



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

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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

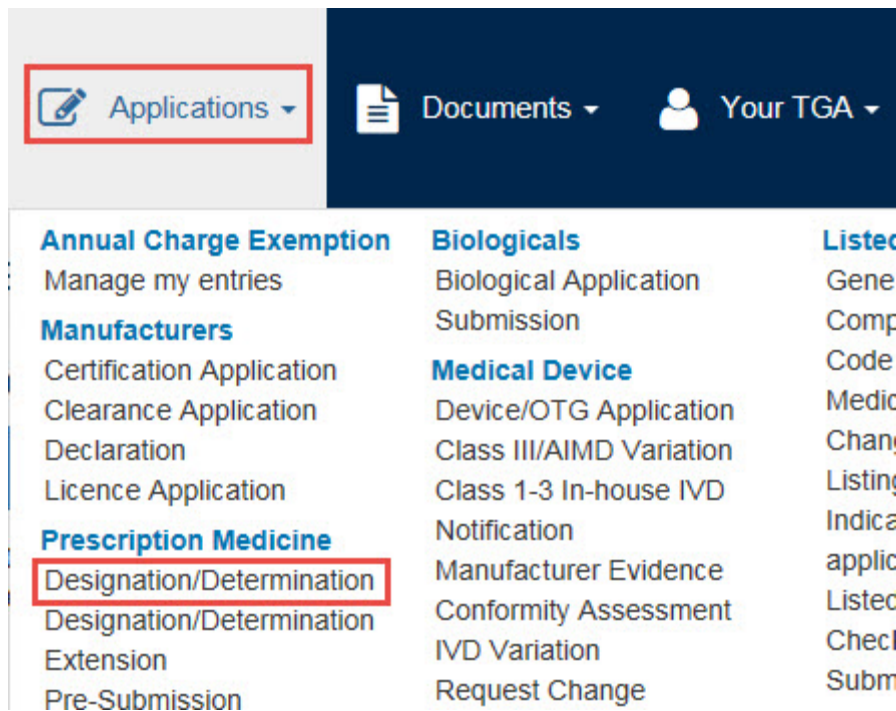
To make an application you will need:

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

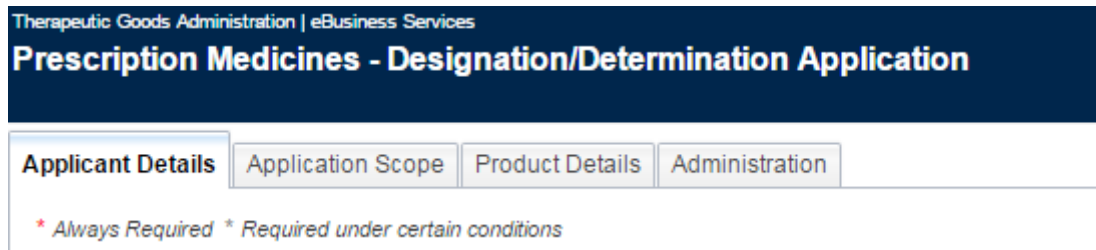
If you do not have a client ID number or access to the TGA Business Services portal, go to [TGA Business Services: getting started with TGA](#) and submit the online [organisation details form](#).

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



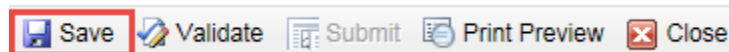
On each tab there are a number of fields to fill in.

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

Saving your draft application

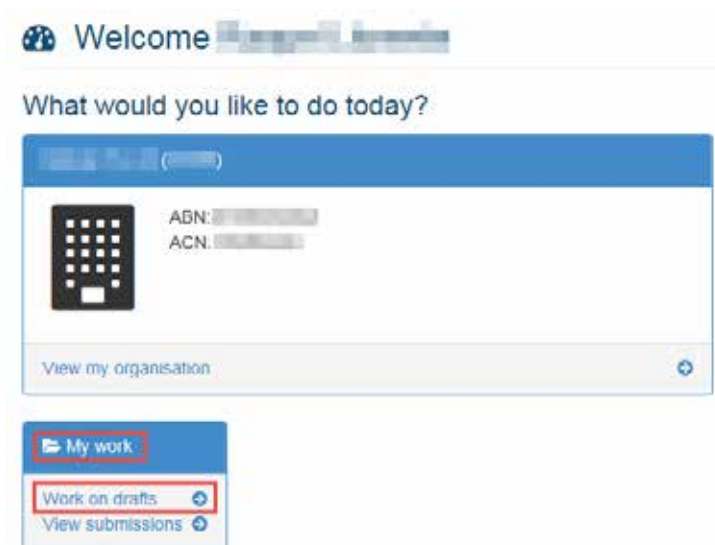
If you need to exit your application before it is complete, you can save it as a draft.

