Medicine shortages/discontinuations – Electronic notification form

User guide

Version 2.0, December 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

Introduction

This document provides guidance to external users, including medicine sponsors, for the medicine shortages – electronic notification form (notification form). It outlines how to submit shortage/discontinuation notifications to the Therapeutic Goods Administration (TGA) through TGA eBusiness Services (TBS), taking into consideration the implementation of mandatory reporting of shortages of all reportable medicines from 1 January 2019.

This guide is one of a number of resources developed and delivered under the Medicine Shortages Information Initiative (MSII) to improve the communication and management of medicine shortage events. This work is a joint initiative of the Medicines Partnership of Australia (comprising the National Pharmaceutical Services Association, Generic and Biosimilar Medicines Association, Pharmacy Guild, Pharmaceutical Society of Australia, Australian Self Medication Industry and Medicines Australia), the Australian Government Department of Health (including the TGA), the Society of Hospital Pharmacists of Australia and the Australian Medical Association.

Who should use this guide?

This document is a reference guide for sponsors of current reportable medicines as defined in the *Therapeutic Goods Act 1989*.

Reportable medicines are defined in the legislation as:

> *(1) For the purposes of this Act, registered goods are a reportable medicine if:*
>
> > *(a) the goods are medicine; and*
> >
> > *(b) either:*
> >
> > > *(i) the medicine contains one or more substances included in Schedule 4 or 8 to the current Poisons Standard; or*
> > >
> > > *(ii) the medicine is determined in an instrument under subsection (2).*
>
> *(2) The Minister may, by legislative instrument, determine medicine for the purposes of subparagraph (1)(b)(ii).*

That is, all prescription medicines that are entered on the Australian Register of Therapeutic Goods (ARTG) and a small number of non-prescription medicines set out in the Reportable Medicines List. The criteria for inclusion of a non-prescription medicine are:

- the medicine is critical to the ongoing health of the patient (for example, salbutamol asthma inhalers)

- inclusion of the medicines is critical for public health (for example, naloxone injections for opioid overdose).

How to use this guide

This guide has been written for users when completing the Medicine shortages – electronic notification form on TBS. This document is written in a task-based manner, with step by step instructions and examples as required.

Assumptions

It is assumed that users are familiar with mouse skills, have a TBS login and have a basic knowledge of the TBS environment. If you require a TBS login, please see Help.

Legislative basis

The Therapeutic Goods Amendment (2018 Measures No. 1) Bill 2018 passed through both houses of the Australian Parliament and received Royal Assent on 21 September 2018.

From 1 January 2019, the *Therapeutic Goods Act 1989* requires the mandatory reporting of shortages (including discontinuations) of reportable medicines.

Medicine shortages and discontinuations of medicines deemed to be of critical patient impact will be mandatorily published on the MSII landing page on the TGA website.

Medicines shortages or discontinuations of medicines deemed to have a medium or low patient impact are also subject to mandatory reporting, but are not subject to mandatory publication.

Help

If you have any questions relating to the notification form or on medicine shortages, please contact the TGA's Medicine Shortages Section on:

- email: medicine.shortages@health.gov.au

- telephone: 02 6232 8850

The TGA TBS Help Desk operates Monday to Friday from 8:30am to 5:00pm AEST, excluding public holidays.

If you have any questions relating to acquiring a TBS login or accessing the TGA TBS site, please contact the Help Desk on:

- email: ebs@health.gov.au

- telephone: 1800 010 624

Medicine shortages – electronic notification form

Overview

A medicine shortages notification form is available from the TGA TBS website. Sponsors can log into TBS and select their own ARTG entries that are or will be involved in a medicine shortage or a discontinuation.

Details of the shortage or discontinuation can be entered and submitted to the TGA electronically.

Benefits

- The notification form uses the same functionality as other TBS applications including saving partially completed forms and an ongoing record of the status, updates and communications.

- If upon submission the TGA requires further information to assess the shortage the notification form can be returned to the sponsor (via push back) and changes and additions can be made and re-submitted.

- Each notification form is owned and controlled by the sponsor; information relating to the product or sponsor activities contained within it cannot be changed or added to by the TGA.

- Early notification of critical patient impact shortages in the absence of full information is still viable as the notification form allows the notification to be validated with reduced mandatory fields for shortages of critical patient impact and subsequently updated.

- Information from one notification form can be copied into another when there is the need to submit multiple ARTG entries at a time, for example for different dosage forms or strengths.

- There is provision for users to attach information such as 'Letters to Prescribers' and/or references to specific web links to support the communication activities.

Using the electronic notification form

Data entry and field types

The method of entering data into fields varies according to the nature of the field. Fields that have a red asterisk (*) against them are mandatory and must have a value entered into them for the application to be valid. You may leave them blank while drafting and still save the application.

1. Radio buttons

If only one option is allowed then radio buttons are used where you can click on the button next to the option needed. For example:

Nature of the shortage: *   ⦿ Anticipated   ◯ Current   ◯ Resolved   ◯ Discontinued

2. Drop-down lists

Fields that can only be entered by choosing an item value from a drop-down list. In field help will appear as grey text before an item is chosen from the drop-down list. For example:

Select the Shortage Reason ▾

3. Numeric fields

This allows the entry of numbers only, not text. Do not enter negative numbers. For example:

[   ] units

4. Free text entry fields

These are boxes that will allow you to type in (or paste) text. These will have varying limits to the amount of text that can be entered. For example:

[   ]

For lengthy fields, if the text entered exceeds the amount displayable in the text box, a vertical scroll bar will appear to allow you to move up and down the text.

5. Search result from a database

Similar to drop-down list boxes, details associated with an ARTG number are found by searching a database rather than selecting from a drop-down list. For example:

[   ] [Search] [Clear]

Getting started

Navigation from the TGA TBS home page

Access the TBS home page by opening the TGA Business Services link on the TGA website.

Should you have an old bookmark that shows this screen:

Then you should click the secure 'Login to Business Services' link found at the bottom of the left-hand pane of menu options (TBS Navigator).

If you are not already logged on, you will be prompted for your user name and password.

This then takes you to your 'Welcome Page' where you navigate to 'Your TGA' in the dark blue ribbon and then choose 'Medicines Shortages' from the drop-down list. Your 'Portal' view will now appear.

Locate the 'Portal' drop-down button at the top-left of the TBS Navigator panel and open.

Locate 'Create Applications and Submissions' and open.

Locate 'Medicine Shortages' and open. Two fields will appear:

- 'Notification', which opens a new form to begin submitting a new notification

- 'Submission', which opens a field that displays previously created notifications and submitted notifications.

Completing the notification form

When the 'Notification' link is selected the user is prompted to provide the answers to two questions:

1. What is the 'Impact of Shortage'?

2. What is the 'Nature of Shortage'?

This is because the answers to these questions will determine how the form displays and the number of mandatory fields the sponsor will be required to complete in order for the notification to validate for submission to the TGA.

Click one radio button for each field, and then click on the 'Continue' button. The pop-up box will close and the notification form will then be visible. The medicine shortage notification form will have six tabs, of which 'Notifier' will be the first.

Please note that this box will only appear when you are creating a notification for the first time. If you are undertaking a variation of an existing notification, this box will not appear.

Minimum information

The minimum information required to submit the notification form advising of a critical patient impact, current or anticipated shortage, is:

- 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

- proposed date of publication on the TGA website.

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

In some cases, a mandatory field may be prepopulated from an earlier part of the reporting form.

If a mandatory field is not completed, the notification will not successfully validate and you will not be able to submit the report. In this situation, the 'Validation Report' will identify which of the fields require completion and you can go directly to those fields (or any other problem identified in the report) by double clicking on the validation message. The form will open at the correct tab and the cursor will be flashing at the field where the data is required.

While the mandatory fields must be completed, further fields can be completed if the information is available.

Current or anticipated shortages of critical patient impact can be submitted in three ways:

1. completing only the required number of mandatory fields

2. completing the mandatory fields and providing some extra information you currently have

3. completing the whole notification form (all fields).

