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1. Scope

This guidance covers the submission of an application for the Active Pharmaceutical Ingredient Master File (APIMF) Procedure via the ePQS Portal Wizard.

2. Prerequisites

Application wizards are accessed via the ePQS Portal landing page – <https://who.my.site.com/ePQS/s/login/>. Therefore, access to the ePQS portal must be granted first. To seek registration apply using the form available on the Portal landing page.

Some types of applications have prerequisite conditions. For instance, a post-prequalification change application can only be created if there exists in the ePQS system at least one accepted or prequalified product for the applicant account.

Many wizards include steps that require the applicant to select an account from within the ePQS database. For instance, when an applicant wishes to create a product site for a product or nominate a reference authority. Users can verify if these accounts exist before commencing an application by referring to the spreadsheet available from the “View ePQS Registered Accounts” tile, as indicated in figure 1.

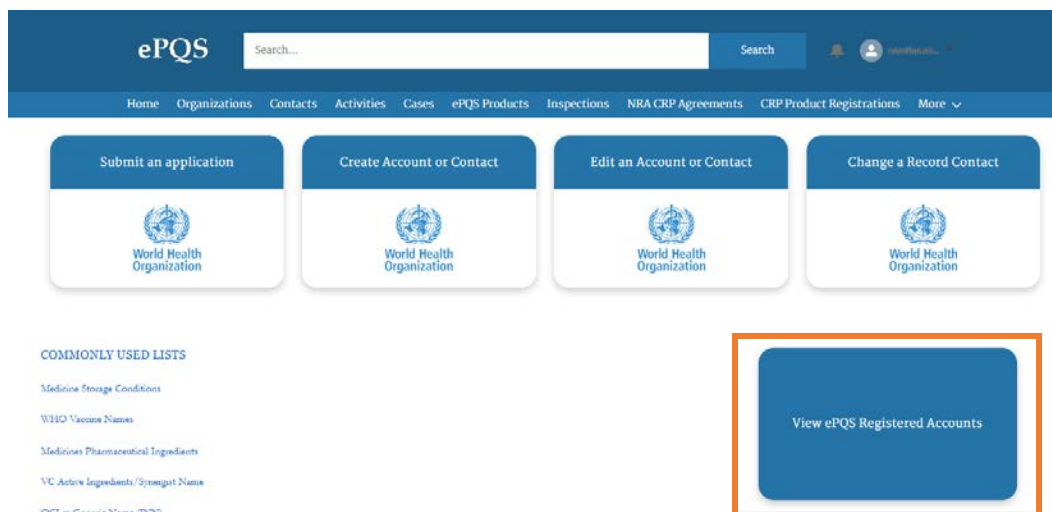


Figure 1: The existence of an Account within the ePQS system can be determined by selecting the indicate - “View ePQS Registered Accounts”

3. Accessing the Portal

Applications wizards are accessed via the ePQS Portal – <https://who.my.site.com/ePQS/s/login/>.

4. Wizard steps

4.1. Wizard commencement

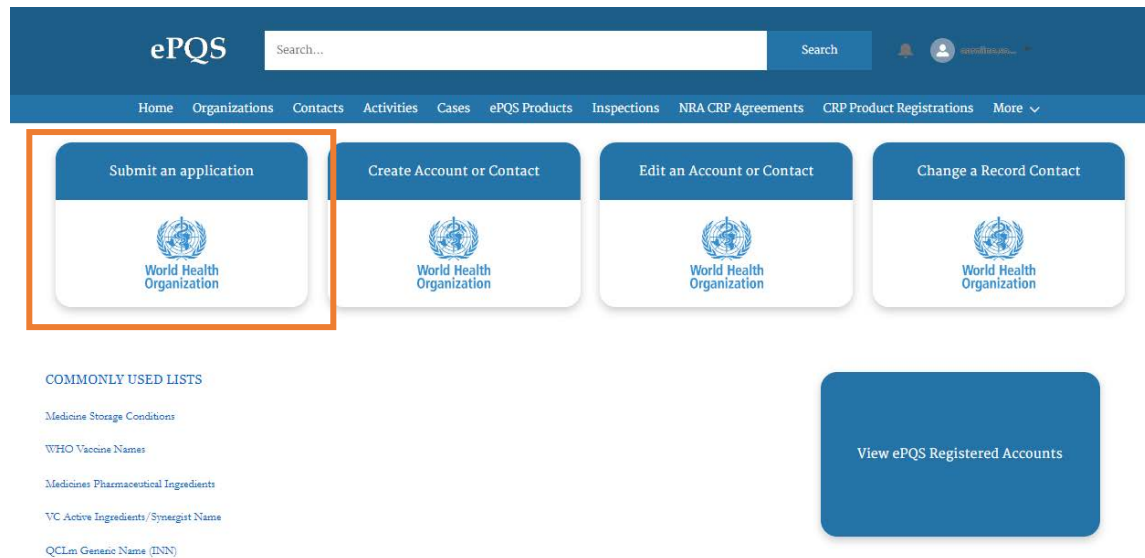


Figure 2: Commence the application process by selecting the Submit an Application tile

An application can be initiated by selecting the *Submit an Application* tile from the portal as indicated in Figure 2.

4.2. Wizard Selection

Having passed the initial “Create a New Application screen”, the system may prompt you to confirm the Applicant organization that is making the application. This occurs if you are a registered user that is associated with more than one Account.

More commonly, you will arrive directly on a screen requesting the nomination of the contacts for this application, figure 3. The system will offer for selection, any contact associated with this account.

ePQS Application Wizard

Organization & Contacts Application Info Product Details Documents Finalize

Choose Contact

Choose Applicant Primary Contact
Nominate a primary contact for this application who is an employee of ePQS Test Account 1 - NonStateActor, and also indicate if there are other secondary people involved.

* Primary Contact
ePQS External Applicant 1

Optionally Choose Secondary Contacts
If needed you can optionally choose a secondary and an alternative secondary contact, or leave the selection as "--None--".

Secondary Contact
--None--

Alternative Secondary Contact Choice
--None--

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Figure 3: As part of the preliminary application steps, Applicants will be asked to nominate contacts for the application, and if applicable the product.

You will then be prompted to select the product type that you wish to lodge an application for.

ePQS Application Wizard

Organization & Contacts Application Info Product Details Documents Finalize

Choose Product Type

Select the product area to narrow down the list of application types.

