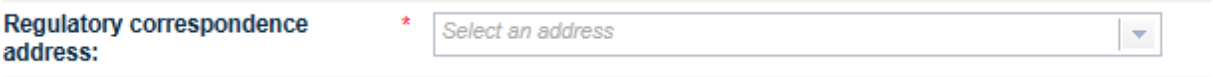
1. The first field on this tab is **Applicant name**. This is a mandatory field and will be automatically populated based on your login details.

If you are logged is as a sponsor you do not need to complete step 2 or step 4. You must complete step 3.

Agents will need to complete all steps.

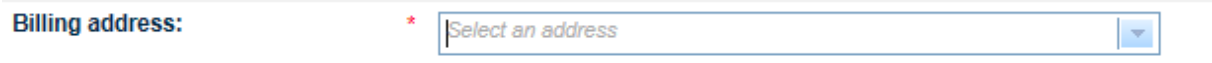
2. The next field is **Sponsor organisation**. This field is mandatory. Click on the arrow at the right of the field and select the appropriate sponsor organisation from the dropdown list.

3. Next, select the appropriate **Regulatory correspondence address** from the drop down menu.



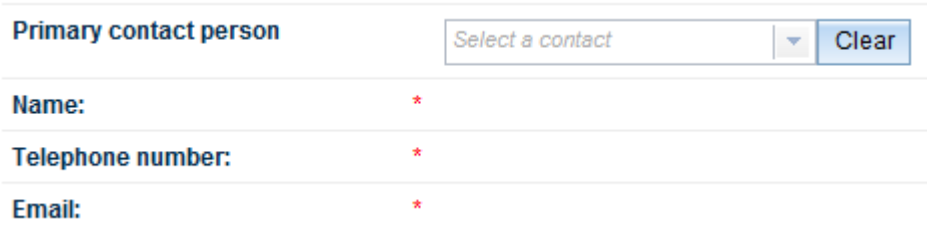
4. Next, indicate whether you wish us to **Send fee invoice to sponsor**. Select either the **Yes** or **No** radio button as appropriate.

5. Once you have selected a sponsor, you will be able to choose the appropriate **Billing address** from the associated dropdown lists.



6. The next field allows you to select a **Primary contact person**. Click on the down arrow at the right of the field to select the appropriate contact person from the dropdown list.

   The Name, Telephone number and Email fields will auto-populate once you have made your selection.

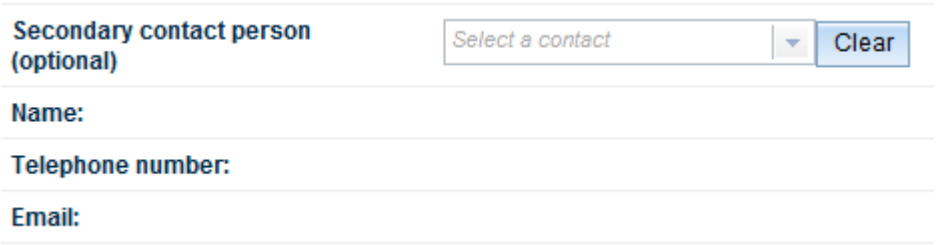


If you are logged in as a sponsor, the fields above will already be populated.

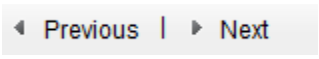
You can change the auto-populated details by clicking on the **Clear** button at the right of the Primary contact person field.

7. Finally, you may also nominate a **Secondary contact person**. This field is not mandatory.

   Click on the down arrow at the right of the field to select from the dropdown list. The Name, Telephone number and Email fields will auto-populate once you have made your selection.



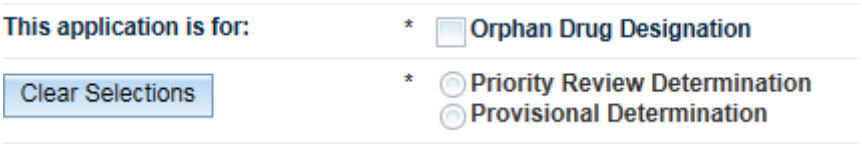
8. When you are done, click on the **Next** button at the bottom left of the browser window to move to the next tab.



The Application Scope tab

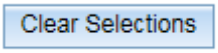
The **Application Scope** tab offers explanatory information on the application process and allows you to indicate if you are applying for Priority review determination, Provisional determination and/or Orphan drug designation. You can also upload supporting documentation from this tab.

Select which determination and/or designation you wish to apply for.



You may select Priority Review Determination OR Provisional Determination AND/OR Orphan Drug Designation.