When submitting an update for this type of notification all fields will be mandatory except the sponsor web address. The sponsor website field is for the sponsor to complete IF AND ONLY IF the sponsor website provided contains information relating to the shortage of the particular medicine that is the subject of the notification. A sponsor website that does not contain information relating to the shortage will not be published. The intention of this field is to provide further information for health professionals and consumers about the management of the shortage.

All other notifications, regardless of the 'Nature of Shortage' or the 'Impact of Shortage', must be submitted with all fields which have a red asterisk (*) completed. The sponsor website does not have a red asterisk and is not mandatory for the reason given above.

Form layout

The top-right of the form displays the 'Status' of the notification form, the 'Notification Id' (generated when the notification form is first saved) and has a free text box to enter a client reference utilised by the sponsor in-house. This client reference will not be visible to the TGA.

Status: Draft	**Notification Id:** MS-2018-NT-00012-1
Client Reference:	*Client reference, not seen by TGA*

The form for submitting a medicine shortage notification is divided into seven tabs:

Notifier	ARTG Entry	Details	Impact	Shortage Action	Supporting Information

These are located at the top-left of the notification form. Navigation through the notification form can be achieved by clicking on the individual tabs or clicking on the buttons located at the bottom-left of the notification form.

< Previous | Next >

Responses provided in preceding tabs affect the appearance/non-appearance of fields in the proceeding tabs so it is advisable that the notification form is filled in sequentially (from the far-left tab through to the far-right tab).

At the bottom-right of the notification form action buttons are located. Their functions are described later on in this guide.

Save | Submit | Validate | Print Preview | Close

As you proceed through the various tabs on the notification form activity boxes will appear which themselves contain 'Help' buttons. These buttons have information relating to the specific function being undertaken in that field.

Steps to creating a notification

Step 1 – Creating a new medicine shortage notification

Logon to TBS. Click on the applications button in the dark blue navigator bar and choose 'Notification' under 'Medicine Shortages'.

Alternatively, navigate to the TBS portal and, within the portal open the 'Create Applications & Submissions', open the 'Medicine Shortages' drop-down arrow.

Select 'Notification'.

The 'Notification' pop-up box will open and you will be asked to select what level of patient impact and to identify the nature of the shortage that you are reporting.

Then click 'Continue'.

Please note, the information provided in response to 'Impact of Shortage' will determine the number of mandatory fields that will be required to be completed in order for the notification to successfully validate. An explanation of the meaning of the questions in each field is provided in Appendix 1.

Step 2 – Notifier information

The pop-up box will close and the notification form will then be visible. The form will have six tabs, of which 'Notifier' will be the first.

You will notice that the 'Sponsor Name' and the 'Primary Contact' fields are prepopulated using the information maintained in TBS attached to your login details.

Please note, only sponsors can submit medicine shortage notifications. If you are not the sponsor of the medicine that you wish to notify, you will not be able to complete the notification form.

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

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

Step 3 – ARTG Entry information

Move to the next tab – 'ARTG Entry'.

Enter the ARTG number of the product you are intending to report and click on the 'Search' button.

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

Complete all other mandatory fields for which you have the required information.

If you have chosen to submit a shortage of critical patient impact you will note there are a reduced number of mandatory fields. You are able to complete more fields if you know the required information, but only the mandatory fields are required for successful validation of the notification.

If you have answered 'yes' to the question 'Do you have a designated sponsor representative within your organisation who is a point of contact on Pharmaceutical Benefits Scheme (PBS) matters?' you will be required to enter the contact details. Ensure that you provide the name of a representative from your sponsor company as they will be the point of contact in your sponsor company if the officers in Technology Assessment and Access Division wish to discuss any PBS matter.

Step 4 - Details

Move to the next tab – 'Details'.

The first question 'When was the shortage known to the sponsor?' is mandatory for any notification. This question is used to calculate the timeframes in critical impact medicine shortage notifications to monitor the sponsor's compliance with the legislated timeframes.

The choice you made in 'Notification' pop-up box in Step 1 regarding 'Nature of Shortage' has been prepopulated.

If you are creating a notification of critical patient impact, you need only complete the mandatory fields. If you are creating any other type of notification, including all discontinuations and low or medium impact shortages, you will be required to complete ALL FIELDS. See picture below; in this screen shot (*) indicates mandatory fields in an initial critical patient impact notification.

The shortage reason should be chosen from the drop-down list and this is a field which is published on the TGA website if the notification is published.

Enter the estimated dates of the shortage; if the notification is for a discontinuation there will only be a shortage 'From' date and you will be requested to enter a 'Deletion from Market Date'.

The 'Deletion from Market Date' is taken to be the date from which the sponsor will no longer hold any stock of the medicine. The product remains on the ARTG at this time, it is just no longer available. The 'Deletion from Market Date' is not to be confused with the date on which the sponsor chooses to cancel the product which removes the product from the ARTG.

You will note that the availability field will be not selectable for an anticipated shortage or for a resolved shortage as in both cases the product is available at the time of notification. If the availability needs to be anything other than 'available' then the shortage is a current shortage and the 'Nature of Shortage' should be changed to reflect the correct status.

The definitions of the terms in the 'Availability' drop-down list are explained in the 'Availability' row of the table under the 'Details' section of Appendix 1.

The question 'Do you consent to this notification being published in the interest of public health?' is NOT visible for any shortage of a critical patient impact as all critical impact shortages and discontinuations will be mandatorily published. For all other type of shortages the sponsor is given the choice and asked to propose a date of publication if they consent to publication. You will note that even if NO is selected in answer to this question, the notification may still be published by the TGA under section 61 of the *Therapeutic Goods Act 1989* if TGA determines that it is in the interest of public health.

If the TGA does make the decision to publish the information on the Medicine Shortages website, the sponsor will be consulted prior to this occurring.

The answers to the remaining questions on this page will assist the TGA in planning a strategy for the management of the shortage. None of this information is published on the TGA website.

Please note:

- You cannot enter a future date in the field 'When was the shortage known to the sponsor?'

- Changing the 'Nature of Shortage' here may result in changes to the required fields in the form.

- For anticipated and resolved shortages the availability field is set to 'available' as per the definitions, this cannot be changed.

- Please make it clear what you mean when you refer to 1 unit (for example, 1 unit = 1 bottle x 30 tablets, or 1 unit = 5 x ampoules of injection, or 1 box of 10 x 100mL bag). This will assist the TGA in understanding the availability of stock when reviewing the notifications provided by different sponsors as different sponsors use different parameters to define 1 unit.

Step 5 – Impact information

Move to the next tab – 'Impact'.

For a notification of critical patient impact, there is only one mandatory field on this tab.

The choice you made in 'Notification' pop-up box in Step 1 regarding 'Impact of Shortage' has been prepopulated as the answer to the last question on this tab. If you chose another impact option, this will change the mandatory fields in the form. You will need to go back and ensure that you have completed all fields or the notification will not successfully pass validation.

Enter all pertinent information requested under this tab. Again, the answers to the remaining questions on this page will assist the TGA in planning a strategy for the management of the shortage.

The definitions of the terms in the 'Status of substitute' options drop-down list are explained in the table under the Impact Section of Appendix 1.

If the medicine in shortage is used by specific population groups these should be indicated in the box provided. This information will assist the TGA in identifying if further management is required. 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', would alert the TGA to undertake further investigation into the availability of alternative preparations. This may also result in the patient impact of the shortage being increased. This would be done in consultation with the sponsor of the medicine in shortage.

Step 6 – Shortage Action information

Move to the next tab – 'Shortage Action'.

If you have planned communication activities, such as letters to pharmacists or wholesalers, you should indicate which you will be implementing by choosing them from the drop-down list. If your communication to a particular group is not all being distributed on the same date, please enter the first date on which the information will be distributed (some sponsors have advised that their information is sent out in batches and occasionally this does not occur on the same date). The first date on which this is distributed will be taken as the date that the information is being made public and will assist the Medicine Shortages Section in being able to answer enquiries relating to the shortage.

