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

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.

Contents

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.

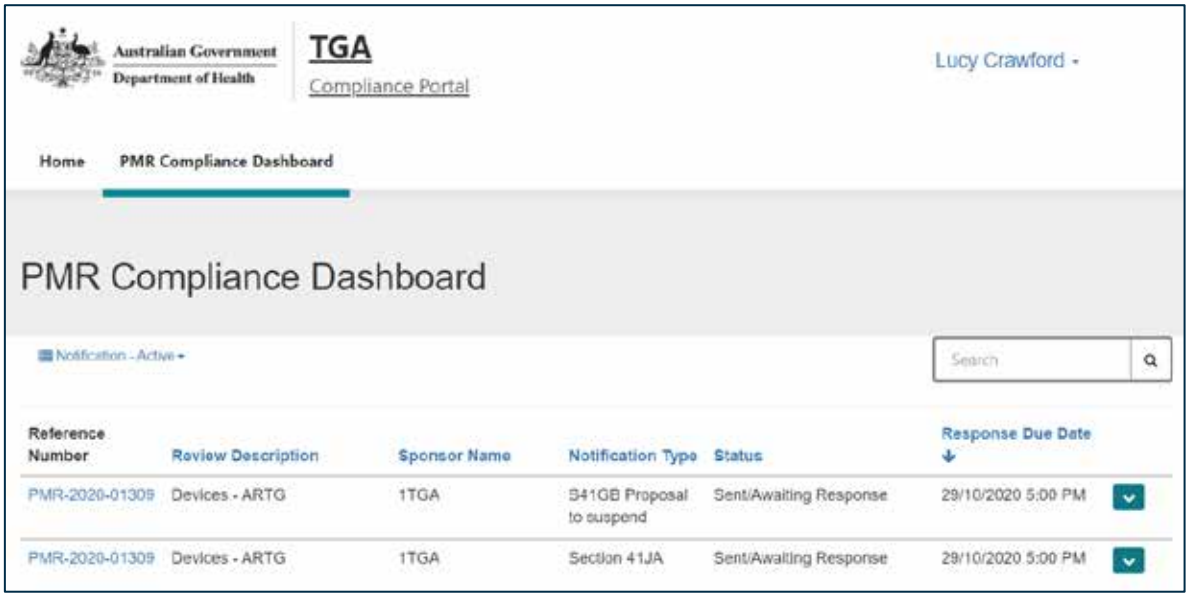
How to login to the PMR compliance dashboard

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.

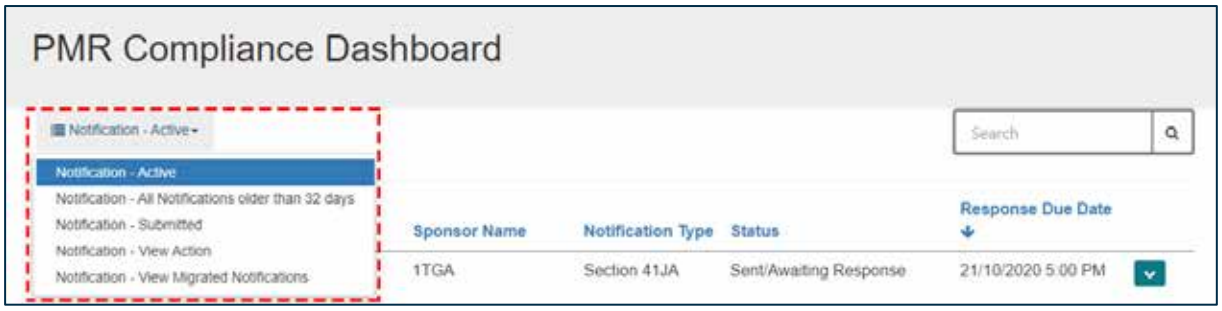
2. You will be directed to the PMR Compliance Dashboard where the Request For Information (RFIs) will be displayed.



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:

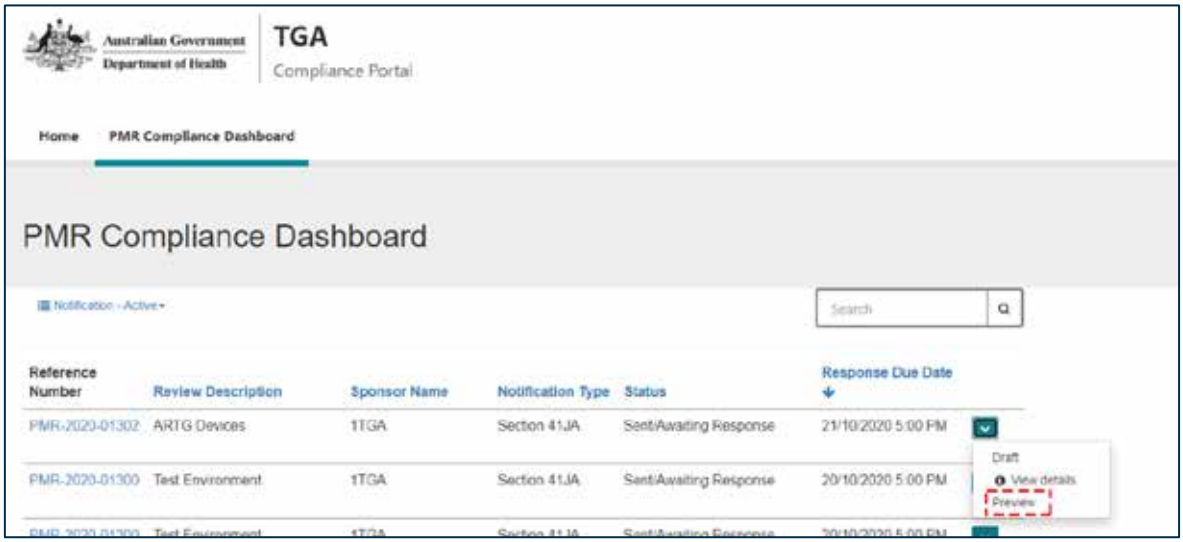
1. Preview your notification
2. Draft a response to your notification

Preview your notification

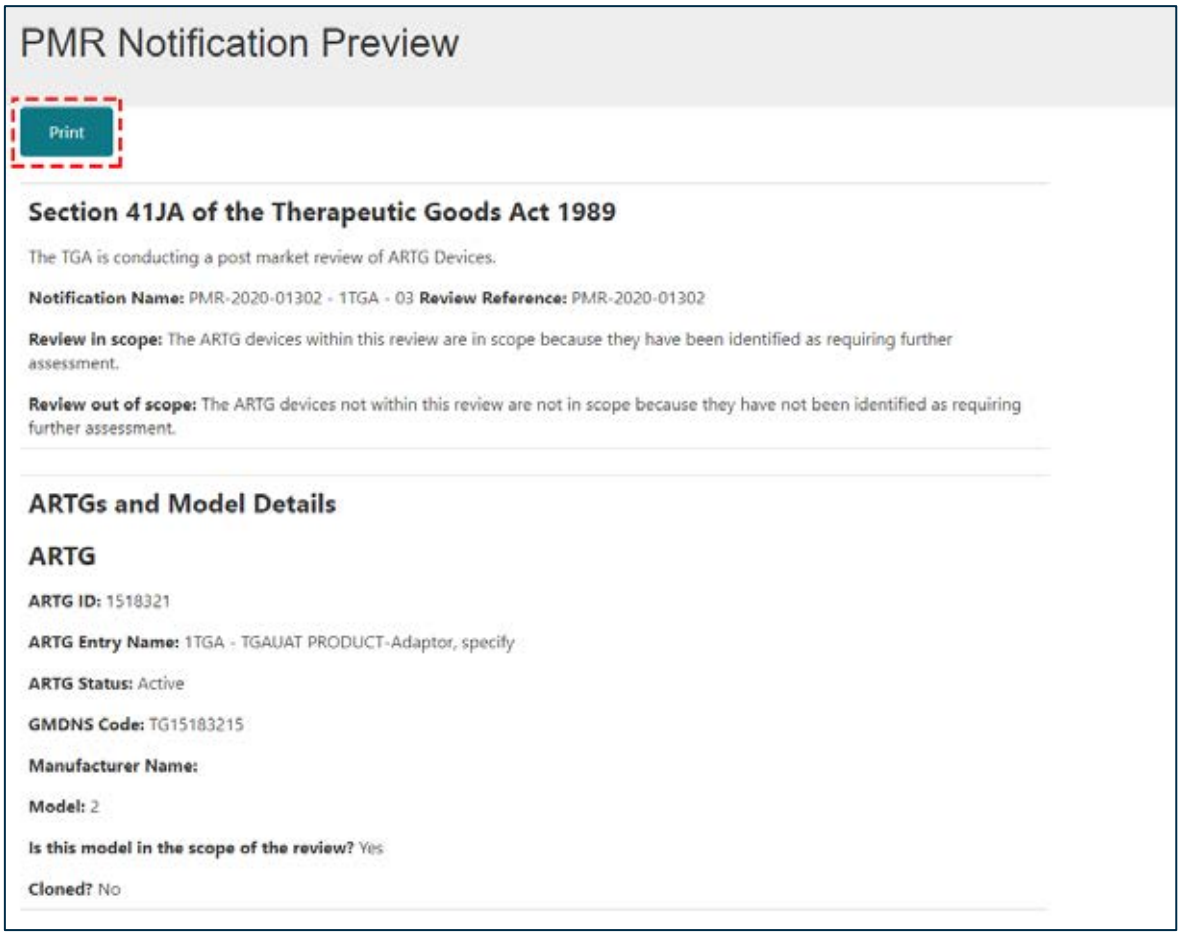
You can view your notification from the **Preview** screen. You cannot add a response from this view. Additionally, selecting **View Details** or the **reference number** will show a 'read-only' preview.

Instructions

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



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.



Instructions

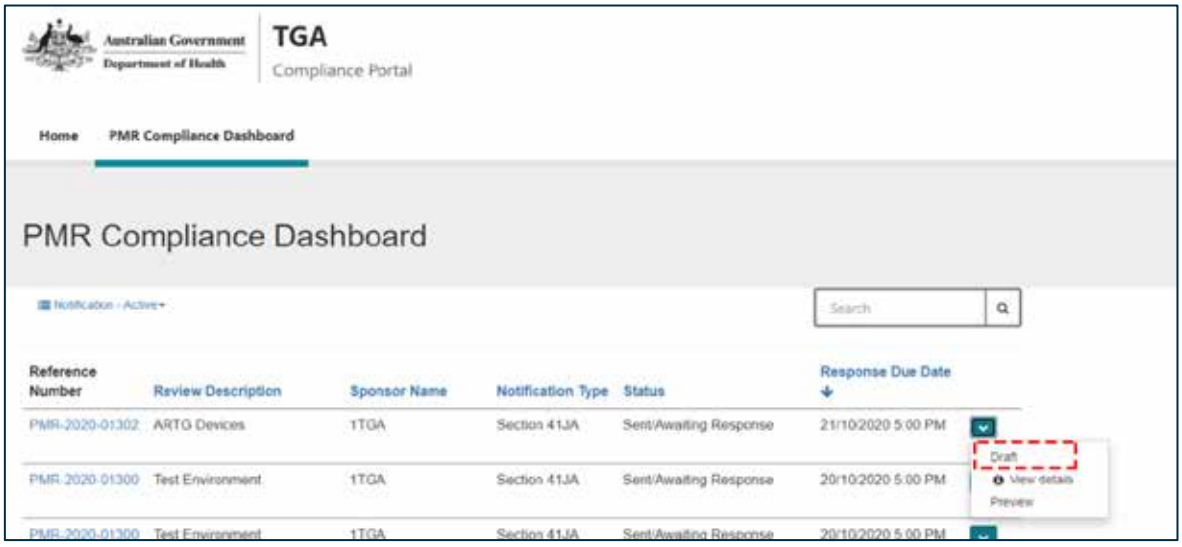
c. Once you have viewed your notification, click on the back-browser button to go back to the PMR Compliance Dashboard.

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.

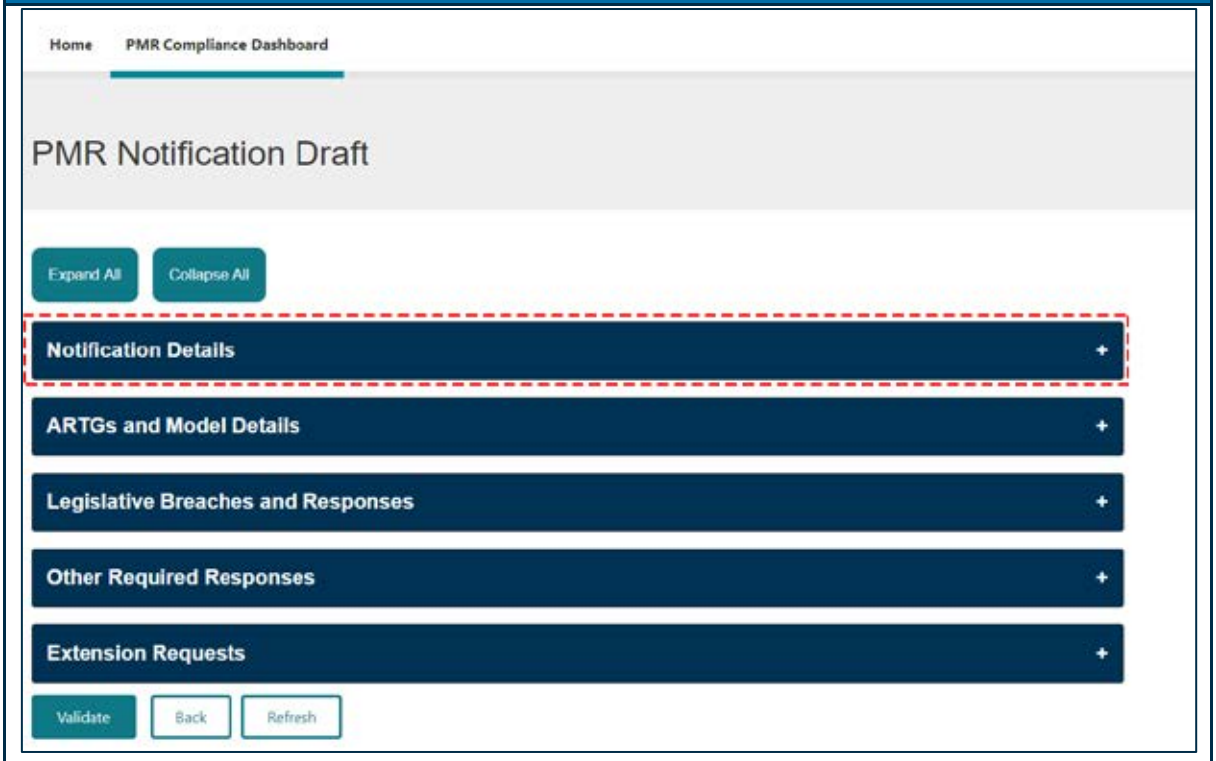
Instructions

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

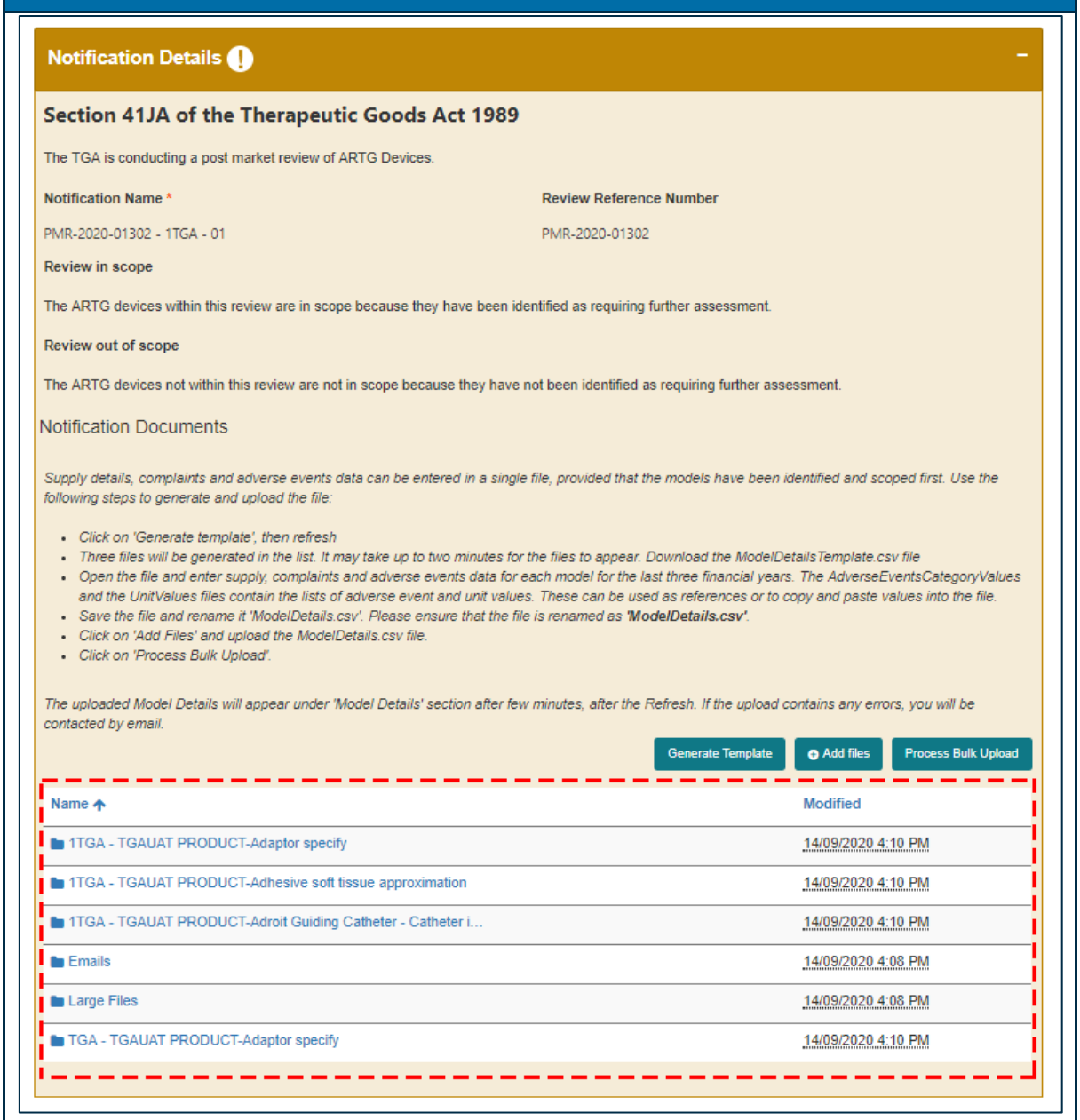


e. In the Notification Details section, you can view the details for the notification.