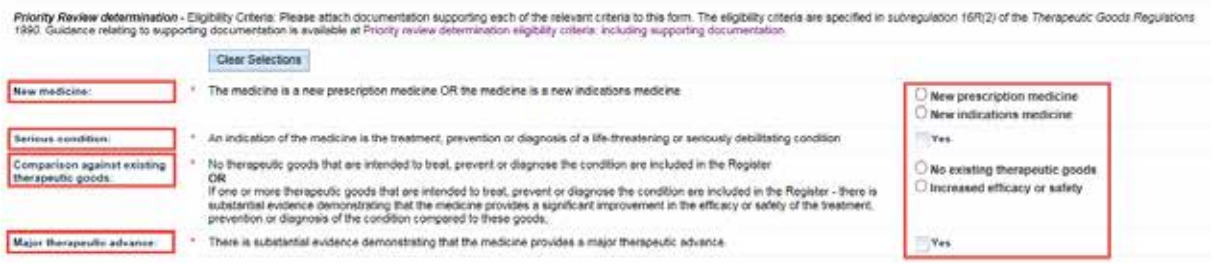
If you make an incorrect selection, click on **Clear Selections** to clear your selection.



Priority Review Determination

Selecting **Priority Review Determination** will open explanatory text and a number of related fields:

- New medicine
- Serious condition
- Comparison against existing therapeutic products
- Major therapeutic advance

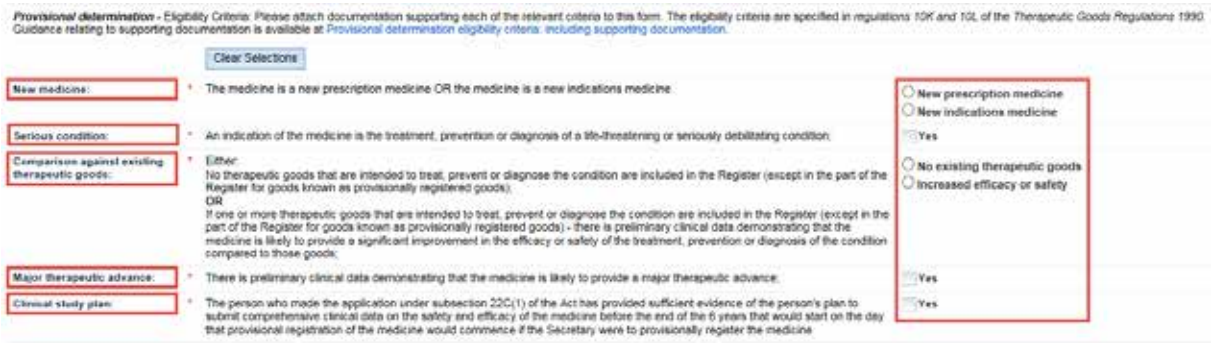


These fields are mandatory. Select an answer for each field in line with the guidance provided.

Provisional Determination

Selecting **Provisional Determination** will open explanatory text and a number of related fields:

- New medicine
- Serious condition
- Comparison against existing therapeutic products
- Major therapeutic advance
- Clinical study plan



These fields are mandatory. Select an answer for each field in line with the guidance provided.

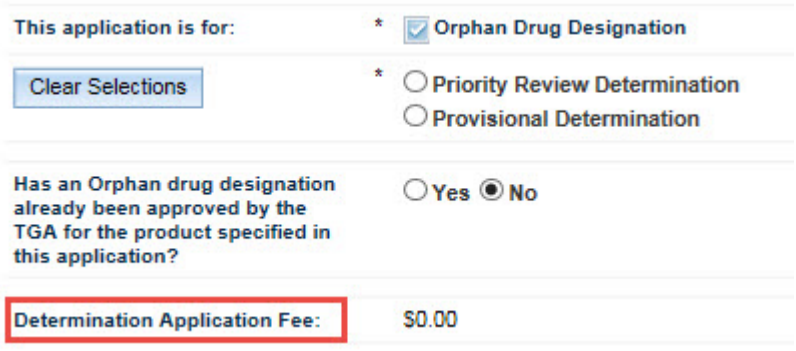
Orphan Drug Designation

Selecting **Orphan Drug Designation** will open explanatory text and a number of related fields.

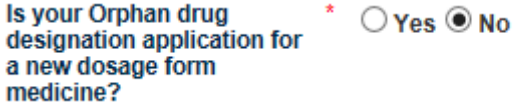
1. The next field asks you to indicate whether the product has **already been designated** an Orphan drug for the proposed indication. Select either **Yes** or **No** as appropriate.

If you wish to select No, you must first click on Yes and then on No to auto-populate the **Determination Application Fee** field.

2. The next field, **Determination Application Fee**, will be auto-populated. If you select **Yes** for the previous question, the field will auto-populate with $0.00. If you select **No**, the field will auto-populate with the appropriate fee.



