



Australian Government

Department of Health

Therapeutic Goods Administration

Medicine shortages/discontinuations – Electronic notification form

User guide

Version 3.0, May 2021

TGA Health Safety
Regulation

A decorative graphic at the bottom of the page consisting of several overlapping, wavy lines in shades of blue, dark blue, and a thin green line, creating a modern, flowing background element.

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About this user guide

This user guide is for sponsors of reportable medicines, which include:

- Schedule 4 (Prescription Only) medicines
- Schedule 8 (Controlled Drug) medicines
- over-the-counter medicines included in the [Therapeutic Goods \(Reportable Medicines\) Determination](#),

It describes how to complete and submit a shortage or discontinuation notice for **reportable medicines**, using the medicine shortages electronic notification form through the [TGA Business Services \(TBS\)](#) portal.

For more information or to contact us, refer to [Medicine shortages](#).

If you have questions or problems accessing TBS, contact the [TGA Business Services](#).

This user guide should be read in conjunction with [Reporting medicines shortages and discontinuations in Australia – Guidance for sponsors](#).

Medicine shortages – electronic notification form

To report a medicine shortage or discontinuation to the TGA, you will need:

- a client identification number
- access to the TBS portal
- to be the medicine sponsor or an authorised agent

For more information on TBS refer to [TGA Business Services: getting started with the TGA](#).

The medicine shortages notification form is available on the TBS portal. You will need to select your Australian Register of Therapeutic Goods (ARTG) entry affected by the shortage or discontinuation and then provide relevant information.

The type of information you will be required to provide will include at least the following:

- impact of the shortage
- nature of the shortage
- sponsor name – auto-populated based on the person who logs in to TBS
- sponsor address
- Australian telephone number for public contact purposes
- medical information email for public contact purposes
- ARTG number – which will provide the ARTG name of the product in shortage
- primary contact - auto-populated based on the person who logs in to TBS. The contact details of someone that the TGA can liaise with regarding the shortage.
- date the shortage was known to the sponsor
- estimated dates for the start and end of the shortage
- availability

Each step in the medicine shortage notification form will have a number of mandatory fields, which are identified with a red asterisk (*).

You must complete all mandatory fields. Further fields can be completed if the information is available. In some cases, a field may be auto-populated from an earlier part of the reporting form.

As you proceed through the various tabs on the form, activity boxes will appear that contain 'Help' buttons. Click on these buttons for further information specific to that field.

Steps to creating a notification

Step 1 - Log in to TBS

Go to the [TGA Business Services](#) website and enter your user name and password.



In the 'Welcome Page' navigate to 'Your TGA' and choose 'Medicines Shortages' from the drop-down list. Your 'Portal' view will now appear.

Click the 'Portal' drop-down button.

Click 'Create Applications and Submissions' drop-down button.

Click 'Medicine Shortages' drop-down button.

Select 'Notification', which opens a new form to begin submitting your notification.



Step 2 – Create a new medicine shortage notification

The 'Notification' pop-up box will open. Select the 'Shortage impact rating' and the 'Nature of Shortage' that you are reporting.

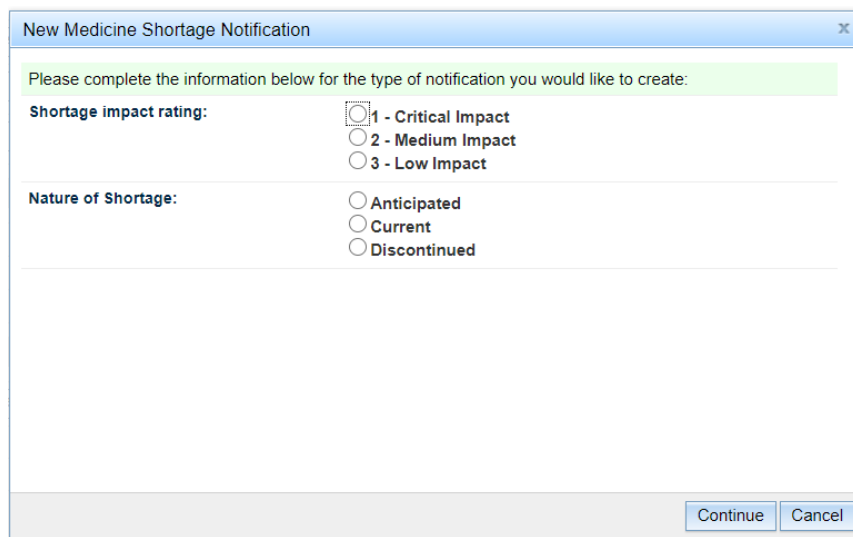
For help in determining the 'Shortage impact rating', see the [interactive decision tool](#).

If you change the impact rating while completing the form, the mandatory fields may also change.

Your response to 'Shortage impact rating' determines the number of mandatory fields (marked with (*)) you must complete before the notification will validate.

If you select critical impact for an anticipated or current shortage, the number of mandatory fields is reduced. This allows you to provide an initial notification promptly telling us about these shortages.

Once we receive your initial notification, you will have **three days** to [update your notification form](#) to complete the full set of mandatory questions. We will remind you about this when we receive the initial notification submission.



New Medicine Shortage Notification

Please complete the information below for the type of notification you would like to create:

Shortage impact rating:

☒ 1 - Critical Impact
☐ 2 - Medium Impact
☐ 3 - Low Impact

Nature of Shortage:

☐ Anticipated
☐ Current
☐ Discontinued

Continue Cancel

Click 'Continue'.

Step 3 – Notifier information

The New Medicine Shortage Notification pop-up box will close and the notification form will display.

The top of the form displays its 'Status', the 'Notification Id' (generated when the notification form is first saved) and a field to enter your client reference.



Status: Draft Notification Id: MS-2018-NT-00012-1
 Client Reference:

We recommend you fill in the notification form sequentially (from the far-left tab through to the far-right tab). Responses provided in each tab affect the fields that appear in the following tabs.



Therapeutic Goods Administration | eBusiness Services

Medicine Shortage Notification

Notifier ARTG Entry Details Impact Shortage Action Supporting Information

* Always Required * Required under certain conditions

The 'Sponsor Name' and the 'Primary Contact' fields are auto-populated using information attached to your login details.

Select a sponsor address from the drop-down list and complete the mandatory fields.

You may provide a secondary contact, but this is not mandatory.

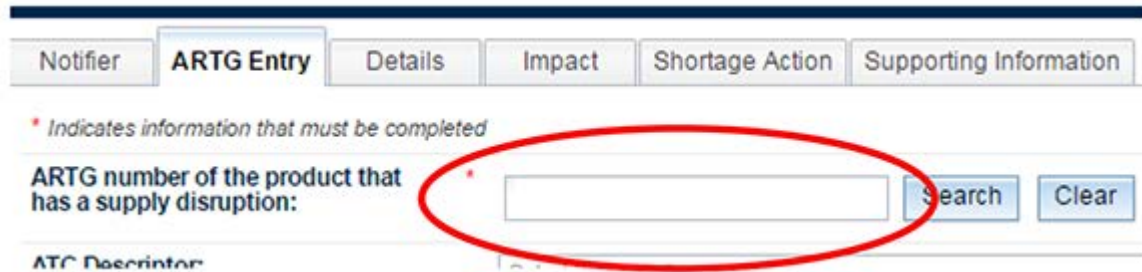
Only the nominated sponsor and authorised agents can submit a shortage notification for a medicine on the ARTG.

