



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

# Post market review compliance dashboard

User guide for sponsors of medical devices

Version 1.2, March 2021

**TGA** Health Safety  
Regulation

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The purpose of this guidance is to help sponsors and manufacturers understand the process in which the TGA expects sponsor and manufacturer to respond to notifications relating to post-market reviews of medical devices.

This is a guide only, and sponsors and manufacturers are encouraged to familiarise themselves with the legislative and regulatory requirements in Australia. If necessary, seek professional advice as it is the responsibility of each sponsor and/or manufacturer to understand and comply with these requirements.

This document will evolve over time and updates and clarifications will be included as required. Feedback on the guidance is always welcome.

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## Introduction

This Post Market Review Compliance Dashboard User Guide provides step-by-step instructions on how to respond to a medical device post-market review notification from the Therapeutic Goods Administration (TGA) through the Post Market Review (PMR) compliance dashboard.

The dashboard is designed to allow sponsors to view any requests or notifications from the TGA, and to respond to them. Requests and notifications may include:

- requirement to provide information and documents;
- requirement to provide samples; and
- proposal to suspend or cancel entries from the Australian Register of Therapeutic Goods (ARTG).

## Role types

In the PMR compliance environment, there are two role types:

- **Drafter:** The drafter can review, upload documents, and edit responses to a notification.
- **Submitter:** The submitter can review, upload documents, edit, and submit responses to a notification.

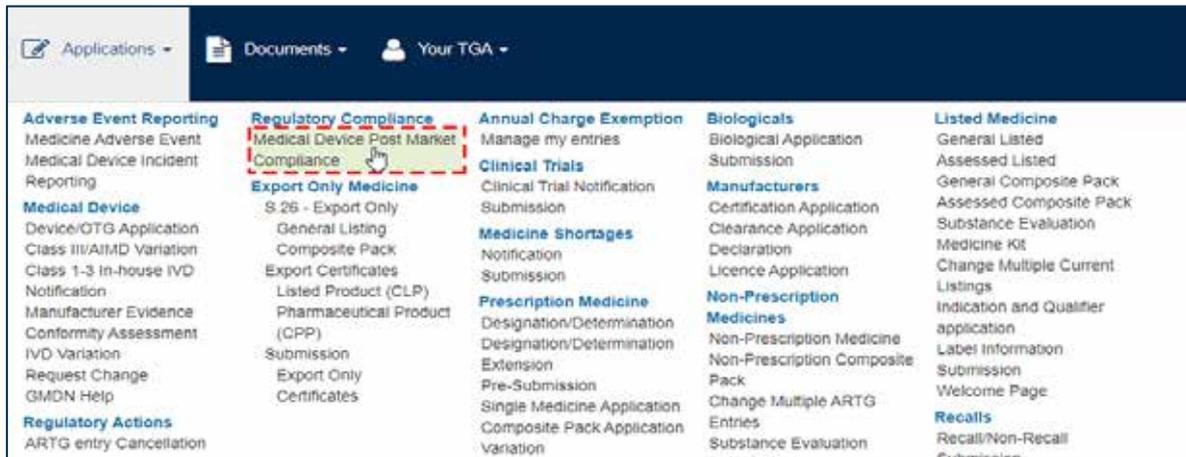
These roles have been designated by your TGA Business Services (TBS) administrator.

# How to login to the PMR compliance dashboard

The PMR compliance dashboard is found within the [TGA Business Services \(TBS\) website](#). Once you log-in with your sponsor user name and password, follow the instructions below:

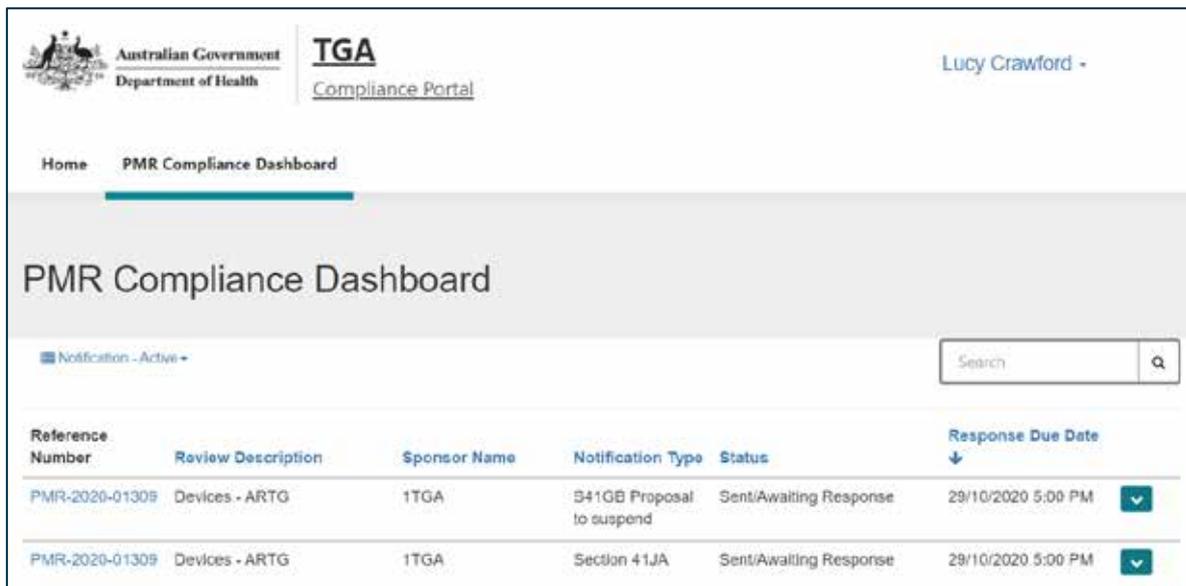
## Instructions

1. Login to TBS; in the Applications section select Medical Device Post Market Compliance.



The screenshot shows the TGA Applications menu. The 'Regulatory Compliance' section is highlighted with a red dashed box, and 'Medical Device Post Market Compliance' is highlighted with a red dashed box and a mouse cursor. Other sections include Adverse Event Reporting, Medical Device, Regulatory Actions, Annual Charge Exemption, Clinical Trials, Medicine Shortages, Prescription Medicine, Biologicals, Manufacturers, Non-Prescription Medicines, and Listed Medicine.

2. You will be directed to the PMR Compliance Dashboard where the Request For Information (RFIs) will be displayed.



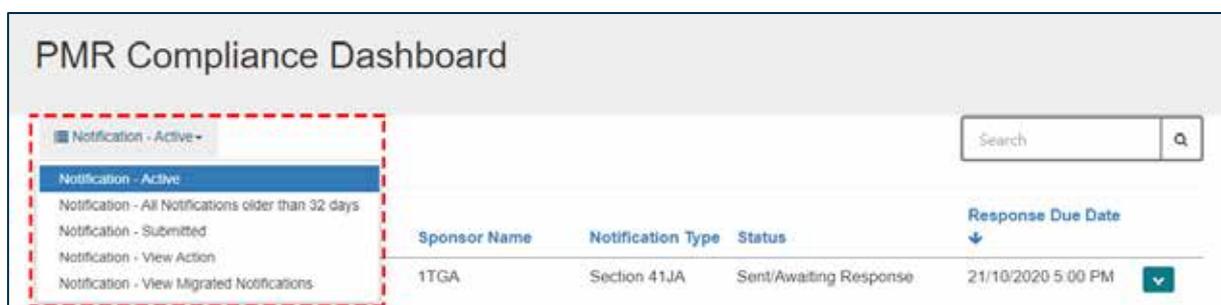
The screenshot shows the PMR Compliance Dashboard. The header includes the Australian Government Department of Health logo, the TGA Compliance Portal, and the user name 'Lucy Crawford'. The main content area displays a table of active notifications.

Reference Number	Review Description	Sponsor Name	Notification Type	Status	Response Due Date
PMR-2020-01309	Devices - ARTG	1TGA	S41GB Proposal to suspend	Sent/Awaiting Response	29/10/2020 5:00 PM
PMR-2020-01309	Devices - ARTG	1TGA	Section 41JA	Sent/Awaiting Response	29/10/2020 5:00 PM

## How to view your notifications

You can sort and view your notifications by the following status:

- **Notification – Active:** Select this option to view for notifications you need to review and submit a response to.
- **Notification – All Notifications older than 32 days:** Select this option to view notifications older than 32 days.
- **Notification – Submitted:** Select this option to view those notifications that a response has already been provided.
- **Notification – View Action:** Select this option to view notifications which provide information on actions being taken by the TGA.
- **Notification – View Migrated Notifications:** Select this option to view notifications which were sent from the TGA prior to the portal being deployed, but are currently in progress.



There are two ways you can view your notifications:

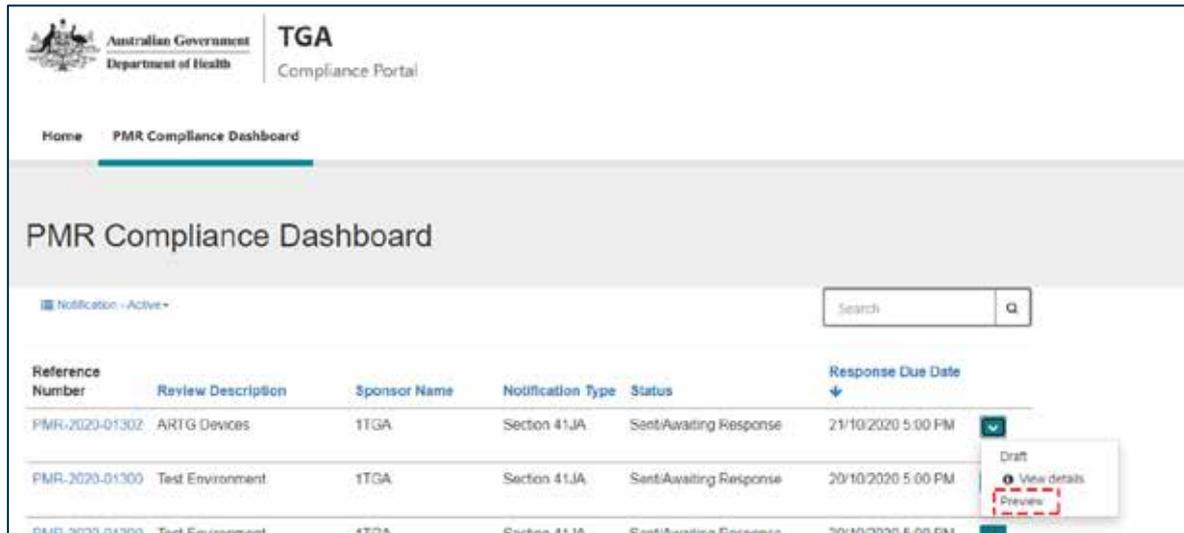
1. Preview your notification
2. Draft a response to your notification

## Preview your notification

You can view your notification from the **Preview** screen. You cannot add a response from this view. Additionally, selecting **View Details** or the **reference number** will show a 'read-only' preview.

## Instructions

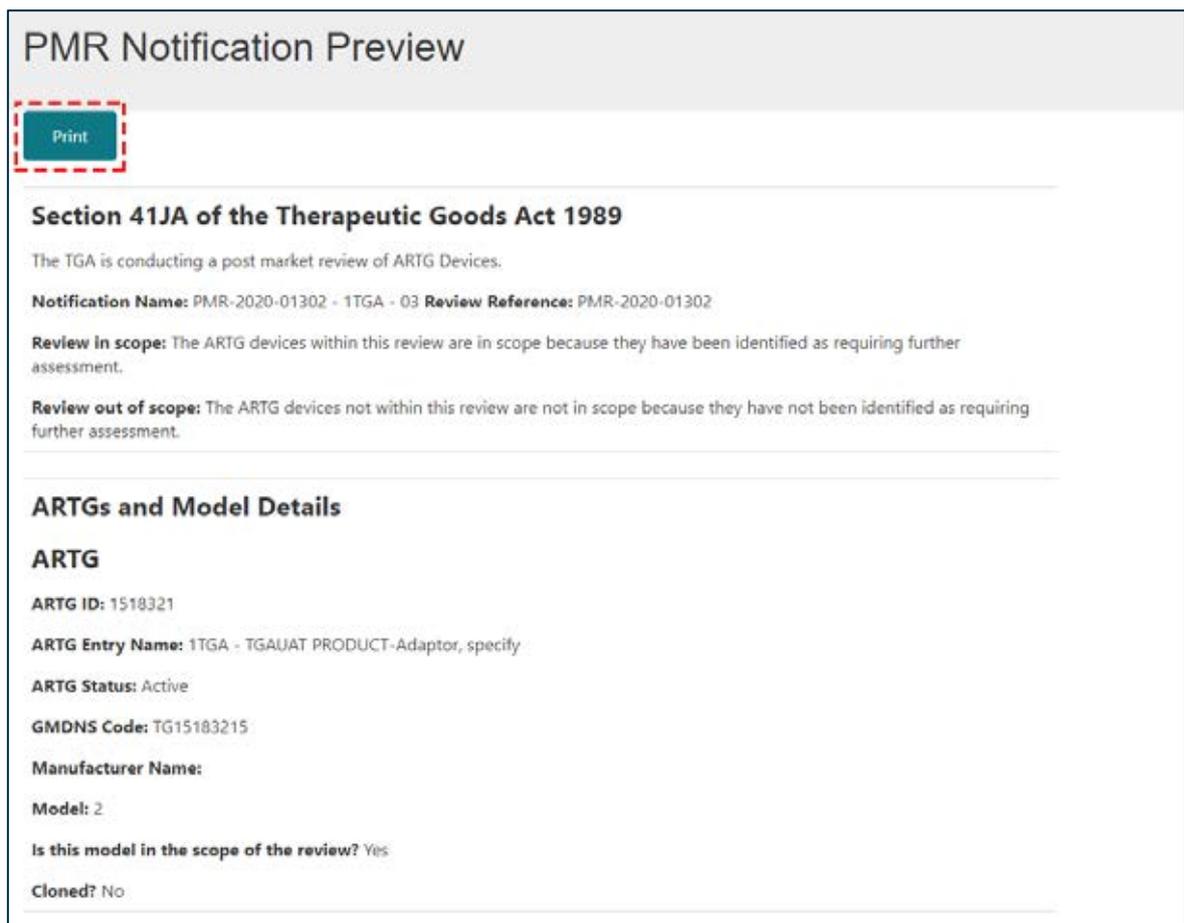
- a. Click on the drop-down arrow and click on **Preview**.