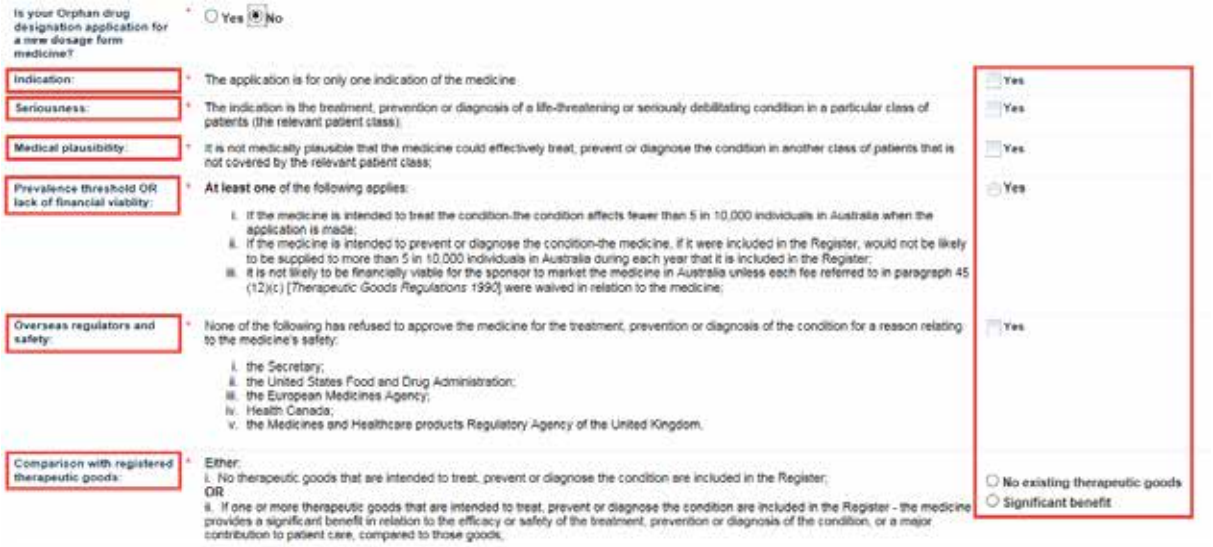
3. Is your Orphan drug designation application for a **new dosage form medicine**? Select **Yes or No** depending on the orphan designation type you are applying for.



4. A set of different criteria will display depending on whether you selected Yes or No to the above question.
   - Indication

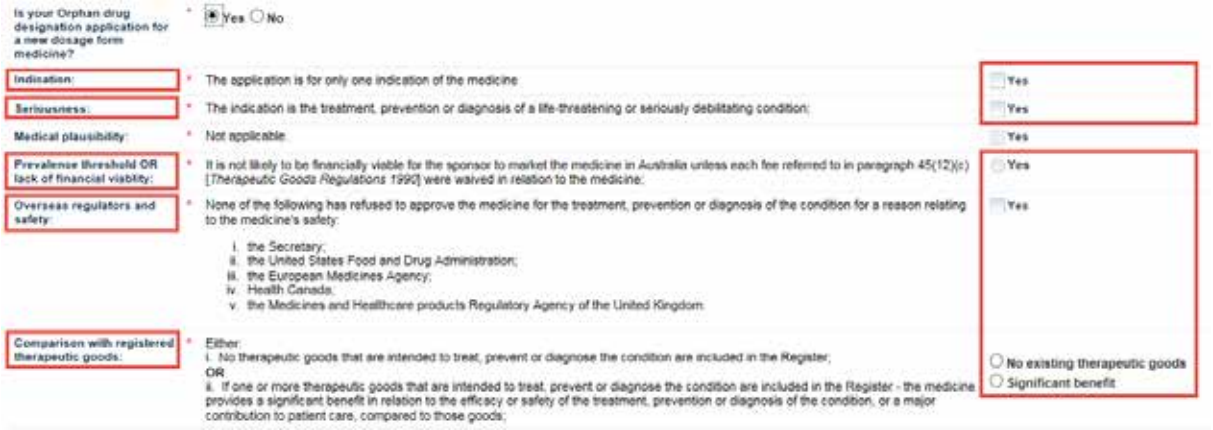
- Seriousness
- Medical plausibility
- Prevalence threshold OR lack of financial viability
- Overseas regulators and safety
- Comparison with registered therapeutic goods

Orphan drug designation – **Not a New Dosage Form** eligibility criteria



OR

Orphan drug designation – **New dosage form** eligibility criteria

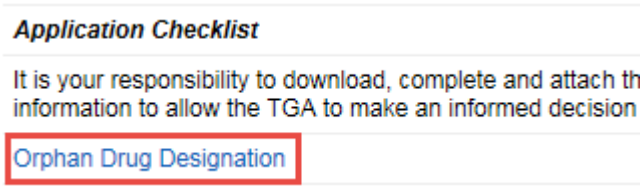


These fields are mandatory. Select an answer for each field in line with the guidance provided.