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**.



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

Drafts

Approval Area:

Sponsor:

Filter on: for

Date	Identifier	Client Reference	Information
2018-03-15			Designation/determination Application
2018-03-14			Designation/determination Application
2017-09-21			
2017-09-21		GMP clearance application Pathos	Pathos Italia SPA

- 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.

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

Applicant name: *



If you are logged in 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.

- 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.

Sponsor organisation: *

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

Regulatory correspondence address: *

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

Send fee invoice to sponsor? Yes No

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

Billing address: *

- 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.

Primary contact person	Select a contact	▼	Clear
Name:	*		
Telephone number:	*		
Email:	*		



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.

- 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.

Secondary contact person (optional)	Select a contact	▼	Clear
Name:			
Telephone number:			
Email:			

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

◀ Previous | ▶ Next

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.

This application is for:

Orphan Drug Designation

Priority Review Determination

Provisional Determination

[Clear Selections](#)

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.

[Clear Selections](#)

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

Priority Review determination - Eligibility Criteria: Please attach documentation supporting each of the relevant criteria to this form. The eligibility criteria are specified in subregulation 16(R)(2) of the Therapeutic Goods Regulations 1990. Guidance relating to supporting documentation is available at [Priority review determination eligibility criteria, including supporting documentation](#).

[Clear Selections](#)

New medicine: The medicine is a new prescription medicine OR the medicine is a new indications medicine

Serious condition: An indication of the medicine is the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition

Comparison against existing therapeutic goods: No therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register OR
 If one or more therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register - there is substantial evidence demonstrating that the medicine provides a significant improvement in the efficacy or safety of the treatment, prevention or diagnosis of the condition compared to these goods.

Major therapeutic advance: There is substantial evidence demonstrating that the medicine provides a major therapeutic advance.

New prescription medicine
 New indications medicine
 Yes
 No existing therapeutic goods
 Increased efficacy or safety
 Yes

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

Provisional determination - Eligibility Criteria: Please attach documentation supporting each of the relevant criteria to this form. The eligibility criteria are specified in regulations 15K and 16L of the Therapeutic Goods Regulations 1990. Guidance relating to supporting documentation is available at [Provisional determination eligibility criteria, including supporting documentation](#).

Clear Selections

New medicine:	* The medicine is a new prescription medicine OR the medicine is a new indications medicine.	<input type="radio"/> New prescription medicine <input type="radio"/> New indications medicine
Serious condition:	* An indication of the medicine is the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition.	<input type="checkbox"/> Yes
Comparison against existing therapeutic goods:	* Either: No therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods); OR If one or more therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods) - there is preliminary clinical data demonstrating that the medicine is likely to provide a significant improvement in the efficacy or safety of the treatment, prevention or diagnosis of the condition compared to those goods.	<input type="radio"/> No existing therapeutic goods <input type="radio"/> Increased efficacy or safety
Major therapeutic advance:	* There is preliminary clinical data demonstrating that the medicine is likely to provide a major therapeutic advance.	<input type="checkbox"/> Yes
Clinical study plan:	* The person who made the application under subsection 22C(1) of the Act has provided sufficient evidence of the person's plan to submit comprehensive clinical data on the safety and efficacy of the medicine before the end of the 6 years that would start on the day that provisional registration of the medicine would commence if the Secretary were to provisionally register the medicine.	<input type="checkbox"/> Yes

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.

- 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.

Has an Orphan Drug designation already been approved by the TGA for the product specified in this application? Yes No



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

- 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.

This application is for: * Orphan Drug Designation

Clear Selections * Priority Review Determination
 Provisional Determination

Has an Orphan drug designation already been approved by the TGA for the product specified in this application? Yes No

Determination Application Fee: \$0.00

- 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.

Is your Orphan drug designation application for a new dosage form medicine? * Yes No

- 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

Is your Orphan drug designation application for a new dosage form medicine? Yes No

Indication: * The application is for only one indication of the medicine.

Seriousness: * The indication is the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition in a particular class of patients (the relevant patient class).

Medical plausibility: * It is not medically plausible that the medicine could effectively treat, prevent or diagnose the condition in another class of patients that is not covered by the relevant patient class.