The screenshot shows the TGA Compliance Portal. The page title is "PMR Compliance Dashboard". Below the title is a search bar and a table of notifications. The table has columns for Reference Number, Review Description, Sponsor Name, Notification Type, Status, and Response Due Date. The first row is highlighted, and a dropdown menu is open, showing options: Draft, View details, and Preview. The 'Preview' option is highlighted with a red dashed box.

Reference Number	Review Description	Sponsor Name	Notification Type	Status	Response Due Date
PMR-2020-01302	ARTG Devices	1TGA	Section 41JA	Sent/Awaiting Response	21/10/2020 5:00 PM
PMR-2020-01300	Test Environment	1TGA	Section 41JA	Sent/Awaiting Response	20/10/2020 5:00 PM
PMR-2020-01303	Test Environment	1TGA	Section 41JA	Sent/Awaiting Response	20/10/2020 5:00 PM

- b. On the **PMR Notification Preview** screen, you can view the details for the notification and you have the option to print a copy of the notification by clicking on the **Print** button.



The screenshot shows the "PMR Notification Preview" screen. At the top left, there is a "Print" button highlighted with a red dashed box. Below the button, the screen displays the following information:

**Section 41JA of the Therapeutic Goods Act 1989**  
 The TGA is conducting a post market review of ARTG Devices.  
**Notification Name:** PMR-2020-01302 - 1TGA - 03 **Review Reference:** PMR-2020-01302  
**Review in scope:** The ARTG devices within this review are in scope because they have been identified as requiring further assessment.  
**Review out of scope:** The ARTG devices not within this review are not in scope because they have not been identified as requiring further assessment.

**ARTGs and Model Details**

**ARTG**  
**ARTG ID:** 1518321  
**ARTG Entry Name:** 1TGA - TGAUAT PRODUCT-Adaptor, specify  
**ARTG Status:** Active  
**GMDNS Code:** TG15183215  
**Manufacturer Name:**  
**Model:** 2  
**Is this model in the scope of the review?** Yes  
**Cloned?** No

## Instructions

- c. Once you have viewed your notification, click on the back-browser button to go back to the PMR Compliance Dashboard.

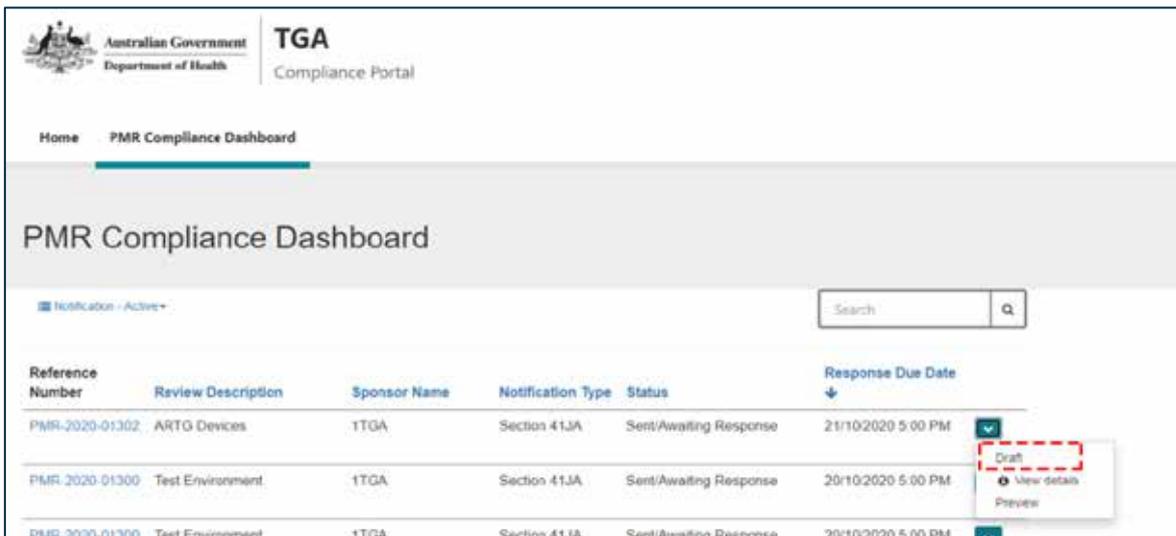


## Draft a response to your notification

The second way you can view your notification is when you respond to a notification. This is the only view in which you can add a response.

## Instructions

- d. Click on the drop-down arrow and click on **Draft**.



- e. In the Notification Details section, you can view the details for the notification.

## Instructions

The screenshot displays the 'PMR Compliance Dashboard' with a breadcrumb trail 'Home > PMR Compliance Dashboard'. The main heading is 'PMR Notification Draft'. Below this, there are two buttons: 'Expand All' and 'Collapse All'. A list of five expandable sections follows, each with a plus sign on the right: 'Notification Details', 'ARTGs and Model Details', 'Legislative Breaches and Responses', 'Other Required Responses', and 'Extension Requests'. The 'Notification Details' section is highlighted with a red dashed border. At the bottom, there are three buttons: 'Validate', 'Back', and 'Refresh'.

## Instructions

Notification Details 

## Section 41JA of the Therapeutic Goods Act 1989

The TGA is conducting a post market review of ARTG Devices.

<b>Notification Name *</b>	<b>Review Reference Number</b>
PMR-2020-01302 - 1TGA - 01	PMR-2020-01302

## Review in scope

The ARTG devices within this review are in scope because they have been identified as requiring further assessment.

## Review out of scope

The ARTG devices not within this review are not in scope because they have not been identified as requiring further assessment.

## Notification Documents

Supply details, complaints and adverse events data can be entered in a single file, provided that the models have been identified and scoped first. Use the following steps to generate and upload the file:

- Click on 'Generate template', then refresh
- Three files will be generated in the list. It may take up to two minutes for the files to appear. Download the ModelDetailsTemplate.csv file
- Open the file and enter supply, complaints and adverse events data for each model for the last three financial years. The AdverseEventsCategoryValues and the UnitValues files contain the lists of adverse event and unit values. These can be used as references or to copy and paste values into the file.
- Save the file and rename it 'ModelDetails.csv'. Please ensure that the file is renamed as 'ModelDetails.csv'.
- Click on 'Add Files' and upload the ModelDetails.csv file.
- Click on 'Process Bulk Upload'.

The uploaded Model Details will appear under 'Model Details' section after few minutes, after the Refresh. If the upload contains any errors, you will be contacted by email.

Generate Template

Add files

Process Bulk Upload

Name 	Modified
 1TGA - TGAUAT PRODUCT-Adaptor specify	14/09/2020 4:10 PM
 1TGA - TGAUAT PRODUCT-Adhesive soft tissue approximation	14/09/2020 4:10 PM
 1TGA - TGAUAT PRODUCT-Adroit Guiding Catheter - Catheter I...	14/09/2020 4:10 PM
 Emails	14/09/2020 4:08 PM
 Large Files	14/09/2020 4:08 PM
 TGA - TGAUAT PRODUCT-Adaptor specify	14/09/2020 4:10 PM



You can view all the document(s) associated to the notification and the list of folders that will hold the document(s) you uploaded as part of your submission.

## Instructions

- f. Click on the notification to download and open a copy of the letter. The notification will appear as a download at the bottom left of the screen.

**Notification Documents**

Supply details, complaints and adverse events data can be entered in a single file, provided that the models have been identified and accepted first. Use the following steps to generate and upload the file:

- Click on 'Generate template' from the header
- Three files will be generated in the list. It may take up to two minutes for the files to appear. Download the ModeDetailsTemplate.csv file
- Open the file and enter supply, complaints and adverse events data for each model for the last three financial years. The AdverseEventCategory values and the Un/NValues files contain the lists of adverse event and unit values. These can be used as references or to copy and paste values into the file
- Save the file and rename it 'ModeDetails.csv'. Please ensure that the file is renamed as 'ModeDetails.csv'.
- Click on 'Add Files' and upload the ModeDetails.csv file
- Click on 'Process Bulk Upload'

The uploaded Mode Details will appear under 'Model Details' section after few minutes after the Refresh. If the upload contains any errors, you will be contacted by email.

[Generate Template](#)
[Add Files](#)
[Process Bulk Upload](#)

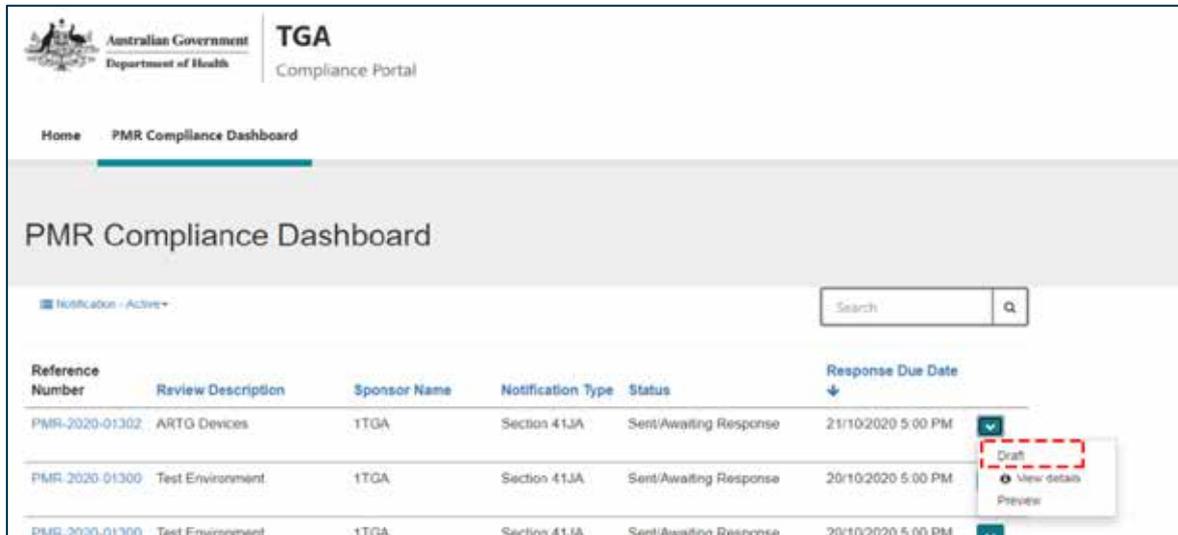
Name	Modified
FreeMarket_14Sep2020 10:11 AM (1 KB)	14/09/2020 4:10 PM
Email_14Sep2020 10:11 AM (1 KB)	14/09/2020 4:10 PM
025-95296 DPMARS TEMP 1.1 (1) s4TJA Requirements for inform...	14/09/2020 4:10 PM

025-95296 DPMARS TEMP 1.1 (1) s4TJA Requirements for inform...

# How to respond to a notification

## Instructions

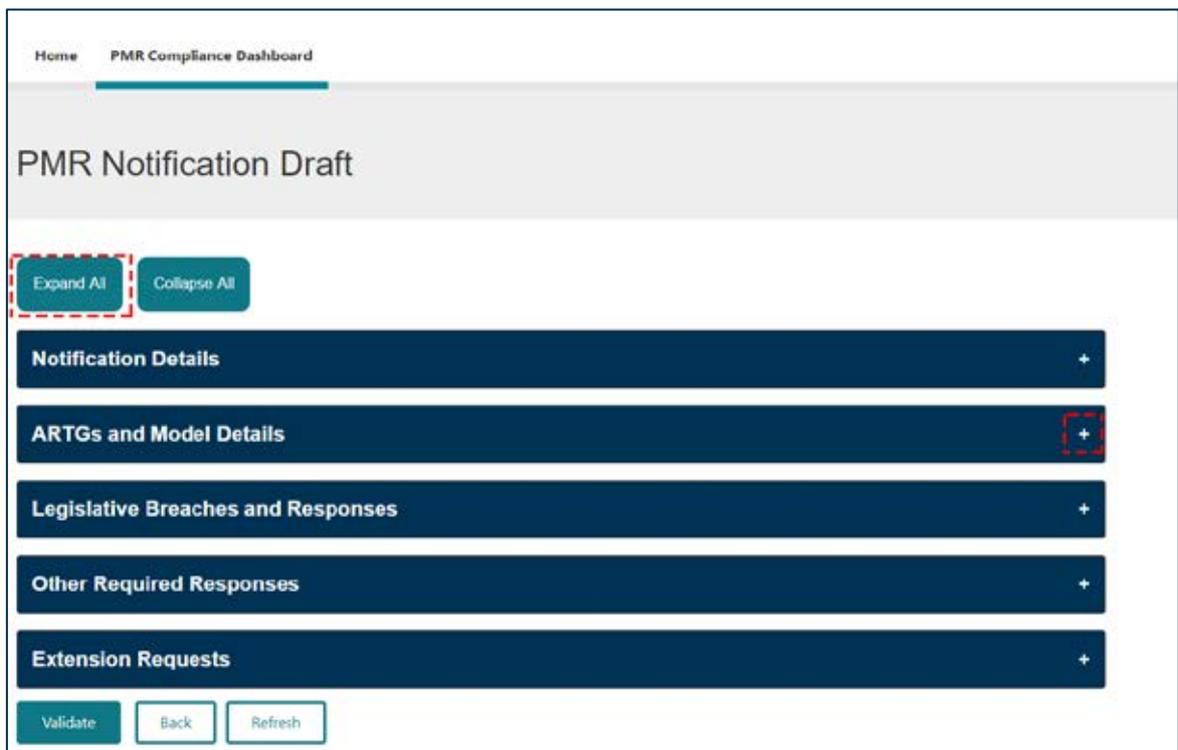
1. Click on the drop down arrow and click on **Draft**.



