

## Table of Contents

1	Scope .....	2
2	Prerequisites .....	2
3	Accessing the Portal.....	2
4	Wizard steps.....	3
4.1	Wizard commencement.....	3
4.2	Wizard Selection.....	3
4.2.1	Subtype: eCTD-Baseline.....	5
4.3	eCTD or Non-eCTD .....	6
4.4	Indicating the Products affected by the Post-PQ Change application. ....	7
4.5	Indicating the changes announced in the Post-PQ Change application. ....	8
5	Document uploading .....	11
5.1	I eCTD document upload.....	11
5.2	Common document upload steps .....	13
6	Submitting the application .....	15
7	Upon Submission.....	16
7.1	Notifications .....	17
8	Saving as a draft and recommencing .....	18
9	Acceptance for assessment .....	18
10	Receiving and responding to questions .....	19
10.1	Receiving requests .....	19
10.2	Responding to requests.....	20
11	Record monitoring.....	21

## 1 Scope

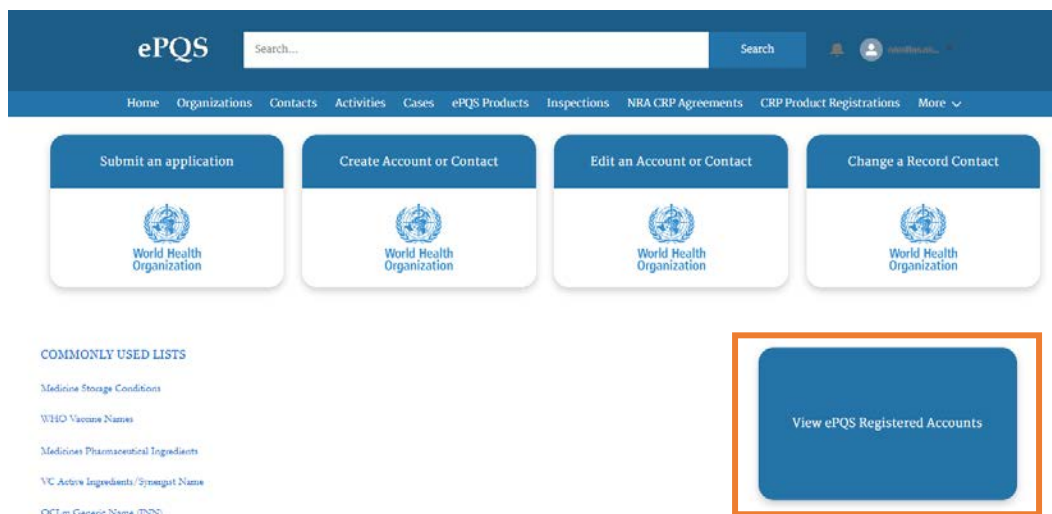
This guidance covers the submission of an application for the Active Pharmaceutical Ingredient Master File (APIMF) post-PQ Change (aka an amendment) via the ePQS Portal Wizard.

## 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 via the form available on the Portal landing page.

Post-prequalification change applications 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.



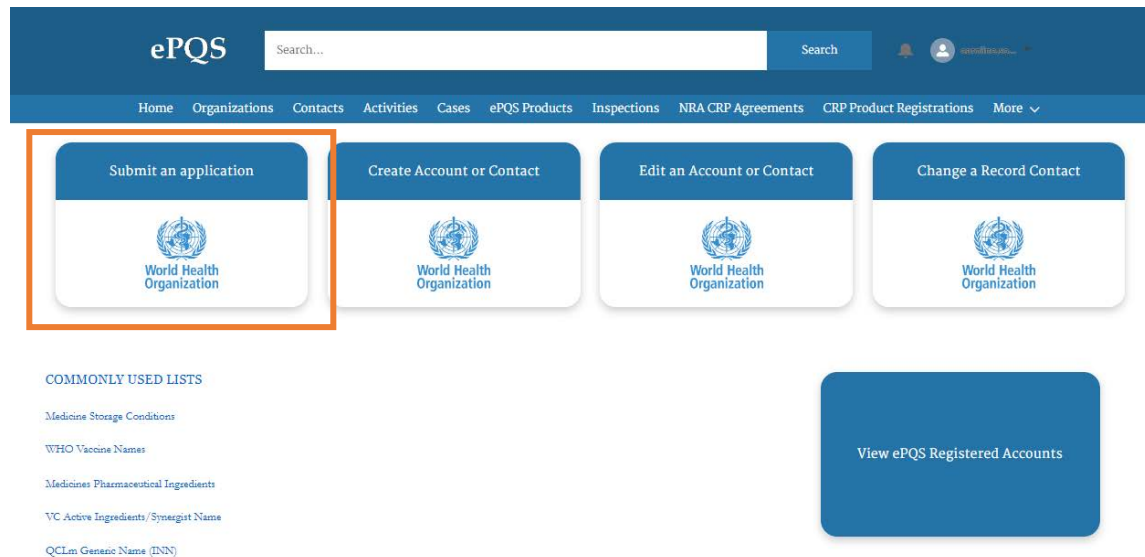
*Figure 1. The existence of an Account within the ePQS system can be determined by selecting the indicate - “View ePQS Registered Accounts”*