Prevalence threshold OR lack of financial viability: * At least one of the following applies:

- If the medicine is intended to treat the condition the condition affects fewer than 5 in 10,000 individuals in Australia when the application is made;
- If the medicine is intended to prevent or diagnose the condition the medicine, if it were included in the Register, would not be likely to be supplied to more than 5 in 10,000 individuals in Australia during each year that it is included in the Register;
- It is not likely to be financially viable for the sponsor to market the medicine in Australia unless each fee referred to in paragraph 45 (12)(c) [Therapeutic Goods Regulations 1990] were waived in relation to the medicine;

Overseas regulators and safety: * None of the following has refused to approve the medicine for the treatment, prevention or diagnosis of the condition for a reason relating to the medicine's safety:

- the Secretary;
- the United States Food and Drug Administration;
- the European Medicines Agency;
- Health Canada;
- the Medicines and Healthcare products Regulatory Agency of the United Kingdom.

Comparison with registered therapeutic goods: * Either:
i. No therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register;
OR
ii. If one or more therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register - the medicine provides a significant benefit in relation to the efficacy or safety of the treatment, prevention or diagnosis of the condition, or a major contribution to patient care, compared to those goods.

Yes
 Yes
 Yes
 Yes
 Yes
 No existing therapeutic goods
 Significant benefit

OR

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

Is your Orphan drug designation application for a new dosage form medicine? Yes No

Indication: * The application is for only one indication of the medicine.

Seriousness: * The indication is the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition.

Medical plausibility: * Not applicable.

Prevalence threshold OR lack of financial viability: * It is not likely to be financially viable for the sponsor to market the medicine in Australia unless each fee referred to in paragraph 45(12)(c) [Therapeutic Goods Regulations 1990] were waived in relation to the medicine.

Overseas regulators and safety: * None of the following has refused to approve the medicine for the treatment, prevention or diagnosis of the condition for a reason relating to the medicine's safety:

- the Secretary;
- the United States Food and Drug Administration;
- the European Medicines Agency;
- Health Canada;
- the Medicines and Healthcare products Regulatory Agency of the United Kingdom.

Comparison with registered therapeutic goods: * Either:
i. No therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register;
OR
ii. If one or more therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register - the medicine provides a significant benefit in relation to the efficacy or safety of the treatment, prevention or diagnosis of the condition, or a major contribution to patient care, compared to those goods.

Yes
 Yes
 Yes
 Yes
 Yes
 No existing therapeutic goods
 Significant benefit

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.

Application Checklist

It is your responsibility to download, complete and attach the information to allow the TGA to make an informed decision

[Orphan Drug Designation](#)

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

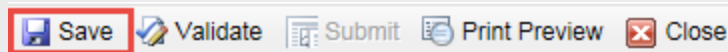
D

- [Designation checklist: for sponsor seeking Orphan Drug designation](#)
This checklist is intended to assist applicants to determine if they have provided all of the necessary information to allow the TGA to make an informed decision on the designation application

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.

Supporting Document Name		Doc

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

Attachment Details x

** Always Required. NB: There is an individual file size limit of 100 MB.*

Description: *

Supporting Document: *

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.

- 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.

- 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.

◀ Previous | ▶ Next

The Product Details tab

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

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

Is the product an existing TGA registered product? Yes No

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

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

ARTG Number(s): *

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

Name of active ingredient(s): *



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

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

Existing indication: *

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

Proposed indication(s): *

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.

Is the proposed indication the same as the proposed orphan indication? * Yes No

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

Is the proposed indication the same as the proposed orphan indication? * Yes No

Proposed orphan indication: *

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.

Dose form(s):

Selected entries:
0 selected

- Application
- Capsule
- Capsule soft enteric
- Capsule, enteric
- Capsule, hard
- Capsule, modified release

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

Trade name:

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

Is the product for prevention, diagnosis or treatment? * Prevention Diagnosis Treatment

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

Is there a companion diagnostic to this product? * Yes No

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.

If applicable, provide details about any overseas regulatory submissions for the product and any designations granted by comparable overseas regulators:

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.

Has an overseas regulatory agency refused to approve the medicine, vaccine or in vivo diagnostic agent for use for the condition for a reason related to its safety or efficacy? * Yes No

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

If Yes answered, please provide details: *

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.

◀ Previous | ▶ Next

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.

Therapeutic Goods Administration | eBusiness Services
 Prescription Medicines - Designation/Determination Application

Applicant Details | Application Scope | Product Details | **Administration** | Status: Applicant Ref-

* Always Required * Required under certain conditions

Manufacturing site clearances: Yes Lodged

Can you give an assurance that all of the Manufacturing Sites relating to the product specified for this application have the appropriate clearances or licences?
 OR
 That clearance, certification or licence applications have been lodged with the TGA

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.