If you are not the medicine sponsor and wish to alert the TGA to a shortage please contact us at medicine.shortages@health.gov.au or +61 2 6289 4646.

Step 4 – ARTG Entry information

Move to the next tab – ‘ARTG Entry’.

Enter the ARTG number of the entry you are reporting and click on the ‘Search’ button. You will only have access to the ARTG entries belonging to your TBS login ID.



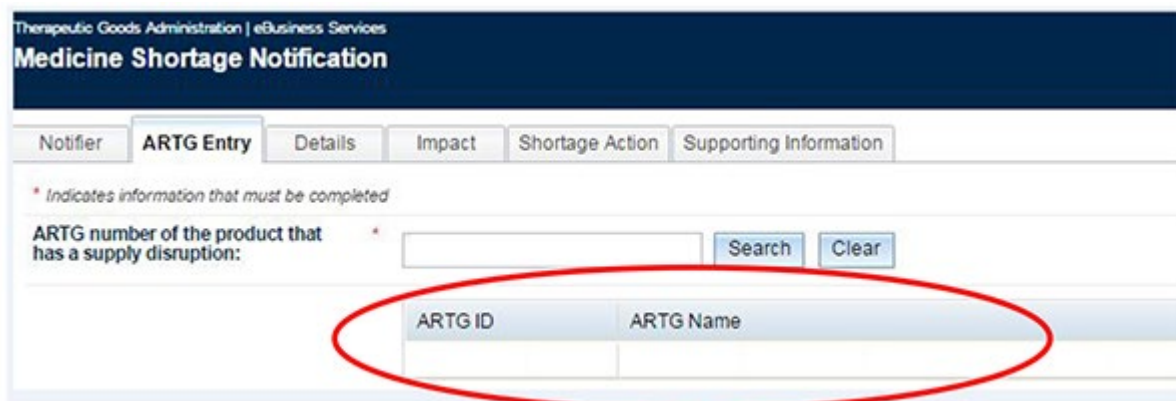
Notifier | **ARTG Entry** | Details | Impact | Shortage Action | Supporting Information

* Indicates information that must be completed

ARTG number of the product that has a supply disruption: *

ATC Descriptor:

You will see the ARTG number and name of the selected product.



Therapeutic Goods Administration | eBusiness Services

Medicine Shortage Notification

Notifier | **ARTG Entry** | Details | Impact | Shortage Action | Supporting Information

* Indicates information that must be completed

ARTG number of the product that has a supply disruption: *

ARTG ID	ARTG Name

If your medicine is on the Pharmaceutical Benefits Scheme (PBS), you will be asked for further details. This includes identifying if you have a designated sponsor representative who is a point of contact on PBS matters. If so, you must enter their relevant contact details on this tab.

ATC Descriptor

Select the Anatomical Therapeutic Chemical (ATC) Descriptor for the product, from the high-level descriptors in the drop-down list. This information allows better searching of the Medicine Shortages Reports Database.

Step 5 – Details

Move to the next tab – ‘Details’.

‘Nature of Shortage’ is auto-populated based on your earlier response in Step 2.

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Medicine Shortage Notification

Notifier | ARTG Entry | **Details** | Impact | Shortage Action | Supporting Information

* Indicates information that must be completed

When was the shortage known to the sponsor? *

Nature of the shortage: *

☒ Anticipated ☐ Current ☐ Discontinued

Shortage reason: *

Select the Shortage Reason

Shortage reason - further information:

Estimated period supply will be affected at wholesaler points: *

From: To:

Availability: Available

Indicate preference for date of publication: *

☐ Date of processing ☐ Deferred publication

Is this shortage related to other medicines within the same Therapeutic class? *

☐ Yes ☐ No

Is this shortage specific to Australia? *

☐ Yes ☐ No

Estimated normal demand volumes for Australia: *

units / month

Estimated percentage share of the Australian market: *

%

Estimated current stock at sponsor / manufacturing level in Australia: *

units

Estimated current stock at wholesaler / distributor level in Australia: *

units

Explain what is meant by 1 unit in this context: *

e.g. 1 unit = 1 bottle x 30 tablets or 1 unit = 5 x ampoules of injection or 1 box of 10 x 100mL bags etc.

< Previous | Next >

Save Submit Validate Print Preview Close

When was the shortage known to the sponsor?

This information is needed to calculate the [legislated timeframes](#), and monitor compliance. You cannot enter a future date.

Shortage reason

Choose the shortage reason from the drop-down list. This information will be included in the published notification on the TGA website. Additional fields may appear depending on the shortage reason selected.

If there is more than one reason for the shortage occurring, consider the root cause of the shortage and select the most appropriate option under 'Shortage reason'.

Note: the shortage reason '**Seasonal depletion of stock**' is for influenza vaccine use only.

If '**Manufacturing**' is selected, the additional field 'Manufacturing site problem' will appear. Select the option that best describes the manufacturing issue causing the shortage from the drop-down list. Your selection under 'Manufacturing site problem' will not be included in the published notification on the TGA website.

If **'Issues/delays with sourcing/importing API'** is selected as the 'Manufacturing site problem', you will be asked to include the Client ID or name and address of the affected API site. This will not be included in the published notification on the TGA website.

You can provide additional information on the cause of the shortage or other factors relating to the shortage under 'Shortage reason - further information'. This is an optional field. Information here will not be included in the published notification on the TGA website.

Shortage dates

Enter the estimated shortage dates in 'Estimated period supply will be affected at wholesaler points:' 'From' and 'To' fields.

For an anticipated shortage, the 'From' date must be in the future. For a current shortage, the 'From' date must be today's date or a past date.

If the shortage dates provided do not correspond with the 'Nature of the shortage', the form will not validate.

Availability

For anticipated and resolved shortages, the availability field is set to 'available' and cannot be changed. If only some stock is available it is a current shortage, change the 'Nature of Shortage' to reflect the correct status.

For current shortages and discontinuations, various options are provided in a drop-down list. Update the notification when needed to change between the different levels to ensure the availability status is as accurate as possible. This important information is visible in the published shortage notification.

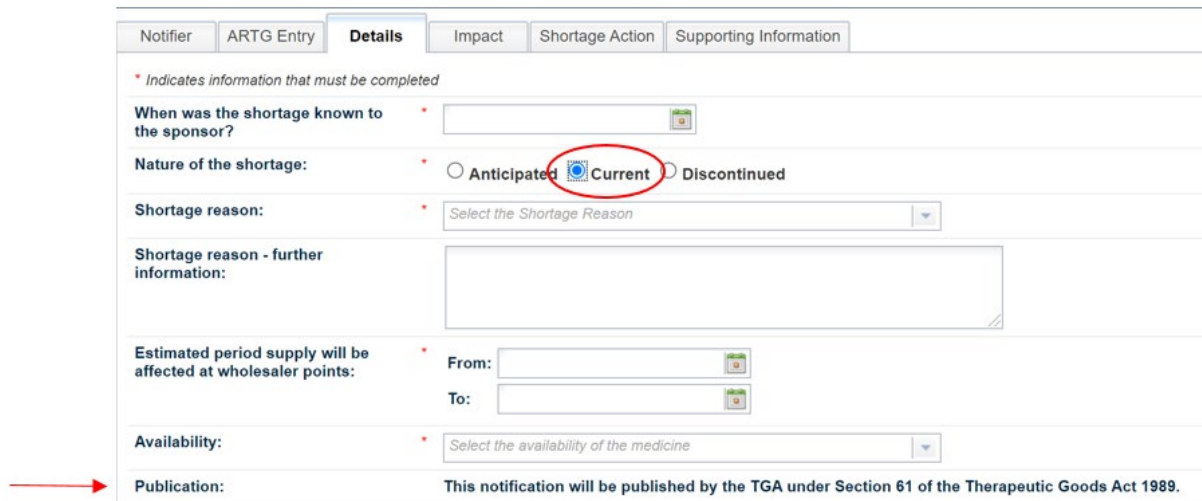
Definitions of Availability Levels:

- **Available** - The product is freely available, there are no constraints or restrictions on supply or availability, no back orders exist.
- **Limited availability** - The product is available in limited quantities throughout the supply chain. Healthcare professionals may have to place back-orders to obtain the product.
- **Only available under NIP or government programs** – FOR VACCINES ONLY – the product is only available for Commonwealth and state/territory vaccination programs and is not available in the private market.
- **Emergency supply only** - The product sponsor is actively imposing controls on the supply of the product at the current time.
- **Unavailable** - The product is not available at this time.
- **Reduction in supply until supply is exhausted** – FOR DISCONTINUATIONS ONLY – there is stock available of the product until supply is no longer available due to the discontinuation.

Publication of information

All medicine shortage and discontinuation notifications are published on the [Medicine Shortage Reports Database](#) on the TGA website.

Current shortages will be published as soon as possible after receipt of the notification. You will not have the option to request deferral of the publication.



Notifier ARTG Entry **Details** Impact Shortage Action Supporting Information

* Indicates information that must be completed

When was the shortage known to the sponsor? *

Nature of the shortage: * ☐ Anticipated ☒ **Current** ☐ Discontinued

Shortage reason: *

Shortage reason - further information:

Estimated period supply will be affected at wholesaler points: * From: To:

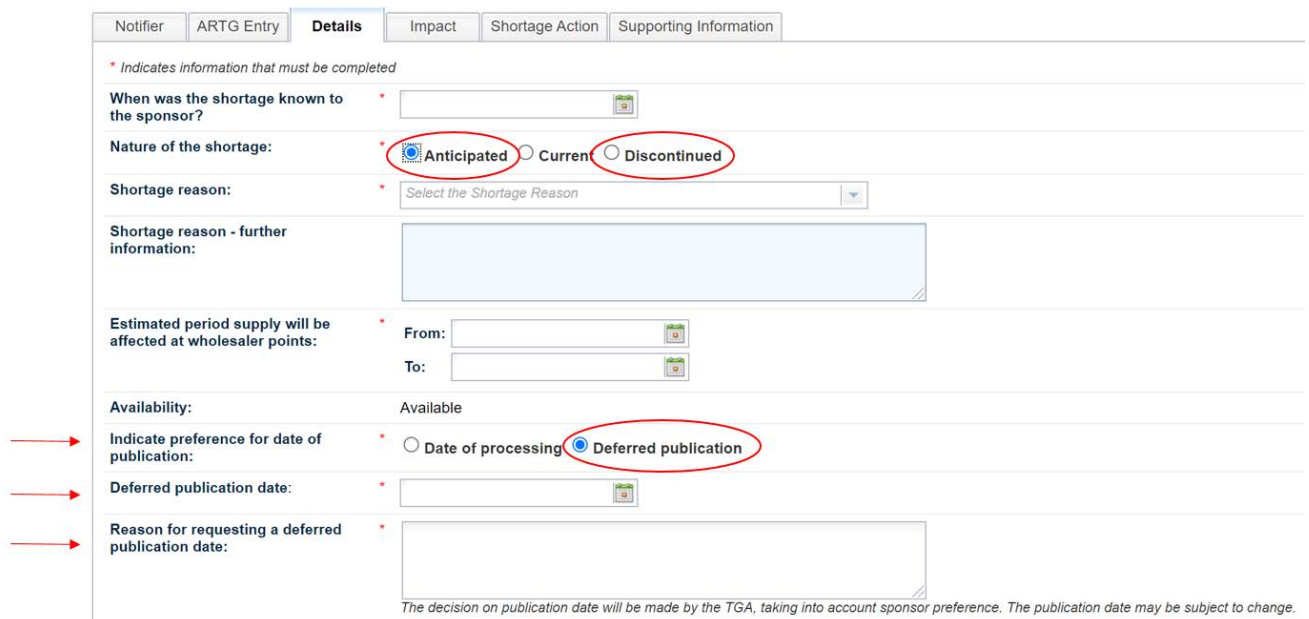
Availability: *

Publication: This notification will be published by the TGA under Section 61 of the Therapeutic Goods Act 1989.

You can request deferral for publication of anticipated shortages and discontinuations. You must provide a reason and select a deferred publication date, but the TGA will decide if there can be a delay.

For anticipated shortages, the proposed deferred publication date must be no less than two weeks prior to the shortage starting, otherwise the form will not validate.

For discontinuations, the proposed deferred publication date must be no less than six months prior to the [‘Deletion from market date’](#) otherwise the form will not validate.



Notifier ARTG Entry **Details** Impact Shortage Action Supporting Information

* Indicates information that must be completed

When was the shortage known to the sponsor? *

Nature of the shortage: * ☒ **Anticipated** ☐ Current ☐ Discontinued

Shortage reason: *

Shortage reason - further information:

Estimated period supply will be affected at wholesaler points: * From: To:

Availability: Available

Indicate preference for date of publication: * ☐ Date of processing ☒ **Deferred publication**

Deferred publication date: *

Reason for requesting a deferred publication date:

The decision on publication date will be made by the TGA, taking into account sponsor preference. The publication date may be subject to change.

Estimated percentage share

Estimate the percentage share that your product holds in the Australian market. This is based on products containing the same active ingredient(s), at the same strength and in the same type of formulation (for example, all extended release tablets).

Do not base this on the share of an active ingredient within a therapeutic class. For example, if your ibuprofen 200mg tablet is in shortage, record the percentage market share of your product against all marketed ibuprofen 200mg tablets in Australia, not as a percentage of all marketed

ibuprofen products or as a percentage of NSAIDs (non-steroidal anti-inflammatory drugs) as a therapeutic class.

Estimated current stock levels

Estimate the stock quantities at sponsor/manufacturing and wholesaler/distributor levels in Australia. The TGA needs this information to determine if shortage management actions are needed.

When you [vary the notification](#), the previous values provided in the fields 'Estimated current stock at sponsor/manufacturing level in Australia' and 'Estimated current stock at wholesaler/distributor level in Australia' will be deleted. Include updated stock figures in these fields with every variation made to a notification so we can continue to assess the shortage with current information.

Explanation of '1 unit'

Clearly state your definition of 1 unit (for example, 1 unit = 1 bottle x 30 tablets, or 1 unit = 5 x ampoules for injection, or 1 unit = 1 box of 10 x 100mL bag). This will help us understand the availability of stock when reviewing notifications for similar products from different sponsors.

Discontinuation notifications

If you are notifying us of a discontinuation, there will only be a shortage 'From' date. This is the date from which **wholesalers** will no longer have stock.