The screenshot shows the 'PMR Compliance Dashboard' with a table of notifications. The table has columns for Reference Number, Review Description, Sponsor Name, Notification Type, Status, and Response Due Date. A dropdown menu is open for the first notification, showing options: Draft, View details, and Preview. The 'Draft' option is highlighted with a red dashed box.

Reference Number	Review Description	Sponsor Name	Notification Type	Status	Response Due Date
PMR-2020-01302	ARTG Devices	1TGA	Section 41JA	Sent/Awaiting Response	21/10/2020 5:00 PM
PMR-2020-01300	Test Environment	1TGA	Section 41JA	Sent/Awaiting Response	20/10/2020 5:00 PM
PMR-2020-01300	Test Environment	1TGA	Section 41JA	Sent/Awaiting Response	20/10/2020 5:00 PM

2. Click on the **Expand All** button to expand all the sections or the **+** button to expand each section.



The screenshot shows the 'PMR Notification Draft' page. At the top, there are 'Expand All' and 'Collapse All' buttons. Below them are several section headers, each with a plus sign (+) to expand it. The 'ARTGs and Model Details' section is highlighted with a red dashed box. At the bottom, there are 'Validate', 'Back', and 'Refresh' buttons.

## How to edit and add ARTGs and Model Details

In the **ARTGs and Model Details** section, you can view the Australian Register of Therapeutic Goods (ARTG) entries that have been included in the notification.

If this notification is an initial request for information (section 41JA or section 31 notification) you may add model details and additional ARTG entries that may be in scope of the post-market review.

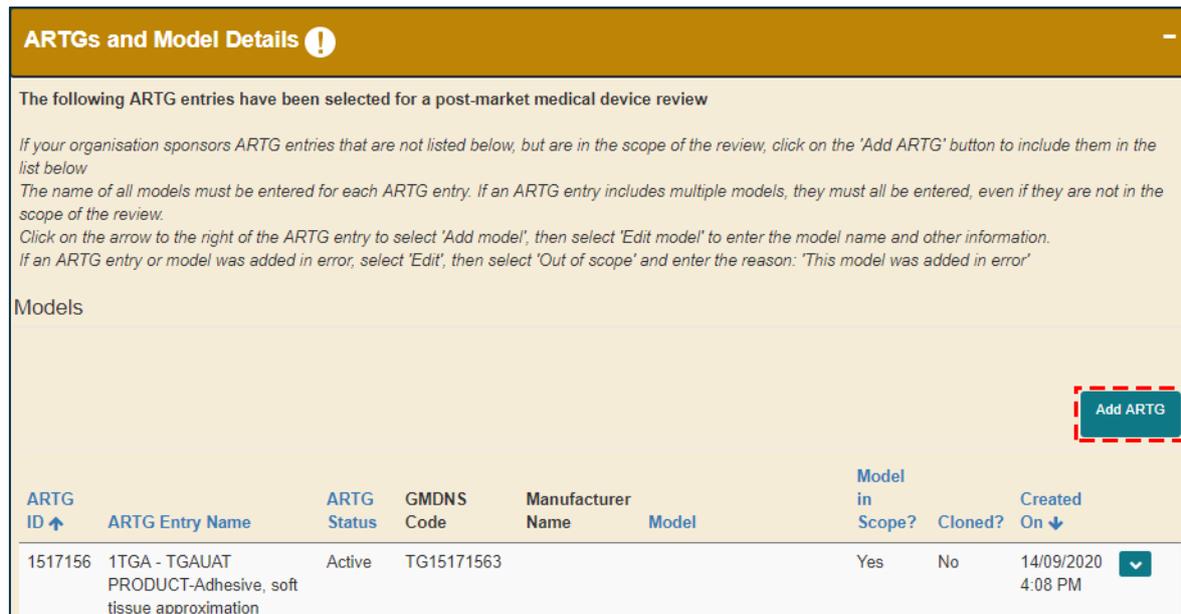
 Adding ARTG entries, model details, and supply information is only available when responding to initial requests for information. For all other notifications you can skip this section and go to the **'How to provide evidence of compliance with requirements'** section.

### Instructions

1. Click on the + button in the **ARTGs and Model Details** section.



2. If you are a sponsor of an ARTG entry that should be included in the post-market review, you can add an additional ARTG entry by clicking on **Add ARTG**.



**ARTGs and Model Details** !

The following ARTG entries have been selected for a post-market medical device review

*If your organisation sponsors ARTG entries that are not listed below, but are in the scope of the review, click on the 'Add ARTG' button to include them in the list below*

*The name of all models must be entered for each ARTG entry. If an ARTG entry includes multiple models, they must all be entered, even if they are not in the scope of the review.*

*Click on the arrow to the right of the ARTG entry to select 'Add model', then select 'Edit model' to enter the model name and other information.*

*If an ARTG entry or model was added in error, select 'Edit', then select 'Out of scope' and enter the reason: 'This model was added in error'*

Models

ARTG ID ↑	ARTG Entry Name	ARTG Status	GMDNS Code	Manufacturer Name	Model	Model in Scope?	Cloned?	Created On ↓
1517156	1TGA - TGAUAT PRODUCT-Adhesive, soft tissue approximation	Active	TG15171563			Yes	No	14/09/2020 4:08 PM

## Instructions

- Click on the search icon.

The screenshot shows a form titled "Add ARTG" with a close button (x) in the top right corner. Below the title is a label "ARTG \*" followed by a long, empty text input field. To the right of the input field is a search icon (magnifying glass) enclosed in a red dashed box. Below the input field is a "Save" button.

- A list of the ARTG entries associated with your sponsor log in (both active and revoked entries) will be available for you to select.
  - Select the ARTG that is related to this post-market review.
  - Click **Select**.

The screenshot shows the "Add ARTG" form with a "Lookup records" dialog box open. The dialog box has a search field and a search icon. Below the search field is a table with the following columns: "ARTG ID", "Good Name", and "Good Status". The first row is selected and highlighted in blue. At the bottom of the dialog box, there are three buttons: "Select", "Cancel", and "Remove value". The "Select" button is highlighted with a red dashed box.

ARTG ID	Good Name	Good Status
1518446	1TGA - TGAUAT PRODUCT-Adaptor, specify	Active
1518321	1TGA - TGAUAT PRODUCT-Adaptor, specify	Active
1517156	1TGA - TGAUAT PRODUCT-Adhesive, soft tissue approximation	Active
1521905	1TGA - TGAUAT PRODUCT-Adroit Guiding Catheter - Catheter, intravascular, guiding	Active

 The list will only contain ARTG entries associated with your login.

## Instructions

5. Click **Save**.

Add ARTG

ARTG \*

1TGA - TGAUAT PRODUCT-Adaptor, specify

Save

6. To enter the model details and other information for your ARTG entry:

- a. Click Edit Model.

**ARTGs and Model Details** !

The following ARTG entries have been selected for a post-market medical device review

*If your organisation sponsors ARTG entries that are not listed below, but are in the scope of the review, click on the 'Add ARTG' button to include them in the list below*

*The name of all models must be entered for each ARTG entry. If an ARTG entry includes multiple models, they must all be entered, even if they are not in the scope of the review.*

*Click on the arrow to the right of the ARTG entry to select 'Add model', then select 'Edit model' to enter the model name and other information.*

*If an ARTG entry or model was added in error, select 'Edit', then select 'Out of scope' and enter the reason: 'This model was added in error'*

Models

Add ARTG

ARTG ID ↑	ARTG Entry Name	ARTG Status	GMDNS Code	Manufacturer Name	Model	Model in Scope?	Cloned?	Created On ↓	
1518321	1TGA - TGAUAT PRODUCT-Adaptor, specify	Active	TG15183215			Yes	No	21/09/2020 2:02 PM	Add Model Edit Model
1517156	1TGA - TGAUAT	Active	TG15171563			Yes	No	14/09/2020	

- b. Enter the model details in the **Model** field.

## Instructions

- c. Select **No** or **Yes** if the model is in-scope of the post-market review. You should refer to the notification for details of the scope of the post-market review. If you select **No**, you need to provide a reason why you consider the ARTG entry/model is not within the scope of the post-market review.

**Edit Model**

ARTG

ARTG ID	ARTG Entry Name
1518321	1TGA - TGAUAT PRODUCT-Adaptor, specify

Model

Model \*

CS6633

Is this model in the scope of the review?

No  Yes

Provide the reason why it is not in scope \*

Attach the English version of the Instructions for Use provided with or on the device.  
It is advised that you include the ARTG and model when entering a file name for easy identification. 'Add Files' support upto 50MB. 'Upload Large files' support upto 5GB. Large File Folder created in SharePoint should not be removed under any circumstance.

7. If there are multiple Models under the one ARTG entry, select Add model. This will clone the ARTG entry and cannot be deleted, but can be marked out of scope with N/A in the model number field if added in error.
- a. Click **Add Model**



The name of all models must be entered for each ARTG entry. If an ARTG entry includes multiple models, they must all be entered, even if they are not in the scope of the review.

## Instructions

### ARTGs and Model Details !

The following ARTG entries have been selected for a post-market medical device review

*If your organisation sponsors ARTG entries that are not listed below, but are in the scope of the review, click on the 'Add ARTG' button to include them in the list below*

*The name of all models must be entered for each ARTG entry. If an ARTG entry includes multiple models, they must all be entered, even if they are not in the scope of the review*

*Click on the arrow to the right of the ARTG entry to select 'Add model', then select 'Edit model' to enter the model name and other information.*

*If an ARTG entry or model was added in error, select 'Edit', then select 'Out of scope' and enter the reason: 'This model was added in error'*

Models

ARTG ID <span style="color: blue;">↑</span>	ARTG Entry Name	ARTG Status	GMDNS Code	Manufacturer Name	Model	Model		Created On <span style="color: blue;">↓</span>	
						In Scope?	Cloned?		
1518321	1TGA - TGAUAT PRODUCT-Adaptor, specify	Active	TG15183215			Yes	No	21/09/2020 2:02 PM	<span style="color: blue;">▼</span>
1517156	1TGA - TGAUAT	Active	TG15171563			Yes	No	14/09/2020	<span style="color: blue;">▼</span>

Add ARTG

Add Model  
Edit Model

b. Click **Proceed**.

### Add Model ✕

---

Do you want to add a Model?

---

Proceed
Cancel

## Instructions

A copy of the ARTG entry for the selected model is created.

Repeat step 6 and edit the model details.

**ARTGs and Model Details** -

The following ARTG entries have been selected for a post-market medical device review

*If your organisation sponsors ARTG entries that are not listed below, but are in the scope of the review, click on the 'Add ARTG' button to include them in the list below*

*The name of all models must be entered for each ARTG entry. If an ARTG entry includes multiple models, they must all be entered, even if they are not in the scope of the review.*

*Click on the arrow to the right of the ARTG entry to select 'Add model', then select 'Edit model' to enter the model name and other information.*

*If an ARTG entry or model was added in error, select 'Edit', then select 'Out of scope' and enter the reason: 'This model was added in error'*

Models

Add ARTG

ARTG ID ↑	ARTG Entry Name	ARTG Status	GMDNS Code	Manufacturer Name	Model	Model in Scope?	Cloned?	Created On ↓	
1518321	1TGA - TGAUAT PRODUCT-Adaptor. specify	Active	TG15183215			Yes	Yes	21/09/2020 2:17 PM	⌵
1518321	1TGA - TGAUAT PRODUCT-Adaptor. specify	Active	TG15183215			Yes	No	21/09/2020 2:02 PM	⌵

For each model of device (both those that you consider to be in-scope and out-of-scope of the post-market review) you will need to upload a copy of the Instructions For Use (IFU). There are two options dependent upon the size of the document:

- “Add files” button to upload documents less than 50MB size.
- “Upload Large files” button to upload documents more than 50MB size.

 Please note, folders are created in the background during this process to store the information so it may take 1 to 2 minutes for the “Add files” and “Upload Large files” buttons to appear.

8. To add files less than 50MB size:

a. Click on **Add files**.

ARTG

ARTG ID: 1518321 ARTG Entry Name: TTGA - TIGALJAT PRODUCT-Adaptor, specify

Model

Model: CS6633

Is this model in the scope of the review?  
 No  Yes

Attach the English version of the instructions for Use provided with or on the device.  
 It is advised that you include the ARTG and model when entering a file name for easy identification. 'Add Files' support upto 50MB. 'Upload Large files' support upto 5GB. Large File Folder created in SharePoint should not be removed under any circumstance.

**Add files** Upload Large files

b. Click **Choose files** and select the file you want to upload. Once you have selected your file, click on **Add files** button.

Add files

Choose files **Choose Files** D20-86296 ...3) (1).docx

Overwrite existing files

**Add files** Cancel

The file you uploaded will be displayed.

Model: CS6633

Is this model in the scope of the review?  
 No  Yes

Attach the English version of the instructions for Use provided with or on the device.  
 It is advised that you include the ARTG and model when entering a file name for easy identification. 'Add Files' support upto 50MB. 'Upload Large files' support upto 5GB. Large File Folder created in SharePoint should not be removed under any circumstance.

**Add files** Upload Large files

Name	Modified
D20-86296 (1) (1).docx	21/09/2020 3:39 PM

c. Select the check-box to acknowledge that at least one file has been uploaded and click **Save**.