If clearance applications have been lodged to the TGA *
 please provide the relevant GMP reference number(s):

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.

Proposed date of submission for registration lodgement to the TGA: *

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.

Nominated TGA clinical unit for this application: *



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

Please consult the TGA website for further information on [clinical units](#).

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.

If this application is related to any other application currently under evaluation by the TGA OR is related to a lapsed Orphan drug designation and/or Priority review or Provisional determination(s), then please provide relevant numbers and details for each submission:

Related Submission	Submission Description
No data available	

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.

Related Submission Details x

Please avoid using commas or semi-colons in the fields on this dialog.

Application submission number: *

Details of the relationship of the submission to this Designation application: *

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.

If this application is related to any other application currently under evaluation by the TGA OR is related to a lapsed Orphan drug designation and/or Priority review or Provisional determination(s), then please provide relevant numbers and details for each submission:

Related Submission	Submission Description
<input type="checkbox"/> 0987654321	submission relationship details 1
<input type="checkbox"/> 5432109876	submission relationship details 2
<input type="checkbox"/> 0964297531	submission relationship details 3

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

Related Submission Details x

Please avoid using commas or semi-colons in the fields on this dialog.

Application submission number: *

Details of the relationship of the submission to this Designation application: *

If this application is related to any other application currently under evaluation by the TGA OR is related to a lapsed Orphan drug designation and/or Priority review or Provisional determination(s), then please provide relevant numbers and details for each submission:

Related Submission	Submission Description
<input type="checkbox"/> 0987654321	submission relationship details 1
<input type="checkbox"/> 5432109876	submission relationship details 2.5
<input type="checkbox"/> 0964297531	submission relationship details 3

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

If this application is related to any other application currently under evaluation by the TGA OR is related to a lapsed Orphan drug designation and/or Priority review or Provisional determination(s), then please provide relevant numbers and details for each submission:

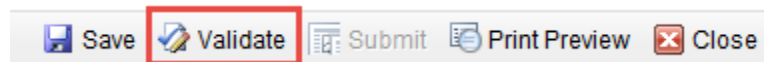
Add **Remove**

Related Submission	Submission Description
<input type="checkbox"/> 0887654321	submission relationship details 1
<input checked="" type="checkbox"/> 5432109876	submission relationship details 2
<input type="checkbox"/> 0884297531	submission relationship details 3

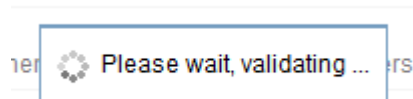
Validating your application

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.

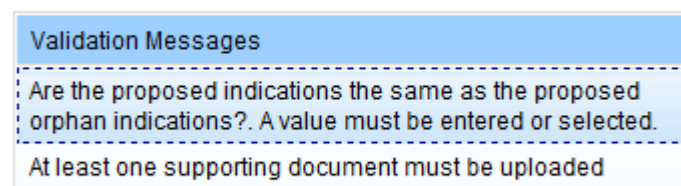


This will trigger a pop-up window.

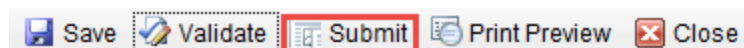


2. If there are any issues with your application, a new pane will open on the right of your browser window. The issues will be listed in this pane.
3. If you double-click on a listed validation issue in this pane, it will open your application at the appropriate tab so you can rectify the issue. (This screenshot shows example messages only. You may have no messages or different messages).

Double click on validation 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.

Declaration x

Applicant organisation	[Redacted]
Billing address	[Redacted]
Regulatory correspondence address	[Redacted]
Primary contact person	[Redacted]
Name of active ingredient(s)	[Redacted]
Designation/determination type(s) applied for	Orphan Drug Designation and Priority Review Determination
Determination application fee *	\$12,300.00

* Note to applicant: if you are applying for Orphan drug designation (as part of a combined Orphan drug - Priority review/Provisional determination application) and your Orphan drug designation application is approved, the determination application fee will be refunded.

I acknowledge that the *Therapeutic Goods Act 1989* and the *Criminal Code* provide for offences and penalties for making statements that are false or misleading in a material particular in or in connection with an application.

I understand that it is my responsibility to include all necessary supporting documentation with my application. This includes completion of the designation/determination checklist.

I understand that, prior to a designation/determination decision being notified to me, I must pay the respective application fee in full (see 'note to applicant' above).

I declare that the information provided in this application form is, to the best of my knowledge, complete, current, and correct.

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

Therapeutic Goods Administration | eBusiness Services

Designation Application - Submission Confirmation

Submission Confirmation

Your application for a Designation/Determination application has been successfully lodged: PM-2018-00180-1

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