You will also need to enter a '**Deletion from Market**' date. This is the date from which you will no longer hold any stock at **sponsor** level, irrespective of stock at wholesaler/distributor level.

If you decide to discontinue a product that already has a shortage notification submitted to the TGA, the 'Deletion from Market' date must be the date you decided to discontinue, not the date when you no longer held stock.

Notifying us of a discontinuation does not affect the entry on the ARTG.

If you want to cancel the ARTG entry, you must follow the appropriate [process for cancellation](#).

If the discontinued product will be replaced with an alternative ARTG entry (for example, a change to the formulation or presentation requires a new ARTG entry), please select 'yes' to this question in the form and include relevant details in the subsequent field. This can be important to patients and pharmacists and included as a management action on the TGA website.

Notifier ARTG Entry **Details** Impact Shortage Action Supporting Information

* Indicates information that must be completed

When was the shortage known to the sponsor? *

Nature of the shortage: * ☐ Anticipated ☐ Current ☒ Discontinued

Shortage reason: * Select the Shortage Reason

Shortage reason - further information:

Explain what is meant by 1 unit in this context: *

e.g. 1 unit = 1 bottle x 30 tablets or 1 unit = 5 x ampoules of injection or 1 box of 10 x 100mL bags etc.

Will this product be replaced with an alternative ARTG product? * ☒ Yes ☐ No

ARTG name and number of the replacement alternative product: *

Consent to publish ARTG name and number of the replacement alternative product? * ☒ Yes ☐ No

When will this product be available to the Australian market? *

Step 6 – Impact information

Move to the next tab – ‘Impact’.

The information from ‘Shortage impact rating’ that you entered in Step 2 will prepopulate the last question on this tab.

For initial notification of a shortage with **critical impact**, the last question is the only mandatory field on this tab.

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Medicine Shortage Notification

Notifier ARTG Entry Details **Impact** Shortage Action Supporting Information

* Indicates information that must be completed

Are there therapeutic alternatives on the Australian market? * ☒ Yes ☐ No

What is the status of substitute options for this product in Australia? * Select the status of substitute options

Are they available in adequate supplies to meet demand? * ☐ Yes ☐ No ☐ Unknown at this time

Provide details:

Do any specific population groups use this product? * ☒ Yes ☐ No

Provide details of the groups and the impact on those groups:

Based on your answers above and the Assessment Framework, what is the shortage impact rating? *

☐ 1 - Critical Impact
☒ 2 - Medium Impact
☐ 3 - Low Impact

If you identified that there are therapeutic alternatives available, select the appropriate option from the 'Status of substitute' drop-down list. The options are:

- **Exact** – same medicine (active ingredient, strength and route of administration).
- **Similar** – same active ingredient but different strength.
- **Appropriate:**
 - different active ingredient but same pharmacological class and adverse reaction profiles when administered to patient in therapeutically equivalent doses, *or*
 - Same active ingredient but different release or bioavailability characteristics (e.g. immediate release vs modified release tablets) that may require consideration of care setting implication.
- **Possible** – different active ingredient within a comparable pharmacological class or mode of action.

Availability of substitute options

In addition to any information you have about supply of the therapeutic alternatives you identified in the earlier question, you will need to check the Medicine Shortages Reports Database to determine if any identified therapeutic alternatives are also in shortage.

If the medicine in shortage is used by specific population groups, these should be indicated in the box provided. This would alert the TGA to undertake further investigation into the availability of alternative preparations.

For example, 'Used in paediatric patients – no other oral liquid available therefore the impact would be substantial in this group' or 'Used routinely in all post-operative patients for X – this group will be unable to undergo surgery until product is available'.

We will review this information to confirm that the proposed impact rating is correct. Any change to impact rating will be done in consultation with the sponsor.

Step 7 – Shortage Action

Move to the next tab – 'Shortage Action'.

Choose from the drop-down list your planned communication action (for example, letters to pharmacists or letters to wholesalers).

The screenshot shows a software window titled 'Communication Activity'. It contains two main input fields: 'Action:' and 'Date of Communication:'. The 'Action:' field is a text box with a small downward-pointing arrow on the right, indicating it is a drop-down menu. This arrow is circled in red. The 'Date of Communication:' field is a text box with a calendar icon on the right. Below these fields is a row of four buttons: 'Help' (with a question mark icon), 'Save' (with a floppy disk icon), 'Save & Close' (with a floppy disk icon), and 'Close' (with a red 'X' icon).

You can only identify one communication action at a time. Select the date you intend to circulate that particular communication, then select save. If more than one action is planned, select another action from the drop-down list, select the date and select save.

After identifying all of your communication actions, click 'Save & Close' to return to the form. Your choice/s will appear as below:

Therapeutic Goods Administration | eBusiness Services

Medicine Shortage Notification

Notifier | ARTG Entry | Details | Impact | **Shortage Action** | Supporting Information

* Indicates information that must be completed

What communication activities have happened or are planned? *

Communication Action	Date of Communication
<input type="checkbox"/> Letter to Pharmacists	12/11/2018

To delete an action, click the checkbox and click remove.

Click 'Yes' or 'No' to indicate whether you have attached the letter. Attach the letter/s to your notification on the 'Supporting Information' tab. If you click 'Yes' and do not attach a letter, the notification will fail to validate.

Notifier | ARTG Entry | Details | Impact | **Shortage Action** | Supporting Information

* Indicates information that must be completed

What communication activities have happened or are planned? *

Communication Action	Date of Communication
<input type="checkbox"/> Letter to Pharmacists	05/04/2021

Are you attaching the letter in the Supporting Information tab? * ☐ Yes ☒ No

Further comments on communications:

Provide further information in the 'Further comments on communication' box if required.

If you have ongoing communication to a particular group, please enter the first date on which the information will be distributed. This will be taken as the date that the information is being made public and will assist us to answer enquiries.

Supply management action

Identify if you are implementing a supply management action. Supply management actions are added in the same way as communication activities.

Notifier ARTG Entry Details Impact **Shortage Action** Supporting Information

* Always Required * Required under certain conditions

What communication activities have happened or are planned?

Communication Action	Date of Communication
<input type="checkbox"/> Pharmacists	27/09/2018

Have you attached the letter? ☐ Yes ☒ No

Further comments on communications:

What supply management actions have happened or are planned?

Management Action	Date of Management Action
<input type="checkbox"/> Constrained Supply	27/09/2018

Further comments on management actions:

Provide further information in the 'Further comments on management actions' box if required.

For example, if your management action was 'Working to expedite request to Pharmaceutical Chemistry Section', you may include the date of submission and the submission number of your Section 14 or Category 3 application. We can then discuss the processing of the application with the section involved.

Step 8 – Supporting Information

Move to next tab – 'Supporting Information'.

Attaching documents

Attach documents, such as letters to health professionals, by clicking on 'Attach File'. Name PDF files with the name of the product and the type of communication.

You may attach multiple documents (if you are writing to multiple stakeholders) by clicking on 'Attach File' for each document. After you add all attachments click 'Save & Close'.

If you are submitting a variation to a medicine shortage notification and you have an updated letter to a stakeholder, we recommend that you remove the old letter from the updated notification and attach the new one.

Each document attached can be up to 20 Megabytes (MB) in size and the maximum total size of all documents and the notification is 100 MB.