Instructions



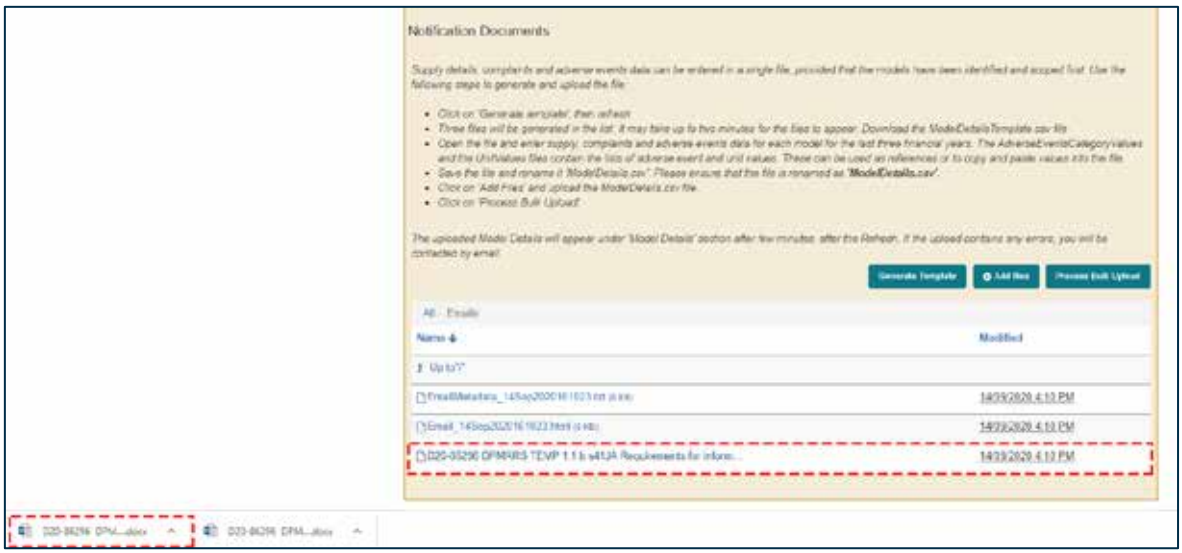
Instructions



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

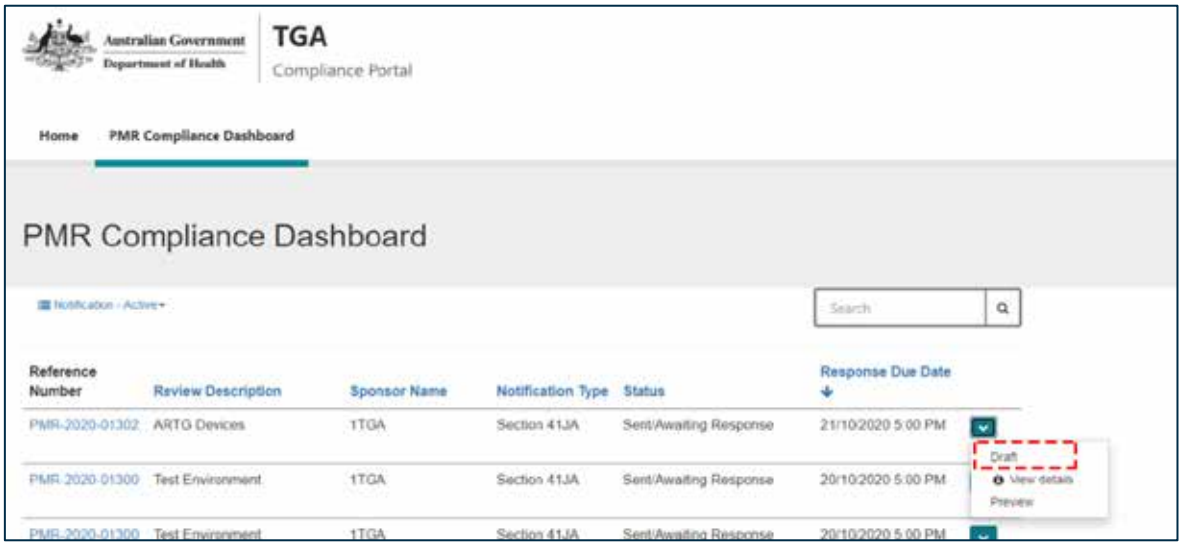
f. Click on the notification to download and open a copy of the letter. The notification will appear as a download at the bottom left of the screen.



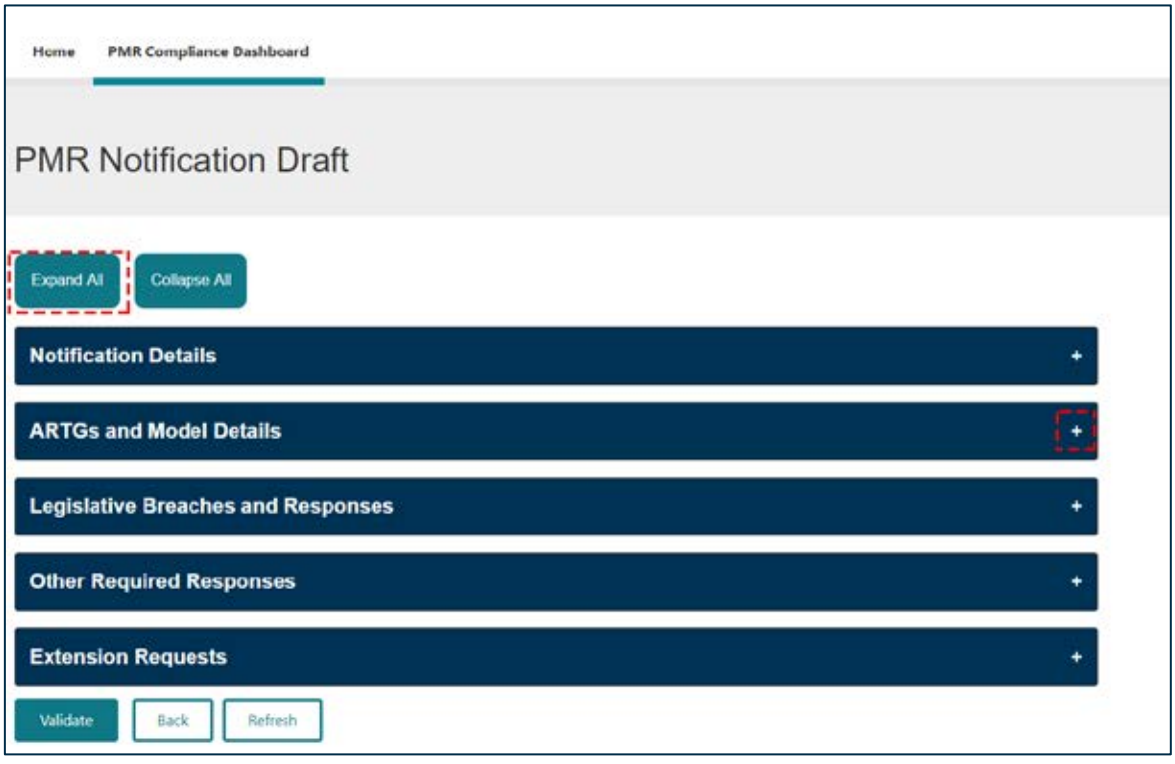
How to respond to a notification

Instructions

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



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



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.

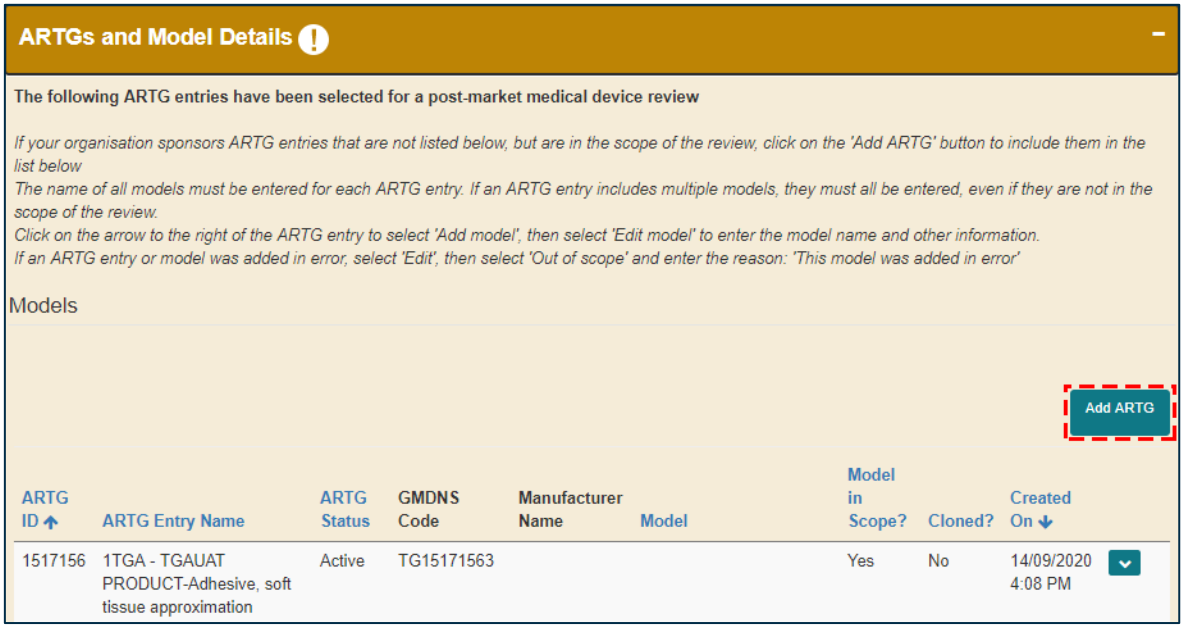
If this notification is an intial request for information (section 41JA or section 31 notification) you may add model details and additional ARTG entries that may be in scope of the post-market review.

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**.



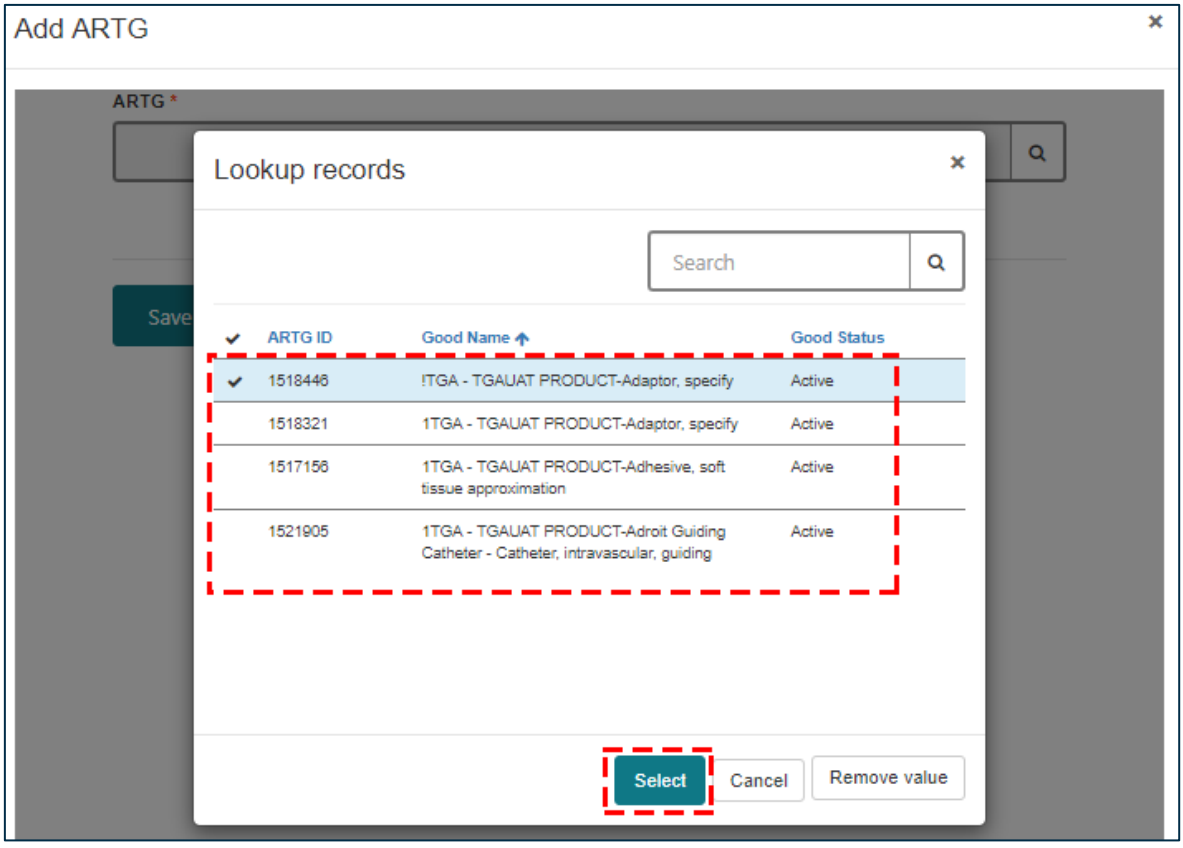
Instructions

3. Click on the search icon.

4. A list of the ARTG entries associated with your sponsor log in (both active and revoked entries) will be available for you to select.

   a. Select the ARTG that is related to this post-market review.

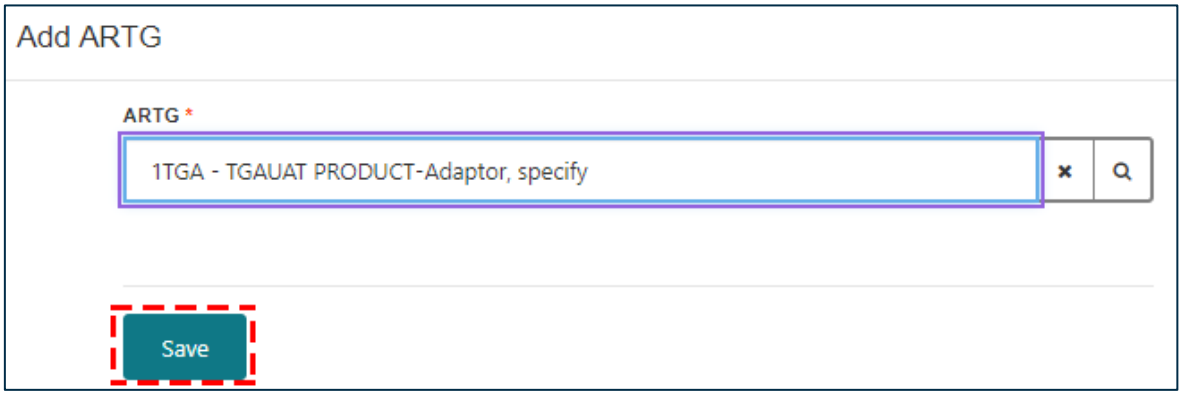
   b. Click **Select**.