Choose the type or types of letters that you have developed for your communication strategy from the drop-down list. The drop-down list can be found by clicking on the down arrow to the right of the 'Action' field.

You can only choose one communication type at a time. Then select the date which you intend to circulate the particular communication type. The [Help] button within the 'Communication Action' box contains information relating to the 'Communication Action' only: further information on adding single and multiple letters, removing letters and further assistance.

If the choice you make is the only letter you wish to attach, choose 'Save & Close' and this will take you back to the form and your choice will appear as below:
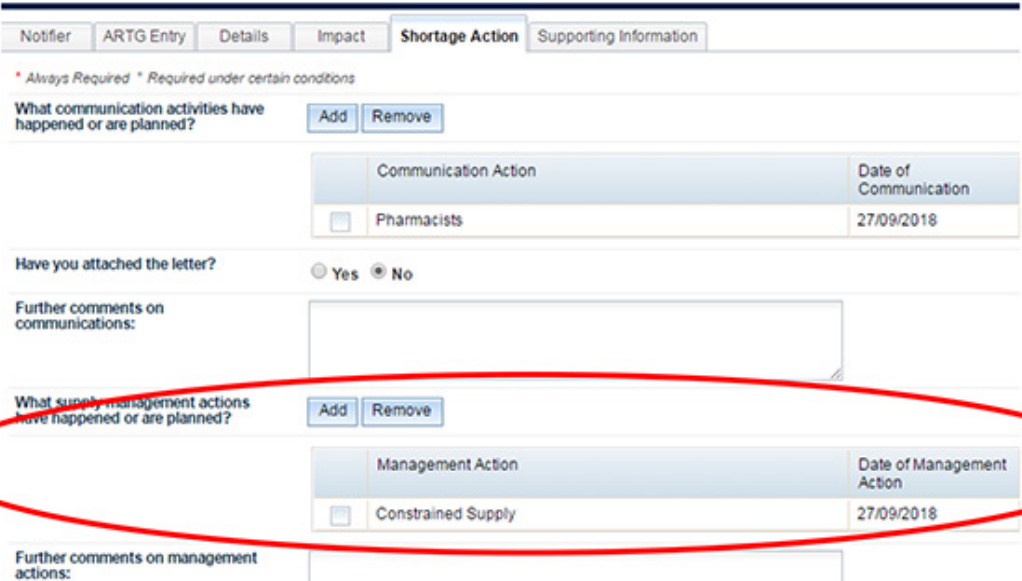

Please note - the checkbox is only used to select a communication activity included in error to enable its removal by clicking 'Remove'.

A reminder question has been included here to alert you to attach the relevant letters. The letter/s will be attached to your notification on the 'Supporting Information' tab. This is a mandatory field. The sponsor must answer 'Yes' or 'No' only. No further action is required on this tab if this is a critical impact shortage notification with minimum mandatory fields. However, if the sponsor has answered 'Yes', the sponsor will be required to attach the letter on the supporting information tab or the notification will fail validation.

If you have a supply management action, please identify it on this tab also. Supply management actions are added in the same way communication activities are added. The [Help] button within the supply 'Management Action' box contains information relating to the supply 'Management Actions' only: further information on adding single and multiple actions, removing letters and further assistance.

If you need to communicate further information to the TGA this can be done using the free text field in the 'Further Comments' box below the list of management actions. For example, if your management action was 'Working to expedite request to Pharm Chem Section', you may like to include the date of submission and the submission number of your Section 14 or Cat 3 application which allows the Medicine Shortages team to discuss the processing of the application with the section involved.

Step 7 – Supporting Information

Move to next tab – 'Supporting Information'.

If you wish to attach a document, such as a letter to a health professional, this is where it is attached. You may choose to attach the document as part of the submission (preferred method) and/or you can email the document separately.

You may attach more than one document if you are writing to multiple stakeholders. To do so, click the 'Save' button and make a second choice. When you have added all attachments click 'Save & Close'. Alternatively, click on 'Attach File' a second time and add the second file.

Please note that if you are submitting a variation of a medicine shortage notification and you do have an updated letter to a stakeholder, Medicine Shortages Section would prefer that the old letter be removed from the updated notification and the new letter be attached. This provides a correct snapshot in time, where the information in the updated notification form and the supplementary letter align.

Attaching documents

It is possible to attach electronic files from your system to the application. For example, you may wish to attach a 'Dear Healthcare Professional Letter' this way. Each document attached can be up to 20 Megabytes (MB) in size and the total size of all documents and the notification, which can be received by the TGA this way, is 100 MB.

When attaching documents first click the 'Attached' radio button, the following field is displayed:

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

Clicking on the 'Select File' button allows you to navigate through your network using the usual Windows navigation protocol. Once chosen, please make the description clear by ensuring that a scanned PDF has been named with the name of the product and the type of communication. Please do not just leave the number generated by the scanning process.

Once a description and file author name has been added the 'Save' button can be clicked to allow another document to be attached, the 'Save & Close' button can be clicked to display the document and previously saved documents, or the 'Close' button can be clicked to display previously saved documents. If documents had been saved they appear as:

	File Name	Created By	Description
☐	DHPL - 25 April 2014.pdf	Andy Anders	Dear Healthcare Professional Letter

Any documents can be removed by clicking the check box and then clicking the 'Remove File' button, a warning will pop up asking you to confirm the removal.

Sending documents

If documents are to be sent to the TGA but not attached to this notification form, first click the 'Sent to TGA – electronic media' radio button and the following field is displayed:

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

Once 'Proposed Send Date', a 'Description' and mode of delivery ('Send by') have been entered, the 'Save' button can be clicked to allow another document description to be added, the 'Save & Close' button can be clicked to display the document to be sent and previously saved documents to be sent, or the 'Close' button can be clicked to display previously saved documents to be sent. If documents to be sent had been saved they appear as:

	Proposed Send Date	Description	Send By
☐	15/05/2014	Dear Healthcare Professional Letter	Fax

Any documents to be sent can be removed by clicking the check box and then clicking the 'Remove' button, a warning will pop up asking you to confirm the removal.

If documents are to be both sent separately to the notification form and attached to the notification form click the 'Or Both' button and both the fields will appear:

Once complete, save the notification by clicking on the 'Save' button in the bottom right-hand corner of the screen.

Step 8 – Validation

You will then need to validate the notification by clicking on the 'Validate' button in the bottom right-hand corner of the screen.

If the notification fails validation, you will receive the following message:
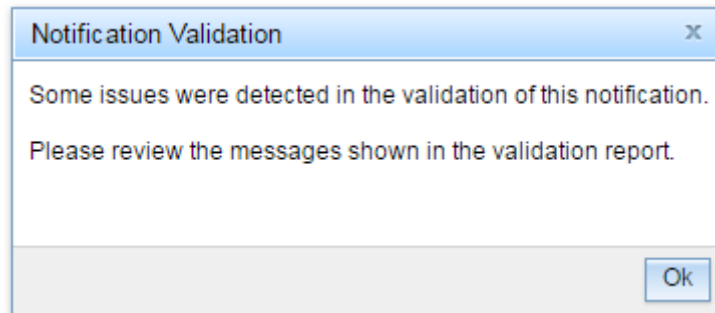
On the right-hand side of the screen, you will see a list of the issues under the heading 'Validation Report'. These issues will need to be rectified before the notification will successfully pass validation.
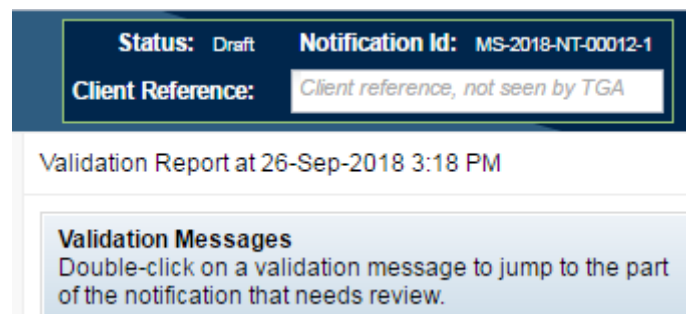
If the notification successfully passes validation, you receive the below message and will be able to proceed to the submission stage.
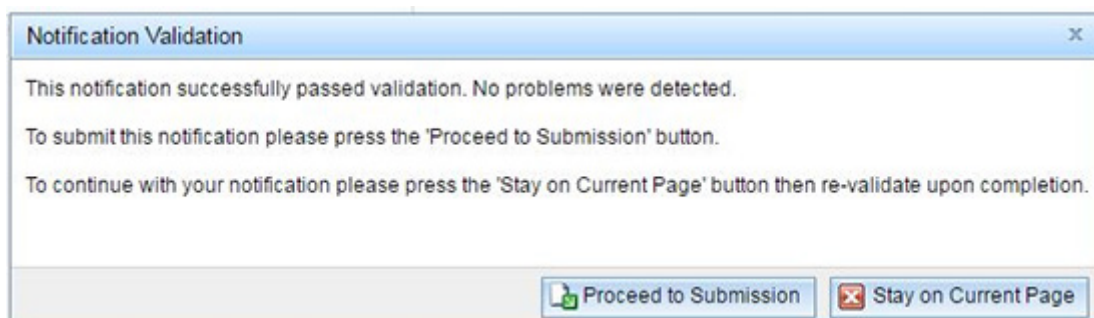
Once you click on the 'Proceed to Submission' button, you will be taken to the submission page.