**Add files** Upload Large files

Name	Modified
D20-86296 (1) (1).docx	21/09/2020 3:39 PM

Please provide your acknowledgement that at least one file has been uploaded

**Save**

9. To add files more than 50MB size:

a. Click on **Upload Large file**.

Edit Model

ARTG

ARTG ID: 1518321

ARTG Entry Name: 1TGA - TGAUAT PRODUCT-Adaptor, specify

Model

Model\*: CS6633

Is this model in the scope of the review?  
 No  Yes

Attach the English version of the Instructions for Use provided with or on the device. It is advised that you include the ARTG and model when entering a file name for easy identification. 'Add Files' support upto 50MB. 'Upload Large files' support upto 5GB. Large File Folder created in SharePoint should not be removed under any circumstance.

There are no folders or files to display.

b. A new window will open directing you to the SharePoint site. Click **Next**.

Microsoft

Sharing Link Validation

You've received a secure link to:

Large Files

Sign in to [redacted] and we'll give you access immediately.

© 2017 Microsoft - Privacy & Cookies

c. Click **Upload** and then **Files**.

DP D365-CCF-Test-Site  
Public group

Home

+ New Upload

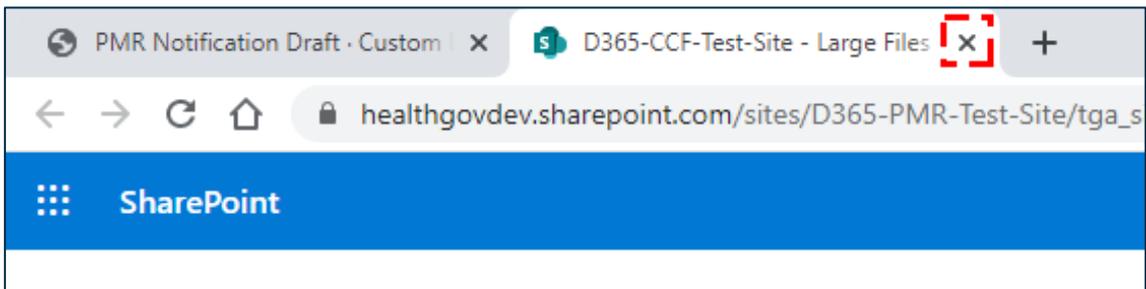
Files

Folder

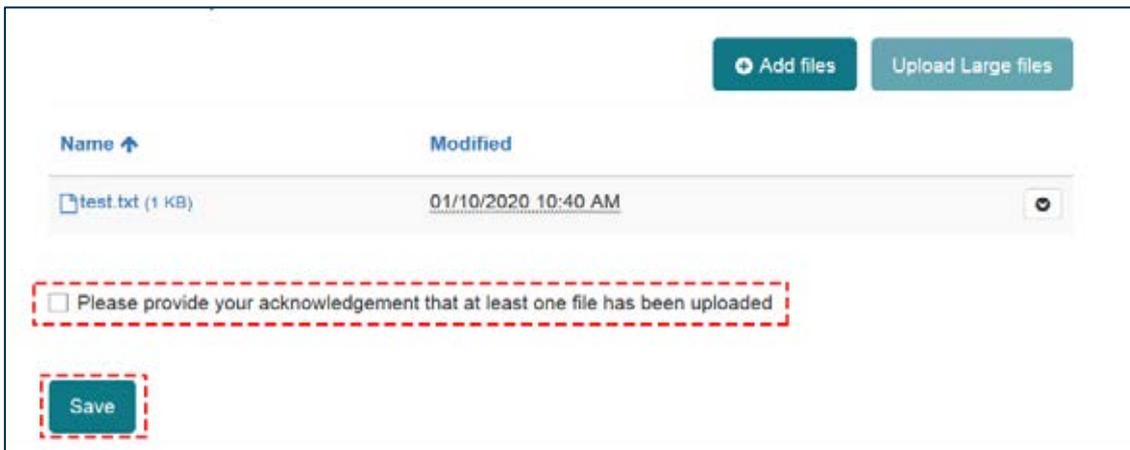
Template

## Instructions

- d. Upload your file and close the window once you have uploaded the large file(s).



- e. Select the check-box to acknowledge that at least one file has been uploaded and click **Save**.



The new model is updated against the ARTG.

ARTG ID	ARTG Entry Name	ARTG Status	GMDNS Code	Manufacturer Name	Model	Model in Scope?	Cloned?	Created On
1518321	1TGA - TGAUAT PRODUCT-Adaptor, specify	Active	TG15183215		CS6633	Yes	Yes	21/09/2020 2:17 PM
1518321	1TGA - TGAUAT PRODUCT-Adaptor, specify	Active	TG15183215			Yes	No	21/09/2020 2:02 PM

For each of the models of devices you will be required to provide supply, complaint, and adverse event details. Please check the notification letter for details on how many financial years you are required to provide data for.

The supply, complaint, and adverse event data can be completed in the Model Details section. You can update the model details for each individual financial year or you can enter the supply details, complaints and adverse events data for all models in a single file using the bulk upload functionality.

## Instructions

**Model Details**

Model details must be added for the last three financial years. Click 'Add Model Financial Year' to add each financial year, then click on the name to add the model details for each year. You can also enter the supply details, complaints and adverse events data for all models into a single file instead of adding them separately for each model by following the instructions in the Notification Documents section.

**Add Model Financial Year**

Name	Model	Financial Year	Number Supplied in Australia	Number Supplied Overseas	Received Complaints	Received Adverse Event Reports	Created On ↓
------	-------	----------------	------------------------------	--------------------------	---------------------	--------------------------------	--------------

Refer to:

- Instructions numbers 10-15 on how to update the model details for each individual financial year.
- Instruction number 16 for instructions on how to use the bulk upload functionality to enter the supply details, complaints and adverse events data for all models in a single file.

10. To update the model details for each individual financial year:

- Click on **Add Model Financial Year** button to select which model you are going to add the financial year data against.

**Model Details**

Model details must be added for the last three financial years. Click 'Add Model Financial Year' to add each financial year, then click on the name to add the model details for each year. You can also enter the supply details, complaints and adverse events data for all models into a single file instead of adding them separately for each model by following the instructions in the Notification Documents section.

**Add Model Financial Year**

Name	Model	Financial Year	Number Supplied in Australia	Number Supplied Overseas	Received Complaints	Received Adverse Event Reports	Created On ↓
------	-------	----------------	------------------------------	--------------------------	---------------------	--------------------------------	--------------

- Click on the magnifying glass to search for the model.

**Add Model Financial Year**

RFI  
PMR-2020-01302 - 1TGA - 01

**Model \***

**Financial Year \***

**Save**

- Select the model and click **Select**.

 Only the models in scope will be displayed.

## Instructions

Lookup records

Search

ARTG ID	ARTG Entry Name	ARTG Status	Model	Created On
✓ 1517156	1TGA - TGAUAT PRODUCT- Adhesive, soft tissue approximation	Active		14/09/2020 4:08 PM
1518321	1TGA - TGAUAT PRODUCT- Adaptor, specify	Active		21/09/2020 2:02 PM
1518321	1TGA - TGAUAT	Active	CS6633	21/09/2020 3:17 PM

d. Select the financial year and click **Select**.

Add Model Financial Year

RFI

PMR-2020

Model

1518321

Financial

Save

Lookup records

Search

FIN 2014/2015	11/03/2020 2:33 PM
FIN 2015/2016	11/03/2020 2:33 PM
FIN 2016/2017	11/03/2020 2:33 PM
FIN 2017/2018	11/03/2020 2:33 PM
✓ FIN 2018/2019	11/03/2020 2:33 PM
FIN 2019/2020	11/03/2020 2:33 PM

< 1 2 3 >

## Instructions

e. Click **Save**.

Add Model Financial Year

RFI

PMR 2020-01302 - 1TGA - 01

Model \*

1518321

Financial Year \*

FIN 2018/2019

Save

The financial year details are updated.

 If you select the incorrect financial year, you can remove the financial year by clicking on **Remove**.

Model Details

Model details must be added for the last three financial years. Click 'Add Model Financial Year' to add each financial year, then click on the name to add the model details for each year. You can also enter the supply details, complaints and adverse events data for all models into a single file instead of adding them separately for each model by following the instructions in the Notification Documents section.

Add Model Financial Year

Name	Model	Financial Year	Number Supplied in Australia	Number Supplied Overseas	Received Complaints	Received Adverse Event Reports	Created On
FIN 2018/2019 - CS5633	1TGA - TGAJAT	FIN 2018/2019					21/09/2020 7:37 PM

Remove

11. The following instructions outline how to add the supply details, complaints and adverse events data. Please check the notification for details on how many financial years you are required to provide data for.

a. Click **Edit**.

Model Details

Model details must be added for the last three financial years. Click 'Add Model Financial Year' to add each financial year, then click on the name to add the model details for each year. You can also enter the supply details, complaints and adverse events data for all models into a single file instead of adding them separately for each model by following the instructions in the Notification Documents section.

Add Model Financial Year

Name	Model	Financial Year	Number Supplied in Australia	Number Supplied Overseas	Received Complaints	Received Adverse Event Reports	Created On
FIN 2018/2019 - CS5633	1TGA - TGAJAT	FIN 2018/2019					21/09/2020 7:37 PM

Edit

This is the overarching screen that will appear.

 Each screen will turn green as you complete each section.

## Instructions

FIN 2018/2019 - 1TGA - TGAUAT PRODUCT-Adaptor, specify

Expand All

Collapse All

Financial Year ✓

Supply Details ⓘ

Complaints ⓘ

Adverse Events ⓘ

Save

Back

12. In the **Supply Details** section:

- a. Enter the **Number Supplied in Australia**. To select the unit measurement in the **Number Supplied Australia – Unit Measurement** field for that financial year, click on the magnifying glass and select one of the options:

- Box
- Each
- Pack
- Other

**Supply Details ⓘ**

Number Supplied in Australia \*

10

Number Supplied Australia - Unit of Measurement \*

Box

Lookup records

Search

Short Description ↑

Box

Each

Other

Pack

Select Cancel Remove value

## Instructions

- b. Enter the number of devices supplied overseas in that financial year.

**Supply Details** ✓

Number Supplied in Australia \*

10

Number Supplied Australia - Unit of Measurement \*

Box

Number Supplied Overseas \*

5

Number Supplied Overseas - Unit of Measurement \*

Each

13. In the **Complaints** section:

You have the option to select **Yes** or **No** if any complaints were received in the selected financial year.

**Complaints** !

Have you received complaints about this model during the financial year?

Yes  No

- a. If you select **No**, complete the Adverse Events section in step 14.
- b. If you select **Yes**, complete the following steps:
- Enter the **Total number of complaints that came from Australia in the financial year**.
  - Enter the **Total number of complaints that came from overseas in the financial year**.
  - Enter at least one **Type of complaint received** and **Number received**.

**Complaints** ✓

Have you received complaints about this model during the financial year?

Yes  No

Total number of complaints that came from Australia in the financial year \*

2

Total number of complaints that came from overseas in the financial year \*

1

Describe the ten most common types of complaints made in **Australia** about the model during the financial year and enter the number of each type of complaint.

1. Type of complaint received *	Number received *
Faulty device	1
2. Type of complaint received	Number received

## Instructions

- c. You have the option to upload supporting documents using the **Add files** and **Upload Large files** function. Refer to step 8 for small files (less than 50MB size) or 10 for large files (more than 50MB size) for step by step instructions on how to upload files.

If you wish to attach supporting documents relating to this complaint type, the English versions can be attached here.  
It is advised that you include the ARTG and model when entering a file name for easy identification. 'Add files' support upto 50MB. 'Upload Large files' support upto 5GB. Large File Folder created in SharePoint should not be removed under any circumstance.

Name ↑	Modified
D20-86296 DPMRRS TEMP 1.1 b s41JA Requirements for inform...	21/09/2020 3:39 PM

-  Any files that have already been uploaded relating to this ARTG entry will be displayed in the list of files.

### 14. In the **Adverse Events** section:

You have the option to select **Yes** or **No** if any adverse event reports were received about this model in the selected financial year.

**Adverse Events** 

Have you received any adverse event reports about this model during the financial year?

Yes  No

- a. If you select No, click Save and refer to step 15.

**Adverse Events** 

Have you received any adverse event reports about this model during the financial year?

Yes  No

If you wish to attach supporting documents relating to this complaint type, the English versions can be attached here.  
It is advised that you include the ARTG and model when entering a file name for easy identification. 'Add files' support upto 50MB. 'Upload Large files' support upto 5GB. Large File Folder created in SharePoint should not be removed under any circumstance.

Name ↑	Modified
D20-86296 DPMRRS TEMP 1.1 b s41JA Requirements for inform...	21/09/2020 3:39 PM

- b. If you select **Yes**, complete the following steps:

- Enter the **Total number of adverse events that came from Australia in the financial year.**
- Enter the **Total number of adverse events that came from overseas in the financial year.**
- Provide a breakdown of the adverse events by type of adverse event (derived from the International Medical Device Regulators Forum Adverse Event Codes <http://www.imdrf.org/documents/documents.asp>). Select at least one common

## Instructions

**Category of adverse event** and **Number reported** for that adverse event type, for that particular model, during that financial year. The ten most prevalent adverse event types can be provided.

- If there were adverse events reported in Australia, the adverse event types are related to the Australian adverse events. If there were no adverse events reported in Australia, the adverse event types are related to the worldwide adverse events. The region is identified in the heading.

- c. You have the option to upload supporting documents relating to this complaint type using the **Add files** and **Upload Large files** function. Refer to step 8 for small files (less than 50MB size) or 10 for large files (more than 50MB size) for step by step instructions on how to upload files.

-  Any files that have already been uploaded relating to this ARTG entry will be displayed in the list of files.

15. Click **Save** and the following message will appear and click on the **Back** button to go back to the previous page.