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

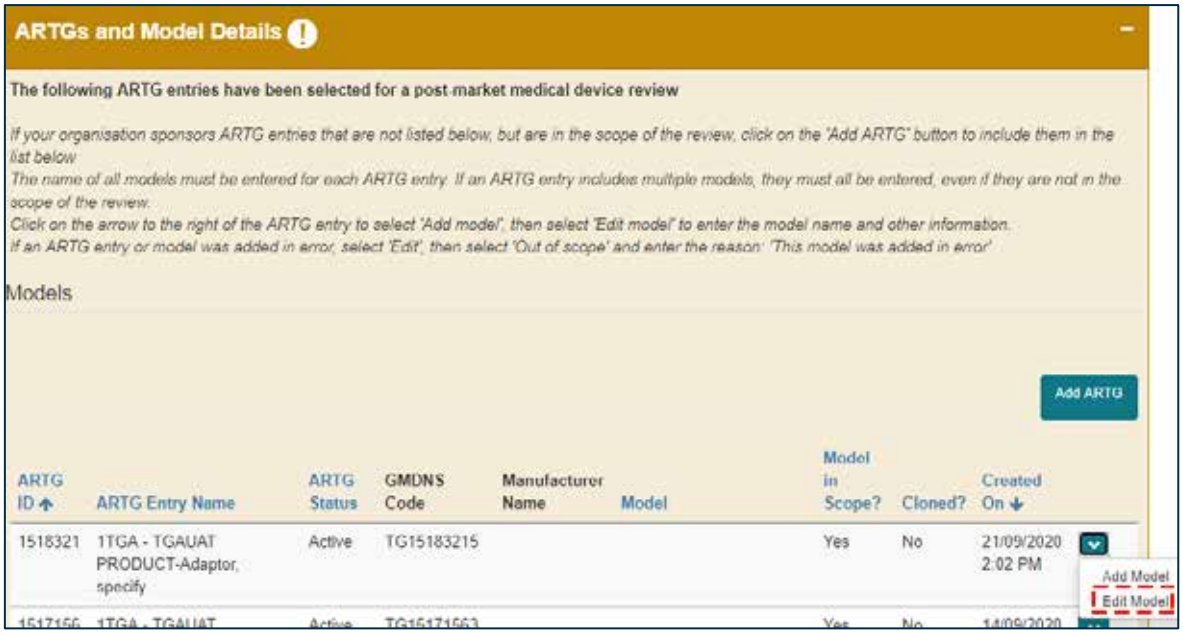
Instructions

5. Click **Save**.



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

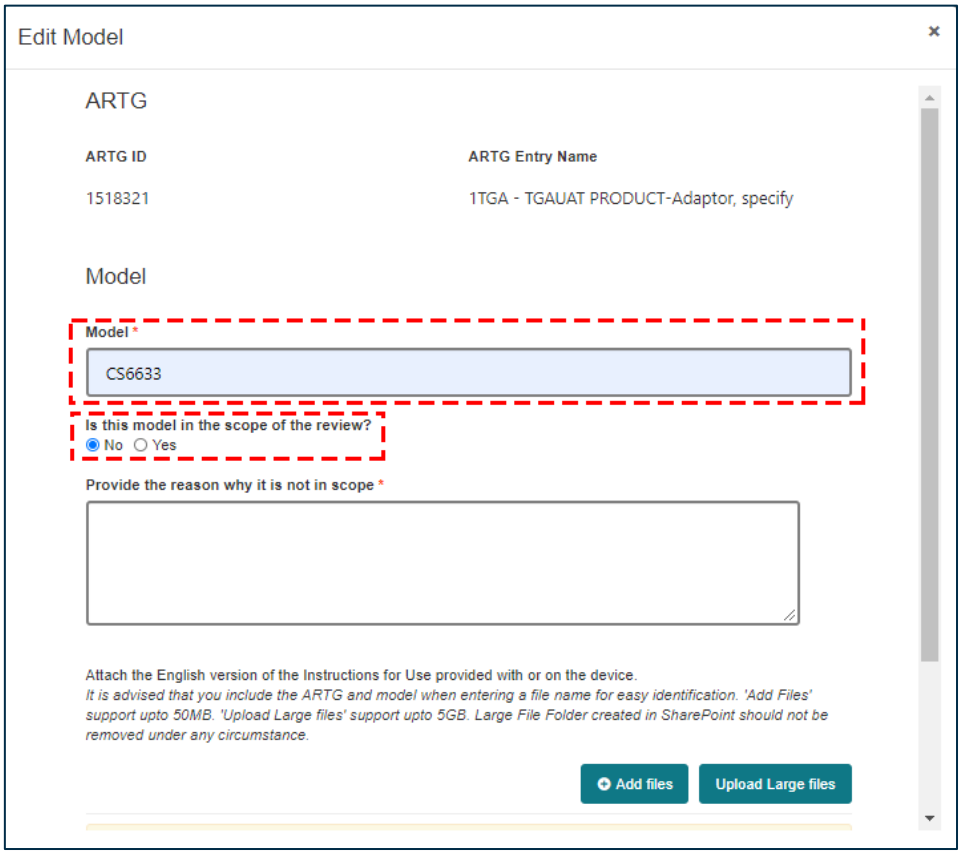
   a. Click Edit Model.



   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.

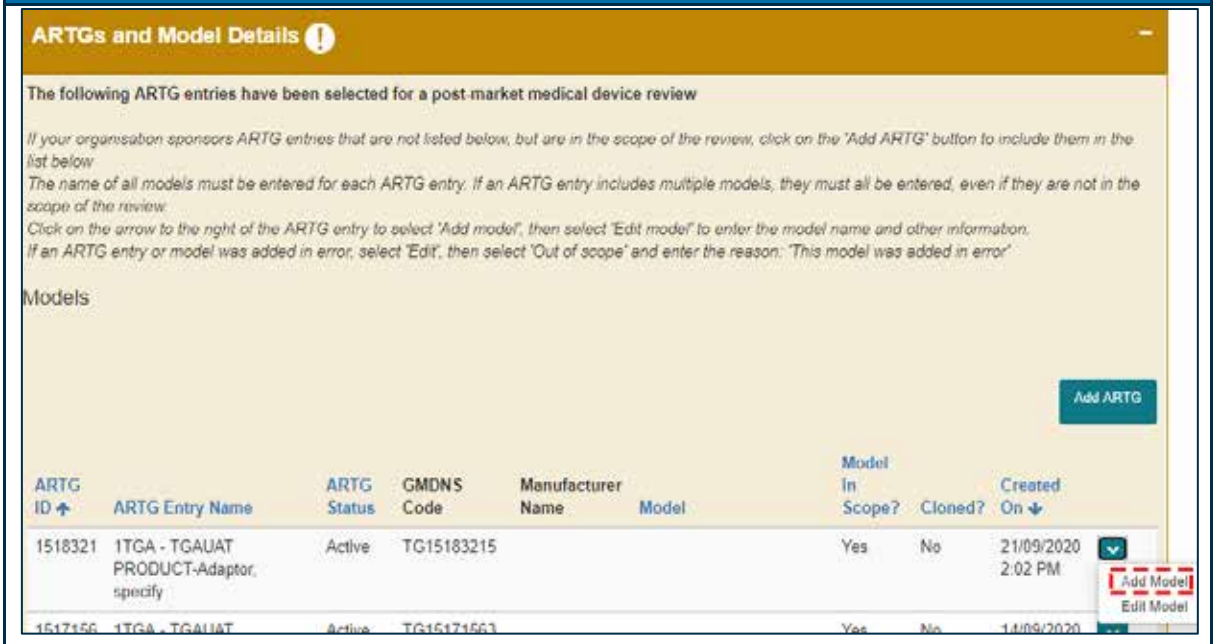


7. If there are multiple Models under the one ARTG entry, select Add model. This will clone the ARTG entry and cannot be deleted, but can be marked out of scope with N/A in the model number field if added in error.

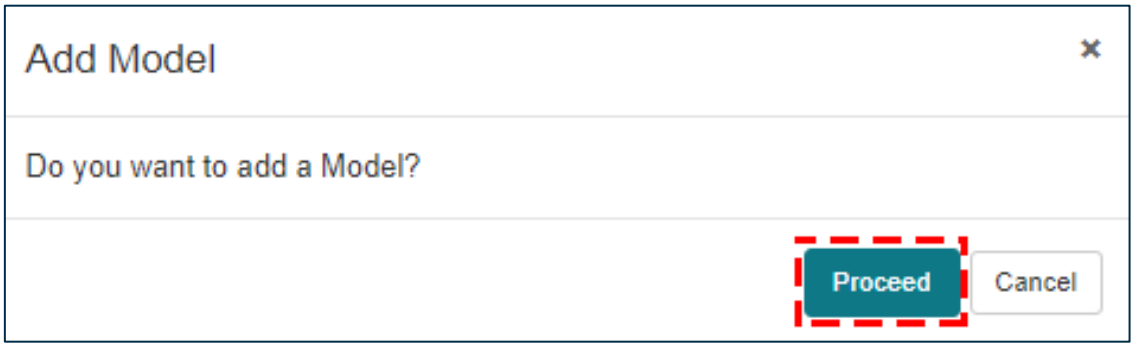
   a. Click **Add Model**

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



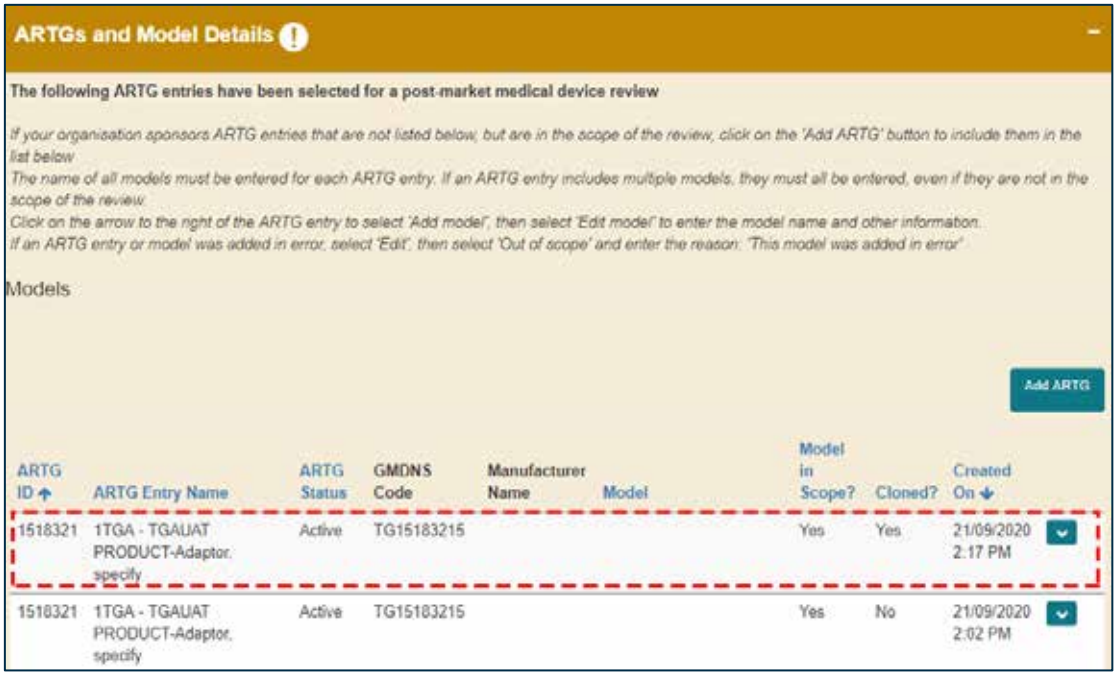
b. Click **Proceed**.



Instructions

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

Repeat step 6 and edit the model details.



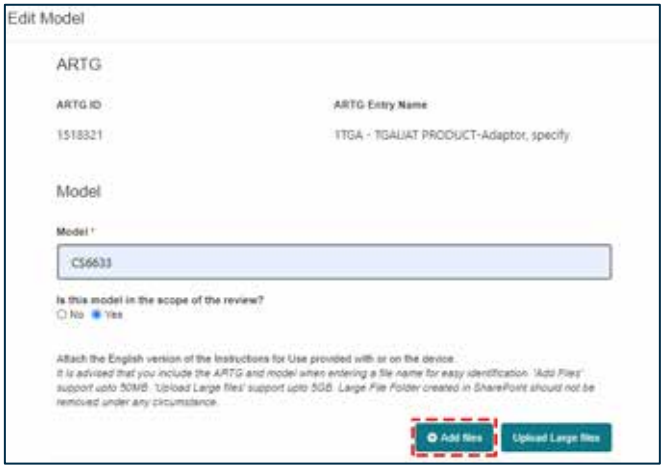
For each model of device (both those that you consider to be in-scope and out-of-scope of the post-market review) you will need to upload a copy of the Instructions For Use (IFU). There are two options dependent upon the size of the document:

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

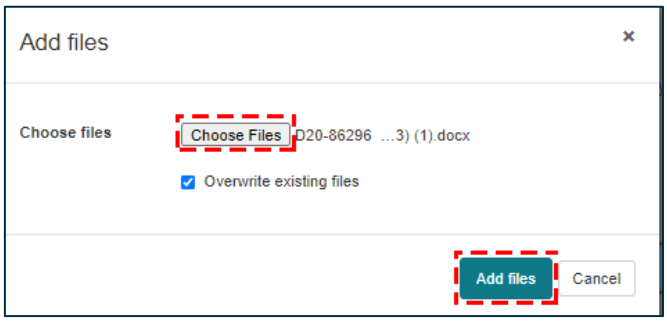
Please note, folders are created in the background during this process to store the information so it may take 1 to 2 minutes for the "Add files" and "Upload Large files" buttons to appear.

8. To add files less than 50MB size:

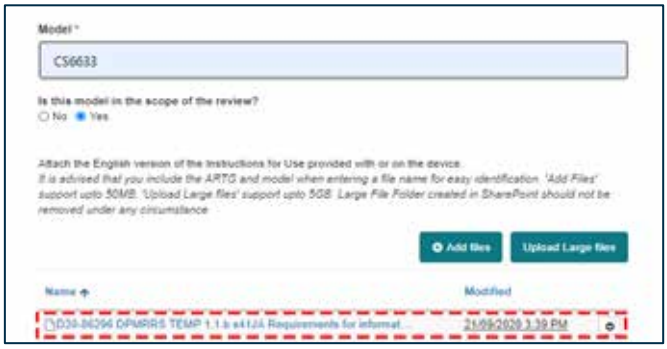
   a. Click on **Add files**.



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



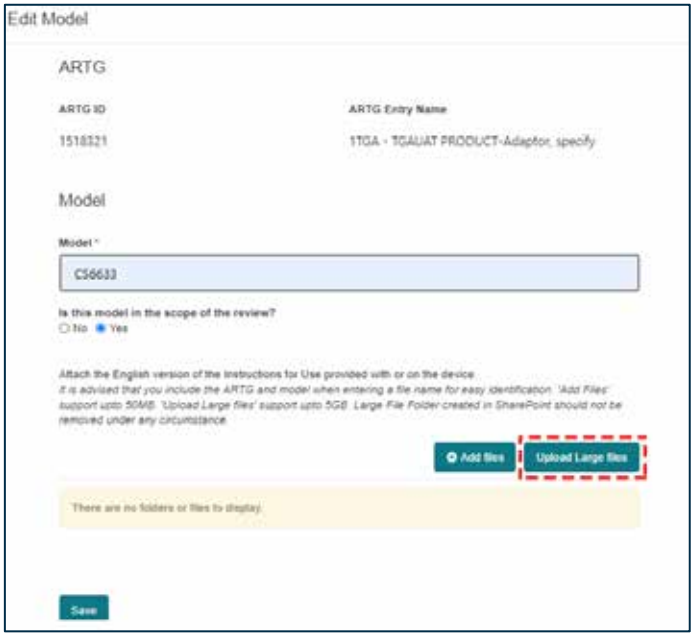
The file you uploaded will be displayed.



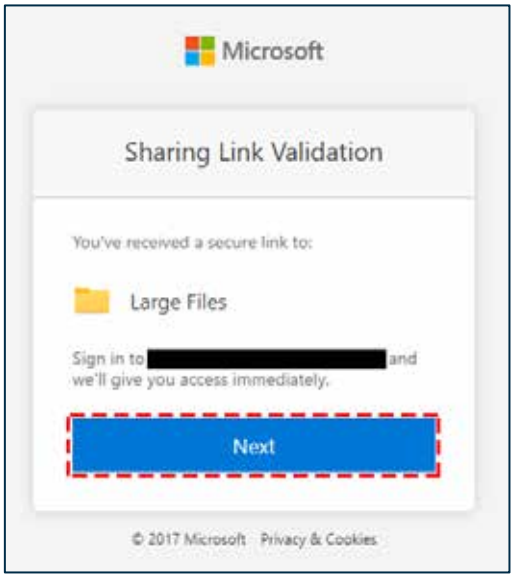
   c. Select the check-box to acknowledge that at least one file has been uploaded and click **Save**.

9. To add files more than 50MB size:

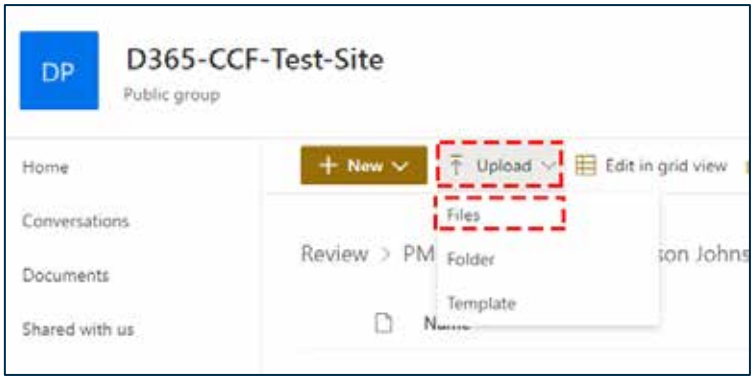
   a. Click on **Upload Large file**.



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

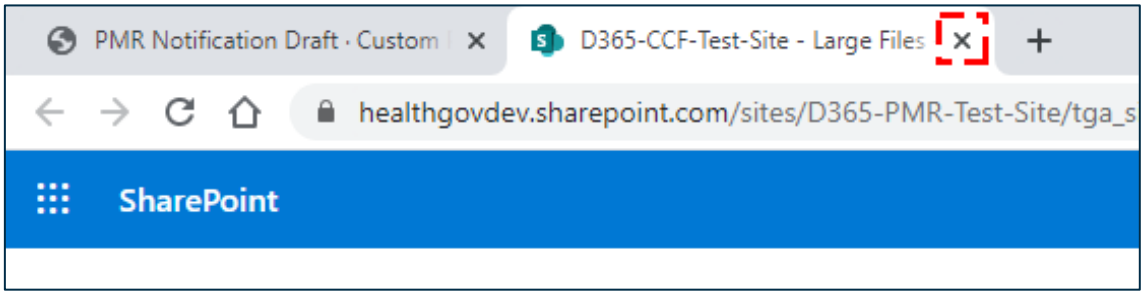


   c. Click **Upload** and then **Files**.