If you make any changes to the document **after** you have received the above 'Notification Validation' message you will need to validate the notification again prior to submitting to the TGA.

Step 9 – Submission

Choose the notification that you wish to submit by ticking the eligible notification.

Choose to submit your notification by clicking the 'Submit' button on the bottom right-hand corner of the screen.
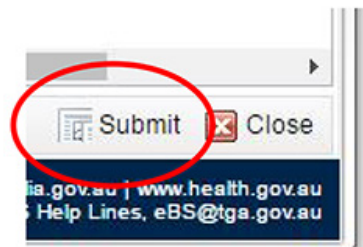
This will take you to the acknowledgement page.

Step 10 – Acknowledgement

You must acknowledge the conditions and continue or the notification will not be submitted. The acknowledgement screen appears:

If you agree, click on the 'Acknowledge and Continue' button.

You may print a copy of the acknowledgement screen **prior** to submitting by clicking on the 'Print' button.

You will receive a message that you notification has been successfully submitted to the TGA, which will look like the following:

Saving

At any point you can save your draft notification, this is achieved by clicking the 'Save' button (![Save]) located at the bottom-right of the notification form. When the notification form is first saved a 'Notification ID' is generated and it is displayed at the top-right of the notification form. If you have saved a notification and then close it, you can find it in the '<u>View Drafts</u>' field in the Portal.

Editing

The notification form can be edited at any time prior to submission. However, if the notification form has been submitted to the TGA for assessment and editing is subsequently required, the TGA can be contacted and the notification form can be returned to <u>drafts</u> for editing. This returned notification form (or push back) will be highlighted **red** for easier identification and 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		

Once the notification has been assessed by the TGA any further changes required will need to be made by a 'Vary Notification', please refer to <u>Varying a notification</u> for further information.

Validation

The notification form can be validated at any time but it must be validated before it can be submitted. This is achieved by clicking on the 'Validate' button located at the bottom-right of the notification form.
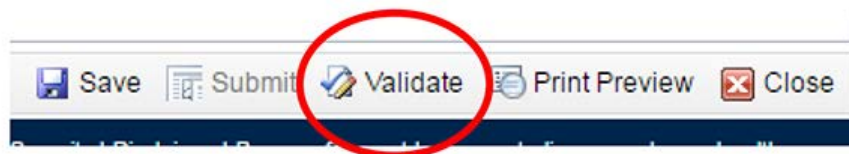
When this button is clicked, checks are made to ensure that all compulsory fields have been completed and whether data is in the correct format i.e. email addresses. If there are no validation errors the notification form's status will change from 'Draft' to 'Passed Validation' and the following pop-up appears:
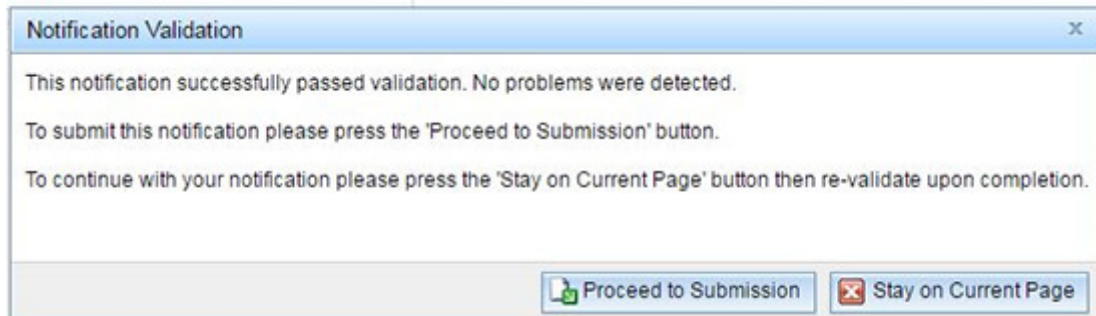
Clicking the 'Proceed to Submission' button takes the user to the 'Submissions' page.

Note: 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 requirement.

Validation errors

If there are validation errors the following pop-up will appear:
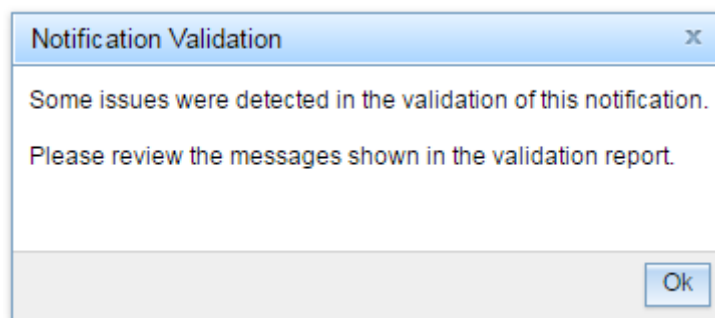
These validation errors will appear at the right-hand side of the notification form in a box as hyperlinks that take you to the incomplete fields when clicked upon.
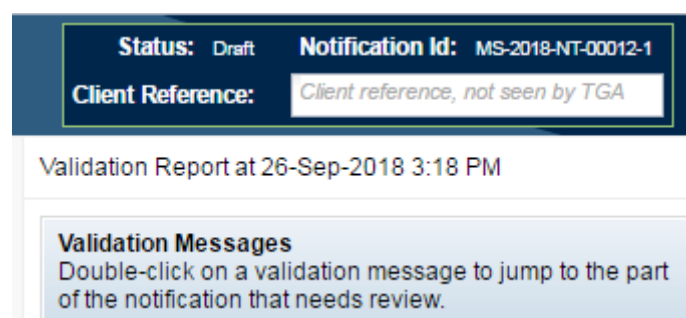
If there are validation errors the notification form status will remain as 'Draft'. If the 'Passed Validation' notification form is saved the following pop-up appears:
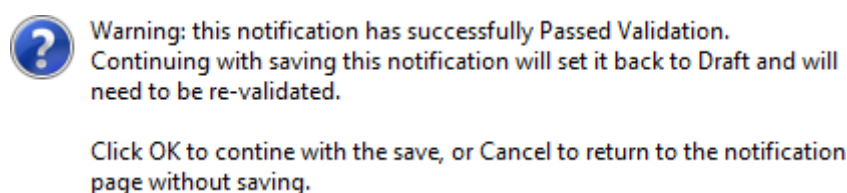
Clicking 'OK' will change its status back to 'Draft' and the form will need to be validated again.

Printing

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

- Clicking the 'Print Preview' button located at the bottom-right of the notification form.