* Product Type

- Active Pharmaceutical Ingredient
- Active Pharmaceutical Ingredient Master File
- Finished Pharmaceutical Product
- Finished Vaccine Product
- IMD Evaluating Laboratory
- Immunisation Device
- In Vitro Diagnostic
- Male Circumcision Device
- Quality Control Laboratory
- Vector Control Active Ingredient
- Vector Control Product
- WHO Prequalification Evaluating Laboratory

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Figure 4: You must first select the associated product type, before selecting the application type.

PLEASE ENSURE YOU CHOOSE THE CORRECT OPTION. Choosing Active Pharmaceutical Ingredient Master File” means you will be offered to file an APIMF procedure application or an Amendment application. Choosing “Active Pharmaceutical Ingredient” means you will be offered to file an API Prequalification application.

On the next screen you will be offered a list of the specific application type(s) and then application subtype(s) (if this is relevant) relevant to the product type (figure 5).

Home Organizations Contacts Activities Cases ePQS Products Inspections NRA CRP Agreements Application Wizard More ▾

ePQS Application Wizard

Organization & Contacts Application Info Product Details Documents Finalize

Choose Application Type

Based on the product type, here is the list of application types available.

* Application Type

APIMF Procedure

Post-PQ Change

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ePQS Application Wizard

Organization & Contacts Application Info Product Details Documents Finalize

Choose Application Subtype

Please enter the following additional information:

* Application Subtype

Standard

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Figure 5: Then you will asked to select application type and sometimes application sub-type.

The system will then playback to you the application you are planning to create. By proceeding, the system will create a draft application record in the system.

ePQS Application Wizard

Organization & Contacts Application Info Product Details Documents Finalize

Confirm Application Details

By proceeding to the next step you will be creating a draft Mx APIMF Application. This draft application will be available in your List View of Cases.

- Application Type: APIMF Procedure
- Application Subtype: Standard
- Product Type: Active Pharmaceutical Ingredient Master File
- Organization: ePQS Test Account 1 - NonStateActor
- Primary Contact: ePQS External Applicant 1

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Figure 6: The system summarizes the application that is to be created.

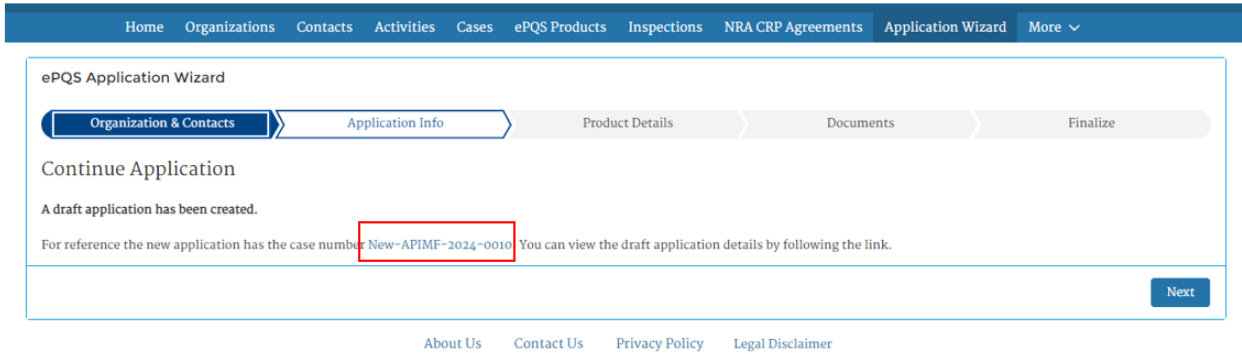


Figure 7: A draft application record has now been created in the system.

This record can now also be located via the global search bar or in the case list view.

If the application sub-type you selected was Abridged, you will be asked to indicate the reference Authority. A picklist of options will be provided for selection.

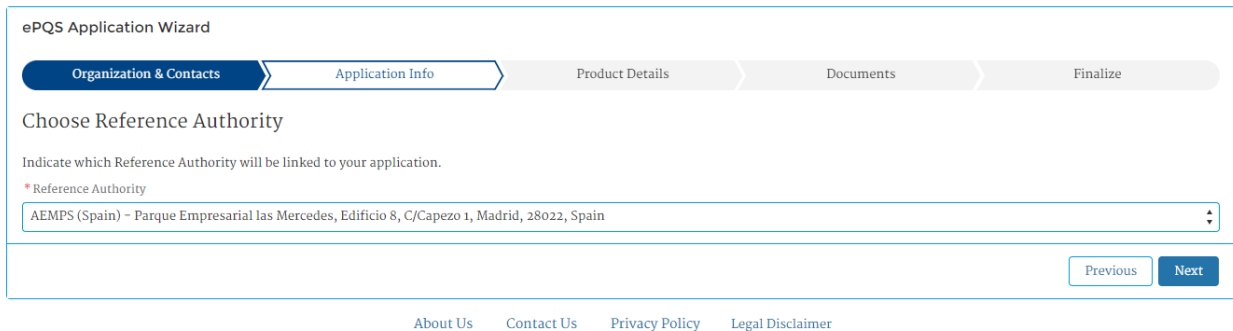


Figure 8: If an Abridged application was selected the applicant will be asked to select the Reference Authority.

4.3. eCTD or non-eCTD

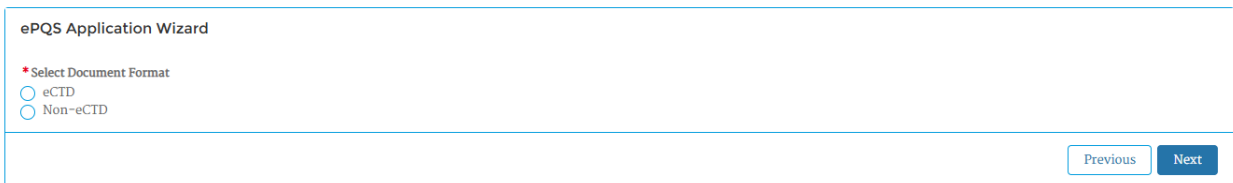


Figure 9: A decision is required if the dossier being filed is in eCTD or non-eCTD format.

The decision to file in eCTD or non-eCTD affects the document uploading steps at the end of the wizard.

4.4. Entering application-specific wizard details

For the APIMF application wizard, the next steps involve completion of APIMF product-related information.

ePQS Resume Wizard

✓ ✓ **Product Details** Documents Finalize

Create a Product

New Product
Since this is a APIMF Procedure type application, a new product will be created of type:

- Active Pharmaceutical Ingredient Master File (APIMF)

It will be linked to your application, New-APIMF-2024-0010.