*“Model Details has been successfully saved. Please click on the ‘Back’ button to go back to the previous page”*

## Instructions

The model details for the selected financial year are updated.

**Model Details**

Model details must be added for the last three financial years. Click 'Add Model Financial Year' to add each financial year, then click on the name to add the model details for each year. You can also enter the supply details, complaints and adverse events data for all models into a single file instead of adding them separately for each model by following the instructions in the Notification Documents section.

[Add Model Financial Year](#)

Name	Model	Financial Year	Number Supplied in Australia	Number Supplied Overseas	Received Complaints	Received Adverse Event Reports	Created On
FIN 2018/2019 - 1TGA - TGAUAT	CS6633	FIN 2018/2019	10	5	Yes	Yes	21/09/2020 7:37 PM

PRODUCT: Adaptor, specify

16. To update the supply details, complaints and adverse events data for all models, for multiple financial years, in a single file, you can use the **bulk upload** functionality:
- You need to generate the bulk upload template from the **Notification Details** section.
  - Click on **Generate Template**.

**Notification Details** !

**Section 41JA of the Therapeutic Goods Act 1989**

The TGA is conducting a post market review of ARTG Devices.

<b>Notification Name *</b>	<b>Review Reference Number</b>
PMR-2020-01302 - 1TGA - 01	PMR-2020-01302

**Review in scope**

The ARTG devices within this review are in scope because they have been identified as requiring further assessment.

**Review out of scope**

The ARTG devices not within this review are not in scope because they have not been identified as requiring further assessment.

**Notification Documents**

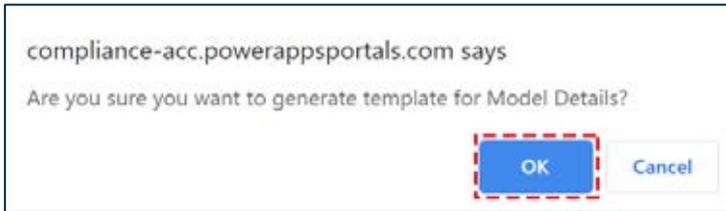
Supply details, complaints and adverse events data can be entered in a single file, provided that the models have been identified and scoped first. Use the following steps to generate and upload the file:

- Click on 'Generate template', then refresh
- Three files will be generated in the list. It may take up to two minutes for the files to appear. Download the ModelDetailsTemplate.csv file
- Open the file and enter supply, complaints and adverse events data for each model for the last three financial years. The AdverseEventsCategoryValues and the UnitValues files contain the lists of adverse event and unit values. These can be used as references or to copy and paste values into the file.
- Save the file and rename it 'ModelDetails.csv'. Please ensure that the file is renamed as '**ModelDetails.csv**'.
- Click on 'Add Files' and upload the ModelDetails.csv file.
- Click on 'Process Bulk Upload'.

The uploaded Model Details will appear under 'Model Details' section after few minutes, after the Refresh. If the upload contains any errors, you will be contacted by email.

[Generate Template](#)
[Add files](#)
[Process Bulk Upload](#)

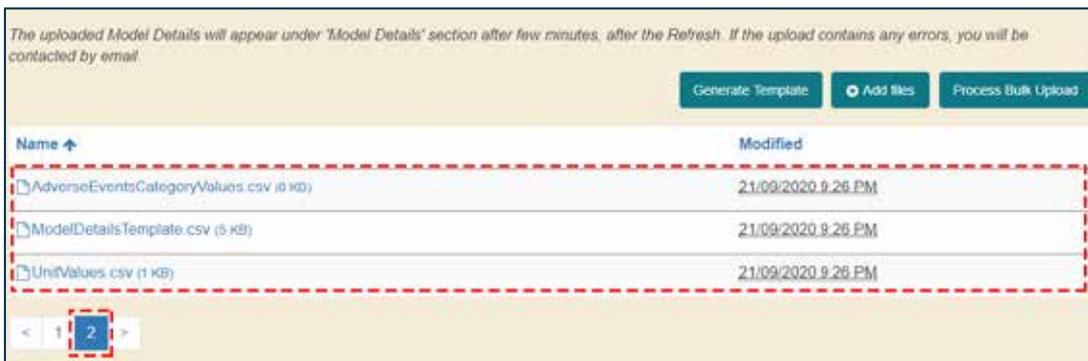
c. Click **OK**.



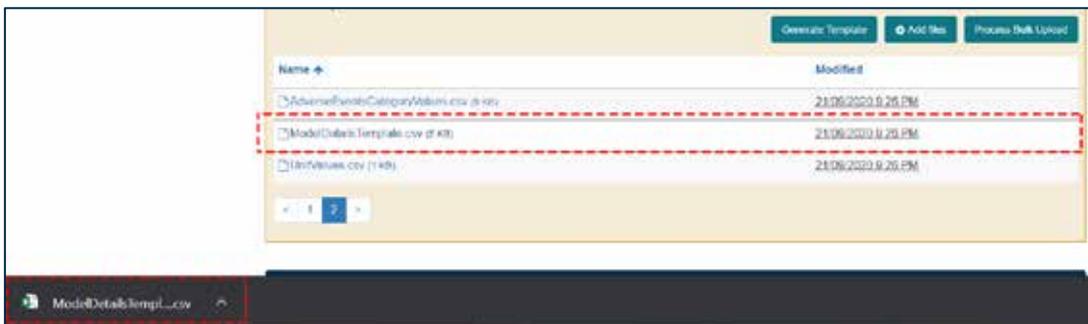
 You may need to click on **Refresh** at the bottom of your screen to view the new template.



d. You may need to go to page 2 to access the bulk upload templates.



e. Open the **ModelDetailsTemplate** file to enter the supply, complaints and adverse events data for each model for the last three financial years.



 You can download and refer to the **AdverseEventsCategoryValues** and **UnitValues** files as references or to copy and paste the values into your ModelDetailsTemplate file as part of the next step.

**AdverseEventsCategoryValues** file:

A	B	C
1. Appropriate Terms/Code Not Available		
2. Biological Problem Identified	Biocompatibility Problem Identified	Endotoxin Contamination
3. Biological Problem Identified	Biological Contamination	Microbial Contamination
4. Biological Problem Identified	Biological Contamination	Microbial Contamination
5. Biological Problem Identified	Cytotoxicity Problem Identified	Carcinogenic Problems
6. Biological Problem Identified	Genotoxicity Problem Identified	Malignancy Problem
7. Biological Problem Identified	Genotoxicity Problem Identified	Malignancy Problem
8. Biological Problem Identified	Immunological Problem Identified	Agglutination Problem
9. Biological Problem Identified	Immunological Problem Identified	Complement Activation Problem
10. Biological Problem Identified	Immunological Problem Identified	Platelet Activation Problem
11. Biological Problem Identified	Immunological Problem Identified	Problem due to Thrombolytic Activation
12. Biological Problem Identified	Material or Material Leachate Pyrogenic Problem	
13. Biological Problem Identified	Reproductive Toxicity Problem Identified	
14. Biological Problem Identified	Unintended Presence of Allergens	
15. Clinical Imaging Problem Identified	Gradient Reduced Field Problem	
16. Clinical Imaging Problem Identified	Image Artifact	
17. Clinical Imaging Problem Identified	Magnetically Induced Movement	
18. Clinical Imaging Problem Identified	Radiation Frequency Induced Overheating	
19. Electrical Problem Identified	Current Leakage Problem	
20. Electrical Problem Identified	Electrical/Electronic Component Problem Identified	
21. Electrical Problem Identified	Hardware Timing Problem Identified	
22. Electrical Problem Identified	Software Problem Identified	

## Instructions

### UnitValues file:

	A
1	Box
2	Each
3	Other
4	Pack
5	

- f. Enter the supply, complaints and adverse events data for each model for the last three financial years

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	AI	AJ	AK
1	Model ID	ATG ID	Model No	Model	Financial Year	Number Supplied in Australia	Number Supplied Overseas	Number of Complaints Received	Number of Complaints Received from Australia	Number of Complaints Received from Overseas	Complaint Type	Number of Adverse Events Received	Number of Adverse Events Received from Australia	Number of Adverse Events Received from Overseas				
2	81425cb3	1518446	ITGA	TGA/AT PROFIN 2021/2018														
3	81425cb3	1518446	ITGA	TGA/AT PROFIN 2019/2019														
4	81425cb3	1518446	ITGA	TGA/AT PROFIN 2017/2020														
5	5a29204e	1518323	ITGA	TGA/AT PROFIN 2019/2018														
6	5a29204e	1518323	ITGA	TGA/AT PROFIN 2018/2019														
7	5a29204e	1518323	ITGA	TGA/AT PROFIN 2019/2020														
8	da0b0e9c	1518323	ITGA	TGCS6633 FIN 2019/2018														
9	da0b0e9c	1518323	ITGA	TGCS6633 FIN 2018/2019														
10	da0b0e9c	1518323	ITGA	TGCS6633 FIN 2019/2020														
11	8a425cb3	1518323	ITGA	TGA/AT PROFIN 2019/2018														
12	8a425cb3	1518323	ITGA	TGA/AT PROFIN 2018/2019														
13	8a425cb3	1518323	ITGA	TGA/AT PROFIN 2019/2020														
14	96d25cb3	1517156	ITGA	TGA/AT PROFIN 2019/2018														
15	96d25cb3	1517156	ITGA	TGA/AT PROFIN 2018/2019														
16	96d25cb3	1517156	ITGA	TGA/AT PROFIN 2019/2020														
17	96d25cb3	1521905	ITGA	TGA/AT PROFIN 2019/2018														
18	96d25cb3	1521905	ITGA	TGA/AT PROFIN 2018/2019														
19	96d25cb3	1521905	ITGA	TGA/AT PROFIN 2019/2020														

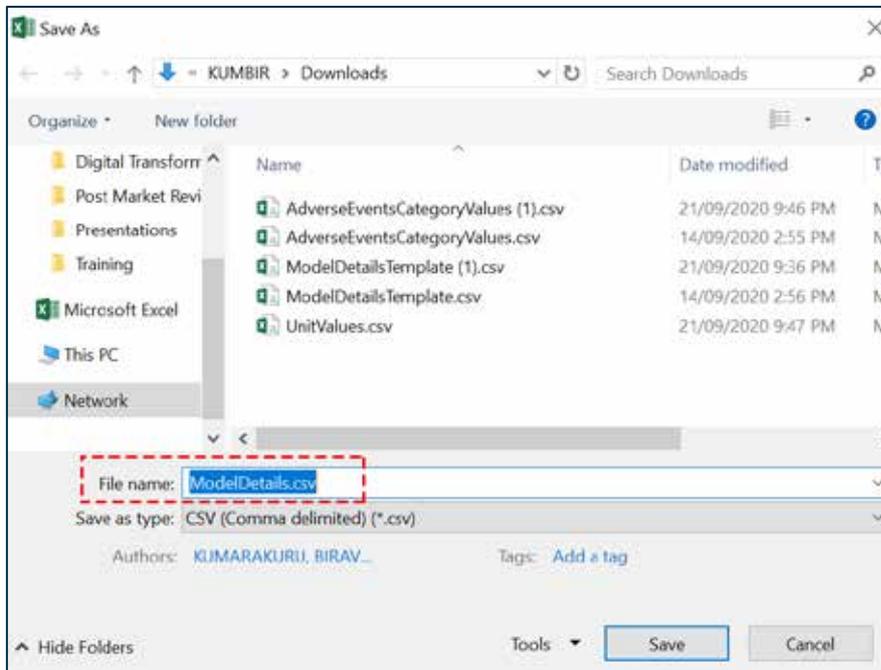
### Please note:

- You must complete all rows or delete the rows you don't need to enter data.
- The following columns are mandatory to complete:
  - Column E: Financial Year
  - Column F: Number Supplied in Australia
  - Column G: Unit
  - Column I: Number Supplied Overseas
  - Column J: Unit
  - Column L: Have you received complaints about this model during the financial year? (Yes/No)
  - Column M: Total number of complaints that came from Australia in the financial year
  - Column N: Total number of complaints that came from overseas in the financial year
  - Column O: type of Complaint Received
  - Column P: Number Received
  - Column AI: Have you received any adverse event reports about this model during the financial year? (Yes/No)
  - Column AJ: Total number of adverse events that came from Australia in the financial year
  - Column AK: Total number of adverse events that came from overseas in the financial year

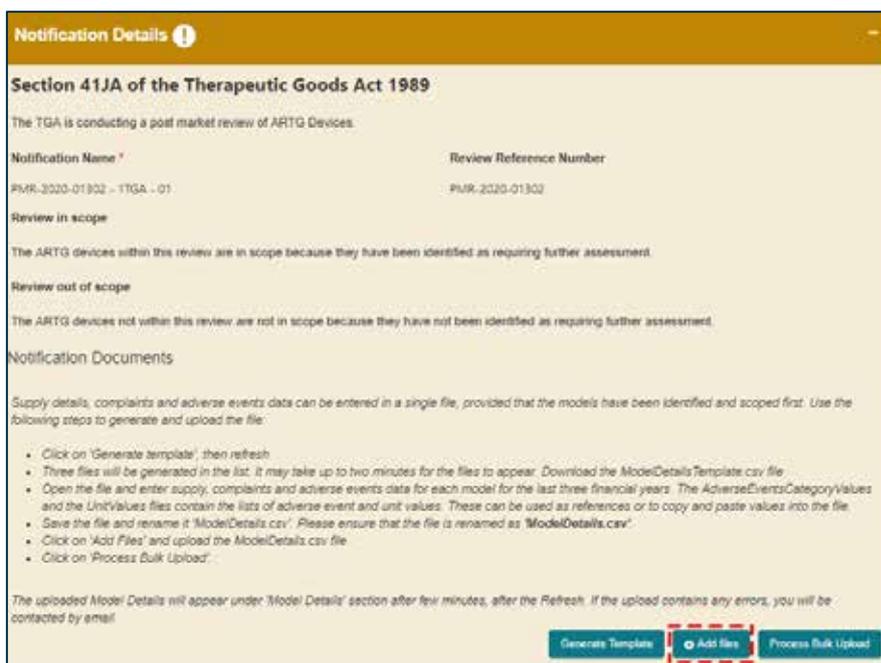
## Instructions

- Column AL: Category of Adverse Event Level 1
- Column AO: Category of Advser Event Number Reported

Once you have completed the required information in the ModelDetailsTemplate file, you need to save the file as “ModelDetails.csv”. Note: it is important to save the file as “ModelDetails.csv” for the system to identify the document.