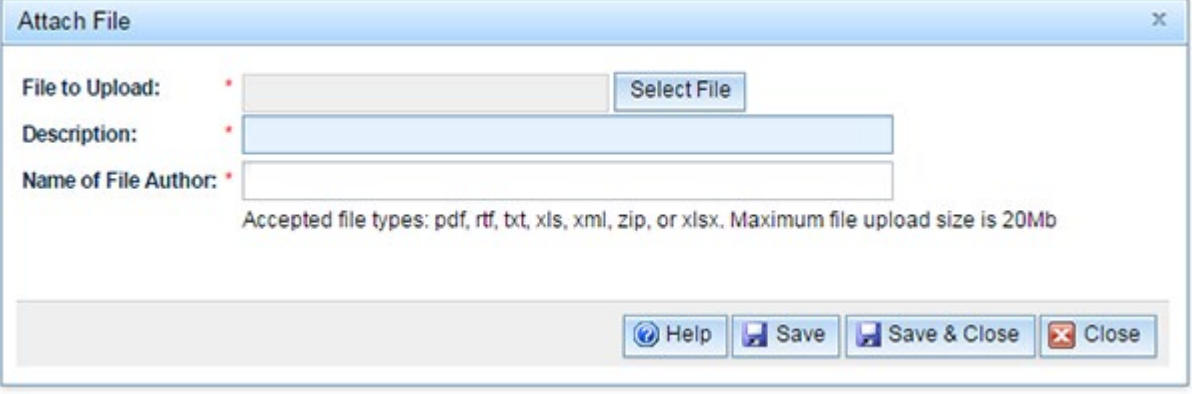
We recommend that you attach documents as part of the submission rather than send them separately.

Click the 'Attached' button, to display the following field:

Supporting data will be: ☒ Attached ☐ Sent to TGA - electronic media ☐ Or Both

Documents attached to this notification:

Click on the 'Attach File' button and the Attach File pop-up appears:



The 'Attach File' pop-up window contains the following fields and controls:

- File to Upload:** A text input field with a red asterisk, followed by a 'Select File' button.
- Description:** A text input field with a red asterisk.
- Name of File Author:** A text input field with a red asterisk.
- Accepted file types:** pdf, rtf, txt, xls, xml, zip, or xlsx. Maximum file upload size is 20Mb.
- Buttons:** Help, Save, Save & Close, and Close.

Click on 'Select File' to choose a file.

If documents are saved to your notification, they appear as:

	File Name	Created By	Description
<input type="checkbox"/>	DHPL - 25 April 2014.pdf	Andy Anders	Dear Healthcare Professional Letter

To remove a document click the check box and then 'Remove File'.

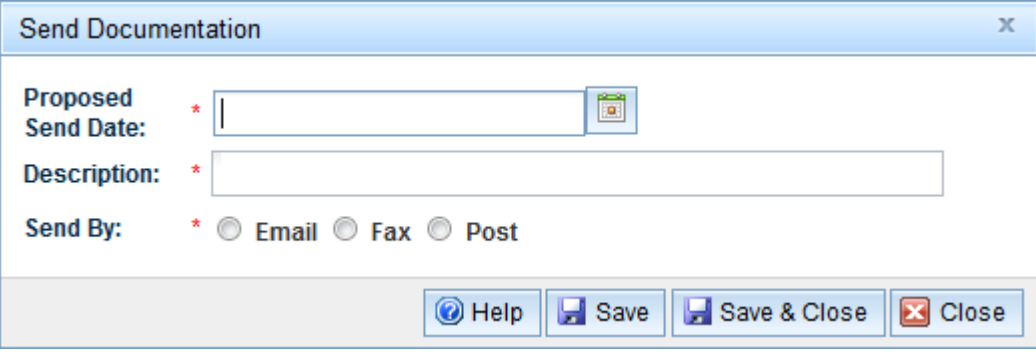
Sending documents

If you are sending documents to the TGA but not attaching them to this notification form, click the 'Sent to TGA – electronic media' button:

Supporting data will be: ☐ Attached ☒ Sent to TGA - electronic media ☐ Or Both

Documents to be sent to TGA:

Click on the 'Add' button and the Send Documentation pop-up appears:



The 'Send Documentation' pop-up window contains the following fields and controls:

- Proposed Send Date:** A text input field with a red asterisk, followed by a calendar icon.
- Description:** A text input field with a red asterisk.
- Send By:** Radio buttons for Email, Fax, and Post, with a red asterisk.
- Buttons:** Help, Save, Save & Close, and Close.

Enter the 'Proposed Send Date', a 'Description' and mode of delivery, click 'Save'. Repeat to enter another document description if sending multiple documents.

Click 'Save & Close' to display the documents as following:

	Proposed Send Date	Description	Send By
<input type="checkbox"/>	15/05/2014	Dear Healthcare Professional Letter	Fax

To remove a document click the check box and then 'Remove'.

Send and attach documents

To both send and attach the documents click the 'Or Both' button and both the fields will appear:

Supporting data will be: ☐ Attached ☐ Sent to TGA - electronic media ☒ Or Both

Documents attached to this notification:

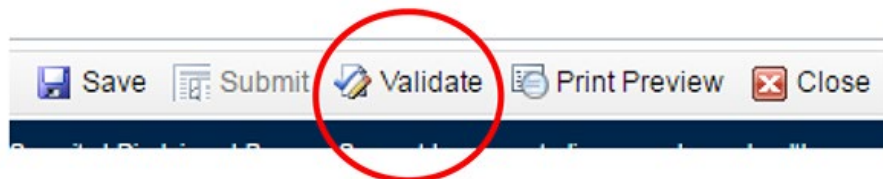
Documents to be sent to TGA:

Once complete, click 'Save'.

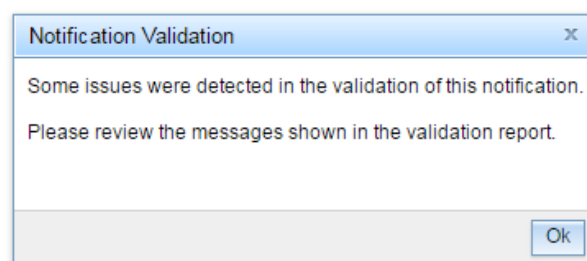


Step 9 – Validation

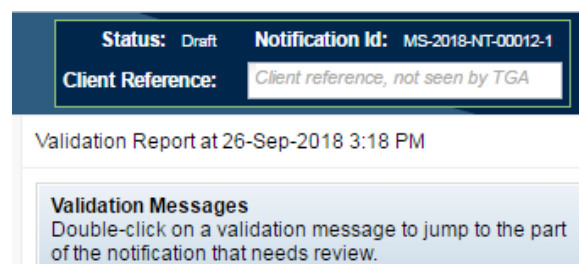
You can validate the notification form at any time but you must validate before you submit. To validate, click on the 'Validate' button at the bottom of the page.