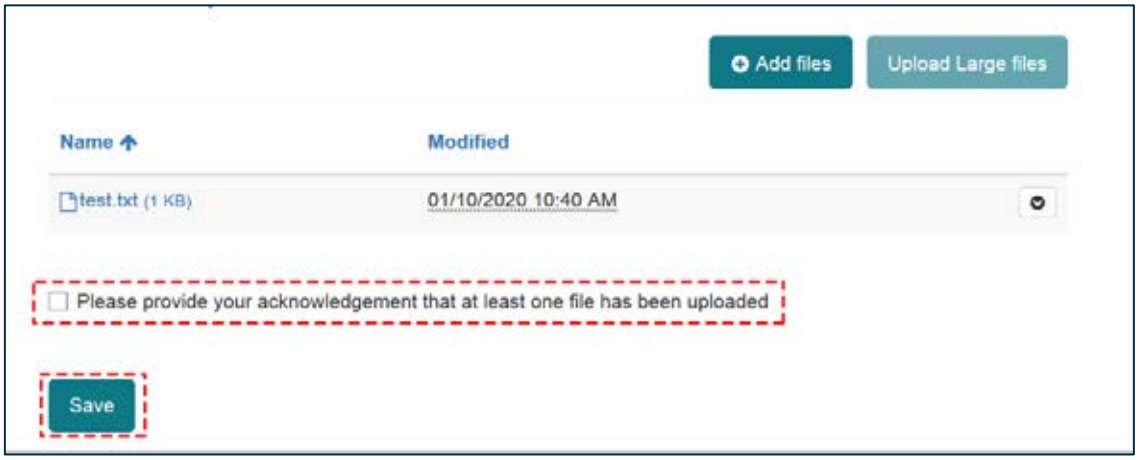


Instructions

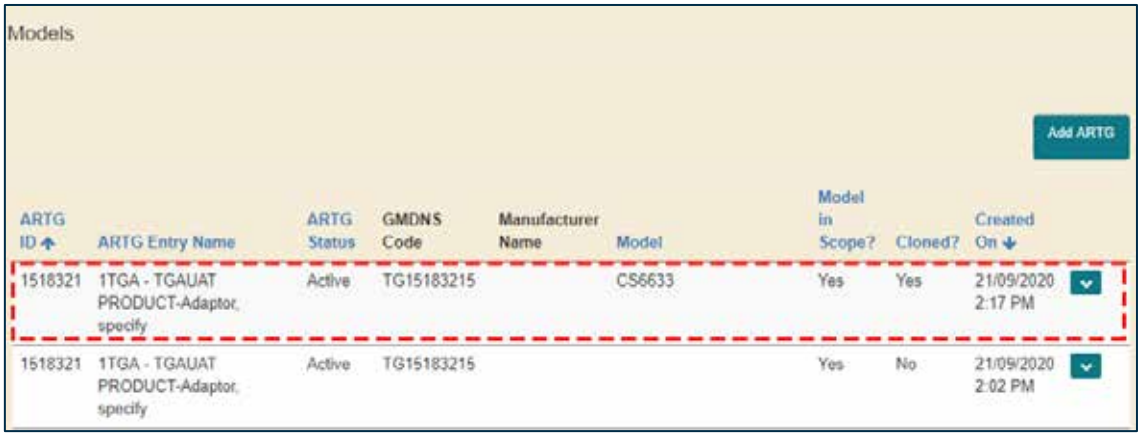
d. Upload your file and close the window once you have uploaded the large file(s).



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.



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

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:

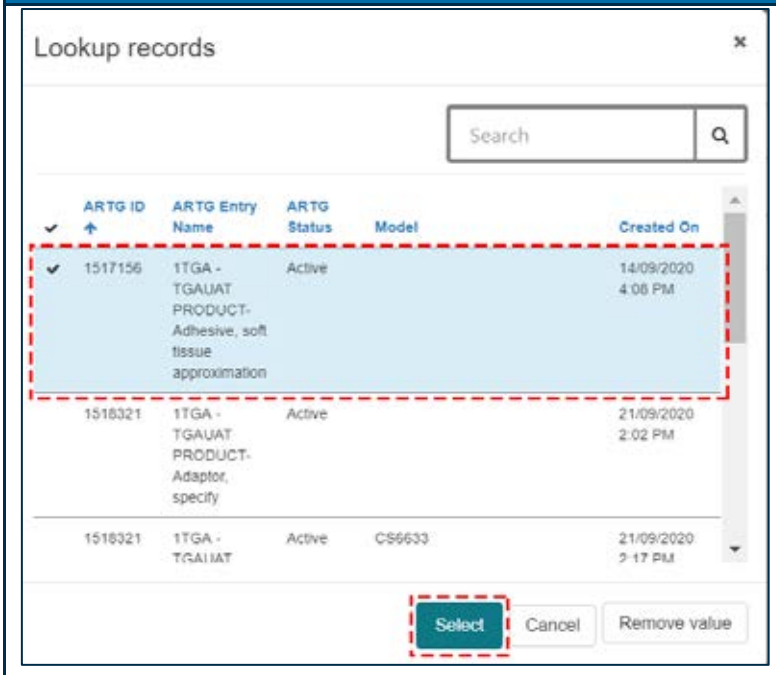
    a. Click on **Add Model Financial Year** button to select which model you are going to add the financial year data against.

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

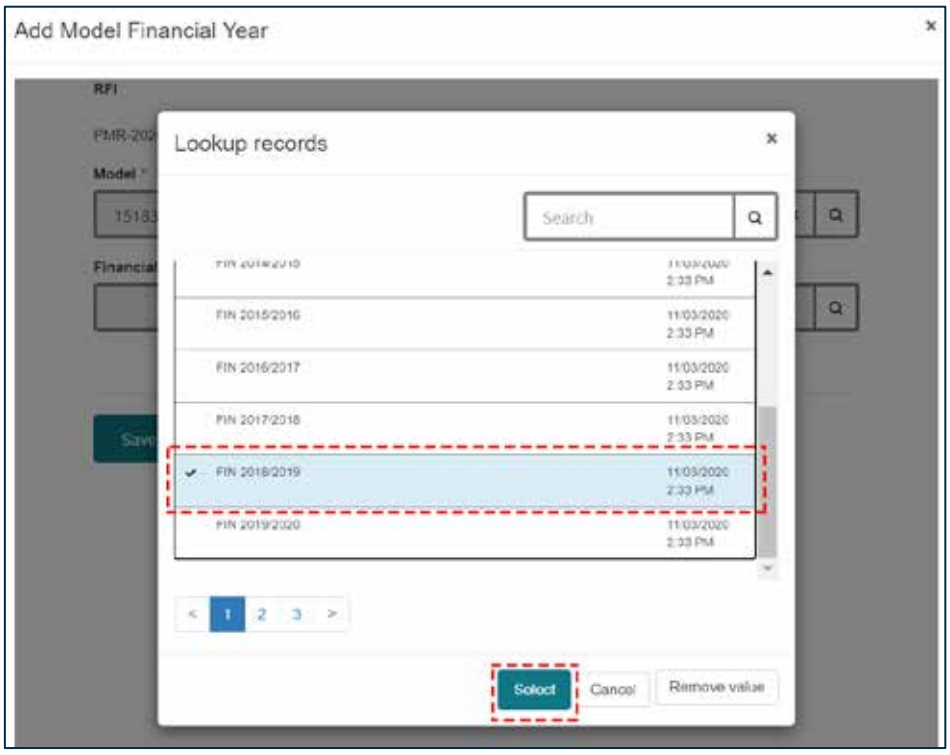
    c. Select the model and click **Select**.

Only the models in scope will be displayed.

Instructions



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

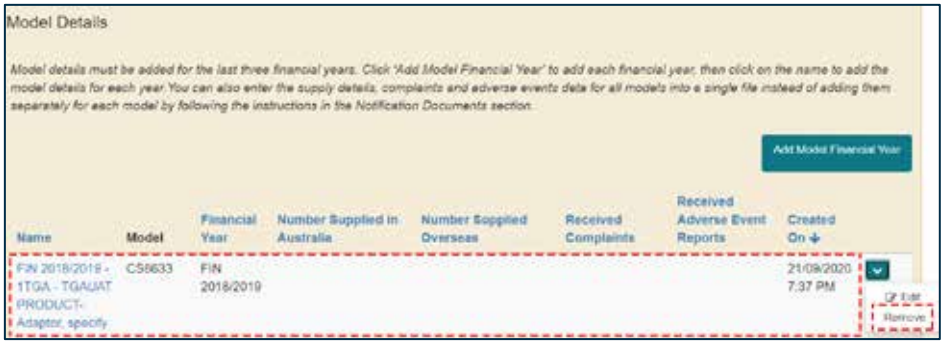


Instructions

e. Click **Save**.

The financial year details are updated.

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



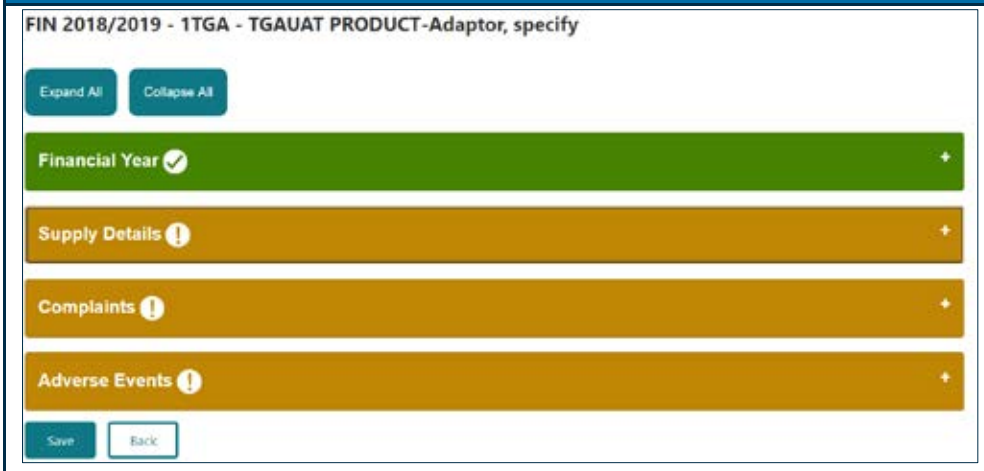
11. The following instructions outline how to add the supply details, complaints and adverse events data. Please check the notification for details on how many financial years you are required to provide data for.

    a. Click **Edit**.

This is the overarching screen that will appear.

Each screen will turn green as you complete each section.

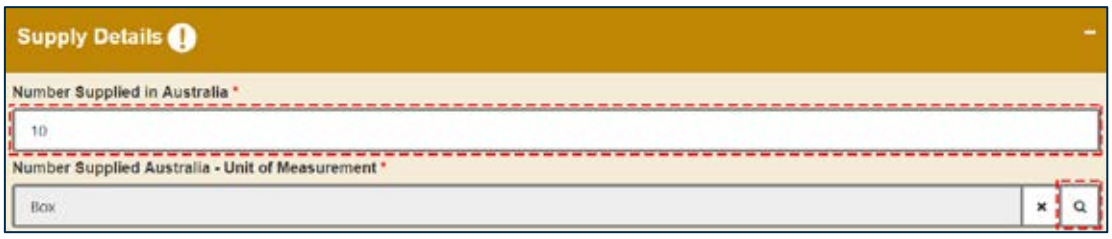
Instructions

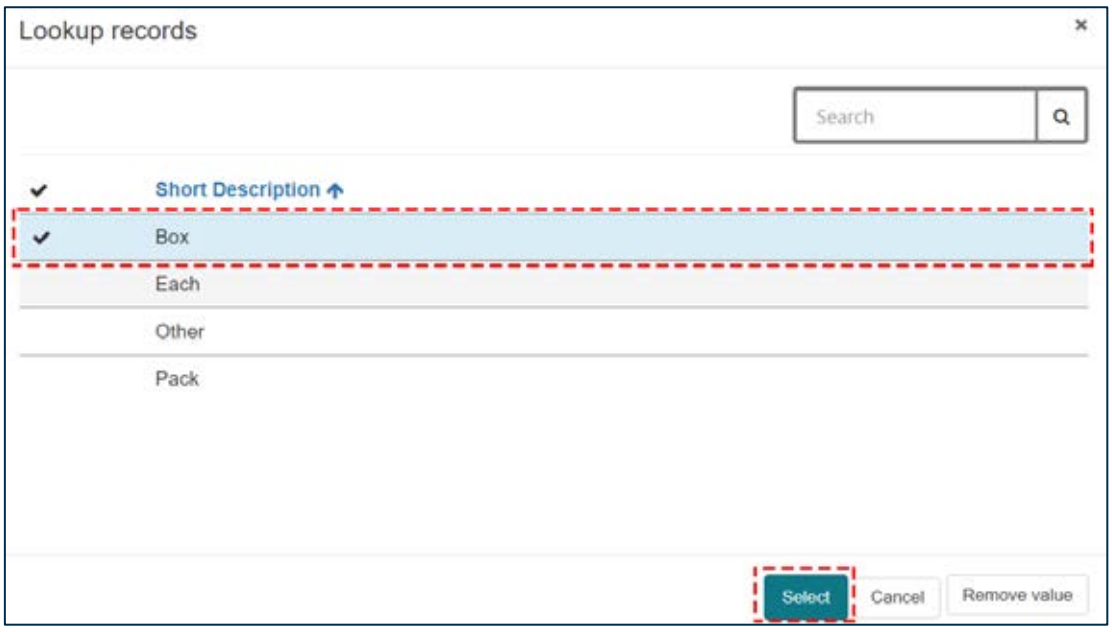


12. In the **Supply Details** section:

    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:

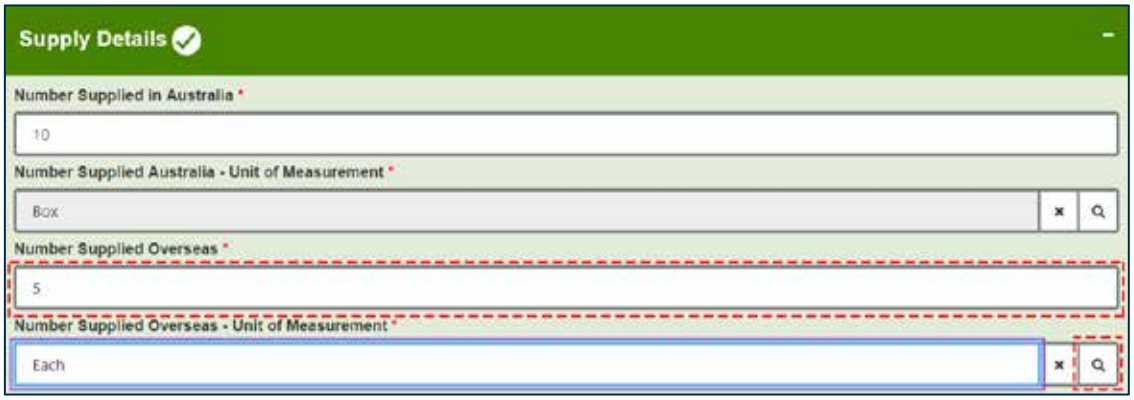
    - Box
    - Each
    - Pack
    - Other





Instructions

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



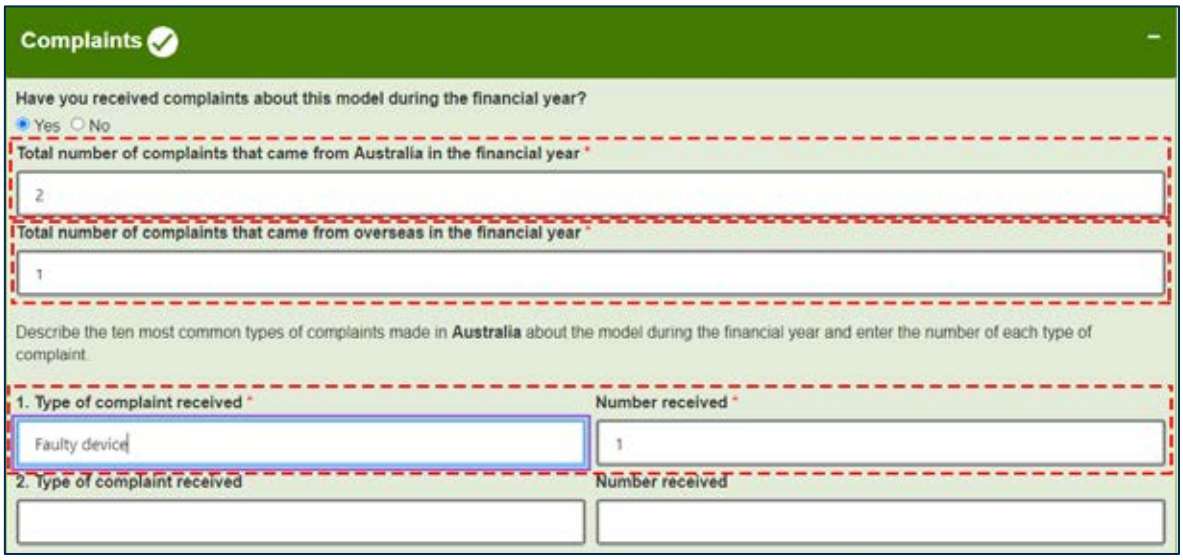
13. In the **Complaints** section:

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

a. If you select **No**, complete the Adverse Events section in step 14.

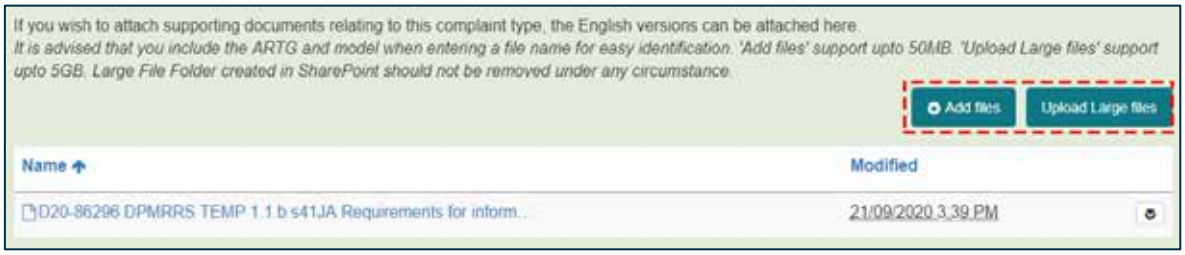
b. If you select **Yes**, complete the following steps:

- 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**.