- Clicking the drop-down arrow, located at the far-left of each individual draft notification listed on the 'View Drafts' page, and then by clicking 'Print Preview'.
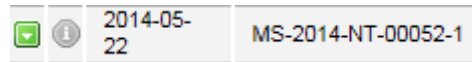
- Clicking the drop-down arrow, located at the far-left of each individual lodged notification listed on the 'View Lodged Submissions' page, and then by clicking 'Print Preview'.
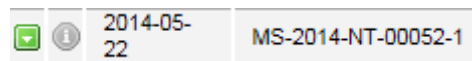
Deleting

Notifications can be deleted at any point up until they are submitted. To do so, open the 'View Drafts' link found at the top of the TBS Navigator.
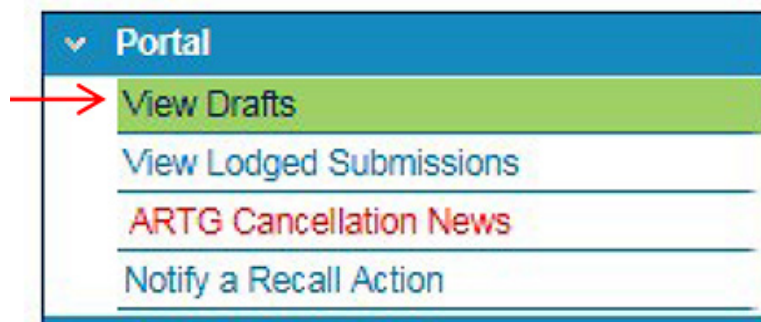
Then by clicking the drop-down arrow, located at the far-left of each individual draft notification listed, and then by clicking 'Delete'.

Copying

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

Information from the copied draft notification form is retained for every field except for some fields located on the 'ARTG Entry' tab such as the ARTG and PBS numbers (please refer to ARTG Entry tab details).

To achieve this proceed to the draft list located via the 'View Drafts' link in the TBS Navigator.
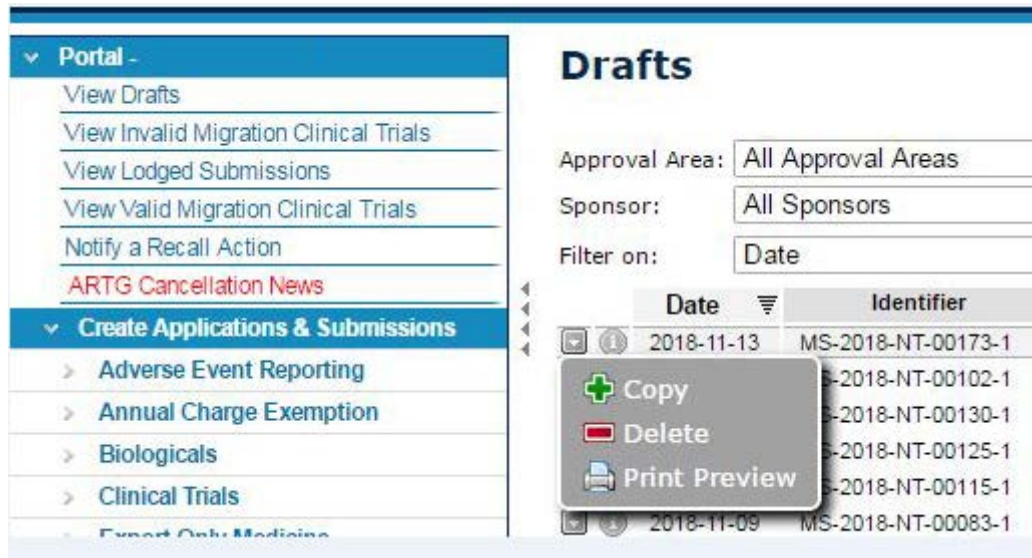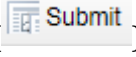
Click the drop-down arrow located at the far-left of the listing and then click on ' ➕ Copy'. The following pop-up appears:
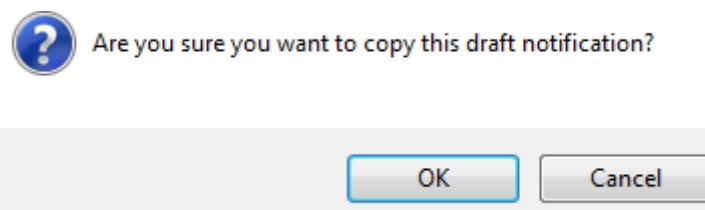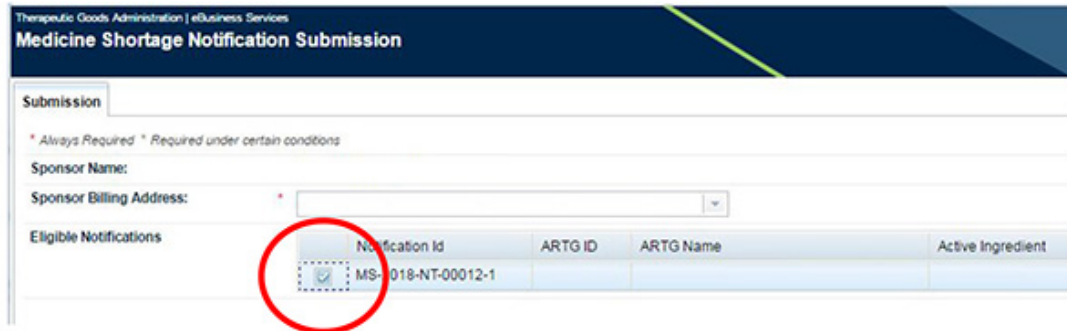
Selecting OK creates a new draft notification form which opens with a new 'Notification Id'.

Submitting

Note: This process is only available to TBS users with submitter access. Please contact your TBS master account holder if you need this requirement.

After a notification form has been validated it can be submitted to the TGA for assessment. They are listed on the Submission page, visible when the 'Submission' link is clicked (located in the TBS Navigator under 'Medicine Shortages'). 'Passed Validation' notification forms can be submitted individually or as a batch. This is achieved by clicking on the check box at the far-left of each listing that is to be submitted, and then by clicking the 'Submit' button ( ) located at the bottom-right of the page.

Choose to submit your notification by clicking the 'Submit' button on the bottom right-hand corner of the screen.
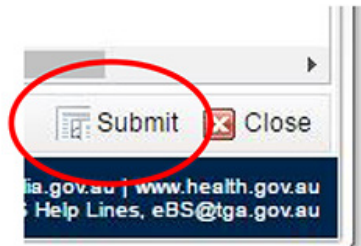
This will take you to the acknowledgement page.

If a user wishes to view a 'Passed Validation' notification form before submitting they are still listed in the 'View Drafts' section for this purpose.

Acknowledgement

When the 'Submit' button is selected the following notification submission acknowledgement appears:

The acknowledgement can be printed by clicking on the 'Print' button and can be cancelled by clicking on either the 'Cancel' button or 'Close' button. To agree to the acknowledgement click on the 'Acknowledge and Continue' button, a submission number is assigned and it is displayed in the following message:

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 initially obtains a Workflow status of 'Submitted – Pending Review' which then changes to 'Pending Assessment' once it has been received by the TGA. (see Submissions section) During this phase the sponsor cannot make any edits or additions to the notification, as well as being unable to delete the notification; the sponsor is able to print the notification though and view it via print preview.

Accessing a notification form

- **'Draft'** notification forms can be viewed, edited, copied, printed, validated or deleted. They are listed in the 'View Drafts' link located on the TBS Navigator.

- **'Passed Validation'** notification forms can be viewed, edited, copied, printed, deleted or submitted. They are listed in the 'View Drafts' link located on the TBS Navigator and in the 'Submission' link also located 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 located 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 located on the TBS Navigator.