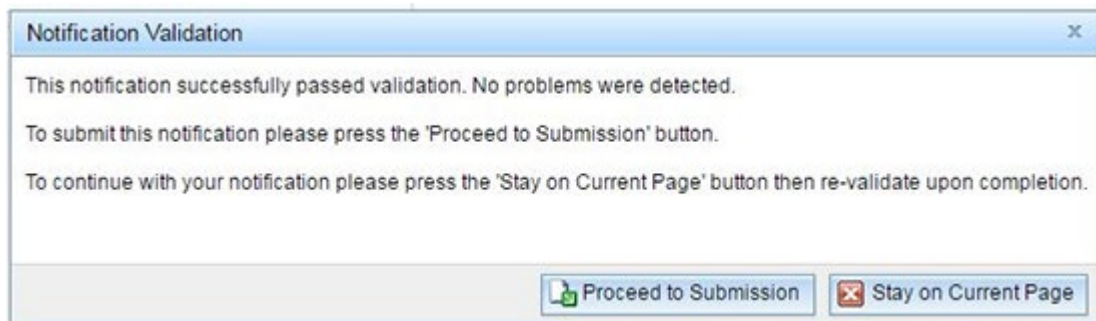
If the notification fails to validate, you will receive the following message:



A list of the issues will appear under the heading 'Validation Report'. You must fix the problems before the form will validate.



If the notification passes validation, you will receive the below message and can proceed to the submission stage.



If you change the document **after** you receive the above 'Notification Validation' message you must validate the notification again prior to submitting.

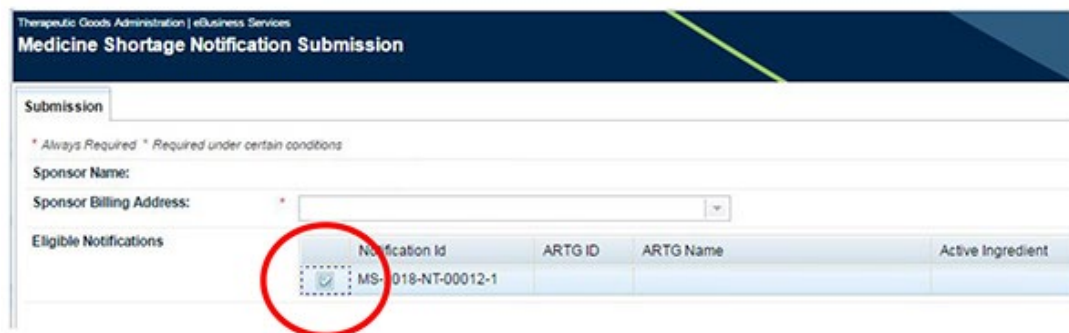
Click on the 'Proceed to Submission' button, to go to the submission page.

The 'Proceed to Submission' button is only available to TBS users with submitter access. Please contact your TBS master account holder if you need this access.

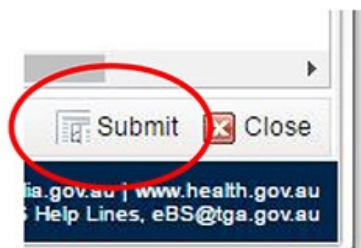
Step 10 – Submission

'Passed Validation' notification forms can be submitted individually or as a batch. To view a 'Passed Validation' notification form before submitting go to the 'View Drafts' section.

Tick the box next to the notification/s you want to submit.



Then click 'Submit'



This will take you to the acknowledgement page.

Step 11 – Acknowledgement

You must acknowledge the conditions in the acknowledgement screen and click 'to complete submitting your notification.

Click 'Print' **prior** to clicking 'Acknowledge and continue' if you wish to print a copy of the acknowledgement screen.

You will receive a message that your notification has been successfully submitted to the TGA:

The notification form is no longer visible in the 'View Drafts' or 'Submission' pages and can now be located via the '**View Lodged Submissions**' link. It will initially display the Workflow status as 'Submitted – Pending Review' which changes to 'Pending Assessment' once it has been received by the TGA (see Submissions).

During this phase you cannot make any edits, additions or delete the notification. You may view it and print it through print preview.

Managing a notification form

Editing

The notification form can be edited at any time **prior** to submission.

However, if you need to edit **after** submitting, contact us to have it returned to your drafts. This returned notification form (or push back) will be highlighted **red** for easier identification. It will need to be validated before it can be resubmitted.

Date ▼	Identifier	Client Reference	Information	Sponsor
2014-05-20	MS-2014-NT-00051-1	None		

To make any changes after we assess the notification you will need to vary a notification.

Varying (updating) a notification form

You are able to vary your submitted notification after we have assessed it and moved it into the 'Medicine Shortage' list.

If you submitted an initial notification for a critical impact shortage you have **three days** from the time you submitted your initial notification, to update your notification to complete the full set of mandatory questions.

To vary a notification form, click the drop-down arrow on the listed notification, and then click 'Vary Notification'.

The notification form will open for editing, the status will change to 'Draft' and it will move to the 'Drafts list'. You can check this by clicking on 'View Drafts'.

You need to validate the varied notification form before you submit it for assessment.

Any variations made to the notification will appear in the 'Changes Made' tab. This tab will appear after validating and before submitting the notification. You can also view these changes at the bottom of your 'Print Preview' document.

The screenshot shows the 'Medicine Shortage Notification' form with several tabs: Notifier, ARTG Entry, Details, Impact, Shortage Action, Supporting Information, and Changes Made. The 'Changes Made' tab is highlighted with a red circle. Below the tabs, the 'Changes Made' section is visible, stating: 'The following changes have been made between this variation and the last approved notification.'

The original notification remains in 'Medicine Shortages' list until the varied notification assessment is completed by TGA and then replaces the original. If a 'Vary Notification' is attempted again while the first variation is still in 'Draft' or being assessed the following message will appear:



An update of this notification has already been initiated. Please edit the existing update instead.

OK

If the original notification was published on the Medicine shortage reports database, any variations made will be reflected on the website on completion of the assessment.

Medicine shortages that occur after a resolved notification

Resolved notifications remain active for 3 months after submission. Within this period, if you need to submit a new notification, contact the Medicine Shortages team. We will archive the existing notification as soon as possible so you can submit a new one. You are **not able to vary a resolved notification**.

You will receive the following validation message if you attempt to submit a new notification but an active notification exists in the system:

Validation Messages

Double-click on a validation message to jump to the part of the notification that needs review.

A shortage notification with notification id MS-2021-NT-00039-1 has already been submitted for ARTG entry
The existing notification must be Closed before submitting a new one for the same ARTG entry.

If it has been more than 3 months since you last submitted a resolved notification for a previous shortage of your product, you can continue to create and submit a new notification without having to contact the Medicine Shortages team.

Printing

The notification form can be printed at any time, before or after submission, by either:

- Clicking the 'Print Preview' button located at the bottom of the notification form.
- Clicking the drop-down arrow on each listed notification on the 'View Drafts' page, and clicking 'Print Preview'.



- Clicking the drop-down arrow on each listed notification on the 'View Lodged Submissions' page, and clicking 'Print Preview'.



Deleting

Notifications can be deleted at any point up until they are submitted. To delete, open the 'View Drafts' link found at the top of the TBS Navigator.



Click the drop-down arrow of the listed notification, and click 'Delete'.