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.

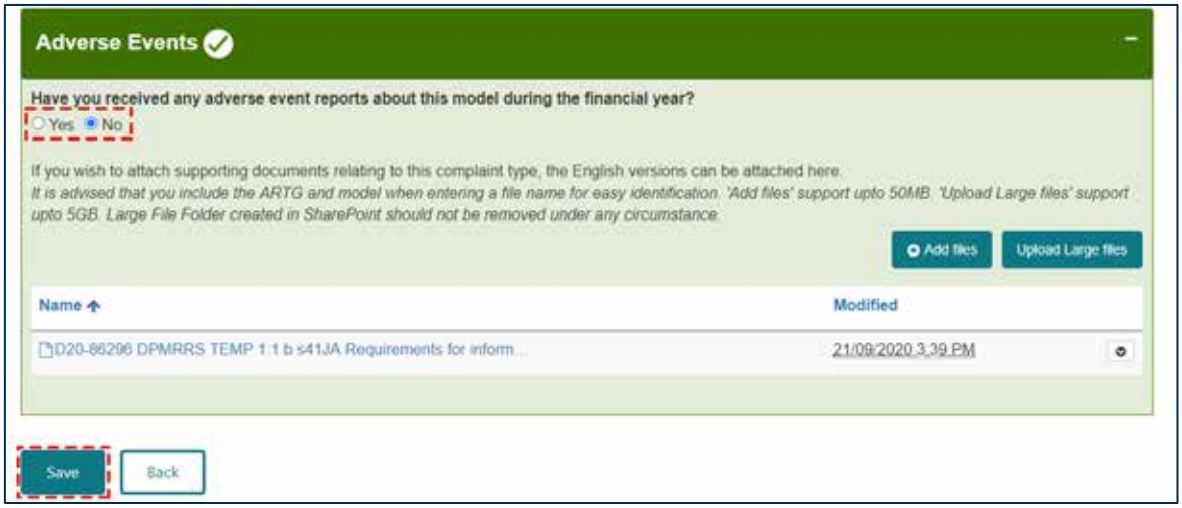


Any files that have already been uploaded relating to this ARTG entry will be displayed in the list of files.

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.

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



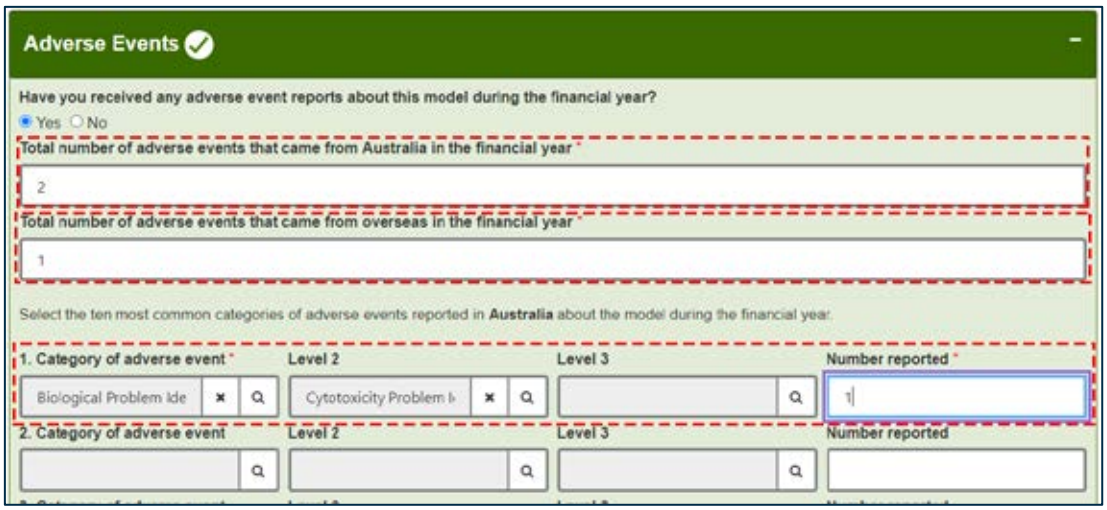
b. If you select **Yes**, complete the following steps:

- 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

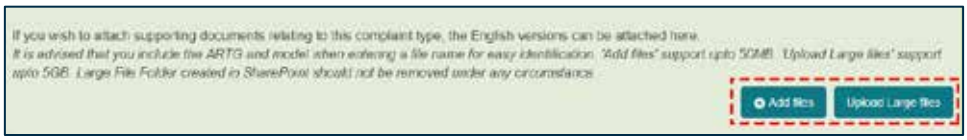
Instructions

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.



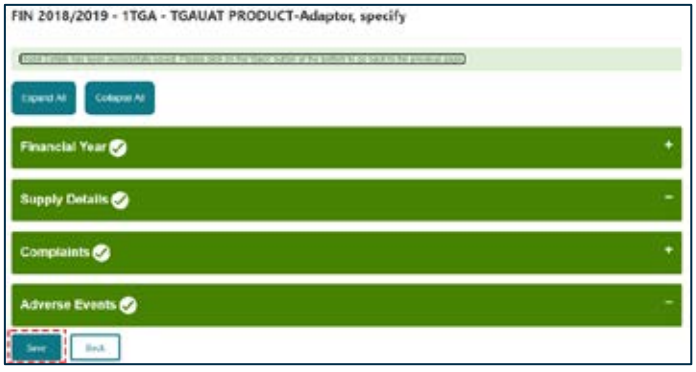
c. You have the option to upload supporting documents relating to this complaint type using the **Add files** and **Upload Large files** function. Refer to step 8 for small files (less than 50MB size) or 10 for large files (more than 50MB size) for step by step instructions on how to upload files.



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

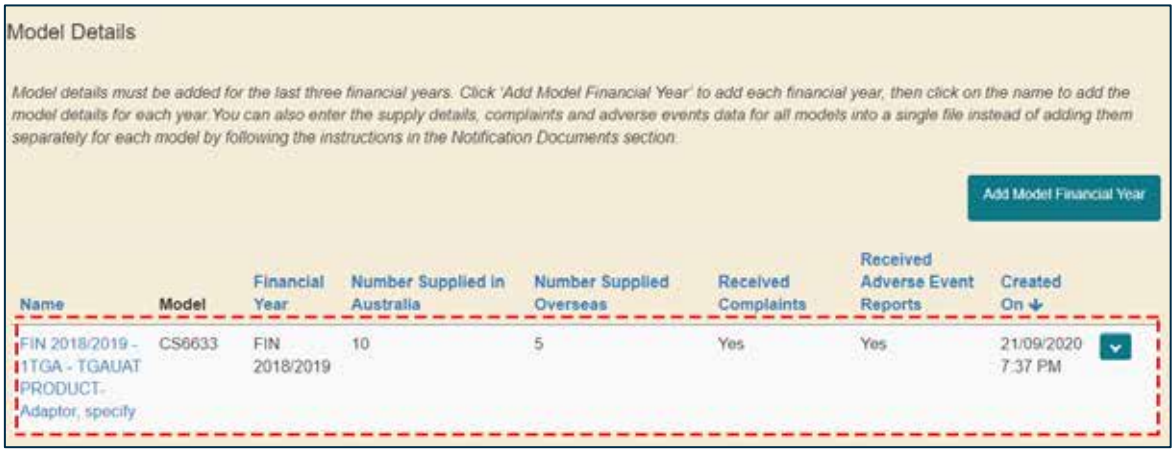
15. Click **Save** and the following message will appear and click on the **Back** button to go back to the previous page.

    "*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.



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:

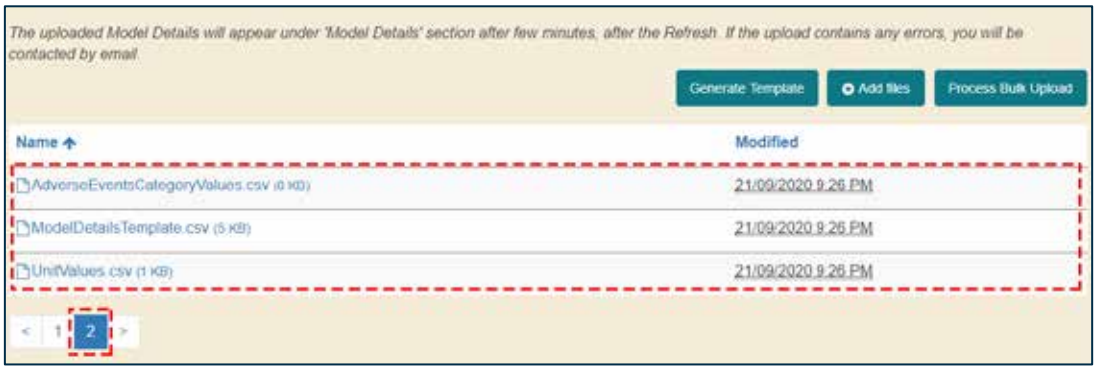
    a. You need to generate the bulk upload template from the **Notification Details** section.

    b. Click on **Generate Template**.

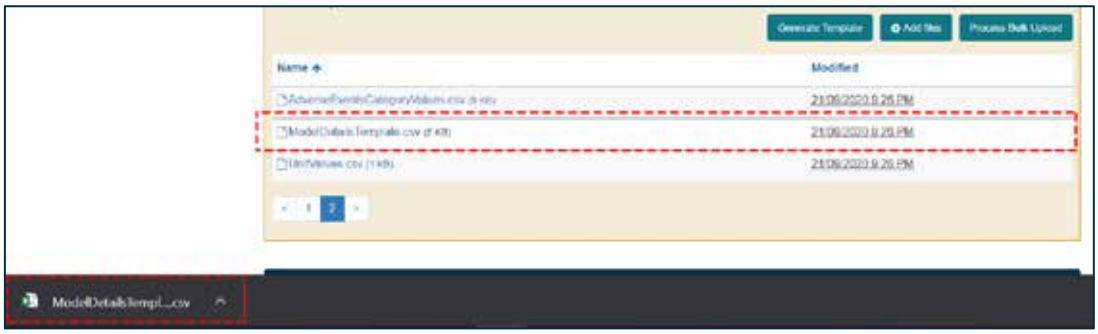
c. Click **OK**.

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.

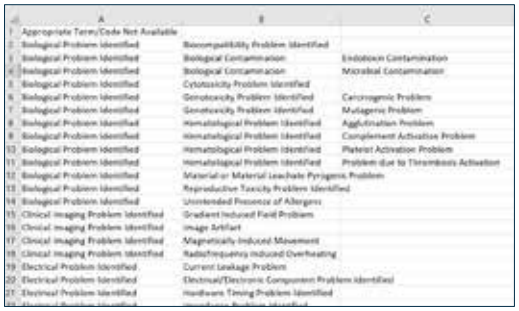


e. Open the **ModelDetailsTemplate** file to enter the supply, complaints and adverse events data for each model for the last three financial years.



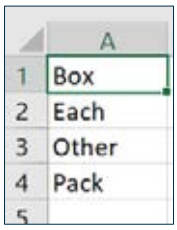
You can download and refer to the **AdverseEventsCategoryValues** and **UnitValues** files as references or to copy and paste the values into your ModelDetailsTemplate file as part of the next step.

AdverseEventsCategoryValues file:



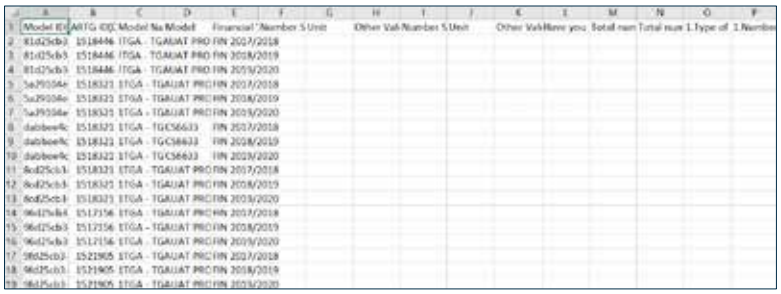
Instructions

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



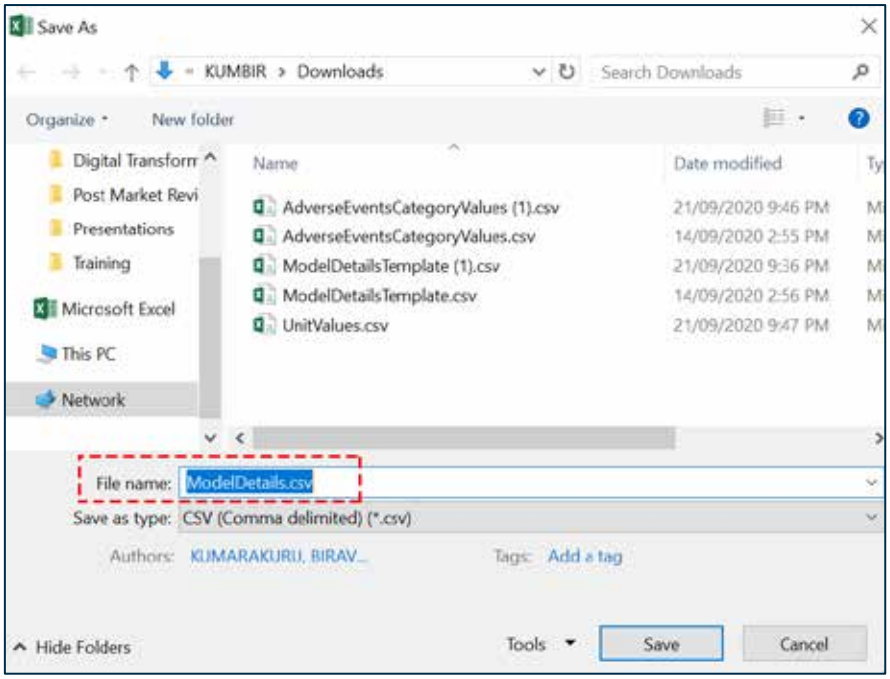
Please note:

- 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

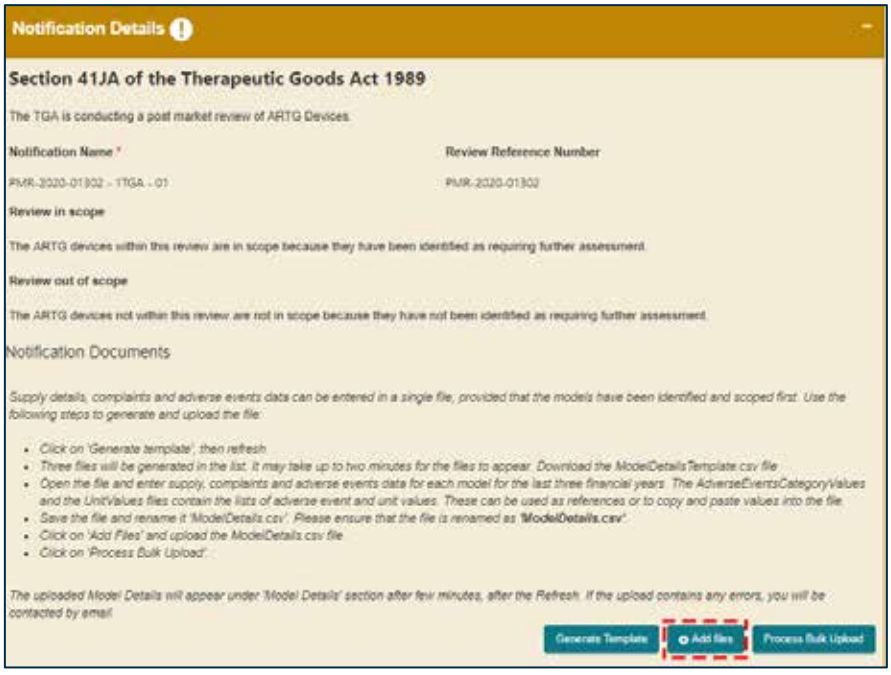
Instructions

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

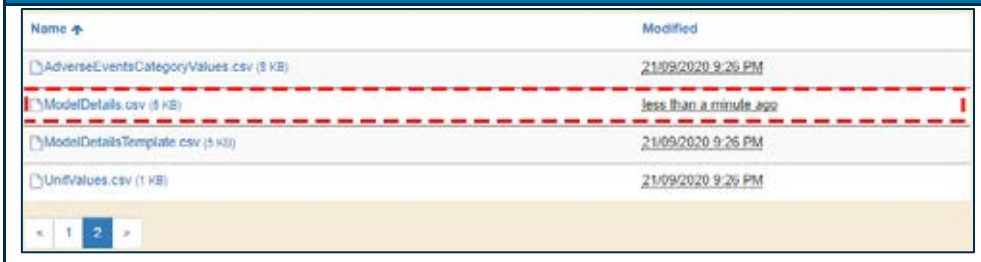
Once you have completed the required information in the ModelDetailsTemplate file, you need to save the file as “ModelDetails.csv”. Note: it is important to save the file as “ModelDetails.csv” for the system to identify the document.