Drafts

You find your drafts by opening your portal and clicking on 'View Drafts'.
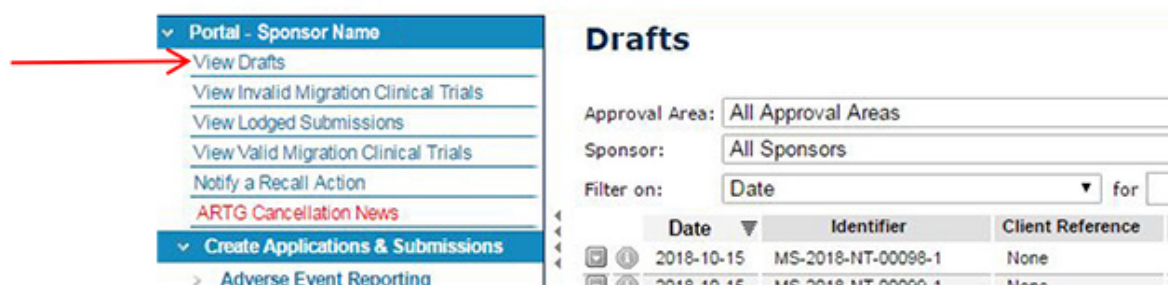
Within this section, medicine shortages notification drafts can be seen, as well as drafts from all other TBS areas such as 'Biologicals' and 'Over The Counter Medicines' sections. The list of drafts can be filtered by 'Approval Area', 'Sponsor' and by 'Date', these filters are located at the top of the page.

All Medicine Shortages listings in drafts can be distinguished from other drafts as their identifier begins with an MS (for example, 'MS-2014-NT-00053-1').

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

To print preview, copy or delete the notification click on the drop-down arrow at the far-left of 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' – these will be highlighted in red.

Submissions

You can find this view by opening your portal and clicking on 'View Lodged Submissions'.

Within this section, medicine shortages notification submissions can be seen, as well as submissions from all other TBS areas such as 'Biologicals' and 'Over The Counter Medicines' sections. The list of notifications submitted can be filtered by 'Approval Area', 'Sponsor' and by 'Date', these filters are located at the top of the page.

All Medicine Shortages listings in drafts can be distinguished from other drafts as their identifier begins with an MS (for example, 'MS-2014-NT-00052-1').

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

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.

The status of the notification can be determined by looking at 'Workflow Status' column:

- **'Submitted – Pending Review':** notification form has yet to be received by the TGA.

- **'Pending Assessment':** notification form has been received by the TGA.

- **'Notification Finalised':** notification form has been assessed by the TGA.

A notification form submitted to the TGA can be returned during assessment if the sponsor requests it or if TGA requests the sponsor revise the notification form. This is termed a 'Push Back'. If a notification form is returned the status changes back to 'Draft' and it is located back in the 'Drafts' list and highlighted red for easier identification:

Changes can now be made to the notification form and it can be validated and then resubmitted again to the TGA for re-assessment. Once a notification form clears TGA assessment it moves 'Medicine Shortages' located under 'Your TGA Information' in the TBS Navigator.

Medicine Shortages

You find this view by opening your 'Portal' drop-down arrow and opening 'Your TGA information', then clicking on 'Medicine Shortage'.

Within this section all medicine shortages notifications that have completed TGA assessment are listed. The list of submitted notifications that are visible can be filtered by 'Sponsor' and by 'Date', these filters are located at the top of the page.

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

To vary the notification or view and print the assessed notification, click on the drop-down arrow at the far-left of the listing and select the appropriate action. This is where you would submit an updated notification from, by choosing 'Vary' and making the relevant changes, for example updating the dates of the shortage, and then re-submitting to the TGA.

Varying (updating) a notification form

Once the TGA has assessed a submitted notification form it will move out of the 'Submission' list (located in the 'View Lodged Submissions' link on the TBS Navigator) and into the 'Medicine Shortage' list (within the 'Your TGA Information' link located on the TBS Navigator). It is from this list that a notification form can undergo a variation.

To vary a notification form, click the drop-down arrow, located at the far-left of each individual assessed notification listed, and then click 'Vary Notification'.

> **Please note:** You are NOT able to vary a resolved notification. If you need to submit a notification of a shortage for a product that has previously been in shortage and resolved you will need to create a new notification. If the previous shortage is still published on the MSII website under the 'Resolved' tab you will need to contact the Medicine Shortages team (email medicine.shortages@health.gov.au or phone 02 6232 8850) to unpublish and archive that notification. You will not be able to submit the new notification until the next day.
>
> If you have a medicine shortage that you think is of critical patient impact and are not able to create a medicine shortage notification immediately because there is still a published resolved notification, you will need to contact the TGA as soon as possible using the above contact details. Medicine Shortages Section will take action to archive the notification immediately. This immediate archiving will enable the sponsor to be able to create and submit a new notification within two hours of notifying the Medicine Shortages Section.

The notification form will open for editing; its status changes to 'Draft' and it is located in the Drafts list found via the 'View Drafts' link located on the TBS Navigator.

The fields that can be varied are outlined in the tables in Appendix 1.

The varied notification form will need to be validated before it can be submitted to the TGA for assessment.

The original notification that was varied remains listed in 'Medicine Shortages' until the varied notification completes TGA assessment 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 had information published on the MSII website, any variations made will be reflected on the website on completion of the assessment by the TGA.

Publishing a notification form

The MSII website has been redesigned to open on a page dedicated to shortages of medicines with critical patient impact. From this page users can navigate to another web page that will hold a consolidated list of medicines shortages. This consolidated webpage will contain a list of all medicines shortage notifications that have been notified to TGA and where publishing has been agreed with the sponsor i.e. shortages and discontinuations of low, medium and critical patient impact. In the interests of transparency and to assist in maintenance of patient care, sponsors of low and medium patient impact are strongly encouraged to allow publishing of the information relating to these shortages on the MSII website.

The initial landing page will hold information relating to any shortage or discontinuation that is of critical patient impact. For critical shortages the TGA will have identified shortage management action(s). These will be published under a separate heading 'TGA Shortage Management Actions'. These will be available by opening the drop-down arrow on the actual medicine shortage page and will provide proposed management action(s) and the progress of these action(s). The TGA management action information will be updated by TGA separately from the 'Notification' form. This information will be identified on the MSII webpage for the individual product as TGA-provided information in the form of 'TGA Management Action'. This will not be visible on the opening page but is accessed by clicking on the medicine ingredient.

What is published?

Information relating to critical impact medicine shortages will be mandatorily published and will appear on both the critical impact medicines shortages list and on the consolidated medicine shortages list. The information that will be published can include:

- sponsor's name

- sponsor's nominated public contact details

- sponsor's nominated website details *

- ARTG number

- ARTG name of medicine (includes name, active ingredient(s), strength, dosage form and container)

- active ingredient(s)

- therapeutic class description

- nature of the shortage

- impact of the shortage

- availability

- reason for the shortage

- estimated shortage dates for current or anticipated shortages

- deletion from market date for discontinued products

- supply information where appropriate.

* Sponsor website details will only be published if they contain information that relates to the management of the medicine shortage.

For medium and low impact medicine shortages, publication is not mandatory but is strongly encouraged to assist health professionals in the management of their patients and to allow consumers access to information relating to their own health.

By choosing 'Yes' to publishing in the notification form for medium and low impact medicine shortages, consent is given to the TGA for some of the information contained within the notification to be published on the MSII website. The information that can be published is the same as above for critical impact medicine shortages.

If the sponsor chooses not to publish the medicine shortages information they will not have to provide a date of publication in the notification form. It is important to note that the TGA does have the power to publish medicine shortage information in the interest of public health even when the sponsor has chosen 'no' to publication. If this should happen, the TGA will contact the sponsor involved and advise that TGA intends to publish the medicine shortage information on the MSII website. This will not be an automatic process without the knowledge of the sponsor. The information that would be published would be the same as above for critical impact medicine shortages.

The TGA can also add information not supplied in the notification form. This will be included in the 'TGA Management Action' field and relates to the management of the shortage rather than the information provided by the sponsor, which relates to the medicine or the reason for the shortage.

When is it published?

The TGA will publish the information on the MSII website as soon as is practicable for medicine shortages that will have a critical patient impact. In other cases (medium and low patient impact shortages) the TGA will publish in alignment with the sponsor's commencement of supply chain communication. This is the date provided by the sponsor on the notification form in the 'Details' tab to the question 'Proposed date of publication on the TGA Medicine Shortages website'.