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Figure 10: As a next step in the APIMF application wizard, an APIMF Product record is created.

As indicated in figure 11, you will be asked to add the active pharmaceutical Ingredient. Note, that once the first two letters of the API are entered, the system will begin to offer options for selection.

ePQS Resume Wizard

Organization & Contacts ✓ Product Details Documents Finalize

Create a Product

New Mx APIMF Product
(Please fill out all required fields)

* Active Ingredient Name (Mx)
Search Mx Pharmaceutical Ingredients...

* Current APIMF Version Number

Therapeutic Area(s): To select multiple items, hold down the Ctrl (PC) or Command (Mac) key

- Analgesics
- Anesthetics
- Antihemorrhagics (Haemophilia)
- Bacterial vaccines (Pneumococcal infections)
- Covid-19

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Figure 11: Information relating to the API, version number, and relevant therapeutic area should next be entered.

You will also be asked to enter the APIMF version number for the submission, and to select one or more therapeutic areas the API pertains to.

On the next screen, figure 12, you have the opportunity to go back to correct the entered information, by selecting “previous”.



Figure 12: By selecting the previous button you can correct the information entered in the previous screen.

By selecting Next, an associated APIMF product record is then created as per figure 13.

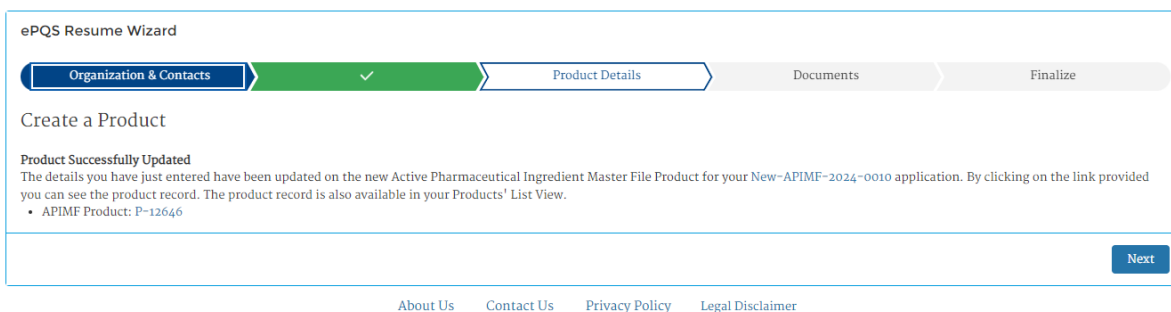


Figure 13: A new APIMF product record is created.

4.5. Product site creation

Once the Product record is created, you are then offered the opportunity to create product site records for the sites undertaking various activities. It is expected that every product must have at least one manufacturing site. To do so, select the Product site radio button and press Next (see figure 14). You will return to this screen eventually in case you need to create another product site.

For APIMF product records, it is required to create product site records for:

- all sites of API manufacture;
- all intermediate manufacturing sites that are not also API manufacturing sites; and
- any micronisation sites if they are not also API sites of manufacture.

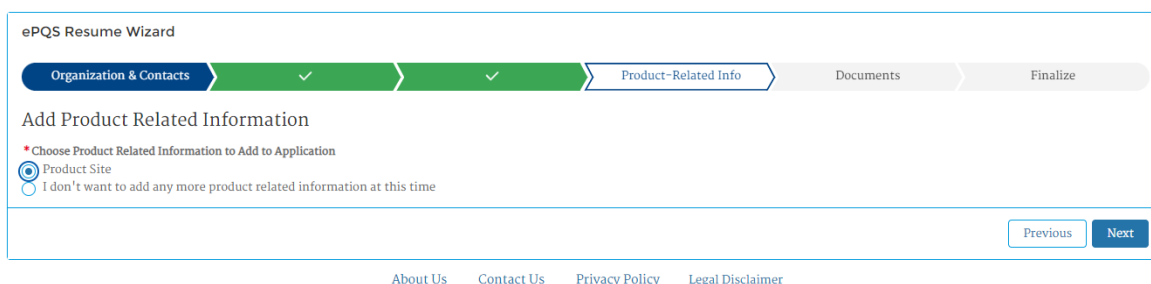


Figure 14: Every APIMF product record must have at least one Product site record

The first step in the product site creation is to identify the Account/Organization representing the site. Enter at least the first three letters of the Account into the Site search field and press next. On the next screen (figure 15), the system will offer to you available accounts within the system matching the entry criteria, to choose from.

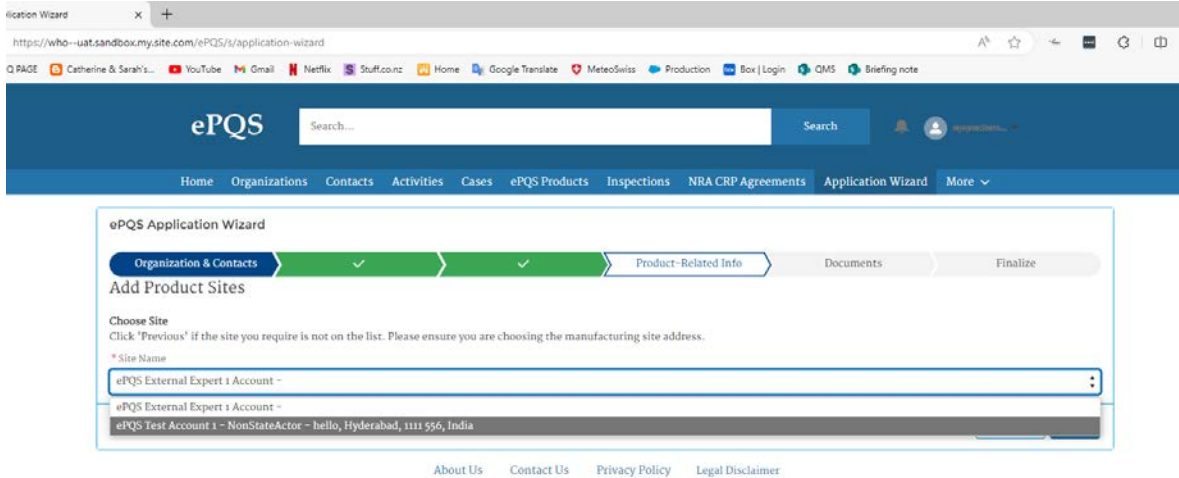


Figure 15: Based on the information entered into the site search field the system returns all accounts matching this name.