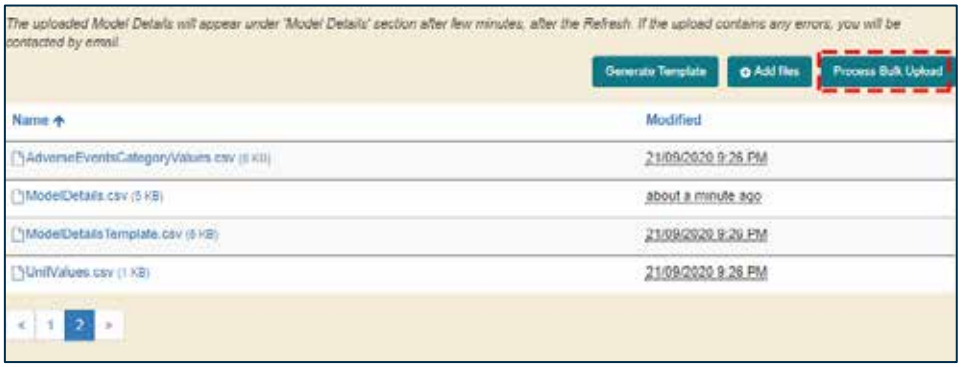
g. To upload the file, click on **Add files** and the new file you uploaded will be saved in the documents section.



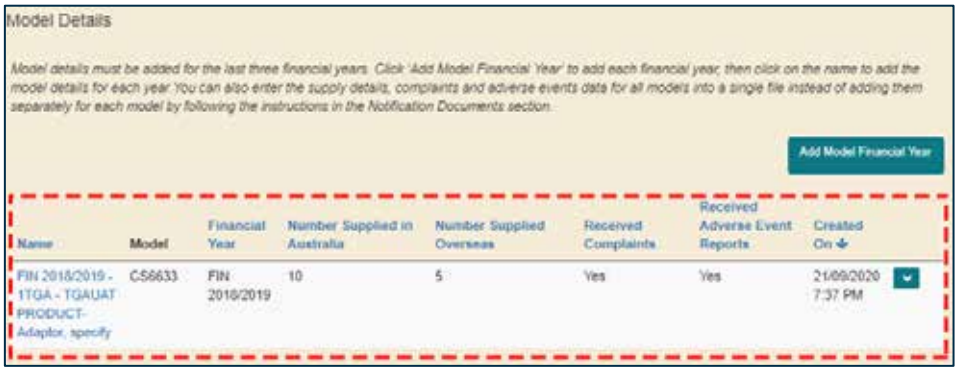
Instructions



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

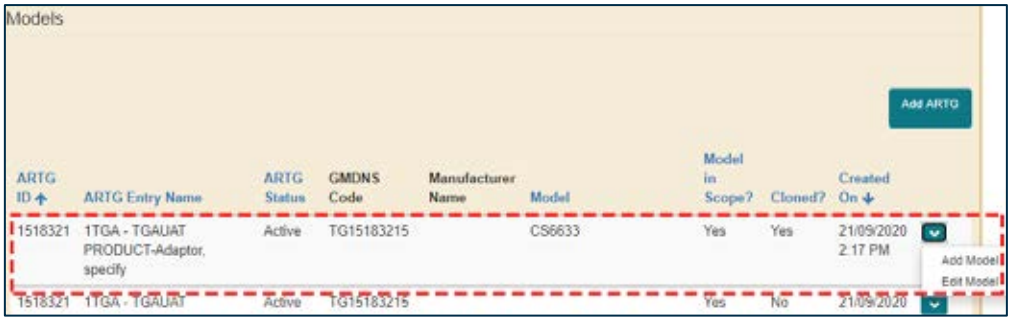


The model details will be uploaded in the ARTGs and Model Details section. If the model details are not uploaded in this section then there was an error when updating the bulk upload file in step 17f. Please make sure you enter all mandatory fields and the right information is entered. If you still have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



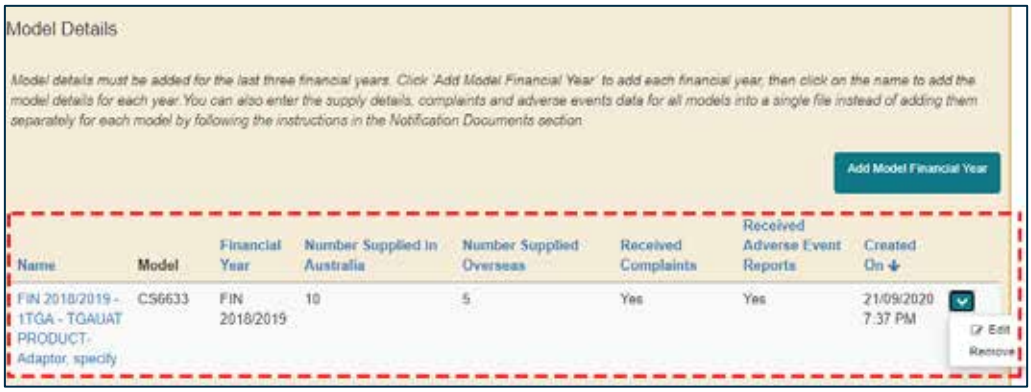
Please note the following relating to the bulk upload functionality:

- 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.

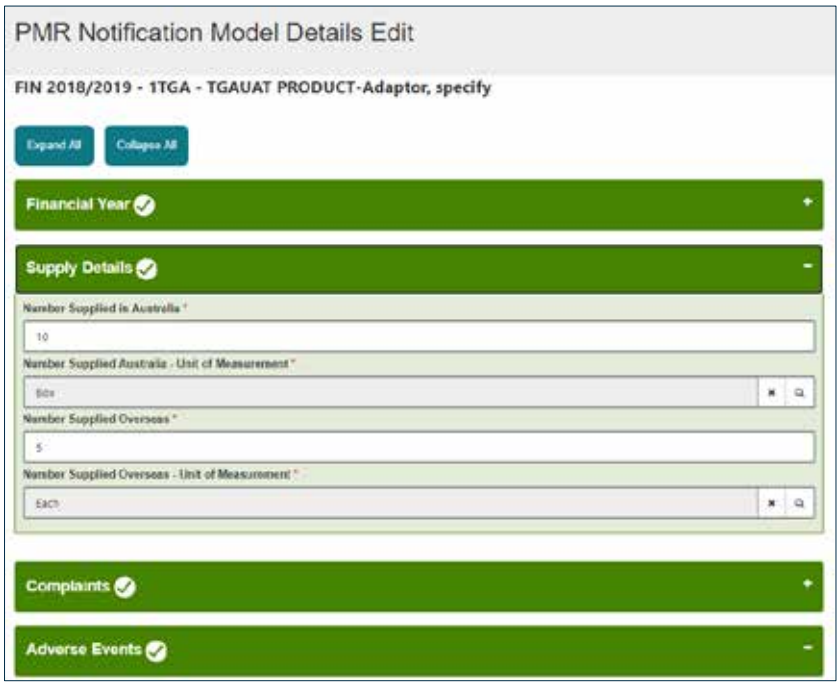


Instructions

- 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**.

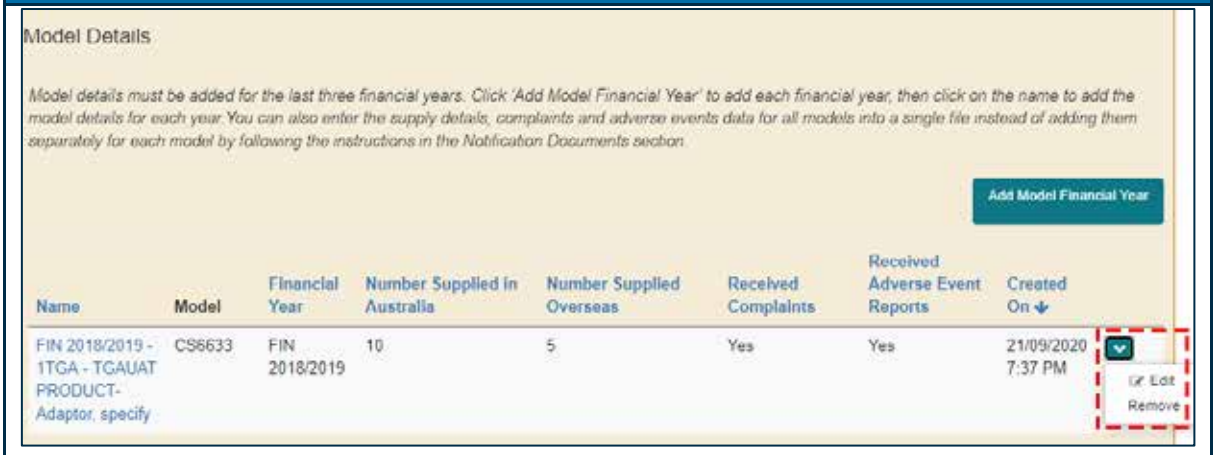


Make the changes in the relevant section.



- 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



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) mailbox. The team will be able to run a bulk removal of your selected files.

How to provide evidence of compliance with requirements

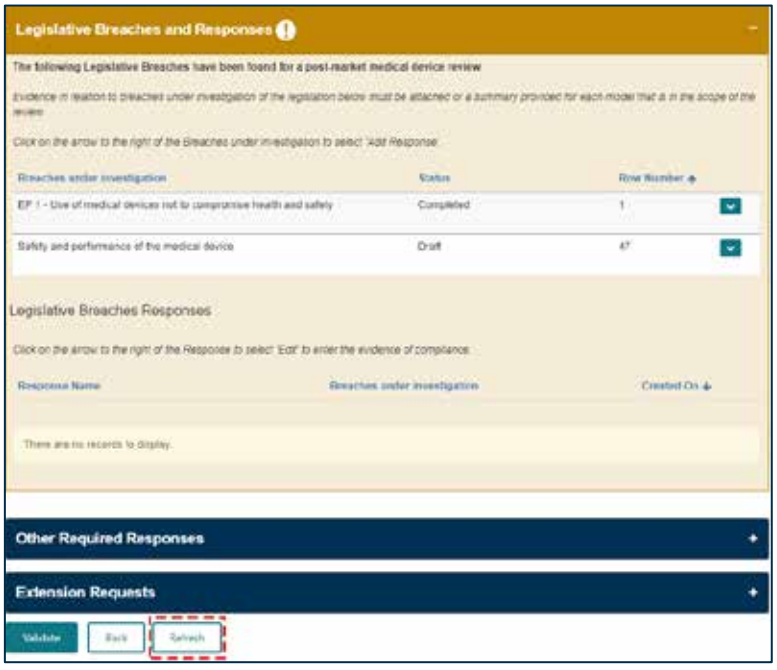
The following instructions outline how to upload the information and documents to demonstrate compliance with the specific areas of the legislation that have been identified in the notification letter.

Instructions

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

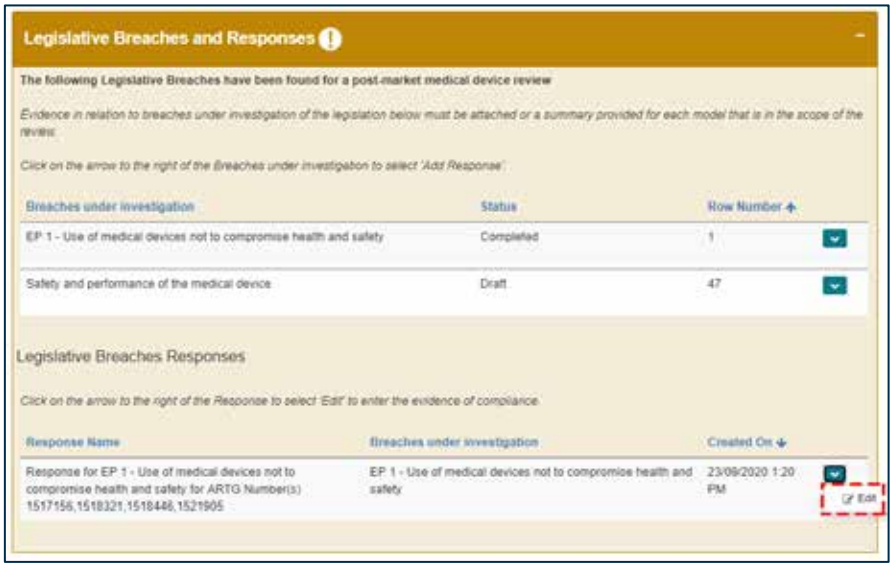
2. Click **Proceed**.

3. Click **Refresh**.



Instructions

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

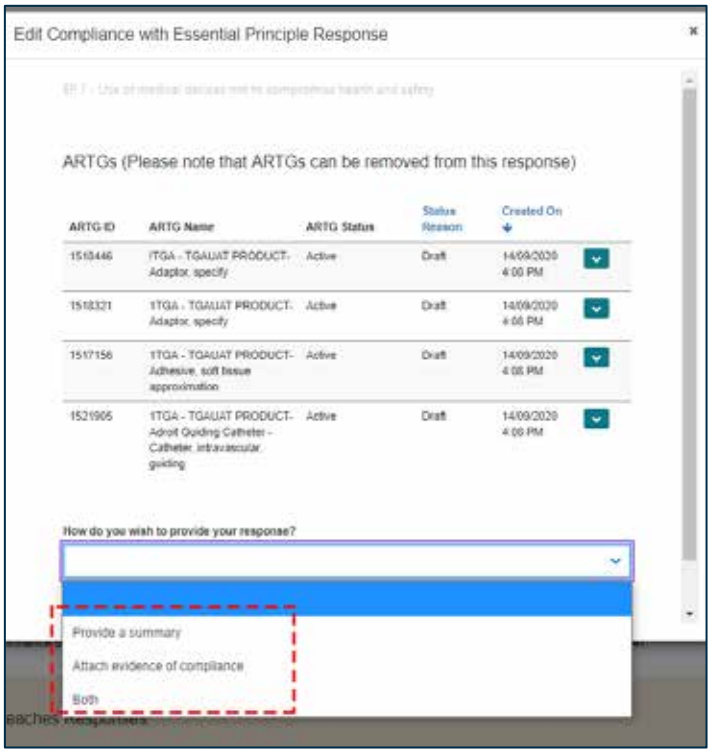


5. Select how you wish to provide your response.

   a. You can choose from one of the three options:

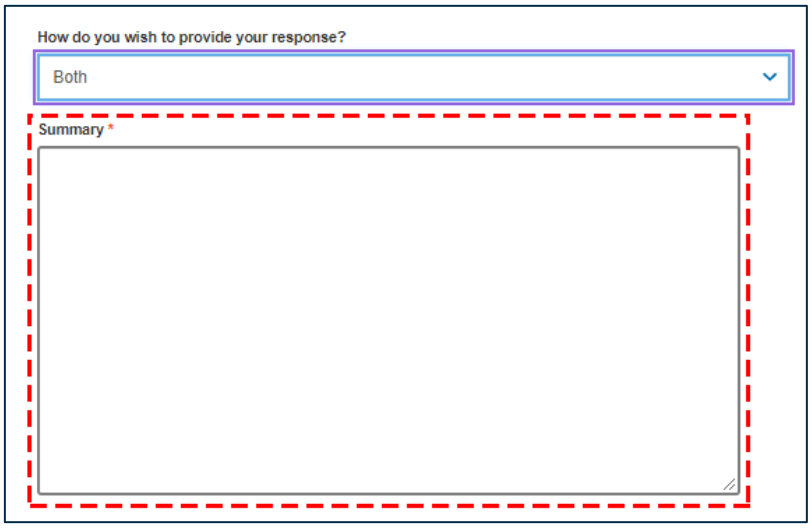
      - Provide a summary
      - Attach evidence of compliance
      - Both

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

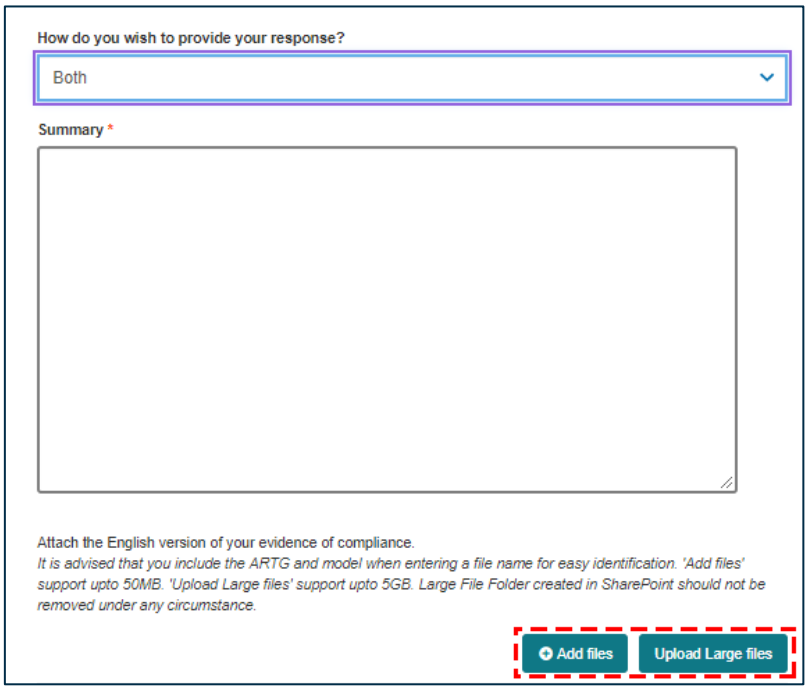


Instructions

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



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



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

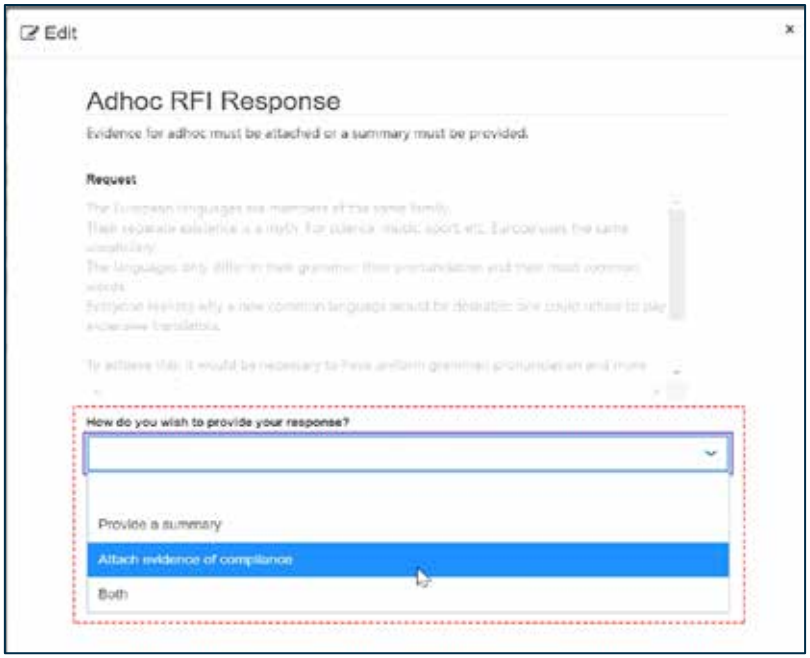
1. Click **Edit** to provide a response to a specific request.