- g. To upload the file, click on **Add files** and the new file you uploaded will be saved in the documents section.



## Instructions

Name ↑	Modified
AdverseEventsCategoryValues.csv (3 KB)	21/09/2020 9:26 PM
ModelDetails.csv (5 KB)	less than a minute ago
ModelDetailsTemplate.csv (5 KB)	21/09/2020 9:26 PM
UniValues.csv (1 KB)	21/09/2020 9:26 PM

h. Click on **Process Bulk Upload** to upload your files.

The uploaded Model Details will appear under 'Model Details' section after few minutes; after the Refresh. If the upload contains any errors, you will be contacted by email.

Name ↑	Modified
AdverseEventsCategoryValues.csv (3 KB)	21/09/2020 9:26 PM
ModelDetails.csv (5 KB)	about a minute ago
ModelDetailsTemplate.csv (5 KB)	21/09/2020 9:26 PM
UniValues.csv (1 KB)	21/09/2020 9:26 PM

The model details will be uploaded in the ARTGs and Model Details section. If the model details are not uploaded in this section then there was an error when updating the bulk upload file in step 17f. Please make sure you enter all mandatory fields and the right information is entered. If you still have issues, please contact the Post Market Devices Team ([postmarketdevices@health.gov.au](mailto:postmarketdevices@health.gov.au)).

**Model Details**

Model details must be added for the last three financial years. Click 'Add Model Financial Year' to add each financial year, then click on the name to add the model details for each year. You can also enter the supply details, complaints and adverse events data for all models into a single file instead of adding them separately for each model by following the instructions in the Notification Documents section.

Name	Model	Financial Year	Number Supplied in Australia	Number Supplied Overseas	Received Complaints	Received Adverse Event Reports	Created On ↓
FIN 2018/2019 - 1TGA - TGAUAT-PRODUCT-Adaptor, specify	C56633	FIN 2018/2019	10	5	Yes	Yes	21/09/2020 7:37 PM

 Please note the following relating to the bulk upload functionality:

- If you have any documents associated to the model details you entered in the large file bulk upload, you can upload it at a candidate level by following steps 8 and 9.

**Models**

ARTG ID ↑	ARTG Entry Name	ARTG Status	GMDNS Code	Manufacturer Name	Model	Model in Scope?	Cloned?	Created On ↓
1518321	1TGA - TGAUAT-PRODUCT-Adaptor, specify	Active	TG15183215	CS6633		Yes	Yes	21/09/2020 2:17 PM
1518321	1TGA - TGAUAT	Active	TG15183215			Yes	No	21/09/2020

## Instructions

- If you need to make any amendments to the saved bulk upload file, it is easier to manually update it from the Model Details section by clicking on **Edit**.

Model Details

Model details must be added for the last three financial years. Click 'Add Model Financial Year' to add each financial year, then click on the name to add the model details for each year. You can also enter the supply details, complaints and adverse events data for all models into a single file instead of adding them separately for each model by following the instructions in the Notification Documents section.

[Add Model Financial Year](#)

Name	Model	Financial Year	Number Supplied In Australia	Number Supplied Overseas	Received Complaints	Received Adverse Event Reports	Created On
FIN 2018/2019 - 1TGA - TGAUAT PRODUCT-Adaptor, specify	C56633	FIN 2018/2019	10	5	Yes	Yes	21/09/2020 7:37 PM

[Edit](#) [Remove](#)

Make the changes in the relevant section.

PMR Notification Model Details Edit

FIN 2018/2019 - 1TGA - TGAUAT PRODUCT-Adaptor, specify

[Expand All](#) [Collapse All](#)

**Financial Year** ✓ +

**Supply Details** ✓ -

Number Supplied in Australia \*

10

Number Supplied Australia - Unit of Measurement \*

Box

Number Supplied Overseas \*

5

Number Supplied Overseas - Unit of Measurement \*

Each

**Complaints** ✓ +

**Adverse Events** ✓ -

- If you need to make several changes to the bulk upload file, it will be easier to remove the file you saved, create a new file and upload the new file. You can remove the document by clicking on **Remove** and follow step 16 again.

## Instructions

### Model Details

Model details must be added for the last three financial years. Click 'Add Model Financial Year' to add each financial year, then click on the name to add the model details for each year. You can also enter the supply details, complaints and adverse events data for all models into a single file instead of adding them separately for each model by following the instructions in the Notification Documents section.

Add Model Financial Year

Name	Model	Financial Year	Number Supplied in Australia	Number Supplied Overseas	Received Complaints	Received Adverse Event Reports	Created On ↓	
FIN 2018/2019 - ITGA - TGAUAT PRODUCT- Adaptor, specify	CS8633	FIN 2018/2019	10	5	Yes	Yes	21/09/2020 7:37 PM	<input type="checkbox"/> Edit <input type="checkbox"/> Remove

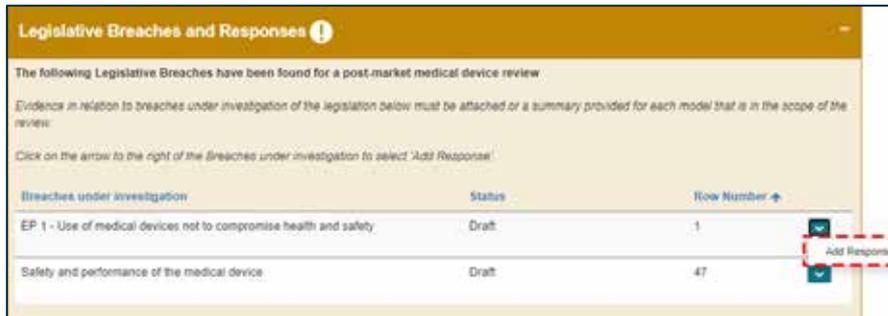
If you have a large number of bulk upload files that you need to make changes to, it will be easier to contact the Post Market team by sending an email to the Post Market devices ([postmarketdevices@health.gov.au](mailto:postmarketdevices@health.gov.au)) mailbox. The team will be able to run a bulk removal of your selected files.

## How to provide evidence of compliance with requirements

The following instructions outline how to upload the information and documents to demonstrate compliance with the specific areas of the legislation that have been identified in the notification letter.

### Instructions

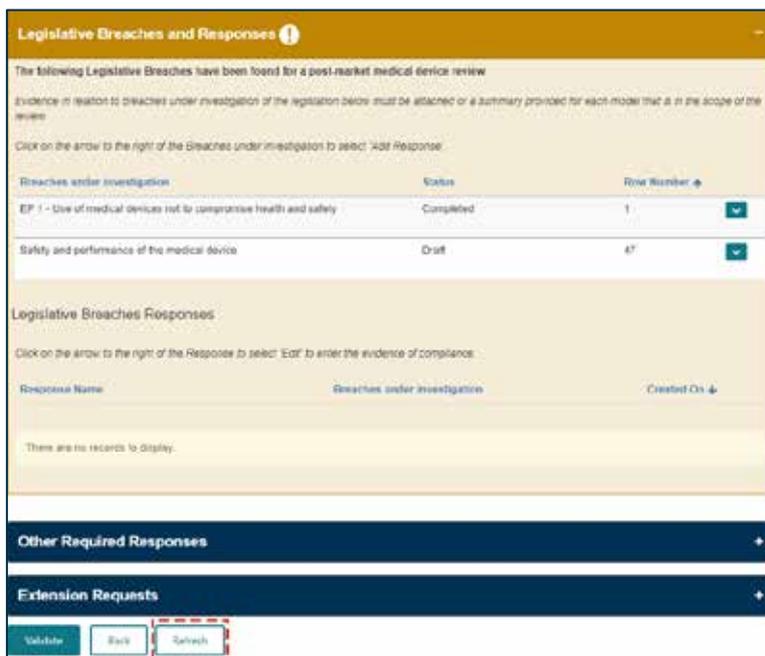
1. Click **Add Response** in the drop down option against the specified 'Breaches under investigation'.



2. Click **Proceed**.



3. Click **Refresh**.



## Instructions

4. Click **Edit** next to the generated response area.

**Legislative Breaches and Responses**

The following Legislative Breaches have been found for a post-market medical device review

Evidence in relation to breaches under investigation of the legislation below must be attached or a summary provided for each model that is in the scope of the review.

Click on the arrow to the right of the Breaches under investigation to select 'Add Response'

Breaches under investigation	Status	Row Number
EP 1 - Use of medical devices not to compromise health and safety	Completed	1
Safety and performance of the medical device	Draft	47

**Legislative Breaches Responses**

Click on the arrow to the right of the Response to select 'Edit' to enter the evidence of compliance

Response Name	Breaches under investigation	Created On
Response for EP 1 - Use of medical devices not to compromise health and safety for ARTG Number(s) 1517156, 1518321, 1518446, 1521905	EP 1 - Use of medical devices not to compromise health and safety	23/09/2020 1:20 PM

5. Select how you wish to provide your response.
- a. You can choose from one of the three options:
- Provide a summary
  - Attach evidence of compliance
  - Both

If you select “Attach evidence of compliance” or “Both”, you must attach minimum one file.

**Edit Compliance with Essential Principle Response**

EP 1 - Use of medical devices not to compromise health and safety

ARTGs (Please note that ARTGs can be removed from this response)

ARTG ID	ARTG Name	ARTG Status	Status Reason	Created On
1518446	ITGA - TGA/AT PRODUCT - Adaptor, specify	Active	Draft	14/09/2020 4:00 PM
1518321	ITGA - TGA/AT PRODUCT - Adaptor, specify	Active	Draft	14/09/2020 4:00 PM
1517156	ITGA - TGA/AT PRODUCT - Adhesive, soft tissue approximation	Active	Draft	14/09/2020 4:00 PM
1521905	ITGA - TGA/AT PRODUCT - Adroit Guiding Catheter - Catheter, intravascular, guiding	Active	Draft	14/09/2020 4:00 PM

How do you wish to provide your response?

- Provide a summary
- Attach evidence of compliance
- Both

## Instructions

- b. In the **Summary** section, provide your response. Note: the summary must be minimum 20 characters.

How do you wish to provide your response?

Both

Summary \*

- c. Refer to steps 8 and 9 for instructions on how to **Add files** and **Upload Large Files**.

How do you wish to provide your response?

Both

Summary \*

Attach the English version of your evidence of compliance.  
It is advised that you include the ARTG and model when entering a file name for easy identification. 'Add files' support upto 50MB. 'Upload Large files' support upto 5GB. Large File Folder created in SharePoint should not be removed under any circumstance.

Add files Upload Large files

- d. Select the check-box to acknowledge that at least one file has been uploaded and click **Save**.

Name ↑	Modified
<input type="checkbox"/> test.txt (1 KB)	01/10/2020 10:40 AM

Please provide your acknowledgement that at least one file has been uploaded

Save

## How to respond to additional information request

If a notification requires additional information on another specific matter, this is where you can provide a response.

### Instructions

1. Click **Edit** to provide a response to a specific request.

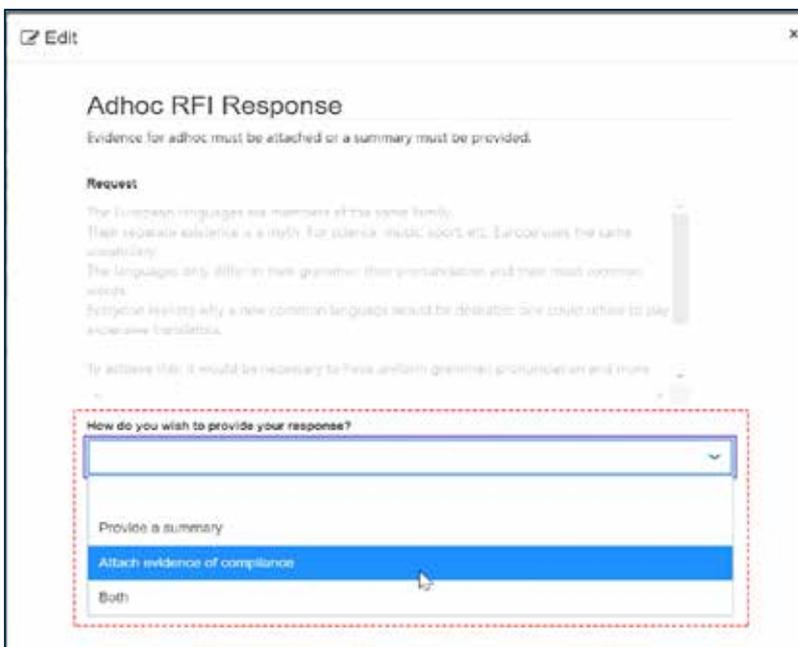


2. Select how you wish to provide your response and complete the details

- a. Select one of the following:

- Provide a summary
- Attach evidence of compliance
- Both

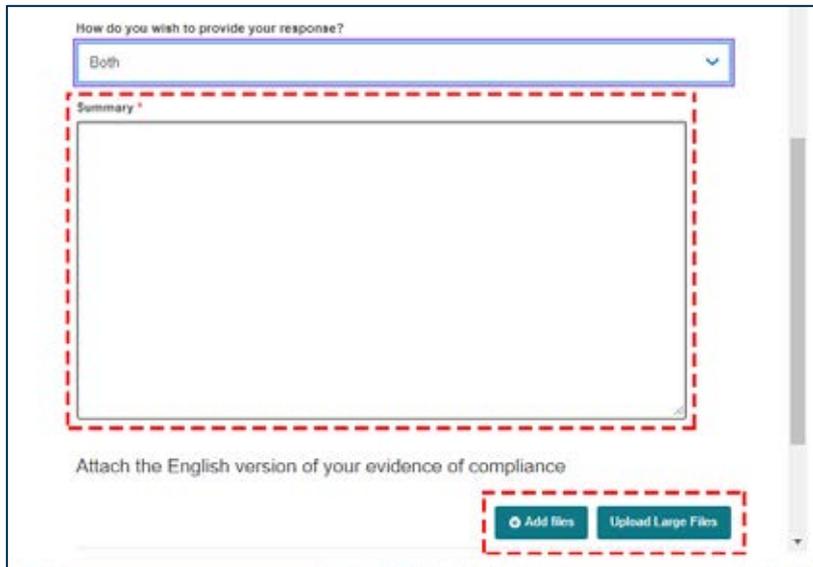
 If you select “Attach evidence of compliance” or “Both”, you must attach minimum one file.