As mention in *Section 2 – Prerequisites*, a list of sites is available for review before commencing. If the site is new to the system, the applicant will need to request creation of the Account before commencing the application. It is also possible to leave the current application and recommence this later. See section 8.

ePQS Application Wizard

Organization & Contacts ✓ Product-Related Info Documents Finalize

Add Product Sites

Select Site Activity
Indicate the site activity and activity types relevant.

* Site Activity
API Manufacture

Activities Conducted at Manufacturing Site - press Ctrl (Cmd on Mac) + Left Arrow or Ctrl (Cmd on Mac) + Right Arrow to move selection to Selected items between lists

Available

- API fermentation: Non sterile
- API fermentation: Sterile
- API intermediate Manufacture
- API micronisation
- API Synthesis: Sterile

Selected

- API Synthesis: Non sterile

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Figure 16: Next, indicate what activity the site is undertaking.

Having located and assigned the correct Account, you will then be asked to complete the type of activity that occurs at this site.

If intermediate manufacture is selected as an activity then you will be asked to enter the name of the intermediate.

ePQS Application Wizard

Organization & Contacts ✓ Product-Related Info Documents Finalize

Add Product Sites

Enter Additional Details
(Please fill out all required fields)

*Intermediate Chemical Name

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Figure 17: If the intermediate manufacture is selected as an activity then you will be asked to enter the name of the intermediate.

As indicated in Figure 19 the system will confirm the details for the product site record. Press next to create the record, or Previous to return for corrections.

ePQS Application Wizard

Organization & Contacts ✓ ✓ Product-Related Info Documents Finalize

Add Product Sites

Check
Is this the site you were expecting to be linked to this product?

- Site Name: ePQS External Expert 1 Account
- Site Street:
- Site City:
- Site Zip/Postcode:
- Site Country:

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Figure 18: Press Next to confirm the details for the product site record and create the record.

ePQS Application Wizard

Organization & Contacts ✓ ✓ Product-Related Info Documents Finalize

Add Product Sites

Success
A new Product Site PS-29980 has been created for the APIMF Product P-12656:

- Site Name: ePQS External Expert 1 Account
- Site Activity: API Manufacture
- Activity Types: API intermediate Manufacture
- Site Address:

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Figure 19: Confirmation of the sites creation should follow.

You will be informed that the Product site has now been created. This is also viewable on the product record, in the record’s related list (figure 20)

ePQS Product P-12656

+ Follow Edit Printable View Delete

Product Type: Active Pharmaceutical Ingredient Master File
 Applicant Organization: ePQS Test Account 1 - NonStateActor
 Product Assessment Procedure: APIMF Procedure - Abridged
 Date of Prequalification/Acceptance:

Details **Related** Preview Document Document Download

API Grades (0)

ePQS Product History (5)

Date	Field	User	Original Value	New Value
29/08/2024, 17:12	Active Ingredient	ePQS External Applicant 1		Ritonavir
29/08/2024, 17:12	Current APIMF Version Number	ePQS External Applicant 1		
29/08/2024, 17:12	Product Subtype	ePQS External Applicant 1		None
29/08/2024, 17:12	Therapeutic Area(s)	ePQS External Applicant 1		
29/08/2024, 17:12	Created.	ePQS External Applicant 1		

View All

Product Sites (1)

Product Site ID	Product Site Status	Site	Site Activity
PS-29980	Pending	ePQS External Expert 1 Account	API Manufacture

View All

Figure 20: Once the site is created it can be seen on the draft Product record from the “related Tab.

You will then loop back to a screen asking if you wish to create another product site record. If all sites have been created select “I don’t want to add any more...” to move to the document upload phase as indicated is figure 21.

ePQS Application Wizard

Organization & Contacts ✓ ✓ Product-Related Info Documents Finalize

Add Product Related Information

* Choose Product Related Information to Add to Application

Product Site

I don't want to add any more product related information at this time

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Figure 21: You can move to the document upload phase by selecting "I do not want to..."

5. Document uploading



Figure 22: Initial document upload screen

5.1. eCTD document upload

If eCTD format was selected earlier in the wizard, the system will now display information that the applicant should use to complete the module 1 envelope for their dossier. The wizard may be closed at this stage and resumed once the dossier sequence file has been published.

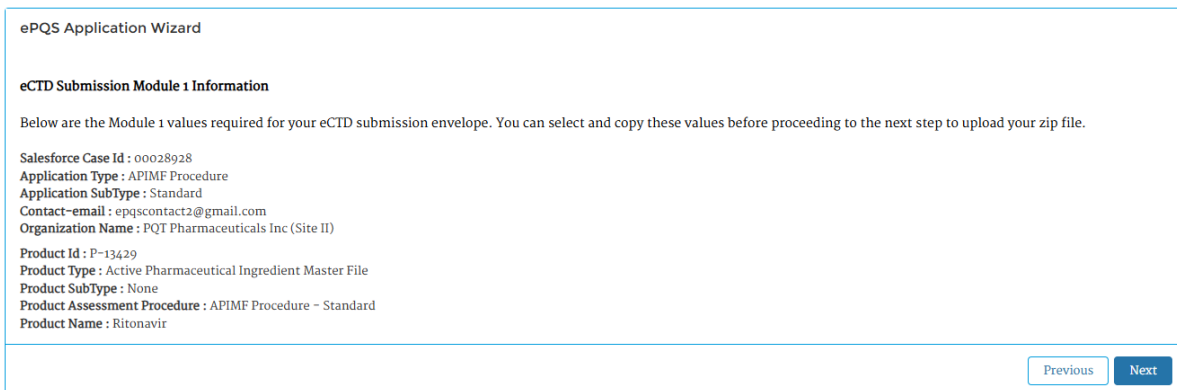


Figure 23: Information is provided for the applicant to complete their Module 1 Envelope information

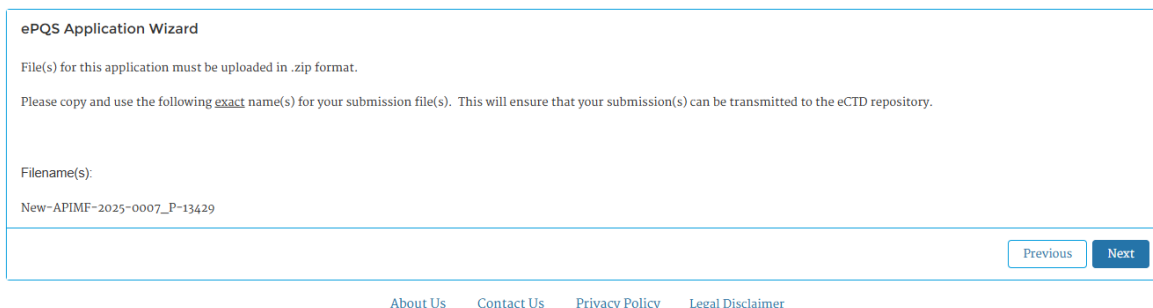


Figure 24: The systems provides the exact name to be used for the uploaded zip file

Next, the system displays the exact name the submitted file should be named. The dossier for a product should be formatted in a single “.zip” file.