## 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. Note, the contacts do not need to be ePQS portal users, although pragmatically likely they are.

Home Organizations Contacts Activities Cases ePQS Products Inspections Notified Agreements Application Wizard more

### 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--

Previous Next

About Us Contact Us Privacy Policy Legal Disclaimer

*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 for 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

Previous Next

About Us Contact Us Privacy Policy Legal Disclaimer

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

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.

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

#### 4.2.1 Subtype: eCTD-Baseline applications

One of the six API Post-Prequalification change application subtypes is the subtype: eCTD-Baseline. The eCTD baseline is intended as the process by which applicants can convert the format of an accepted APIMF from non-eCTD to eCTD. The associated product must be eCTD non-compliant.

The system will the check to see if there are any eligible products that match the applicant company. For an APIMF Post-PQ change this means an APIMF with the status of Accepted.

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*Figure 6. The system will confirm there is an APIMF eligible for a Post-PQ change*

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

Previous Next

About Us Contact Us Privacy Policy Legal Disclaimer

*Figure 7. The system summarizes the application is to be created*

ePQS Application Wizard

Organization & Contacts Application Info Product Details Documents Finalize

### Continue Application

A draft application has been created.

For reference the new application has the case number PQC-APIMF-2024-0096. You can view the draft application details by following the link.

Next

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*Figure 8. 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.

### 4.3 eCTD or Non-eCTD

ePQS Application Wizard

\*Select Document Format

☐ eCTD

☐ Non-eCTD

Previous Next

About Us Contact Us Privacy Policy Legal Disclaimer

*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.

The decision to file in eCTD or non-eCTD also affects the APIMFs that maybe associated with a Post-PQ Change application. A Post-PQ Change application in eCTD format necessarily requires that all associated products are eCTD compliant and visa versa.

#### 4.4 Indicating the Products affected by the Post-PQ Change application.

For the APIMF Post-PQ application wizard, the next steps involve associating one or more APIMFs to the application and listing the change types being proposed.

The screenshot shows the 'ePQS Resume Wizard' interface. At the top, a progress bar has five steps: 'Organization & Contacts' (checked), 'Add Change Information' (checked), 'Post-PQ Changes' (active), 'Documents', and 'Finalize'. Below the progress bar, the title 'Add Change Information' is followed by the instruction: 'You will need to list the products that are being changed, and also record the change types that apply'. Under the heading 'Either', there are three radio button options: 'Add products that are the subject of post-prequalification changes' (selected), 'Add one or more pieces of information about the change, including the type', and 'No more at this time'. A 'Next' button is located at the bottom right. At the very bottom of the page, there are links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

*Figure 10. You will then be asked to add the relevant products or change types being proposed*

At least one product needs to be added. To do so select the radio button and press Next.

The system will offer you a list of APIMFs that are eligible. These being accepted APIMFs from the same company. And, only APIMFs that are eCTD or non-eCTD depending if an eCTD or non-eCTD application is being submitted.

The screenshot shows the 'ePQS Resume Wizard' interface. The progress bar now shows 'Organization & Contacts' (checked), 'Add Change Information' (checked), and 'Post-PQ Changes' (active). The title 'Select Products' is followed by the instruction: 'Choose a product that is the subject of a change. Only those with a status of Prequalified or Acceptable are available.' Below this, a note states: '\* Product(s): To select multiple items, hold down the Ctrl (PC) or Command (Mac) key'. A search bar contains the text 'P-12646 UAT - Ritonavir'. At the bottom right, there are 'Previous' and 'Next' buttons. The footer links 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer' are also present.