- b. In the **Summary** section, provide your response. Note: the summary must be minimum 50 characters.

## Instructions

- c. If you wish to attach a document, refer to steps 9 and 10 for instructions on how to **Add files** and **Upload Large Files**.



How do you wish to provide your response?

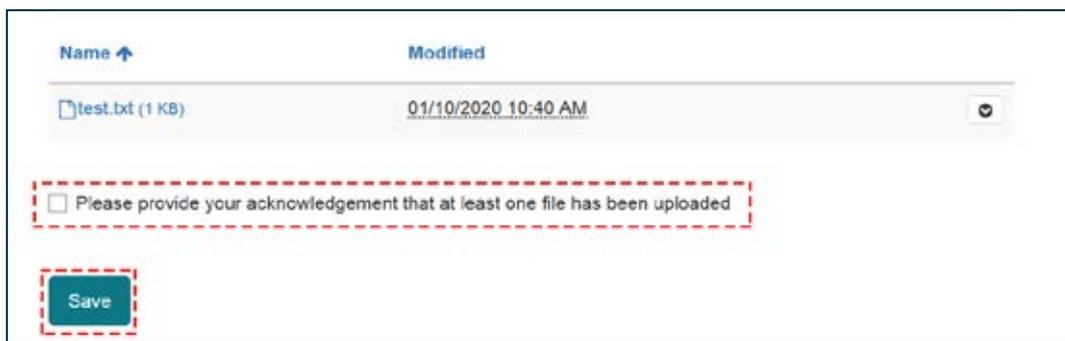
Both

Summary \*

Attach the English version of your evidence of compliance

Add files Upload Large Files

- d. Select the check-box to acknowledge that at least one file has been uploaded and click **Save**.



Name ↑	Modified
 test.txt (1 KB)	01/10/2020 10:40 AM

Please provide your acknowledgement that at least one file has been uploaded

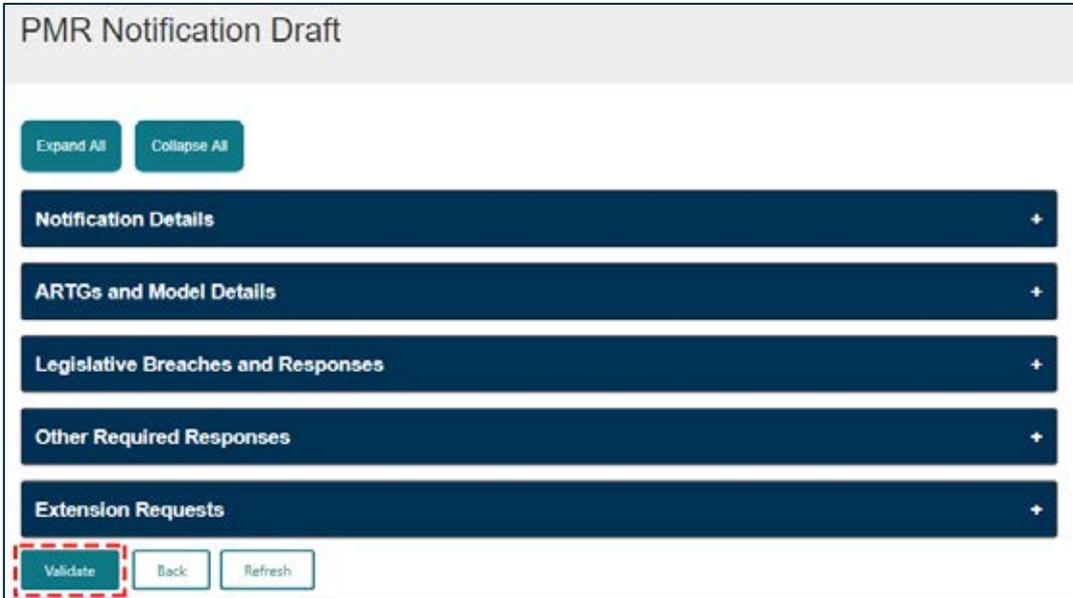
Save

## How to submit the information

### Instructions

1. If you are ready to submit your response, click **Validate**.

 Only the Submitter will be able complete the following steps to submit the response.



PMR Notification Draft

Expand All Collapse All

Notification Details +

ARTGs and Model Details +

Legislative Breaches and Responses +

Other Required Responses +

Extension Requests +

Validate Back Refresh

2. Once the response has been successfully validated, click **Preview** to preview your responses.

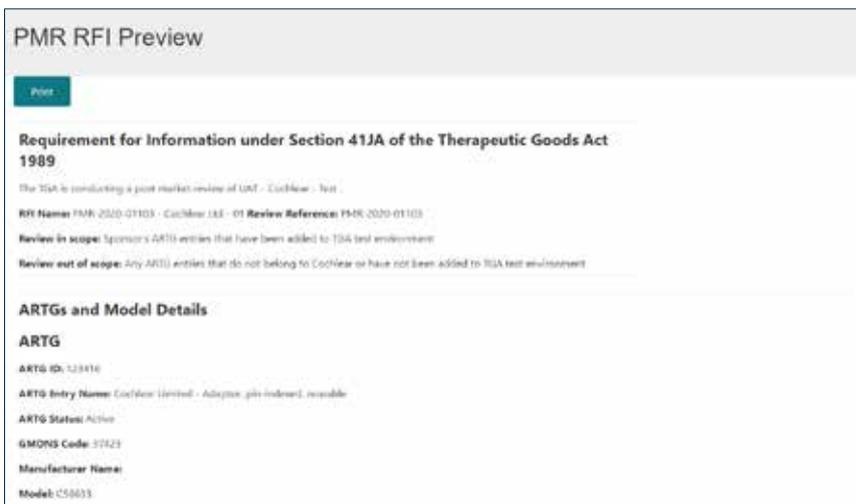


PMR RFI Draft

This RFI has been successfully validated. Please click on the 'Preview' button to preview RFI responses. Click on the 'Declare' button to declare RFI completion.

Preview Declare

 You can preview the notification before you submit it.



PMR RFI Preview

Print

**Requirement for Information under Section 41JA of the Therapeutic Goods Act 1989**

The TGA is conducting a post market review of LMT - CoCleave - Test

**RFI Name:** PMR-2020-01103 - CoCleave LMT - 01 **Review Reference:** PMR-2020-01103

**Review in scope:** Sponsor's ARTG entries that have been added to TGA test environment

**Review out of scope:** Any ARTG entries that do not belong to CoCleave or have not been added to TGA test environment

**ARTGs and Model Details**

**ARTG**

ARTG ID: 123456

ARTG Entry Name: CoCleave Limited - Adapton, gln-Indevant, ivandale

ARTG Status: Active

GMONS Code: 37123

Manufacturer Name:

Model: C5003

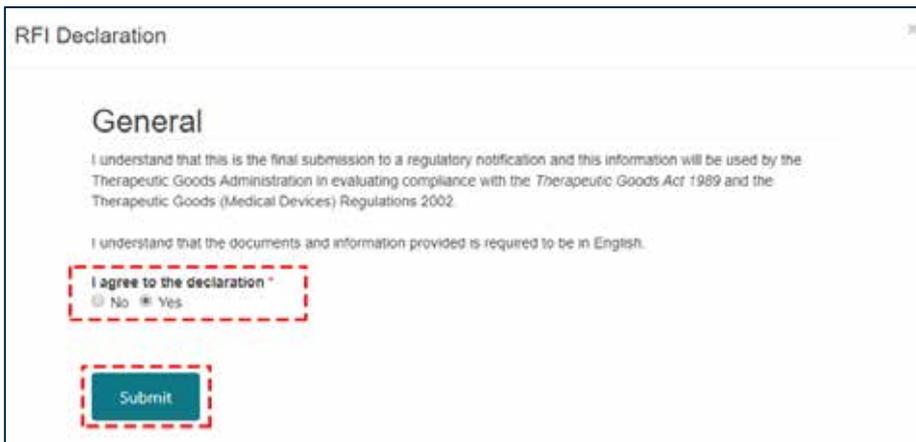
## Instructions

### 3. Click **Declare**.



### 4. Select **Yes** if you agree to the declaration.

#### a. Click **Submit**.



### 5. Click **OK**.



# How to request for an extension

If you are having difficulty providing the information in the required timeframe and need an extension, you can submit a request. Please note, that a request for extension may not be able to be provided in all cases.

## Instructions

### 1. Click **Draft**.

PMR Compliance Dashboard

Requests for Information - Active

Search

Reference Number	Review Description +	Sponsor Name	RFI Type	Status	Response Due Date	
PMR-2020-01103			Section 41AA	Sent/Awaiting Response	11/06/2020 5:00 PM	▼
PMR-2020-01104			Section 41AA	Sent/Awaiting Response	11/06/2020 5:00 PM	▼
PMR-2020-01234			S41GB Proposal to suspend	Sent/Awaiting Response	09/07/2020 5:00 PM	▼
PMR-2020-01234			S41GN(2) Proposal to Cancel	Sent/Awaiting Response	09/07/2020 5:00 PM	▼
PMR-2020-01216			Section 41AA	Sent/Awaiting Response	15/07/2020 5:00 PM	▼
PMR-2020-01234			Section 41AA	Sent/Awaiting Response	13/07/2020 5:00 PM	▼

Draft  
View (1/1)  
Private

### 2. Click on the + button to expand the Extension Requests section.

Expand All Collapse All

Request For Information Details +

ARTGs and Model Details +

Legislative Breaches and Responses +

Other Required Responses +

Extension Requests +

Validate Back Refresh

### 3. Click **Request Extension**.

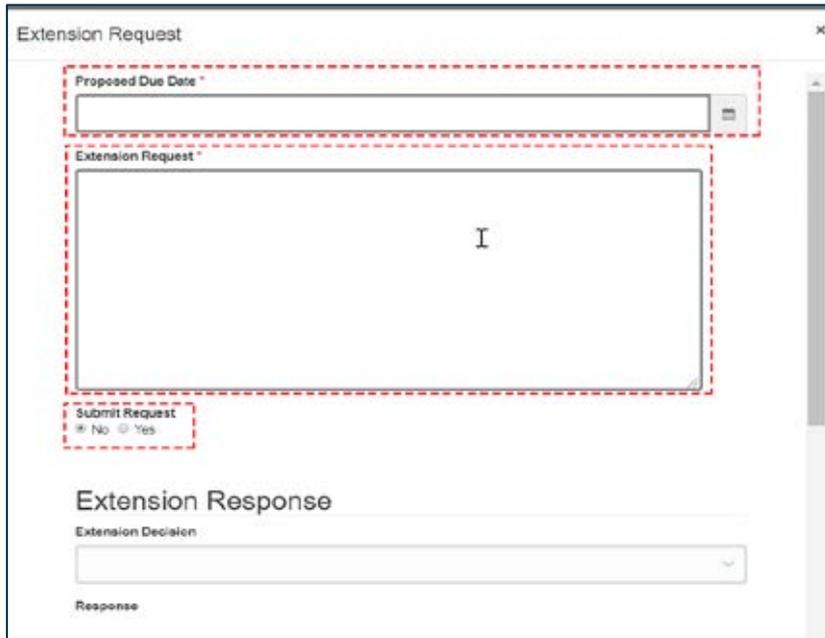
Extension Requests 1

Request Extension

Proposed Due Date	Extension Decision	New Due Date	Submit Request?	Created On	
30/07/2020	Pending	05/06/2020 8:00 AM	Yes	30/04/2020 11:24 AM	▼
10/06/2020	Disapproved		Yes	30/04/2020 11:23 AM	▼

## Instructions

4. Complete the fields.
  - a. In the **Proposed Due Date** field, enter the new date. Note: this date must be later than the current RFI date.
  - b. In the **Extension Request** field, enter the reason for requesting for an extension.
  - c. If you're ready to submit the request, select **Yes**. If not, select **No** to save the request and submit at a later date.