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

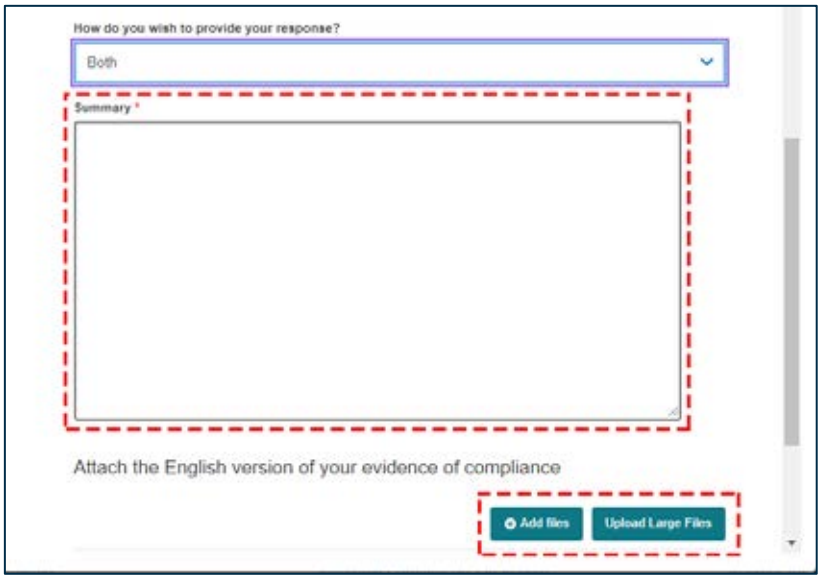
If you select “Attach evidence of compliance” or “Both”, you must attach minimum one file.



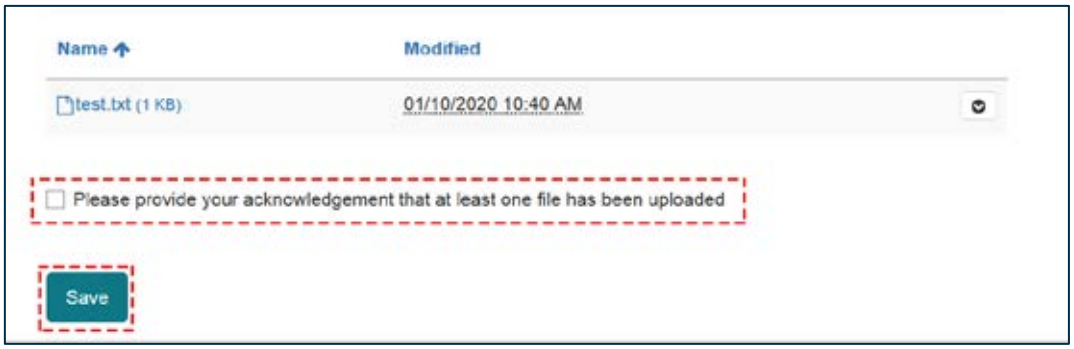
   b. In the **Summary** section, provide your response. Note: the summary must be minimum 50 characters.

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**.



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

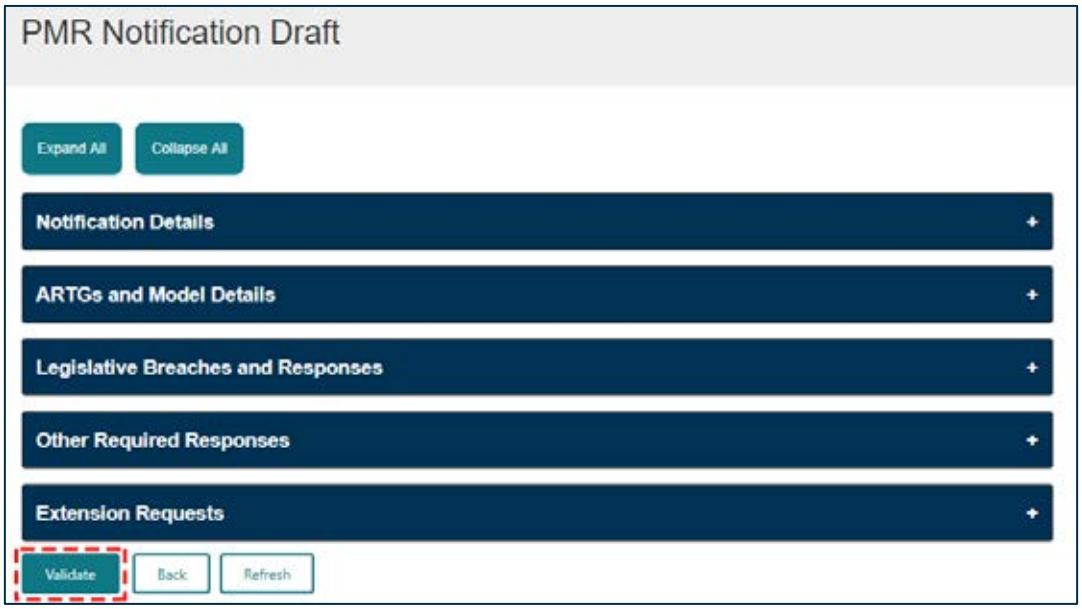


How to submit the information

Instructions

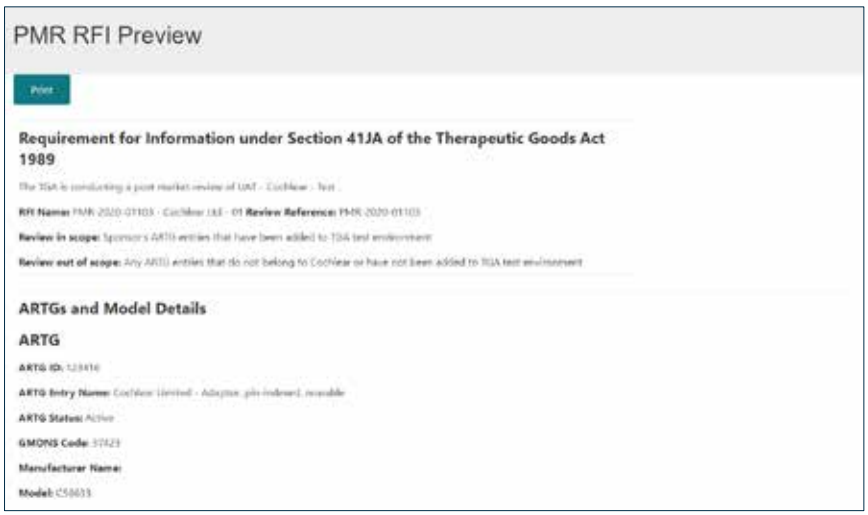
1. If you are ready to submit your response, click **Validate**.

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



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

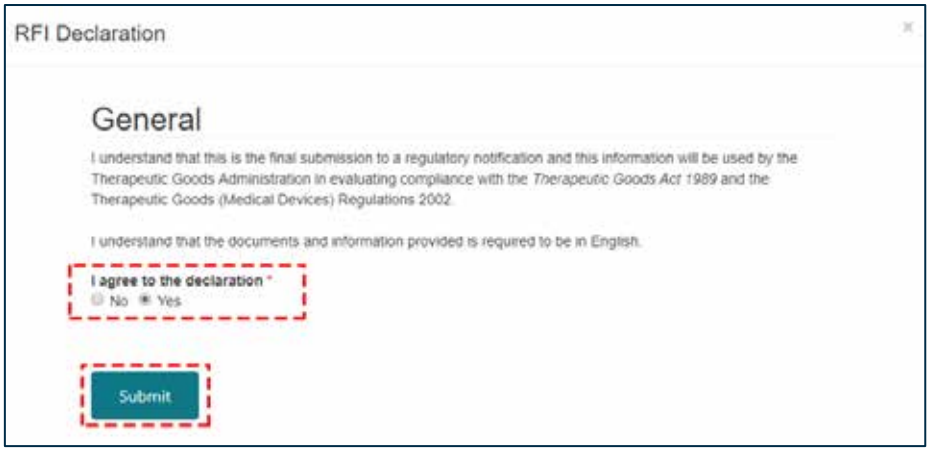
You can preview the notification before you submit it.



Instructions

3. Click **Declare**.

4. Select **Yes** if you agree to the declaration.
    a. Click **Submit**.



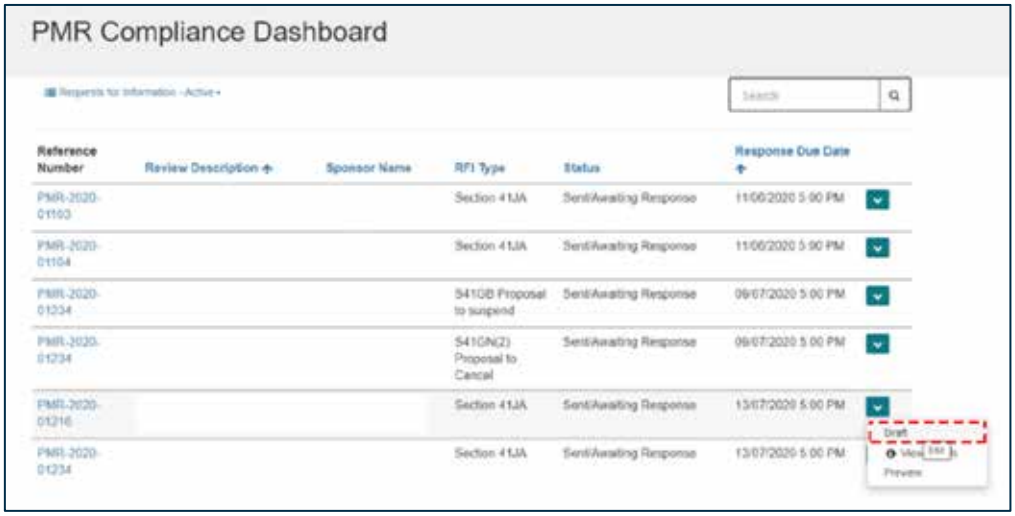
5. Click **OK**.

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**.



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

3. Click **Request Extension**.

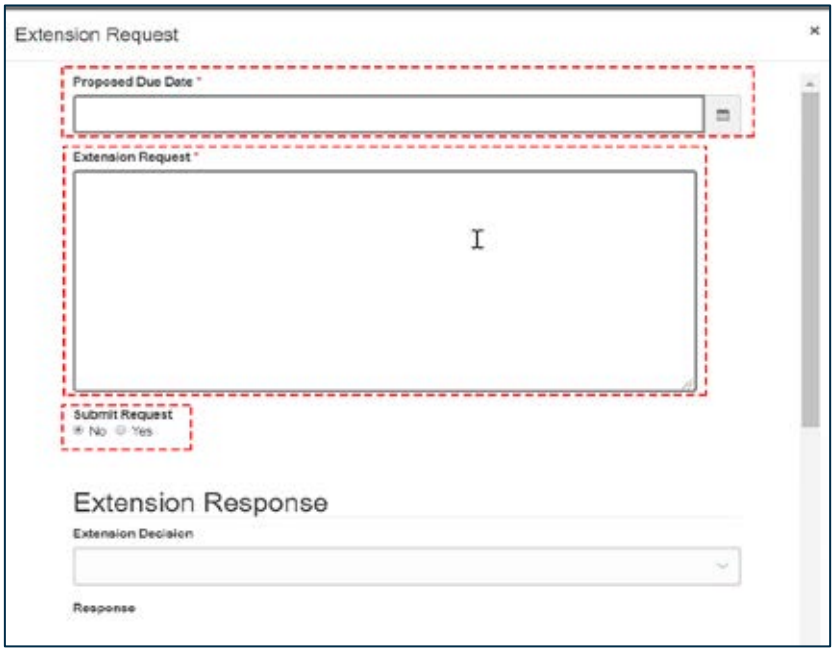
Instructions

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.

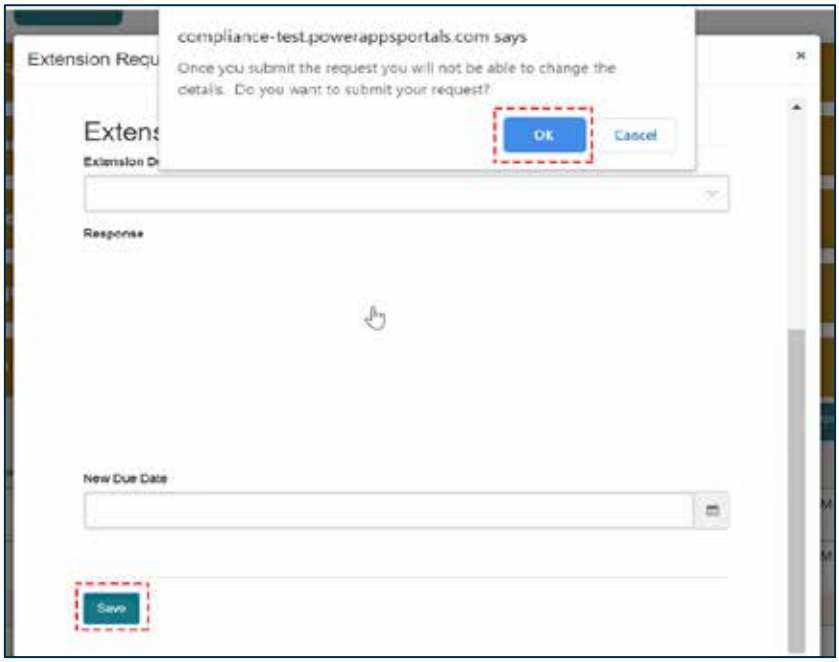
   b. In the **Extension Request** field, enter the reason for requesting for an extension.

   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.



5. Click **Save**.

   a. Click **OK**.



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

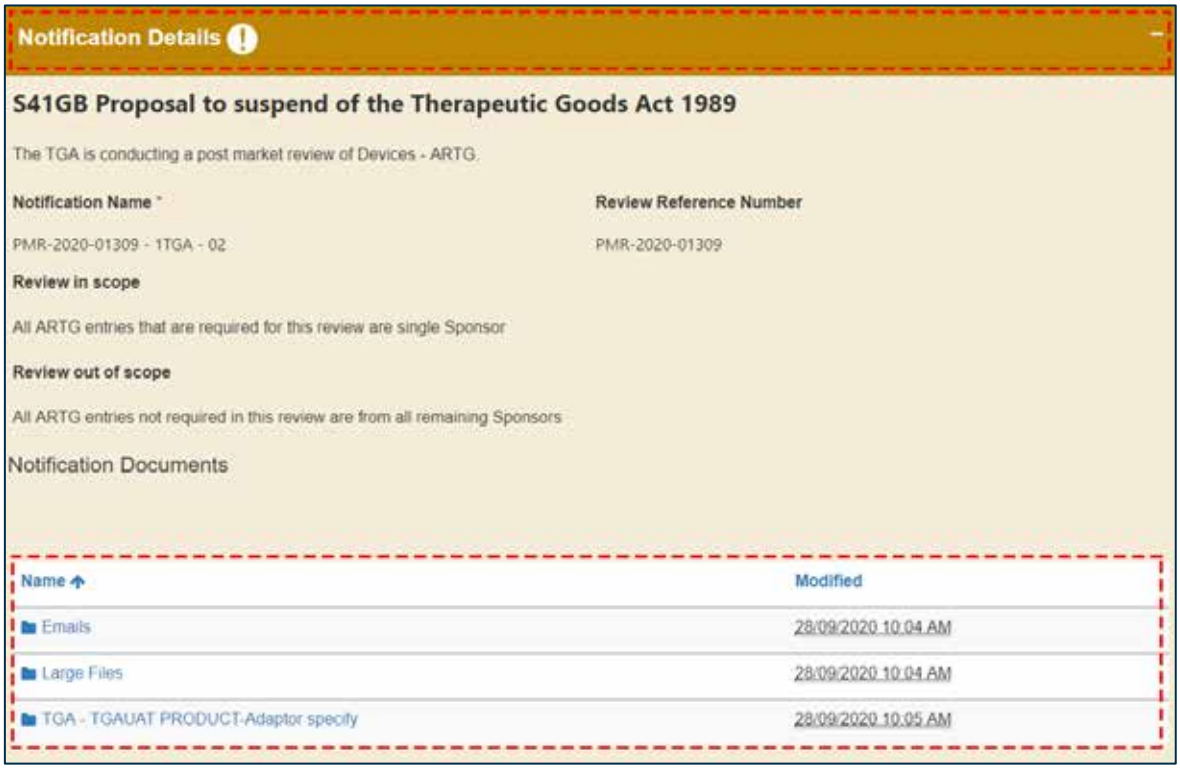
You can view and respond to these types of notifications by following the instructions below.