5.2. Common document upload steps

The next steps are common to both eCTD and non-eCTD uploads.

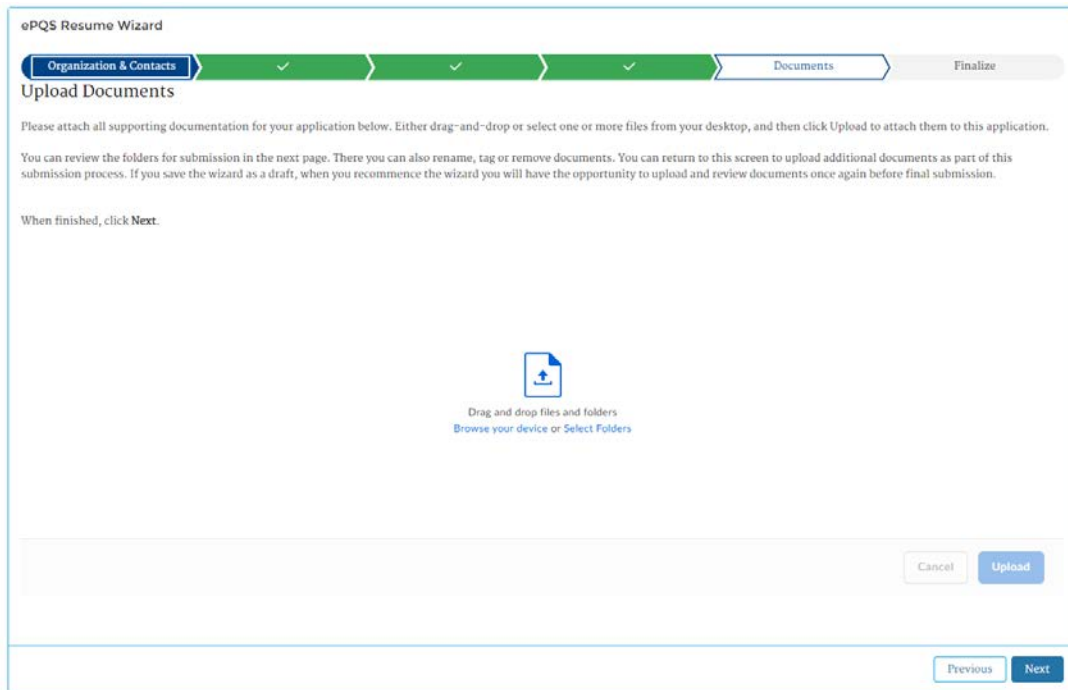


Figure 25: Document upload screen

On the document upload screen you can upload single files, multiple files or folders. Press next once these are selected.

Please note that non-eCTD dossiers should not be uploaded as a Zip file, but as folders or documents.

You will be asked to confirm upload, you can also cancel and go back to the previous screen (figure 26).

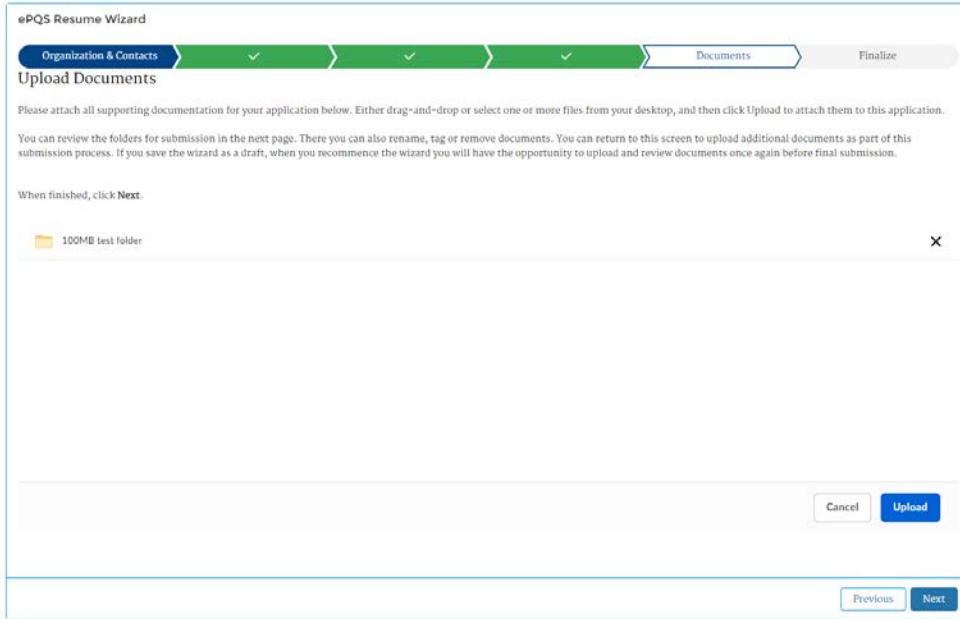


Figure 26: Confirmation of the upload is required

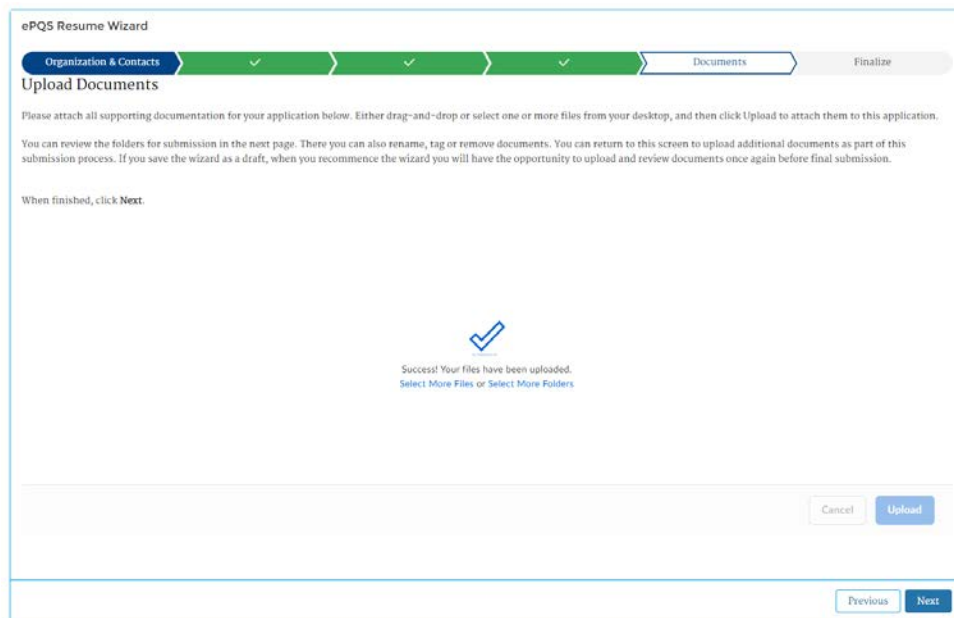


Figure 27: If the documents have uploaded successful a confirmation screen will appear