Has it published?

This information is provided on the 'Medicine Shortages' list of notifications that has been TGA assessed, located on the TBS Navigator under the 'Your TGA Information' link.

	Received ▼	Identifier	Impact	Product Name	Active Ingredient	Published	Sponsor
☐ ⓘ	2018-10-24	MS-2018-NT-00091-1	Medium			Yes	
☐ ⓘ	2018-10-15	MS-2018-NT-00048-1	Critical			No	
☐ ⓘ	2018-10-15	MS-2018-NT-00043-1	Critical			Yes	

Legislative basis for publication

The information published to the MSII website and the date this occurs is intended to occur with the full consent of the sponsor. It is recognised that there may be situations where consent is not given to the TGA or is not possible. In cases where it is in the interest of public health that the information be released the TGA has the option to publish without this consent under section 61(5C) of the *Therapeutic Goods Act 1989*.

Appendix 1

Table column headings explained

The tables below identify the data to be collected within each tab and how it will be used. The column headings are:

- Field title – how the field is described on the notification form.

- Explanation – explanation on why this data is required and what it will be used for.

- Mandatory – is the field required to be completed prior to the notification form being submitted to the TGA. This is further split between information for initial critical notifications only and information for all other notifications.

- Copied – indicates which fields are duplicated when an existing **draft** notification is copied to create a new **draft** notification form.

- Published – identifies the fields that will be published on the TGA website.

- Variation – identifies the fields that can be edited when a variation to an existing completed notification is created by a sponsor.

New Medicine Shortage Notification

(Pop-up box – for initial notification only)

| Field title | Explanation | Mandatory | | Copied | Published | Variation |
		Critical	All others			
Impact of shortage	As determined by the Sponsor – refer to the Management and communication of medicine shortages in Australia – Guidance for sponsors and other stakeholder bodies.	Yes	Yes	No pop-up box for a copied notification	Yes	No pop-up box for a variation
Nature of shortage	As determined by the Sponsor – refer to the Management and communication of medicine shortages in Australia – Guidance for sponsors and other stakeholder bodies.	Yes	Yes	No pop-up box for a copied notification	Yes	No pop-up box for a variation

Tab 1 – Notifier

Field title	Explanation	Mandatory				
		Critical	**All others**	**Copied**	**Published**	**Variation**
Sponsor Name:	This is prepopulated based on the TBS logon ID used.	Yes	Yes	Yes	Yes	No
Sponsor Address:	Select from addresses recorded in TBS for this sponsor.	Yes	Yes	Yes	No	No
Australian telephone number for public contact purposes:	This number will be used by the public if further information is sought.	Yes	Yes	Yes	Yes	Yes
Medical information email for public contact purposes:	This email will be used by the public if further information is sought.	Yes	Yes	Yes	No	Yes
Primary Contact	This will be the point of contact for communications with the TGA – Prepopulated from TBS login. If a different representative from the sponsor is responsible for varying the notification to provide an update these fields will automatically populate with their details.					
Name:	Prepopulated from TBS login	Yes	Yes	Yes	No	No
Phone Number:	Prepopulated from TBS login	Yes	Yes	Yes	No	No
Email Address:	Prepopulated from TBS login	Yes	Yes	Yes	No	No
Secondary Contact	This will be the point of contact for communications with the TGA if the Primary contact is unavailable.					
Name:	Chosen from drop-down list	No	No	Yes	No	Yes

Field title	Explanation	Mandatory		Copied	Published	Variation
		Critical	All others			
Phone Number:	Prepopulated with chosen secondary contact name details	No	No	Yes	No	Yes
Email Address:	Prepopulated with chosen secondary contact name details	No	No	Yes	No	Yes

Tab 2 – ARTG entry

Field title	Explanation	Mandatory				
		Critical	All others	Copied	Published	Variation
ARTG number of the product that has a supply disruption:	Only those ARTG entries that belong with the TBS logon ID can be accessed. A search using the ARTG number returns the following ARTG entry details: • ARTG # • ARTG name • Active ingredient • Strength • Dosage form	Yes	Yes	No	Yes	No
ATC Descriptor:	To enable a user of the medicine shortages website to sort by therapeutic class an ATC descriptor needs to accompany the report of the medicine undergoing a shortage. These ATC descriptors are at level 1.	No	Yes	Yes	Yes	Yes
Are all pack sizes for this ARTG entry affected?	Approximately 50% of all ARTG entries have multiple packs sizes listed. As all pack sizes under a single ARTG may not have a supply issue this question is used to distinguish these.	No	Yes	No	No	Yes
What are the affected pack sizes?	Appears when 'No' radio button is selected for question above. Please describe the pack sizes that are affected by the shortage here.	No	Yes	No	No	Yes
Is this ARTG entry listed in the PBS?	If this ARTG entry is listed on the PBS, the Technology Assessment and Access Division will be made aware of the shortage.	No	Yes	No	No	Yes

Field title	Explanation	Mandatory				
		Critical	All others	Copied	Published	Variation
Please provide the PBS number for this listing:	Appears when 'Yes' radio button is selected for question above. The Technology Assessment and Access Division will be made aware of the information	No	Yes	No	No	Yes
Do you have the contact details of sponsor's nominated PBS contact?	Appears when 'Yes' radio button is selected for question above. This person will be the point of contact in your company if the Technology Assessment and Access Division needs to contact your company.	No	Yes	Yes	No	Yes
PBS Contact Details	Appears when 'Yes' radio button is selected for question above. Used if the Technology Assessment and Access Division needs to contact the responsible person in your company.					
Name:	Appears when 'Yes' radio button is selected for question above.	No	Yes	Yes	No	Yes
Phone Number:	Appears when 'Yes' radio button is selected for question above.	No	Yes	Yes	No	Yes
Email Address:	Appears when 'Yes' radio button is selected for question above.	No	Yes	Yes	No	Yes

Tab 3 – Details

Field title	Explanation	Mandatory		Copied	Published	Variation
		Critical	All others			
When was the shortage known to the sponsor?	This is the date on which the sponsor became aware that there was, or will be, a shortage of the medicine in Australia. This date cannot be a future date.	Yes	Yes	Yes	No	No
Nature of the shortage:	Has the shortage started, ended or yet to begin? Is the product discontinued? This will have prepopulated based on the decision made in the first New Medicine Shortage Notification pop-up screen. This can be changed here but be aware that changes may result in changes to the nature of fields displayed and the number of mandatory fields in the notification.	Yes	Yes	Yes	Yes	Yes
Shortage reason:	Most enquires to the TGA on medicine shortages ask for a reason for the shortage. This is published on the TGA website. Selecting 'Other' brings up a free text box. The free text is not published. Selecting 'Manufacturing' brings up a drop-down list of manufacturing reasons and if other is chosen here there is another free text box to be completed. Only 'Manufacturing' is published as the reason on the TGA website.	No	Yes	Yes	Yes	Yes

		Mandatory				
Field title	**Explanation**	**Critical**	**All others**	**Copied**	**Published**	**Variation**
Estimated period supply will be affected at wholesaler points: **From:**	The 'From date' is the date from which supply of the medicine is affected. The date entered into this field cannot be a date in the past for an anticipated shortage. For both current and anticipated shortages this date cannot be later than the 'To' date below.	Yes	Yes	Yes	Yes	Yes
Estimated period supply will be affected at wholesaler points: **To:**	The 'To date' is the date by which the period of shortage is estimated to be over. 'To date' field is not displayed if 'Discontinued' is selected as Nature of the shortage.	Yes	Yes	Yes	Yes	Yes
Availability	For Anticipated shortages and resolved shortages 'available' is prepopulated and cannot be changed. For current shortages and discontinuations a drop-down list of levels of availability are available to best represent the current situation of the product. Sponsors should ensure that this is kept current as this is published on the TGA website. 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**	Yes	No	Yes	Yes	Yes