Instructions

1. Click **Draft**.

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

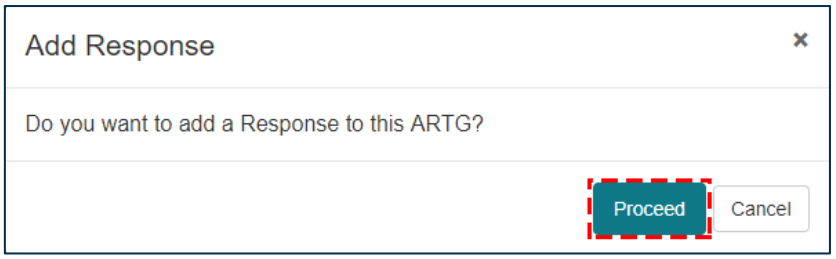
In the Notification Documents section, you can view all the documents associated to this notification.



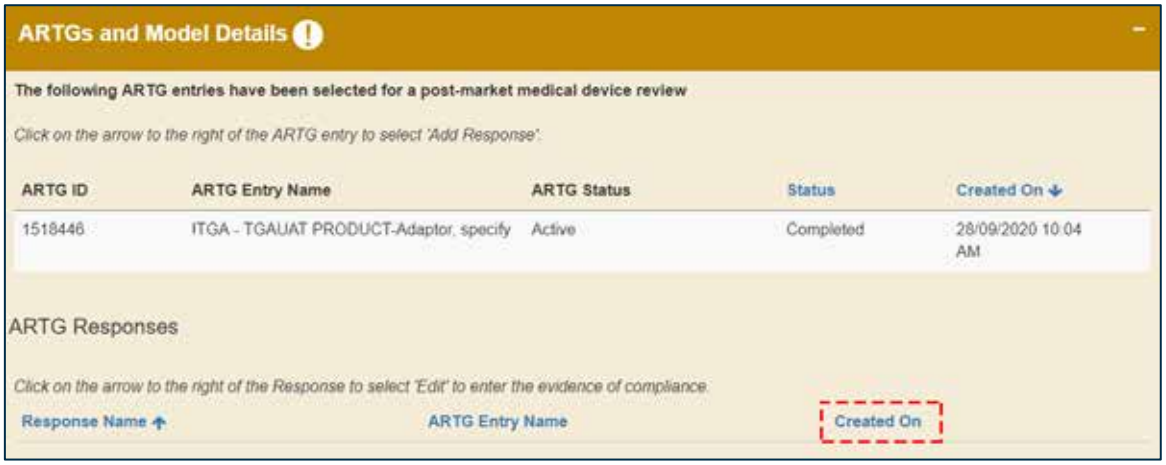
Instructions

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

4. Click **Proceed**.



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

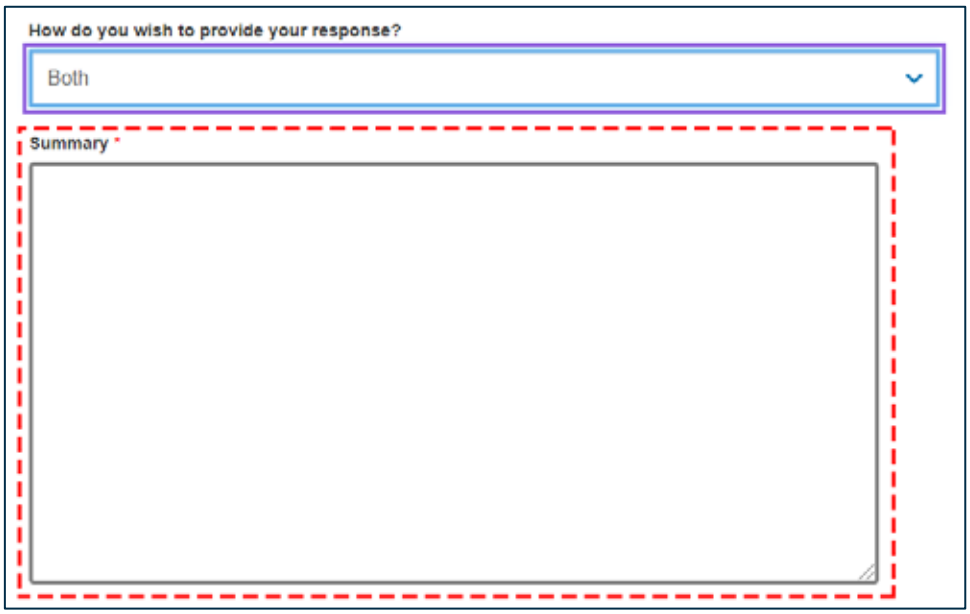


6. Click **Edit**.

Instructions

7. Select how you wish to respond.

8. Enter your summary.



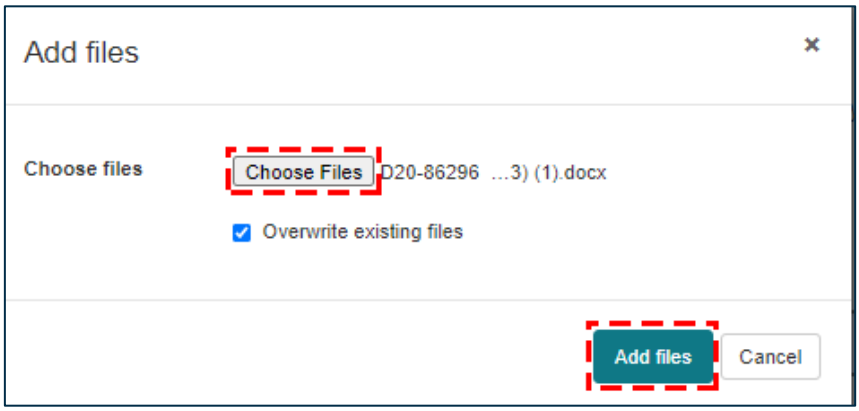
9. Upload your files. You have two options ("Add files" and "Upload Large files") to upload a copy of the Instructions For Use (IFU), for both in scope and out of scope devices. Refer to instructions:

   - 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.

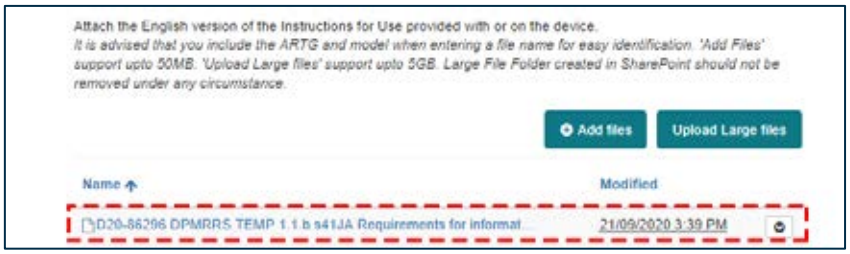
Please note, folders are being created in the background to store information so it may take 1 to 2 minutes for the "Add files" and "Upload Large files" buttons to appear.

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

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



The file you uploaded will be displayed.

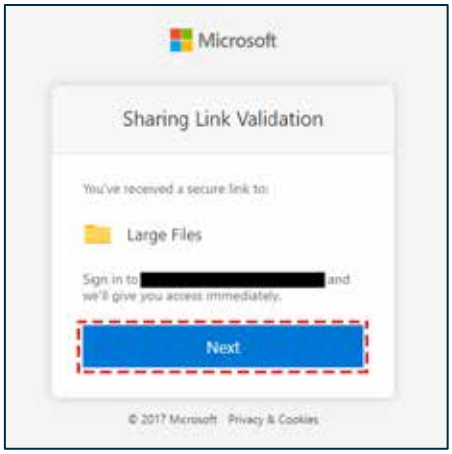


Select the check-box to acknowledge that at least one file has been uploaded and click **Save**.

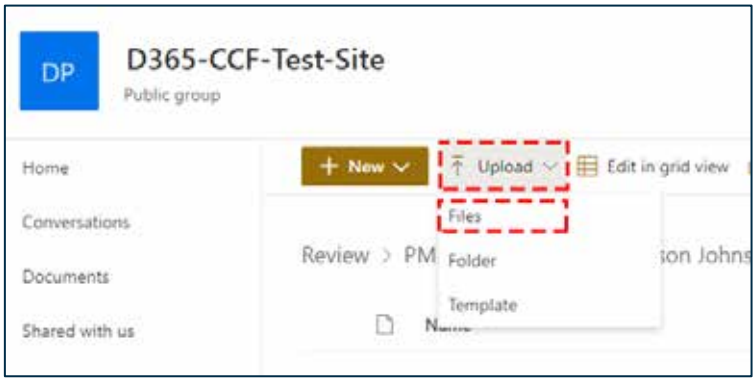
Instructions

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

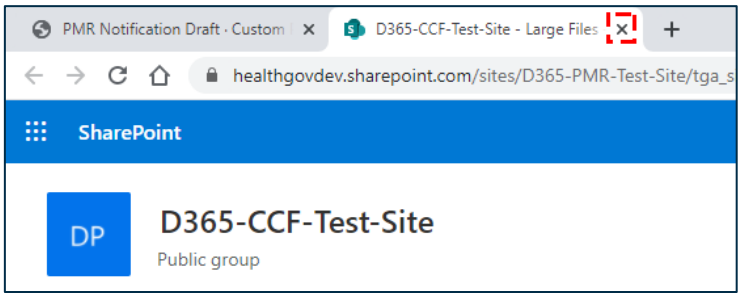
A new window will open directing you to the SharePoint site. Click **Next**.



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

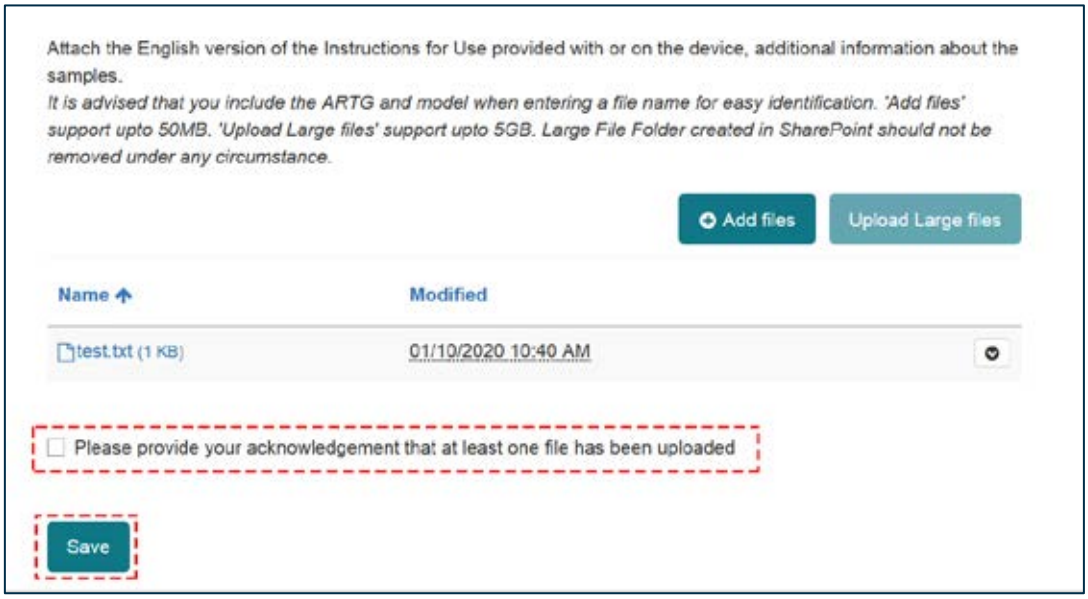


Close the window once you have uploaded the large file(s).



Instructions

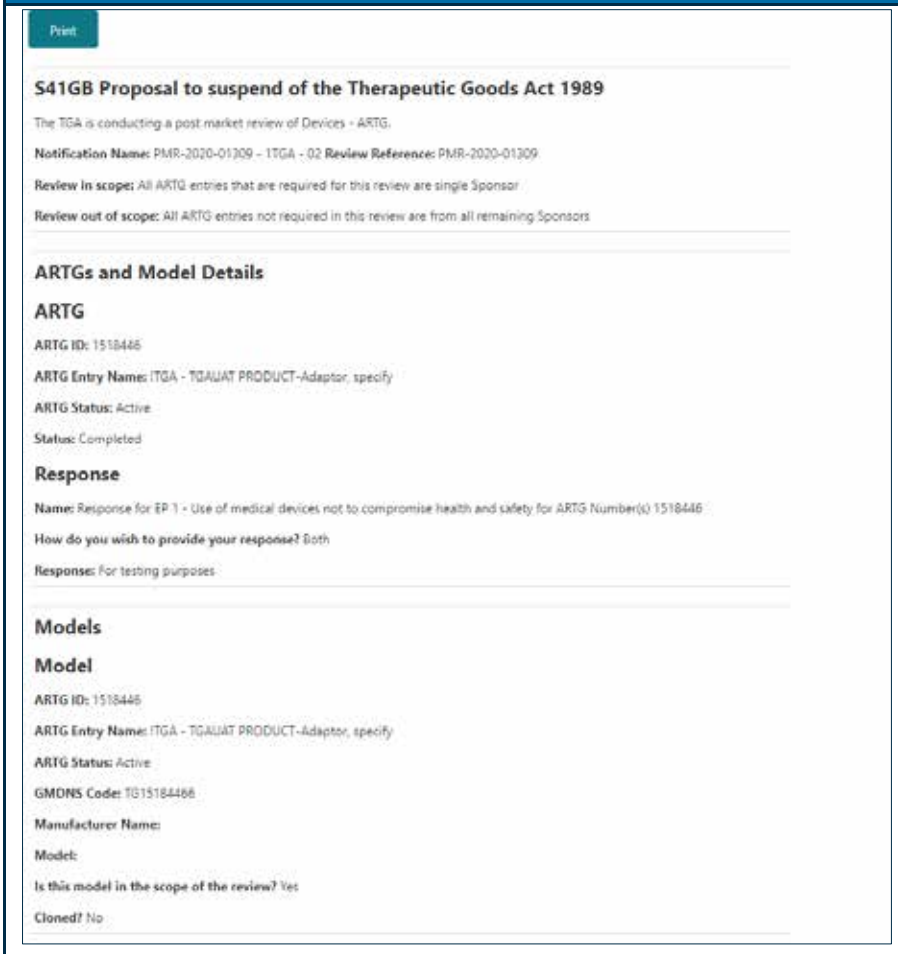
Select the check-box to acknowledge that at least one file has been uploaded and click **Save**.



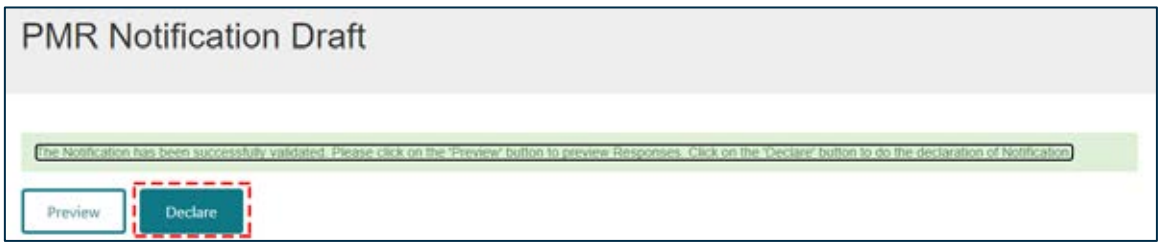
10. Click on **Validate**.

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

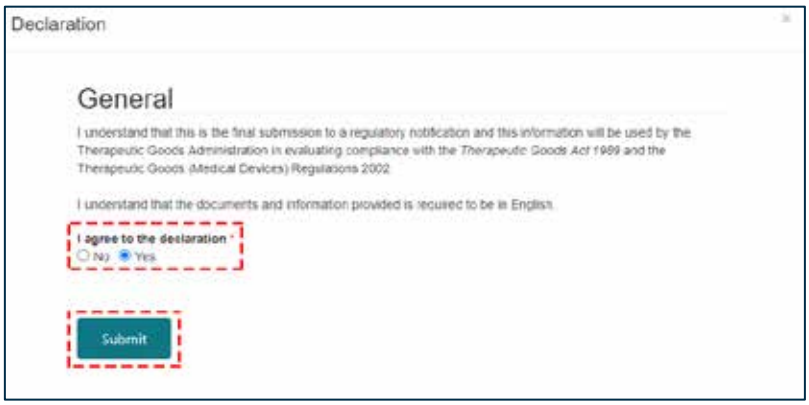
Instructions



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

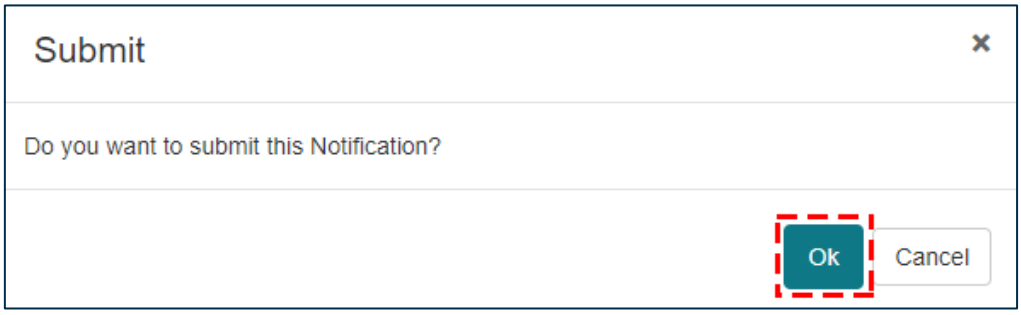


13. Select **No** or **Yes** if you agree to the declaration and click **Submit**.



Instructions

14. Click **OK**.



Version history

Version	Description of change	Author	Effective date
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

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Reference/Publication #