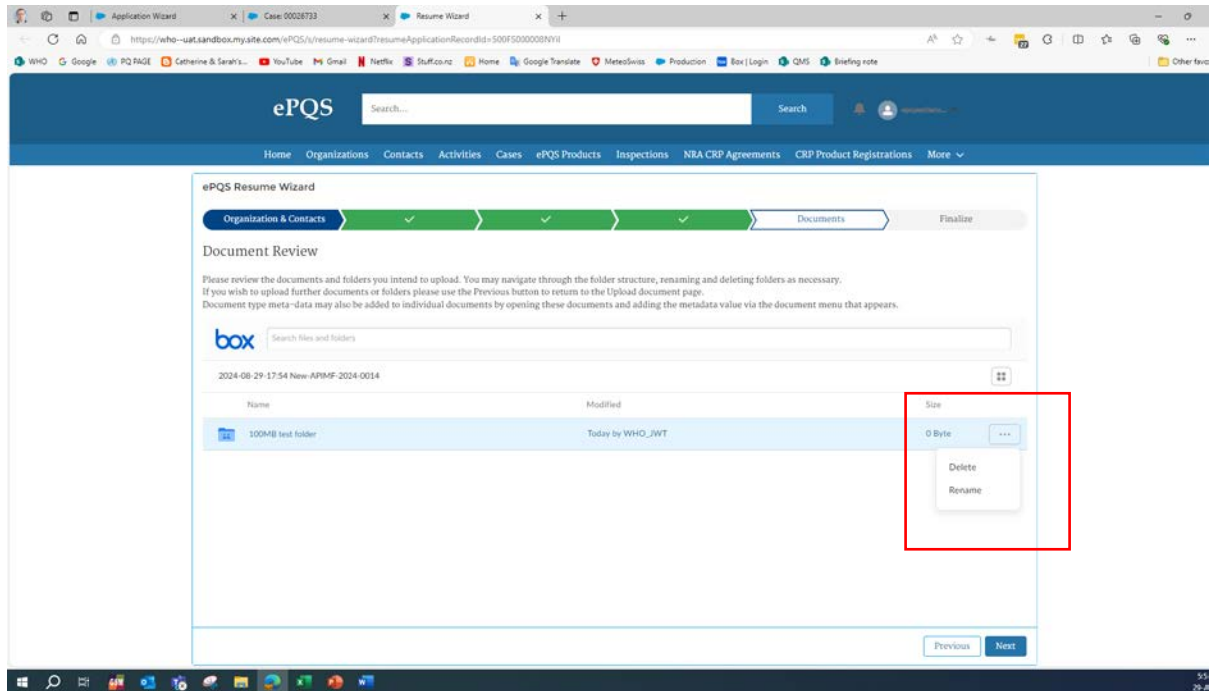


Figure 28: Document review screen where the uploaded files can be adjusted if necessary

Before moving to submission you will be asked to review the files intended to be submitted. You can delete or rename the documents. You can also navigate through the uploaded folder structure to make more granular changes.

6. Submitting the application

The screenshot shows the 'ePQS Application Wizard' interface. At the top, a progress bar indicates that the 'Organization & Contacts' step is complete, followed by three more steps, and a 'Finalize' button. Below the progress bar, the heading 'Review Application' is displayed. A paragraph of text explains the importance of reviewing the application before submission. Two case identifiers are provided: 'Case ID: New-APIMF-2025-0007' and 'Product or Laboratory ID: P-13429'. A section titled 'Submit, Save or Discard' asks the user to choose an option: 'Ready to submit?'. Three radio buttons are listed: 'Yes', 'No, save existing draft application and product (if applicable)', and 'No, discard this draft application and product (if applicable)'. A red warning message states: 'Your application cannot be submitted. eCTD submissions require all files to be .zip format and named as specified in previous steps. Please click 'Previous' to correct your file(s) before submitting.' At the bottom right, there are 'Previous' and 'Next' buttons.

Figure 29: Final screen before submitting

The final screen before submitting has three options. Save as a draft (see section 8), submitting, or discarding the application. If you discard the application, the application and product record will no longer be visible in the application and product lists. It can still be found via the global search bar. Periodically, the ePQS Admin officer will delete these records.

The system will warn the applicant if the eCTD document requirements have not been met with respect to file name and the type and number of files. Press the “previous” button to move backwards in the wizard, back to the document upload step, to revise the files to be uploaded.

The screenshot shows the 'ePQS Resume Wizard' interface. At the top, there is a search bar and a 'Search' button. Below the search bar, a navigation menu includes 'Home', 'Organizations', 'Contacts', 'Activities', 'Cases', 'ePQS Products', 'Inspections', 'NRA CRP Agreements', 'CRP Product Registrations', and 'More'. The main content area shows the 'ePQS Resume Wizard' with a progress bar indicating that the 'Organization & Contacts' step is complete, followed by three more steps, and a 'Finalize' button. Below the progress bar, the heading 'Application Submitted' is displayed. A paragraph of text states: 'The application wizard has now finished - click on the Finish button to be redirected to the detailed page of your submitted application.' At the bottom right, there is a 'Finish' button. At the bottom of the page, there are links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

Figure 30: Confirmation screen

Currently there is a bug that displays “Invalid” once finished is selected. This can be disregarded. Simply select a new list or refresh the screen.