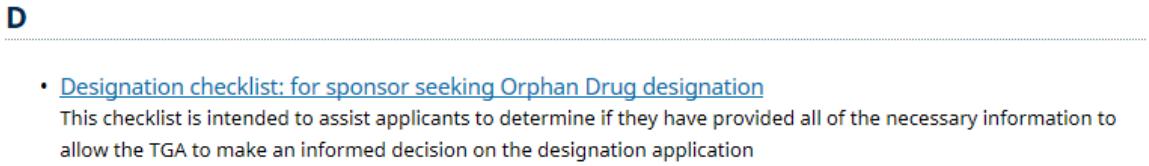
There are no fees for Orphan drug designation applications.

If you are applying for both Orphan drug designation and either Priority review or Provisional determination at the same time, you will be charged the applicable determination fee. However, if your Orphan drug designation is granted, your determination application fee will be refunded.

5. The Application Scope tab also offers a link to the **Application Checklists**, which will become available depending on the application scope you select at the top of the tab.

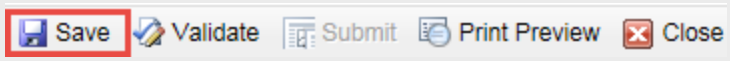


These links will take you to a form page, where you can access the application checklists under **D** for **Designation/determination checklist**.

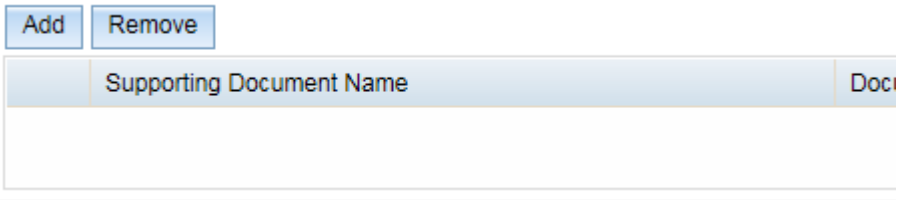


6. You can upload **Supporting Documentation** at the bottom of this tab. See our guidance on the eligibility criteria and supporting documentation for Priority review determination, Provisional determination and Orphan drug designation for more information.

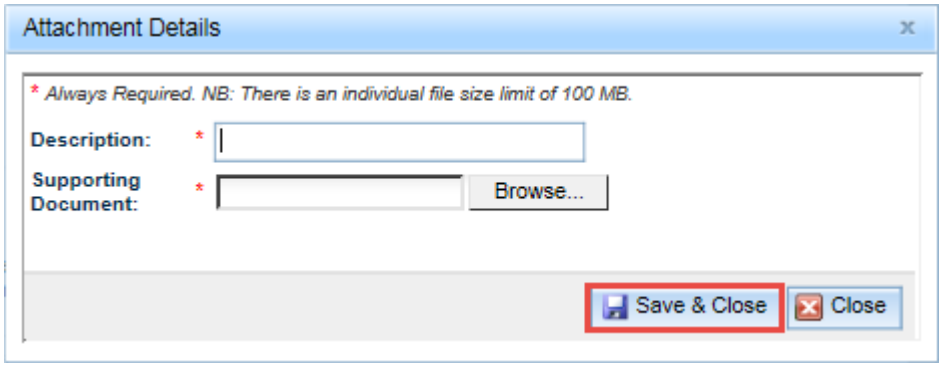
Note: the Add and Remove buttons will be greyed out until you have saved the form at least once. To activate these buttons, click on the **Save** button at the bottom right of your window.



Once you have saved the document, the Add and Remove buttons will become active. Click on the **Add** button to upload a supporting document.



7. This will open an **Attachment Details** pop-up window.



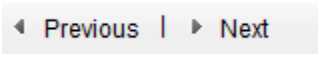
Both fields in the Attachment Details pop-up window, **Description** and **Supporting Document**, are mandatory. Enter a description of the file and then click on the **Browse** button at the right of the Supporting Document field to find and upload the document.

8. Click on **Save & Close** to upload your file.

Any file you upload must meet the formatting requirements outlined in parts A and B of the general dossier requirements.

Upload separate documents for each determination and designation you are applying for.

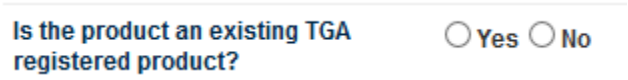
9. Click on the **Next** button at the bottom left of the browser window to move to the next tab, or click on Previous to go back.