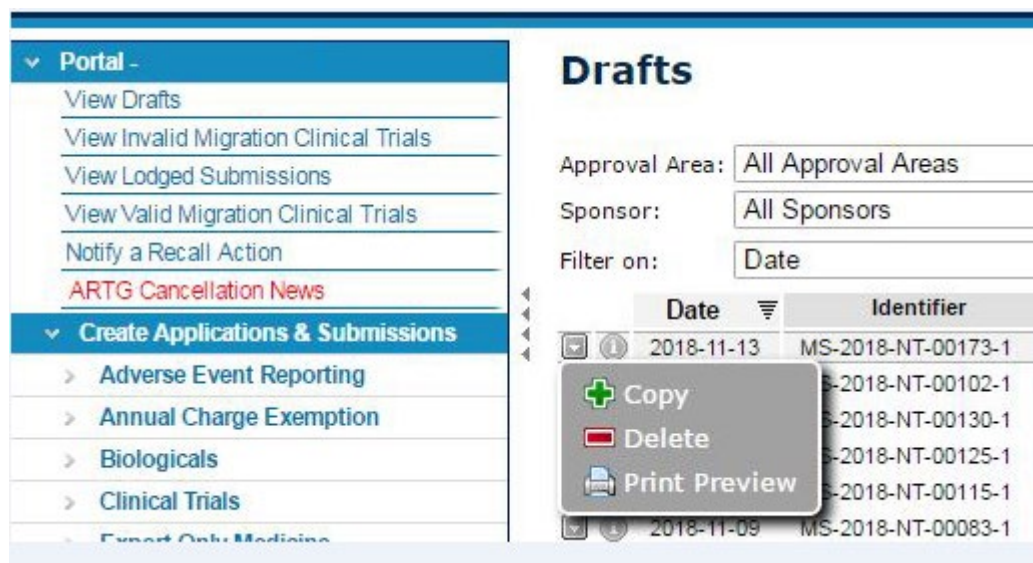


Copying

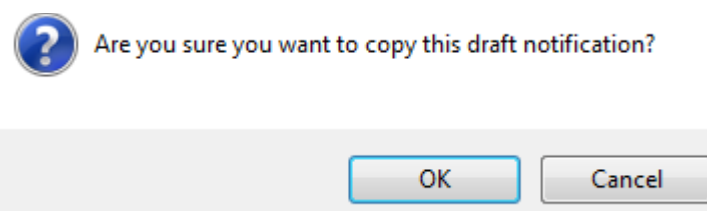
Any **draft** notification form can be copied to create a new draft notification form. This speeds up the notification process if multiple products have similar shortage details.

Information from the copied draft notification form is retained for every field except those with information identifying the product, for example, ARTG and PBS numbers (refer to [ARTG Entry tab](#) details).

To copy a draft notification go to the draft list by clicking 'View Drafts' in the TBS Navigator.



Click the drop-down arrow on the listing and then click on '+ Copy'. The following pop-up appears:



Selecting OK creates a new draft notification form, which opens with a new 'Notification Id'.

Accessing a notification form

You can access your notification form from different places in the TBS Navigator depending on its stage of completion.

- **'Draft'** notification forms can be viewed, edited, copied, printed, validated or deleted. They are listed in the **'View Drafts'** link on the TBS Navigator.
- **'Passed Validation'** notification forms that have not been submitted can be viewed, edited, copied, printed, deleted or submitted. They are listed in both the **'View Drafts'** and **'Submission'** links on the TBS Navigator.
- **'Submitted for assessment'** notification forms can only be printed and viewed via print preview. They are listed in the **'View Lodged Submissions'** link on the TBS Navigator.
- **'TGA Assessed'** notification forms can be printed and viewed via print preview. They can also be updated through a vary notification action. They are listed in the **'Medicine Shortages'** link under the 'Your TGA Information' link on the TBS Navigator.

Drafts

To view your drafts open your portal and click on 'View Drafts'.



In this section, you can view all your draft submissions to the TGA, not just medicine shortages notifications. The list can be filtered by 'Approval Area', 'Sponsor' and 'Date'. These filters are located at the top of the page.

Medicine shortages notifications can be distinguished from other drafts by 'MS' at the start of their identifier (for example, 'MS-2021-NT-00053-1').

To view a medicine shortages draft click on it under any of the five column headings:

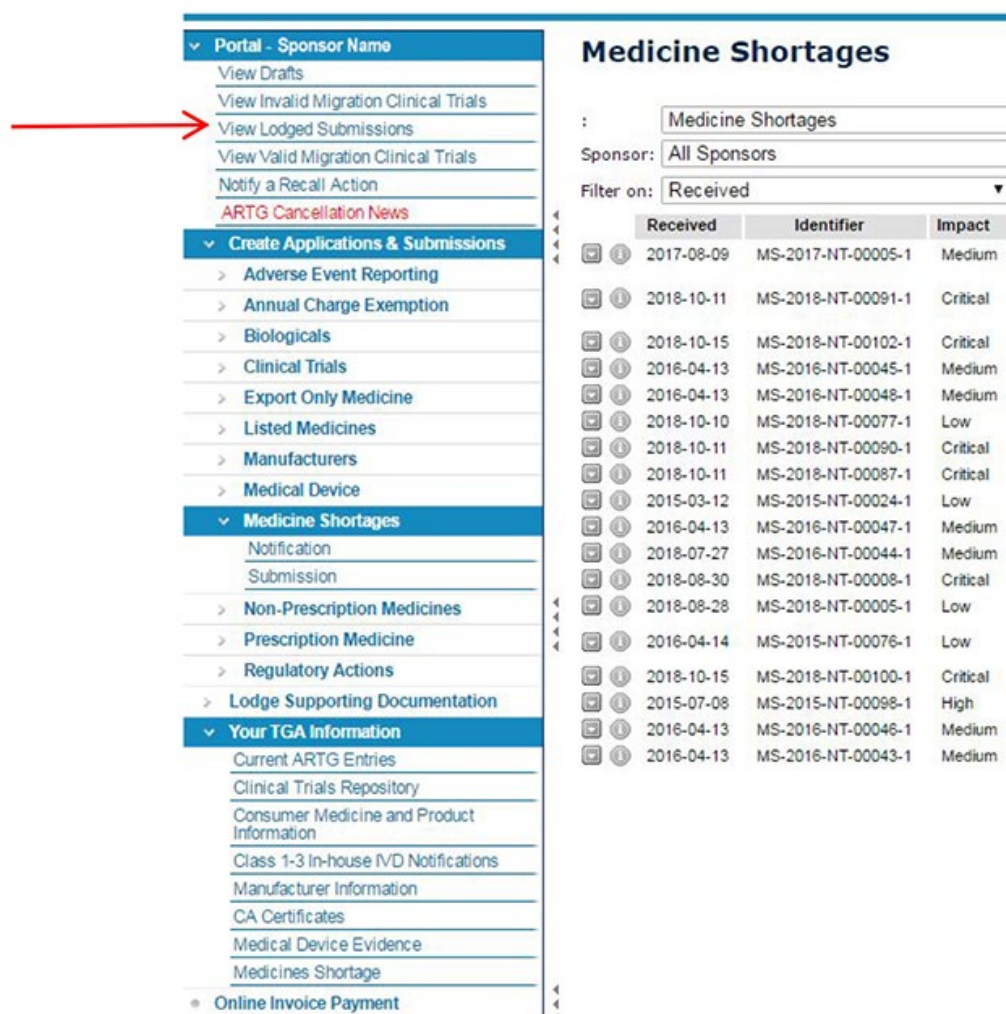
Date	Identifier	Client Reference	Information	Sponsor
2014-05-22	MS-2014-NT-00053-1	None		

To print preview, copy or delete the notification, click on the drop-down arrow on the listing and select the appropriate action.

Any submitted notifications that are returned by the TGA as push backs will appear here in 'View Drafts'.

Submissions

To view your submissions, open your portal and click on 'View Lodged Submissions'.