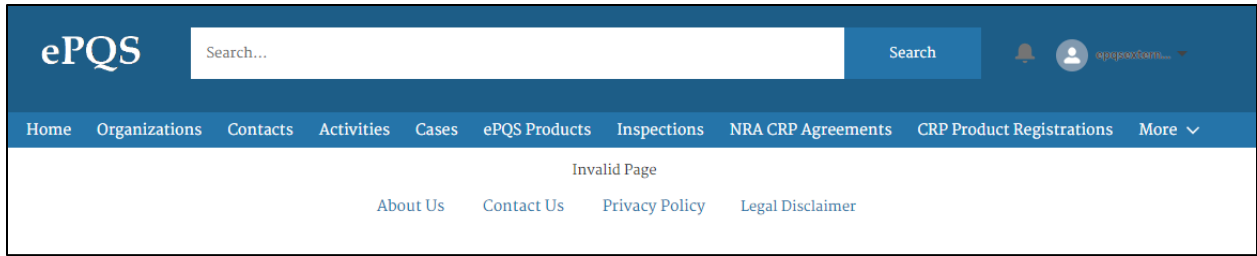


Figure 31: Currently there is a bug once you press finish. Simply refresh the page to continue in the portal

7. Upon Submission

Several changes are made to the application and product record once submitted.

First, the ownership of the record changes to an internal assessment queue, meaning the record is no longer editable (see figure 32). Second, the status of the application changes from Draft to Under Screening. Finally, the Date Application Submitted is entered or updated by the system.

The screenshot shows a case record for 'New-APIMF-2024-0013'. At the top, there are buttons for '+ Follow', 'Edit', 'Resume Application Wizard', and 'New Component(s)'. Below this, a summary row displays: Case Record Type (Mx APIMF Application), Case Number (00026722), Status (Under Screening), Applicant Organization (ePQS Test Account 1 - NonStateActor), and Date of Prequalification/Acceptance. A navigation bar includes 'Details', 'Related', 'Activities', 'Preview Document', 'Document Download', and 'Document Submission'. The 'General Details' section is expanded, showing a table of fields:

ePQS Case ID	New-APIMF-2024-0013	Case Owner	ePQS Mx API Queue
WHO Application Number	New-APIMF-2024-0013	Status	Under Screening
WHO Product ID	P-12650	Applicant Organization	ePQS Test Account 1 - NonStateActor
Product Type		Applicant Organization (Legal)	

Red boxes in the original image highlight the 'Case Owner' and 'Status' fields, indicating their updated values after submission.

Figure 32: Record ownership and status changes once submitted

If an eCTD submission has been submitted, the eCTD compliance field on the application and product records will be updated initially to tentative. If eCTD validation step is successful the eCTD Compliance will then be set to Yes. If the eCTD validation step is unsuccessful, the eCTD Compliance value will remain as Tentative.

7.1. Notifications

An email notification is sent to the Primary contact of the application confirming the submission of the application.

If an eCTD application has been submitted, a further email notification will be received within approximately 30 minutes informing the applicant of the validation outcome of the submitted sequence. The eCTD validation report is placed in the Correspondence (External) folder of the application record as seen in figure 33.

Case **New-APIMF-2025-0007** + Follow Edit Resume Application Wizard New Component(s) ▼

Case Record Type	Case Number	Status	Applicant Organization	Date of Prequalification/Acceptance
Mx APIMF Application	00028928	Draft	PQT Pharmaceuticals Inc (Site II)	

Details Related Activities **Preview Document** Document Download Document Submission

box Search files and folders

New-APIMF-2025-0007 ☰


Name	Modified	Size
 Correspondence (External)	Today	0 Byte

Figure 33: eCTD validation reports are placed in the Correspondence (External) folder of the application

8. Saving as a draft and recommencing

Draft applications can be restarted from the application record by selecting the Resume Application Wizard button on the specific draft application.

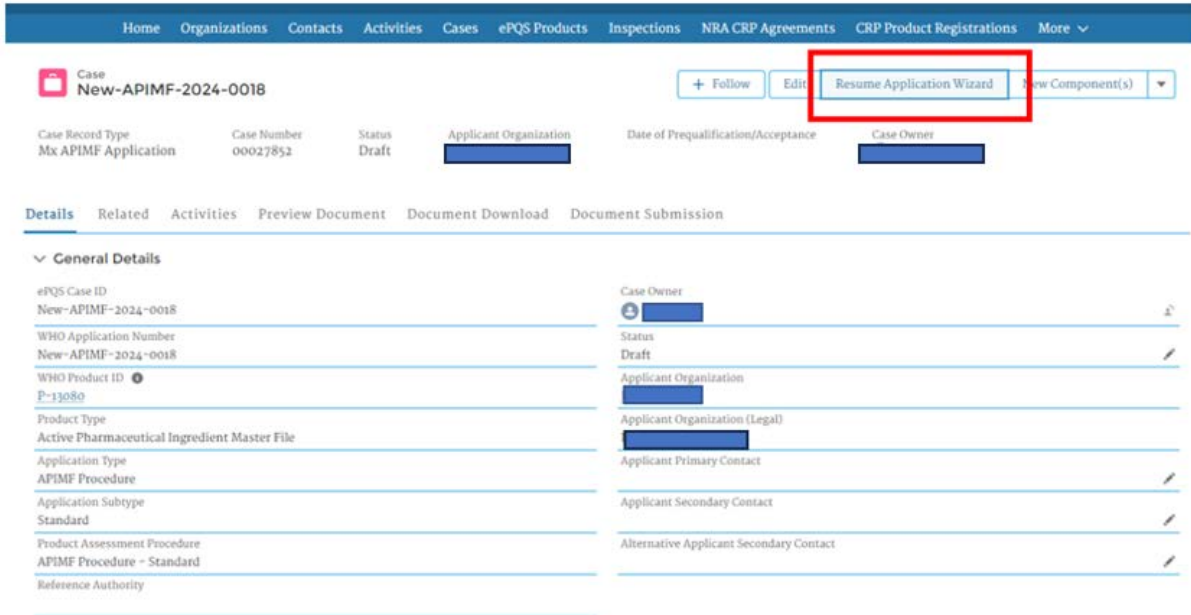


Figure 34: Figure 7: Select the Resume Application Wizard button to recommence the application wizard.

The application wizard when restarted commences from the next applicable section

NOTE: There is a bug in the wizard currently. This means that upon resumption the user is taken directly to the document upload section. Please avoid closing the wizard before reaching the document upload steps. If this occurs for any reasons please reach out to ePQS@who.int for assistance.

Should the application stay in draft for more than 60 days an email reminder will be sent to the application's primary contact.

9. Acceptance for assessment

If the screening is successful, the API Assessment group will accept the application for assessment. This results in the change in status of the Product and Application record to Under Assessment.