The Product Details tab

Enter information about your product on the **Product Details** tab.

1. The first field asks if your medicine is an **existing TGA registered product**. Select **Yes** or **No** as appropriate.



If you select **Yes,** two additional fields, ARTG Number(s) and Existing indication, will open.

2. Enter the ARTG Number of your product in the **ARTG Number(s)** field.

3. Next, enter the active ingredient in the **Name of active ingredient(s)** field. This field is mandatory.

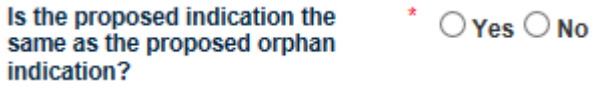
This form does not validate the ARTG number and ingredients against the ARTG database. Please enter this information correctly.

4. Enter the existing indication for your product in the **Existing indication** field.

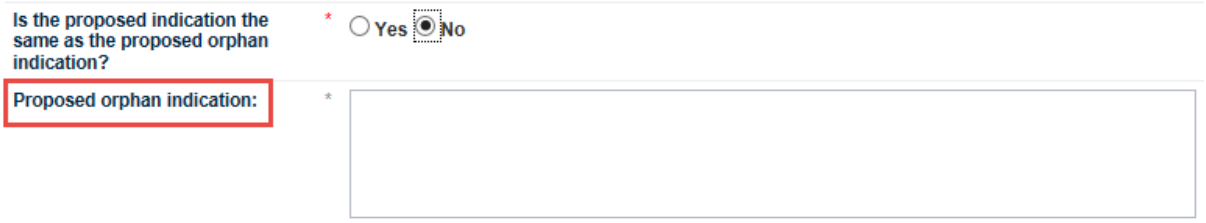
5. In the **Proposed indication(s)** field, enter the indication you propose the product be used for. This field is also mandatory.

For **Orphan designations** two additional questions (6 and 7 below) will be displayed.

6. The next field **Is the proposed indication the same as the proposed orphan indication?** will only appear if you are applying for Orphan drug designation. Select **Yes** or **No** as appropriate.



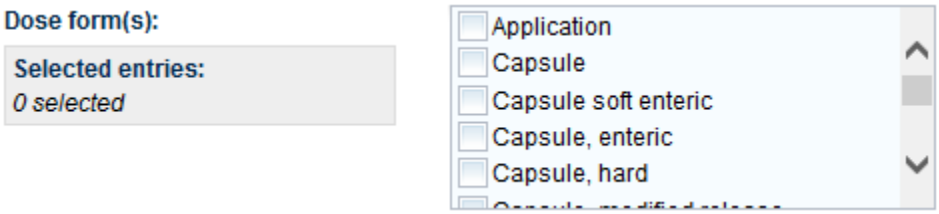
7. If you select **No** another field, **Proposed orphan indication**, will open.



Enter your proposed orphan indication in this field.

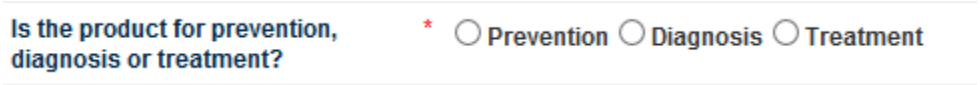
8. In the **Dose form(s)** field, select all the forms the product is supplied in. You may select as many dosage forms as apply.

   Tick the box to the left of the dose form you wish to select. Use your mouse to scroll through the listed dose forms, or click on the arrows at the right of the field to move up and down through the list.

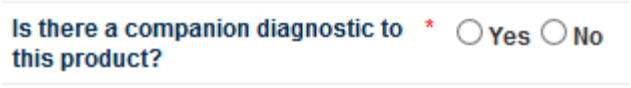


9. Enter the trade name of the product in the **Trade name** field. This field is not mandatory.

10. The next field, **Is the product for prevention, diagnosis or treatment?** is mandatory. Select the appropriate answer from the three radio buttons.



11. Select **Yes** or **No** for the next field, **Is there a companion diagnostic to this product?.** This field is also mandatory.



If you answer **Yes** to this question, you will not be required to provide more information on the companion diagnostic in the form. However, you should include information on the companion diagnostic in your supporting documentation which is attached to the form.

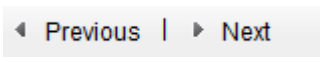
Requirements are outlined in our guidance on the eligibility criteria and supporting documentation for Priority review, Provisional determination and Orphan drug designation.

12. If there have been any overseas regulatory submissions for the product, or it has been granted a designation (or equivalent status) by a **comparable overseas regulator**, enter the details in the next field.