The screenshot shows the TGA portal interface. On the left is a navigation menu with the following sections:

- Portal - Sponsor Name**
 - View Drafts
 - View Invalid Migration Clinical Trials
 - View Lodged Submissions (highlighted with a red arrow)
 - View Valid Migration Clinical Trials
 - Notify a Recall Action
 - ARTG Cancellation News
- Create Applications & Submissions**
 - Adverse Event Reporting
 - Annual Charge Exemption
 - Biologicals
 - Clinical Trials
 - Export Only Medicine
 - Listed Medicines
 - Manufacturers
 - Medical Device
- Medicine Shortages**
 - Notification
 - Submission
- Non-Prescription Medicines**
- Prescription Medicine**
- Regulatory Actions**
- Lodge Supporting Documentation**
- Your TGA Information**
 - Current ARTG Entries
 - Clinical Trials Repository
 - Consumer Medicine and Product Information
 - Class 1-3 In-house IVD Notifications
 - Manufacturer Information
 - CA Certificates
 - Medical Device Evidence
 - Medicines Shortage
- Online Invoice Payment**

On the right, the 'Medicine Shortages' section is displayed. It includes filters for 'Sponsor' (All Sponsors) and 'Filter on' (Received). Below the filters is a table with the following columns: Received, Identifier, and Impact.

Received	Identifier	Impact
2017-08-09	MS-2017-NT-00005-1	Medium
2018-10-11	MS-2018-NT-00091-1	Critical
2018-10-15	MS-2018-NT-00102-1	Critical
2016-04-13	MS-2016-NT-00045-1	Medium
2016-04-13	MS-2016-NT-00048-1	Medium
2018-10-10	MS-2018-NT-00077-1	Low
2018-10-11	MS-2018-NT-00090-1	Critical
2018-10-11	MS-2018-NT-00087-1	Critical
2015-03-12	MS-2015-NT-00024-1	Low
2016-04-13	MS-2016-NT-00047-1	Medium
2018-07-27	MS-2016-NT-00044-1	Medium
2018-08-30	MS-2018-NT-00008-1	Critical
2018-08-28	MS-2018-NT-00005-1	Low
2016-04-14	MS-2015-NT-00076-1	Low
2018-10-15	MS-2018-NT-00100-1	Critical
2015-07-08	MS-2015-NT-00098-1	High
2016-04-13	MS-2016-NT-00046-1	Medium
2016-04-13	MS-2016-NT-00043-1	Medium

In this section, you can view all your submissions to the TGA, not just medicine shortages notifications. The list can be filtered by 'Approval Area', 'Sponsor' and 'Date'. These filters are located at the top of the page.

Medicine shortages notifications can be distinguished from other submissions by 'MS' at the start of their identifier (for example, 'MS-2021-NT-00052-1').

Information for each submitted medicine shortages notification is listed under these five column headings:

Received	Identifier	Workflow Status	Description	Product Name
2014-05-23	MS-2014-NT-00052-1	Pending Assessment		

To view or print the submitted notification, click on the drop-down arrow at the far-left of the listing and select the 'Print Preview' button.

Workflow status of submissions

The 'Workflow Status' column displays the status of the notification.

Submissions

Approval Area:

Sponsor:

Filter on: for

Received	Identifier	Workflow Status
2018-10-24	MS-2018-NT-00092-1	Pending Assessment
2018-10-02	MS-2015-NT-00024-1	Pending Assessment

- **'Submitted – Pending Review'**: notification form has **not been received** by the TGA.
- **'Pending Assessment'**: notification form **has been received** by the TGA.
- **'Notification Finalised'**: notification form **has been assessed** by the TGA.

Medicine Shortages

Click your 'Portal' drop-down arrow, then 'Your TGA information', then click on 'Medicine Shortage'.

Portal - Sponsor Name

- View Drafts
- View Invalid Migration Clinical Trials
- View Lodged Submissions
- View Valid Migration Clinical Trials
- Notify a Recall Action
- ARTG Cancellation News
- Create Applications & Submissions
 - Adverse Event Reporting
 - Annual Charge Exemption
 - Biologicals
 - Clinical Trials
 - Export Only Medicine
 - Listed Medicines
 - Manufacturers
 - Medical Device
- Medicine Shortages
 - Notification
 - Submission
- Non-Prescription Medicines
- Prescription Medicine
- Regulatory Actions
- Lodge Supporting Documentation
- Your TGA Information
 - Current ARTG Entries
 - Clinical Trials Repository
 - Consumer Medicine and Product Information
 - Class 1-3 In-house IVD Notifications
 - Manufacturer Information
 - CA Certificates
 - Medical Device Evidence
 - Medicines Shortage
 - Online Invoice Payment

Medicine Shortages

Sponsor:

Filter on:

Received	Identifier	Impact
2017-08-09	MS-2017-NT-00005-1	Medium
2018-10-11	MS-2018-NT-00091-1	Critical
2018-10-15	MS-2018-NT-00102-1	Critical
2016-04-13	MS-2016-NT-00045-1	Medium
2016-04-13	MS-2016-NT-00048-1	Medium
2018-10-10	MS-2018-NT-00077-1	Low
2018-10-11	MS-2018-NT-00090-1	Critical
2018-10-11	MS-2018-NT-00087-1	Critical
2015-03-12	MS-2015-NT-00024-1	Low
2016-04-13	MS-2016-NT-00047-1	Medium
2018-07-27	MS-2016-NT-00044-1	Medium
2018-08-30	MS-2018-NT-00008-1	Critical
2018-08-28	MS-2018-NT-00005-1	Low
2016-04-14	MS-2015-NT-00076-1	Low
2018-10-15	MS-2018-NT-00100-1	Critical
2015-07-08	MS-2015-NT-00098-1	High
2016-04-13	MS-2016-NT-00046-1	Medium
2016-04-13	MS-2016-NT-00043-1	Medium

All medicine shortages notifications that have completed TGA assessment are listed here.

The list of submitted notifications that are visible can be filtered by 'Sponsor' and 'Date'. These filters are located at the top of the page.

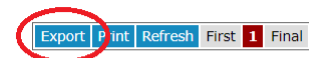
Assessed medicine shortages notifications list information under the following thirteen column headings:

Identifier	ARTG ID	Product Name	Active Ingredient	Shortage Status	Wholesaler affected period from	Wholesaler affected period to	Deletion from market	Shortage Impact Rating	Availability	Received	Published	Sponsor
MS-2021-NT-00028-1										2021-04-18	Yes	

To vary or view and print the assessed notification, click on the drop-down arrow on the listing and select the appropriate action.

You can export the displayed data by clicking on 'Export' in the top right hand corner. You can export the data as HTML, Excel or XML.

Medicine Shortages



:

Sponsor:

Filter on: for

See [Medicine shortages](#) for more information.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Management and Coordination/ Office of Scientific Evaluation	26/05/2014
V1.1	Reflect changes in TBS notification form	Management and Coordination/ Office of Scientific Evaluation	02/06/2014
V2.0	Revised after the introduction of legislation regarding mandatory reporting of medicine shortages	Medicine Shortages Section, Pharmacovigilance and Special Access Branch	21/12/2018
V3.0	Update and re-write to reflect changes to the mandatory reporting of all medicine shortages and enhances to the TBS portal and notification form.	Medicine Shortages Section, Pharmacovigilance and Special Access Branch/Regulatory Guidance	May 2021

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Reference/Publication #