Subsequently, you will receive an email from the API assessment group confirming the acceptance of assessment of the application as per normal business processes.

This ends the initial steps in the wizard and initial application process.

10. Receiving and responding to questions

Receiving and uploading documents in response to screening or assessment queries occurs in the same manner as described below.

10.1. Receiving requests

The primary means for alerting an applicant that there are questions or information required is via email. In case further information is required, you will be contacted by the API group by email.

If a letter has been sent with the email, a copy of this letter can be located in the Correspondence (External) folder, which is accessible via the application record as indicated in figure 35.

Name	Modified	Size
Correspondence (External)	Tue Aug 27 2024	0 Byte

Figure 35: Formal correspondence is located in the applications external Correspondence folder. It can be previewed and downloaded.

In addition, you will notice that an Activity has been opened in the name of the primary contact (figure 36). And, the system will have been sent an email alerting the assignee to this (figure 37).

Activity No...	Subject	Owner Last Name	Related To ...	Status	Start Date	Due Date	End Date
1 EA-004807	Request for Information (Screening)	ePQS Test Contact 1		In-Progress	05/05/2022		
2 EA-004812	Suspended	ePQS Test Contact 1		In-Progress	05/05/2022		
3 EA-006194	Request for Information	ePQS Test Contact 1	00018191	Completed	15/02/2003		15/08/2003
4 EA-020567	Request for Information (Screening)	Applicant 1	00026722	In-Progress	02/09/2024		

Figure 36: Outstanding tasks can be viewed via the activity list

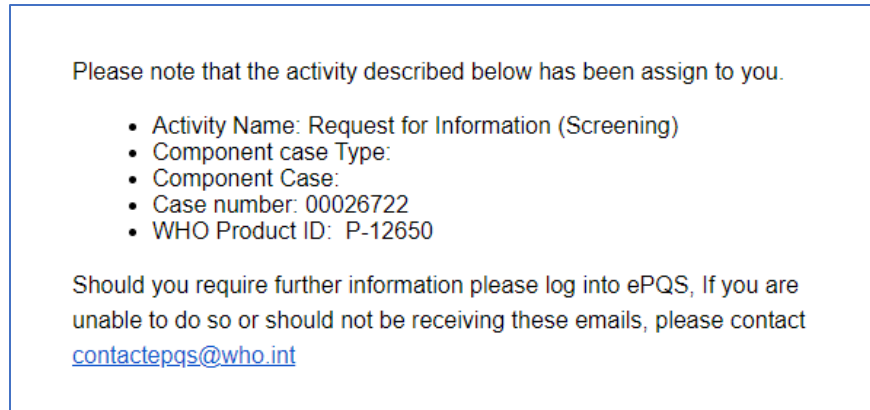


Figure 37: When an activity is assigned an accompanying email is also sent

10.2. Responding to requests

To upload documents in response to questions raised, or in response to eCTD validation requests, proceed to the application and select the document submission tab. **Do not start a new application wizard.**

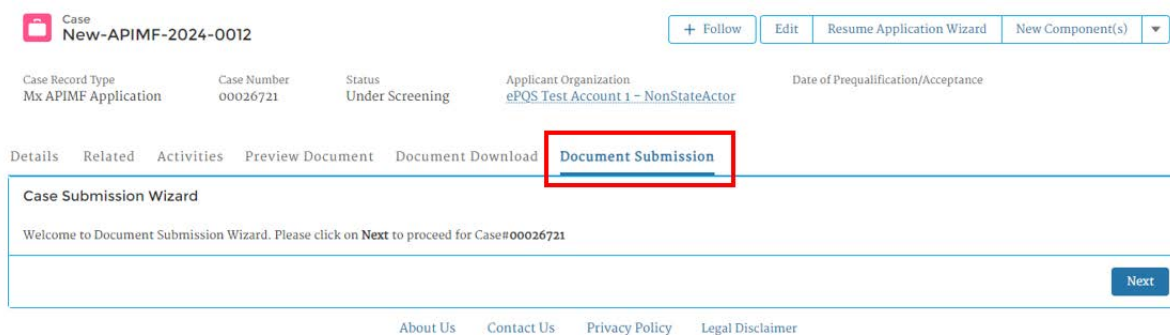


Figure 38: Documents can be uploaded via the application record, using the Document submission tab.

This commences a short wizard to upload documents. The wizard functions in the same way as the document steps in the initial wizard. Note, like initial submission information, uploaded information cannot be seen once submitted.

If the application was made in eCTD format, then subsequent responses must also be in eCTD. In such situations, the system will display the information for the Module 1 envelope and exact file name, as it did for the initial submission (see figure 23 and 24).

An email notification is sent to the Primary contact of the application confirming the submission of the application.

In addition to any correspondence you might send to the assessment team alerting them to the response, you can also signal your response by changing the status of the activity to “actioned” as indicated in figure 39.

The screenshot shows a form with three main sections: Information, Case Information, and System Information. The Information section includes fields for Related To (Case), Related To (Inspection), Activity Name (Request for Information (Screening)), Due Date, Start Date (05/05/2022), and End Date. The Case Information section includes Case Record Type, WHO Product ID, and Component Type. The System Information section includes Created By (Kingsley Aboagye AWUKU, 05/05/2022, 14:26) and Last Modified By (Kingsley Aboagye AWUKU, 26/05/2022, 13:51). The Status dropdown menu is open, showing 'Actioned' as the selected option. The Activity Outcome is 'Under Screening' and the Activity Phase is 'Under Screening'. There are 'Cancel' and 'Save' buttons at the bottom.

Figure 39: By changing the status of the pending activity to Action this signals to the assessment team a response has been submitted.

Once your response has been reviewed, and assuming this is a valid response, the assessment team will change the status and outcome of the activity, and enter the end date.

The screenshot shows the same form as Figure 39, but with updated values. The Status is now 'Completed' and the Activity Outcome is 'Received'. The Response Date is '02/09/2024'. The End Date is also '03/09/2024'. The Activity Name is 'Request for Information (Screening)'. The Case Record Type is 'Mx APIMF Application' and the WHO Product ID is 'P-12650'. The Component Type is empty. The Owner is 'ePOS External Applicant 1'. There are 'Cancel' and 'Save' buttons at the bottom.

Figure 40: Once the response is reviewed the activity will be further updated

This completes the response to a request for screening information.

11. Record monitoring

Further guidance on other aspects of the portal will be provided in separate documents, but generally speaking you can monitor the status of your applications, product and activities using the various list views available from the menu bar at the top of the portal landing page