13. The final field on this tab is also mandatory. Select the **Yes** or **No** radio button to indicate whether the product has been **refused approval by any overseas regulatory agency** for safety or efficacy reasons.

If you select **Yes**, an additional field will open. Enter the **details** of the refusal in this field.

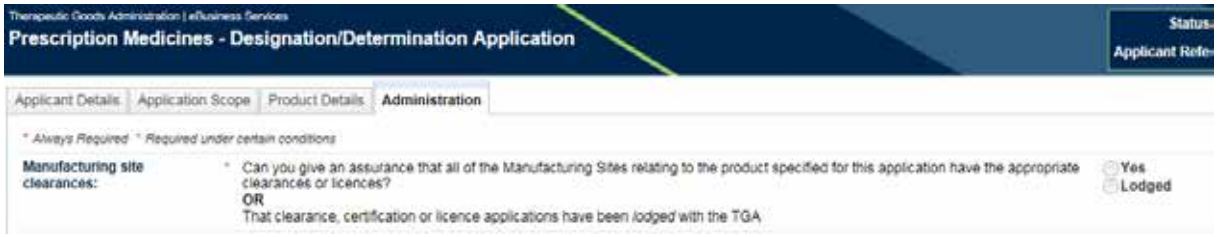
14. Click on the **Next** button at the bottom left of the browser window to move to the next tab, or click on Previous to go back.



The Administration tab

Enter details about previous applications, clearances and other administrative matters on the Administration tab.

1. The first field on this tab is **Manufacturing site clearances** (only if applying for Priority review determination). Select the appropriate radio button to answer this question, either **Yes** or **Lodged**. This field will not appear unless you are applying for Priority review determination.



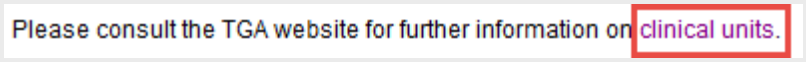
2. If you have lodged a clearance application with TGA, provide the **GMP reference number** in the next field. This field is optional if you are applying for Provisional determination and/or Orphan drug designation.

   Please include reference numbers for all applications that have been **lodged** or **approved** by TGA. If you have selected **Lodged** in response to the question above, entering information into this field is mandatory.

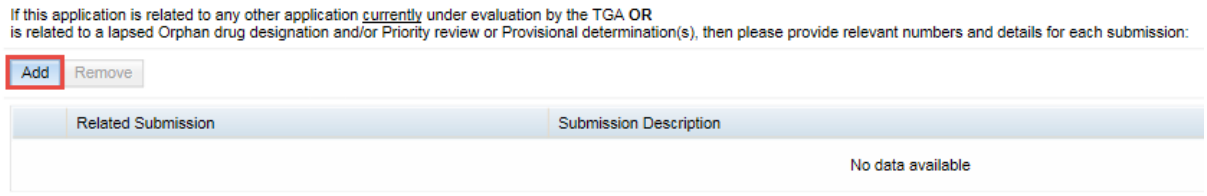
3. The next field, **Proposed date of submission** for registration lodgement to the TGA, is mandatory. Click on the calendar icon at the right of the field to select the appropriate date.

4. The **Nominated TGA clinical unit** for this application field is also mandatory. Select a clinical unit from the dropdown list at the right of this field.

If you need more information on clinical units, click on the link to the right of this field.



5. The final fields on this tab allow you to enter information on any other **related applications** that TGA may currently be evaluating OR relevant lapsed Priority review or Provisional determination applications, or Orphan drug designation applications. Click the **Add** button to enter details.

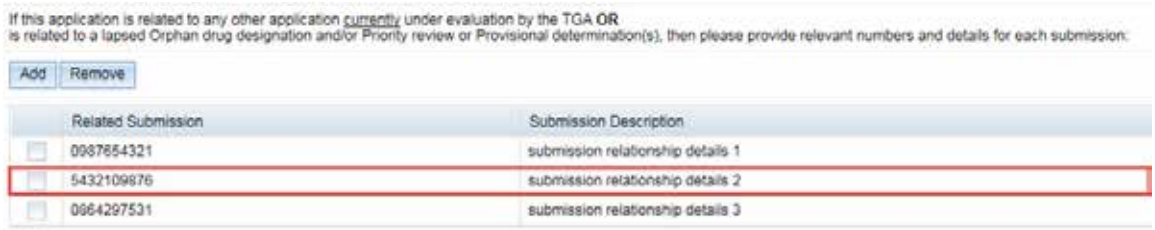


In the **Related Submission Details** window, enter the **Application submission number** of any related application, and provide details of **how the submission is related** to your application in the next field. Click **Save & Close.**