Extension Request

Proposed Due Date \*

Extension Request \*

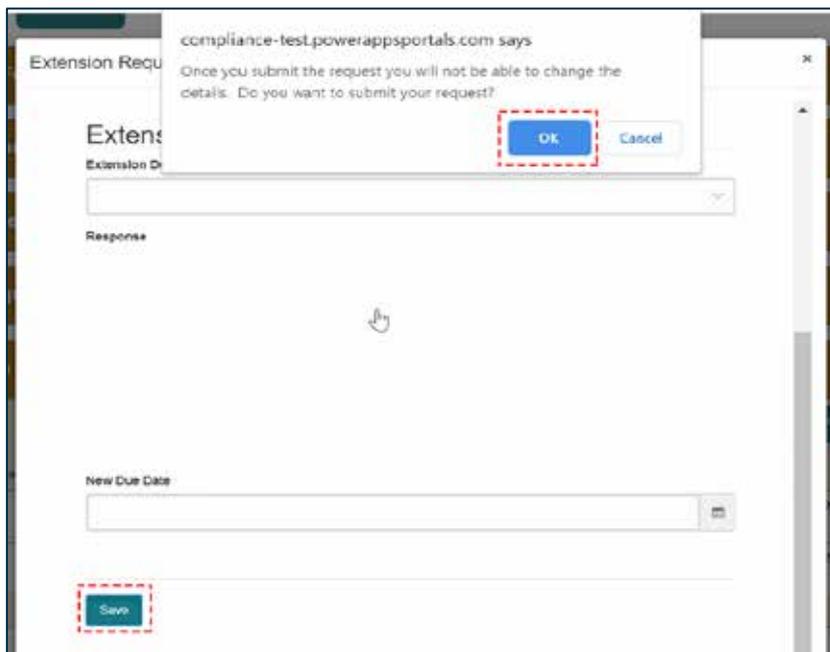
Submit Request  
No Yes

Extension Response

Extension Decision

Response

5. Click **Save**.
  - a. Click **OK**.



compliance-test.powerappsportals.com says  
Once you submit the request you will not be able to change the details. Do you want to submit your request?

OK Cancel

Extension Decision

Response

New Due Date

Save

# How to respond to a “Proposal to cancel” or “Proposal to suspend”

You can view and respond to these types of notifications by following the instructions below.

## Instructions

1. Click **Draft**.

**PMR Compliance Dashboard**

Notification - Active

Search

Reference Number	Review Description	Sponsor Name	Notification Type	Status	Response Due Date	
PMR-2020-01309	Devices - ARTG	TTGA	S41GB Proposal to suspend	Sent/Awaiting Response	29/10/2020 5:00 PM	<b>Draft</b>
PMR-2020-01309	Devices - ARTG	TTGA	Section 41JA	Sent/Awaiting Response	29/10/2020 5:00 PM	View details Preview

2. You can view the notification details in the **Notification Details** section.

In the Notification Documents section, you can view all the documents associated to this notification.

**Notification Details**

**S41GB Proposal to suspend of the Therapeutic Goods Act 1989**

The TGA is conducting a post market review of Devices - ARTG.

Notification Name	Review Reference Number
PMR-2020-01309 - TTGA - 02	PMR-2020-01309

**Review in scope**  
All ARTG entries that are required for this review are single Sponsor

**Review out of scope**  
All ARTG entries not required in this review are from all remaining Sponsors

**Notification Documents**

Name	Modified
Emails	28/09/2020 10:04 AM
Large Files	28/09/2020 10:04 AM
TGA - TGAUAT PRODUCT-Adaptor specify	28/09/2020 10:05 AM

## Instructions

3. In the **ARTGs and Model Details** section, click on **Add Response** to respond to the selected ARTG.

**ARTGs and Model Details** !

The following ARTG entries have been selected for a post-market medical device review

Click on the arrow to the right of the ARTG entry to select 'Add Response'.

ARTG ID	ARTG Entry Name	ARTG Status	Status	Created On ↓
1518446	ITGA - TGAUAT PRODUCT-Adaptor, specify	Active	Draft	28/09/2020 10:04 AM

**Add Response**

4. Click **Proceed**.

**Add Response** ×

Do you want to add a Response to this ARTG?

**Proceed** Cancel

5. Click on **Created On** to enter the evidence of compliance for the selected ARTG.

**ARTGs and Model Details** !

The following ARTG entries have been selected for a post-market medical device review

Click on the arrow to the right of the ARTG entry to select 'Add Response'.

ARTG ID	ARTG Entry Name	ARTG Status	Status	Created On ↓
1518446	ITGA - TGAUAT PRODUCT-Adaptor, specify	Active	Completed	28/09/2020 10:04 AM

**ARTG Responses**

Click on the arrow to the right of the Response to select 'Edit' to enter the evidence of compliance.

Response Name ↑	ARTG Entry Name	Created On ↑
Response for EP 1 - Use of medical devices not to compromise health and safety for ARTG Number(s) 1518446	ITGA - TGAUAT PRODUCT-Adaptor, specify	02/10/2020 3:30 PM

**Created On**

6. Click **Edit**.

**ARTG Responses**

Click on the arrow to the right of the Response to select 'Edit' to enter the evidence of compliance.

Response Name	ARTG Entry Name	Created On ↑
Response for EP 1 - Use of medical devices not to compromise health and safety for ARTG Number(s) 1518446	ITGA - TGAUAT PRODUCT-Adaptor, specify	02/10/2020 3:30 PM

**Edit**

## Instructions

### 7. Select how you wish to respond.

**Edit ARTG Response**

ARTG  
TGA - TGAUAT PRODUCT/Adaptor, specify

Legislative Breaches

Breaches under investigation Row Number ↕

EP 1 - Use of medical devices not to compromise health and safety	1
---	---

How do you wish to provide your response?

- Provide a summary
- Attach evidence of compliance
- Both

### 8. Enter your summary.

How do you wish to provide your response?

Both

Summary

### 9. Upload your files. You have two options (“Add files” and “Upload Large files”) to upload a copy of the Instructions For Use (IFU), for both in scope and out of scope devices. Refer to instructions:

- 9a to use the “Add files” button to upload documents less than 50MB size.
- 9b to use the “Upload Large files” button to upload documents more than 50MB size.



Please note, folders are being created in the background to store information so it may take 1 to 2 minutes for the “Add files” and “Upload Large files” buttons to appear.

- a. Click on **Add files** button to upload files less than 50MB size.

Attach the English version of your evidence of compliance.  
It is advised that you include the ARTG and model when entering a file name for easy identification. 'Add files' support upto 50MB. 'Upload Large files' support upto 5GB. Large File Folder created in SharePoint should not be removed under any circumstance.

There are no folders or files to display.

Click **Choose files** and select the file you want to upload. Once you have selected your file, click on **Add files** button.

Add files ✕

Choose files  D20-86296 ...3) (1).docx

Overwrite existing files

The file you uploaded will be displayed.

Attach the English version of the Instructions for Use provided with or on the device.  
It is advised that you include the ARTG and model when entering a file name for easy identification. 'Add Files' support upto 50MB. 'Upload Large files' support upto 5GB. Large File Folder created in SharePoint should not be removed under any circumstance.

Name ↑	Modified
 D20-86296 DPMRRS TEMP 1.1 b s41JA Requirements for informat...	21/09/2020 3:39 PM

Select the check-box to acknowledge that at least one file has been uploaded and click **Save**.

Attach the English version of the Instructions for Use provided with or on the device, additional information about the samples.  
It is advised that you include the ARTG and model when entering a file name for easy identification. 'Add files' support upto 50MB. 'Upload Large files' support upto 5GB. Large File Folder created in SharePoint should not be removed under any circumstance.

Name ↑	Modified
 test.txt (1 KB)	01/10/2020 10:40 AM

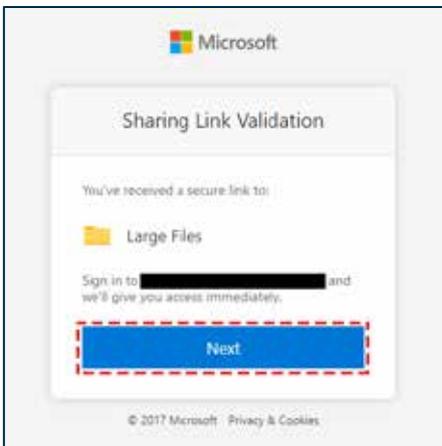
Please provide your acknowledgement that at least one file has been uploaded

**Instructions**

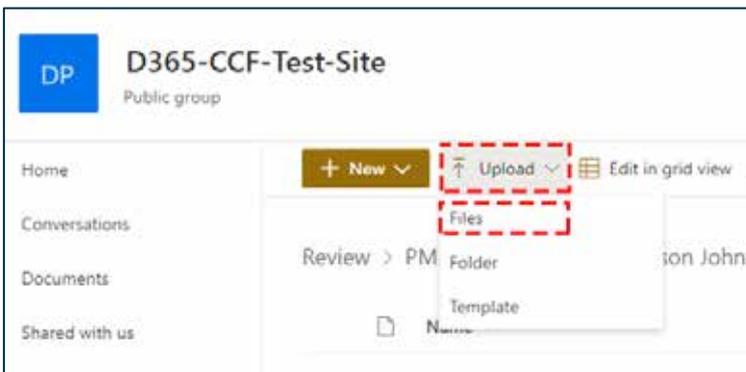
b. Click on **Upload Large files** button to upload files more than 50MB size.



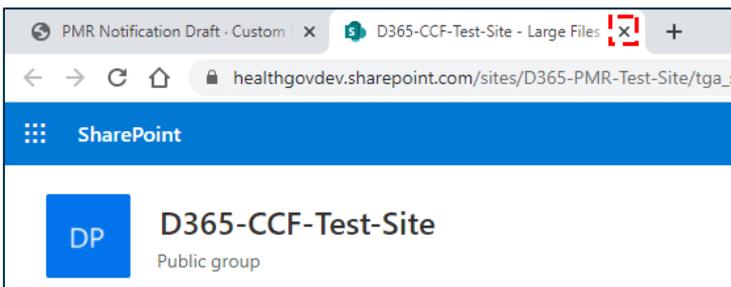
A new window will open directing you to the SharePoint site. Click **Next**.



Click **Upload** and then **Files**.



Close the window once you have uploaded the large file(s).



## Instructions

Select the check-box to acknowledge that at least one file has been uploaded and click **Save**.

Attach the English version of the Instructions for Use provided with or on the device, additional information about the samples.  
*It is advised that you include the ARTG and model when entering a file name for easy identification. 'Add files' support upto 50MB. 'Upload Large files' support upto 5GB. Large File Folder created in SharePoint should not be removed under any circumstance.*

Name ↑	Modified
<input type="checkbox"/> test.txt (1 KB)	01/10/2020 10:40 AM

Please provide your acknowledgement that at least one file has been uploaded

10. Click on **Validate**.

**Other Required Responses** +

11. Click **Preview** to view your responses.

PMR Notification Draft

The Notification has been successfully validated. Please click on the 'preview' button to preview Responses. Click on the 'Declare' button to do the declaration of Notification

## Instructions

Print

### S41GB Proposal to suspend of the Therapeutic Goods Act 1989

The TGA is conducting a post market review of Devices - ARTG.

**Notification Name:** PMR-2020-01309 - ITGA - 02 **Review Reference:** PMR-2020-01309

**Review in scope:** All ARTG entries that are required for this review are single Sponsor

**Review out of scope:** All ARTG entries not required in this review are from all remaining Sponsors

### ARTGs and Model Details

#### ARTG

ARTG ID: 1518446

ARTG Entry Name: ITGA - TGAUAT PRODUCT-Adaptor, specify

ARTG Status: Active

Status: Completed

#### Response

Name: Response for EP 1 - Use of medical devices not to compromise health and safety for ARTG Number(s) 1518446

How do you wish to provide your response? Both

Response: For testing purposes

### Models

#### Model

ARTG ID: 1518446

ARTG Entry Name: ITGA - TGAUAT PRODUCT-Adaptor, specify

ARTG Status: Active

GMDNS Code: TG15184466

Manufacturer Name:

Model:

Is this model in the scope of the review? Yes

Cloned? No

12. If no further changes needs to be made, click **Declare**.

### PMR Notification Draft

This Notification has been successfully submitted. Please click on the "Review" button to review Responses. Click on the "Declare" button to do the declaration of Notification.

Preview

Declare

13. Select **No** or **Yes** if you agree to the declaration and click **Submit**.

Declaration

### General

I understand that this is the final submission to a regulatory notification and this information will be used by the Therapeutic Goods Administration in evaluating compliance with the Therapeutic Goods Act 1989 and the Therapeutic Goods (Medical Devices) Regulations 2002.

I understand that the documents and information provided is required to be in English.

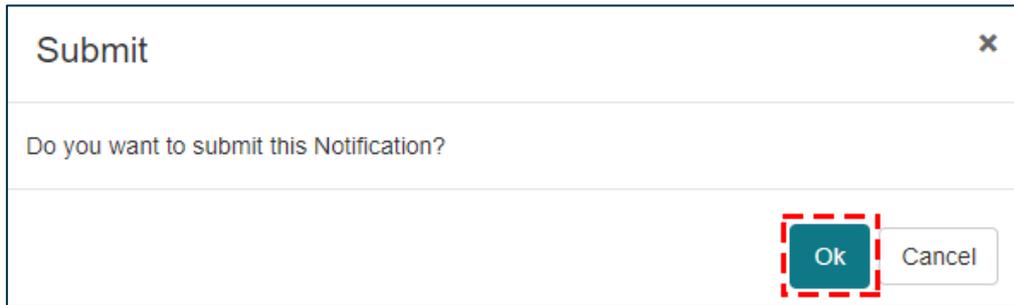
I agree to the declaration

No  Yes

Submit

## Instructions

14. Click **OK**.



The image shows a dialog box titled "Submit" with a close button (X) in the top right corner. The main text of the dialog asks, "Do you want to submit this Notification?". At the bottom right, there are two buttons: "Ok" and "Cancel". The "Ok" button is highlighted with a red dashed border, indicating it is the target for the instruction.

## Version history

<b>Version</b>	<b>Description of change</b>	<b>Author</b>	<b>Effective date</b>
V1.0	Original publication	Medical Devices Surveillance Branch	October 2020
V1.1	Minor additions to clarify drafting of responses process	Medical Devices Surveillance Branch	December 2020
V1.2	Minor additions to clarify drafting process and order of processes	Medical Devices Surveillance Branch	March 2021

## **Therapeutic Goods Administration**

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Reference/Publication #