		Mandatory				
Field title	**Explanation**	**Critical**	**All others**	**Copied**	**Published**	**Variation**
	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 the supply of the product at the current time. • **Unavailable** - The product is not available at this time.					
Deletion from market date:	Appears only if 'Discontinued' is selected as Nature of shortage. This is the date at which there is no stock remaining at the sponsor level. This is NOT the date the product is cancelled from the ARTG.	Yes	Yes	Yes	Yes	Yes
Do you consent to this notification being published in the interest of public health?	Please note that if you choose 'No' the notification may still be published by the TGA under section 61 of the *Therapeutic Goods Act 1989*. If this were to happen the TGA would notify the sponsor prior to the notification being published.	N/A	Yes	Yes	Yes	Yes
Proposed date of publication on the TGA Medicine Shortages website:	This is the date you choose to publish the publishable information within this notification form onto the medicine shortages website. Note: the actual publication may be delayed by a couple of days if there is a high volume of notifications to be processed.	Yes	Yes	Yes	No	Yes

		Mandatory				
Field title	Explanation	Critical	All others	Copied	Published	Variation
Is this shortage related to other medicines within the same Therapeutic class?	Answer will assist the TGA in assessing the extent of the shortage and assist in developing the strategy to manage the shortage.	No	Yes	Yes	No	Yes
Please enter the details for the other medicines:	Appears when 'Yes' radio button is selected for question above. Answer will assist the TGA in assessing the extent of the shortage and assist in developing the strategy to manage the shortage.	No	Yes	Yes	No	Yes
Is this shortage specific to Australia?	Answer will assist the TGA in assessing the extent of the shortage and assist in developing the strategy to manage the shortage.	No	Yes	Yes	No	Yes
Estimated normal demand volumes for Australia:	Answer will assist the TGA in assessing the extent of the shortage and assist in developing the strategy to manage the shortage.	No	Yes	Yes	No	Yes
Estimated percentage share of the Australian market:	This refers to the share within the market of products containing the actual therapeutic ingredient not the share of the therapeutic class off the ingredient, for example specific vs NSAIDs. Answer will assist the TGA in assessing the extent of the shortage and assist in developing the strategy to manage the shortage.	No	Yes	Yes	No	Yes

		Mandatory				
Field title	Explanation	Critical	All others	Copied	Published	Variation
Estimated current stock at sponsor / manufacturing level in Australia:	Answer will assist the TGA in assessing the extent of the shortage and assist in developing the strategy to manage the shortage. One unit is defined by the sponsor below.	No	Yes	Yes	No	Yes
Estimated current stock at wholesaler / distributor level in Australia:	Answer will assist the TGA in assessing the extent of the shortage and assist in developing the strategy to manage the shortage. One unit is defined by the sponsor below.	No	Yes	Yes	No	Yes
Please explain what is meant by 1 unit in this context:	By defining what you mean by 1 unit you assist the TGA in understanding the exact situation with respect to product quantities available. This assist TGA in understanding the overall situation as different sponsor use different definitions.	No	Yes	Yes	No	Yes

Tab 4 – Impact

		Mandatory				
Field title	**Explanation**	**Critical**	**All others**	**Copied**	**Published**	**Variation**
Are there therapeutic alternatives on the Australian market?	Answer will assist the TGA in assessing the extent of the shortage and assist in developing the strategy to manage the shortage.	No	Yes	Yes	No	Yes
What is the status of substitute options for this product in Australia?	Appears when 'Yes' radio button is selected for question above. Answer will assist the TGA in assessing the extent of the shortage and assist in developing the strategy to manage the shortage. Definitions of the status: • **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 dose form** that may require consideration of care setting implication • **Possible** – different active ingredient but comparable pharmacological class or mode of action • **None** – unique pharmacology no substitute medicine or alternative treatment options exist • **Unknown at this time**	No	Yes	Yes	No	Yes

		Mandatory				
Field title	**Explanation**	**Critical**	**All others**	**Copied**	**Published**	**Variation**
Are they available in adequate supplies to meet demand?	Appears when 'Yes' radio button is selected for question above. Answer will assist the TGA in assessing the extent of the shortage and assist in developing the strategy to manage the shortage.	No	Yes	Yes	No	Yes
Provide details:	Appears when 'Yes' radio button is selected for question above. Answer will assist the TGA in assessing the extent of the shortage and assist in developing the strategy to manage the shortage.	No	No	Yes	No	Yes
Do any specific population groups use this product?	Examples may be oncology patients, patients with dermatological conditions, paediatric population, etc. Answer will assist the TGA in assessing the extent of the shortage and assist in developing the strategy to manage the shortage.	Yes	Yes	Yes	No	Yes
Provide details of the group and the impact on that group:	Appears when 'Yes' radio button is selected for question above. Answer will assist the TGA in assessing the extent of the shortage and assist in developing the strategy to manage the shortage.	No	Yes	Yes	No	Yes

		Mandatory				
Field title	**Explanation**	**Critical**	**All others**	**Copied**	**Published**	**Variation**
Based on your answers to the above and your understanding of the Assessment Framework what ranking would you assign to the product experiencing a supply disruption?	This will have prepopulated based on the decision made in the first New Medicine Shortage Notification pop-up screen. This can be changed here but be aware that changes may result in changes to the nature of fields displayed and the number of mandatory fields in the notification.	Yes	Yes	Yes	Yes	Yes

Tab 5 – Shortage action

		Mandatory				
Field title	**Explanation**	**Critical**	**All others**	**Copied**	**Published**	**Variation**
What communication activities have happened or are planned?	Can select up to 5 options that will assist the TGA in coordinating communications and shortage management in parallel with the sponsor. They are letters to: • patient advocacy groups • pharmacists • prescriber • subject matter experts, colleges, etc. • wholesalers The date of communication is the date that you intend to send the letter to the group. If the letters are to be sent out in batches, then the date should reflect the first date that the communication is released.	No	Yes	Yes	No	Yes
Are you attaching the letter in the supporting information tab?	This is a reminder to attach the letter on the following tab. If you answer yes here, the notification will not validate without an attachment being present. It is mandatory to answer this question but not mandatory to attach a letter.	Yes	Yes	Yes	No	Yes

Field title	Explanation	Mandatory				
		Critical	All others	Copied	Published	Variation
Further comments on communications:	Will assist the TGA in coordinating communications and shortage management in parallel with the sponsor. This is a free text field to communicate information to the Medicine Shortages Section around communications.	No	No	Yes	No	Yes
What supply management actions have happened or are planned?	Can select up to eight options that will assist the TGA in coordinating communications and shortage management in parallel with the sponsor. They are: • Alternate manufacturing changes • Apply for 19A • Constrained supply • No further action product discontinued • Working to expedite request to Pharm Chem Section • Working to expedite next shipment • Importation of Stock for SAS use • Supply of substitute medicine approved under section 19A	No	Yes	Yes	No	Yes

		Mandatory				
Field title	**Explanation**	**Critical**	**All others**	**Copied**	**Published**	**Variation**
Further comments on management actions:	Will assist the TGA in coordinating communications and shortage management in parallel with the sponsor. This is a free text field to communicate information to the Medicine Shortages Section around sponsor supply management actions.	No	No	Yes	No	Yes

Tab 6 – Supporting information

Field title	Explanation	Mandatory		Copied	Published	Variation
		Critical	All others			
Supporting data will be:	Support information such as a Dear Healthcare Professional Letter can be attached to this notification form or sent to the TGA by other electronic media. If supporting information is to be sent by other electronic media please provide an estimation of the date the support information will be sent to the TGA	No	No	Yes	No	Yes
Sponsor website: (ONLY where medicine shortage information is available)	This URL will be a link on the medicine shortages website that will take the user to the sponsor's webpage where the sponsor has provided information relating to the medicine shortage or its management. **Please note:** This website will be published IF AND ONLY IF the sponsor website has information relating to the management of the shortage.	No	No	Yes	Yes, but only if the website relates to the management of the medicine shortage	Yes

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

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

Reference/Publication #