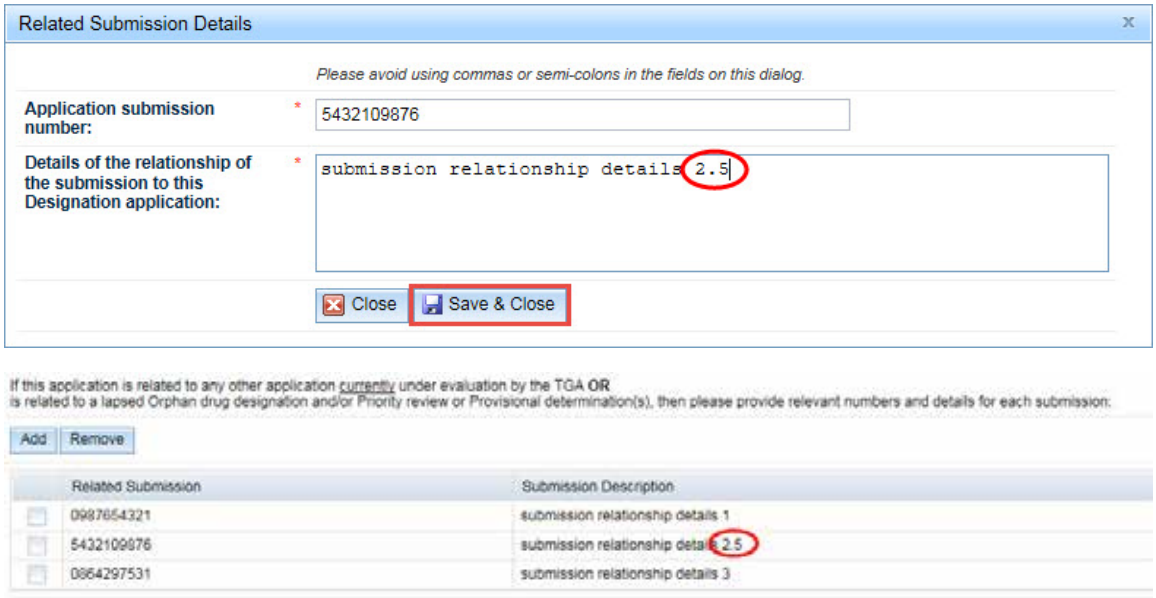
Please do not use commas or semicolons in this dialog box.

If you wish to add more submissions, repeat these steps until you have added them all.

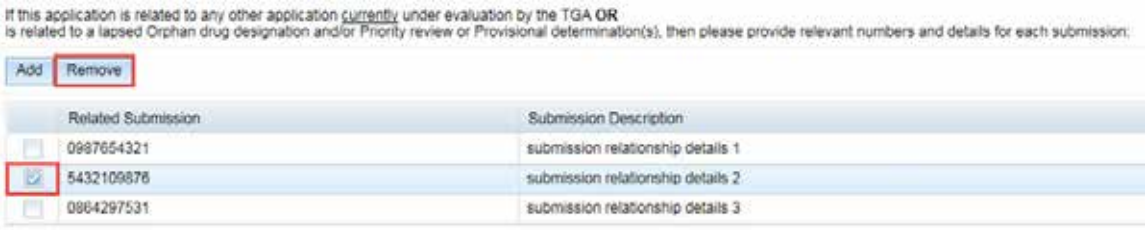
You can edit a submission by double clicking on the relevant row.



Making the required changes, then clicking **Save & Close**.



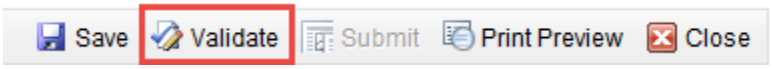
You can remove a submission by ticking the check-box to the left of the submission and clicking the **Remove** button.



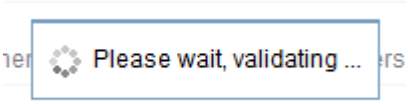
Validating your application

After you have saved the form, the **Validate** radio button will become active. You must validate your application before you can submit it.

1. Click on the **Validate** button at the bottom right of your browser window.

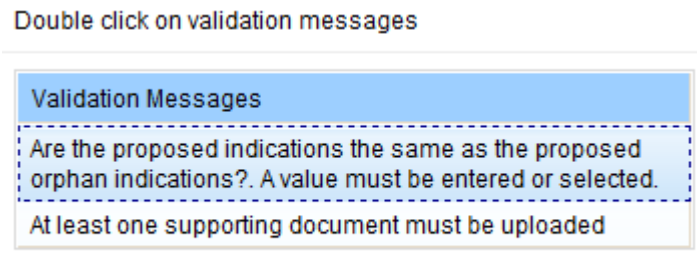


This will trigger a pop-up window.

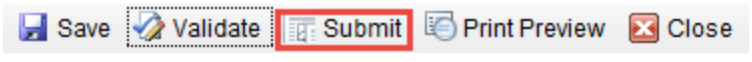


2. If there are any issues with your application, a new pane will open on the right of your browser window. The issues will be listed in this pane.

3. If you double-click on a listed validation issue in this pane, it will open your application at the appropriate tab so you can rectify the issue. (This screenshot shows example messages only. You may have no messages or different messages).



4. When you have rectified all issues, click validate again. Once validation is successful the **Submit** button at the bottom right of your browser window will become active.

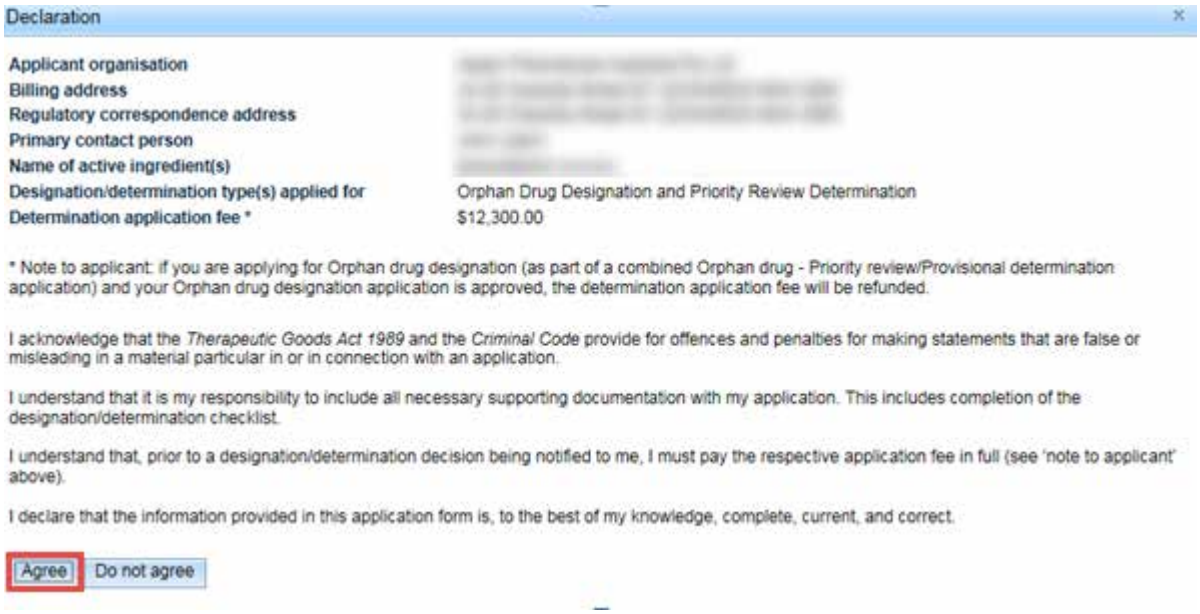


You are now ready to submit your application.

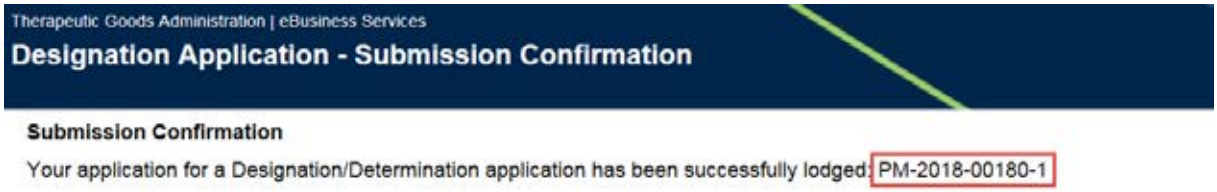
Submitting your application

When you are ready to submit your application, click on the **Submit** button at the bottom right of the browser window. This will open a **Declaration** pop-up window.

Check the details in the declaration. If the details are correct and you agree with the acknowledgements, click on the **Agree** button at the bottom left of the pop-up.



Your submission will be lodged and you will be assigned an application number.



You can close the completed application by clicking on the **Close** button at the bottom right of your browser window.

Application assessment

For more information on how we will assess your application(s), see the Priority review determination, Provisional determination and Orphan drug designation step-by-step guides.

If you have read the guidance and still require assistance, please contact: AET.Application.Entry.Team@health.gov.au.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Prescription Medicines Authorisation Branch	July 2017
V1.1	Updates to include the provisional pathway and other minor edits	Prescription Medicines Authorisation Branch and Regulatory Guidance Team	March 2018

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

D17-528029