*Figure 11. You are then asked to choose from a list of eligible products*

The screenshot shows the 'ePQS Resume Wizard' interface. The progress bar shows 'Organization & Contacts' (checked), 'Add Change Information' (checked), and 'Post-PQ Changes' (active). The title 'Add Products' is followed by a 'Success' message: 'The following product(s) have been linked with your PQ-APIMF-2024-0096 application: P-12646 UAT'. A 'Next' button is located at the bottom right. The footer links 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer' are also present.

You can repeat this process to add further APIMFs.

You are then returned to the original decision screen in figure 10, where you can associate further products or move on to add information about the change type.

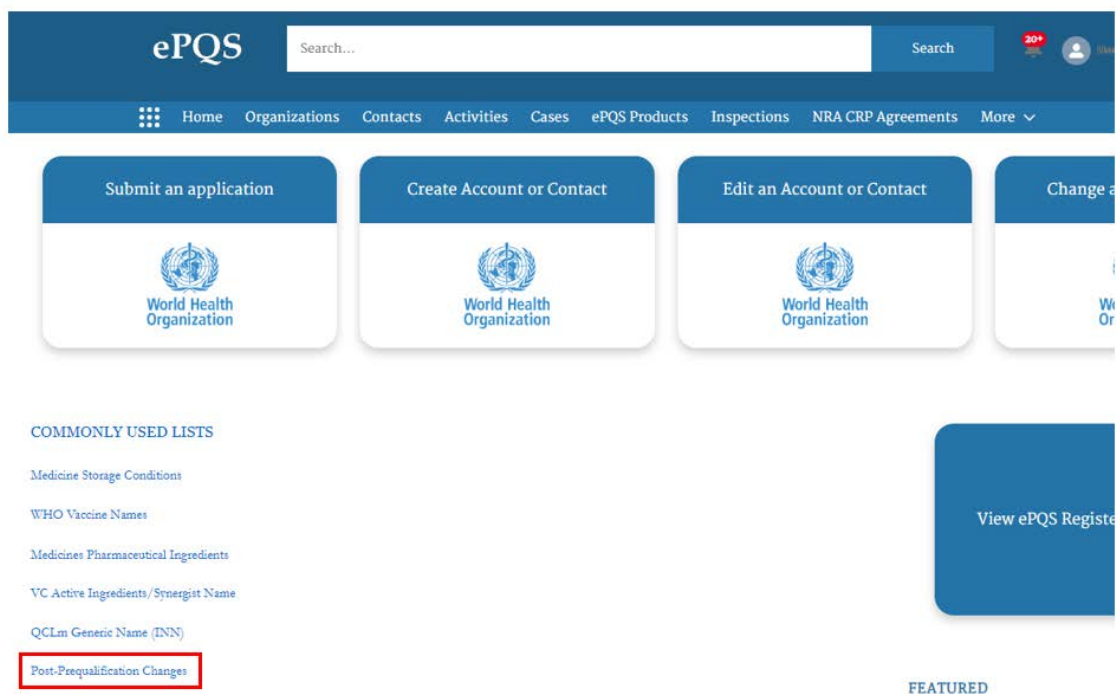
**Figure 13.** Select the radio button to add change information

The screenshot shows the ePQS Resume Wizard interface. The wizard is at the 'Add Change Info' step, which is highlighted in green. The previous step, 'Organizations & Contacts', is also highlighted in green. The next step, 'Post-PQ Changes', is highlighted in grey. The 'Documents' and 'Finalize' steps are also highlighted in grey. The 'Add Change Info' section has a dropdown menu for 'Change Type' with the following options:

- Amend 010 Baseline - ASN
- Amend 010 New APISF revision (new) - ASN
- Amend 010 New APISF revision (old) - ASN
- Amend 020 Change in site name of Intermediate of API manufacturer - ASN
- Amend 020 Change in site name of SM manufacturer - ASN
- Amend 020 Change in APISF holder name - ASN
- Amend 020 Selection of manufacturing block on site - API or intermediate - ASN**
- Amend 020 Selection of manufacturing block on site - API or intermediate - ASN
- Amend 020 Change in document numbering - API specification related - ASN
- Amend 020 Addition of new site - testing - ASN
- Amend 020 Addition of new site - testing - API
- Amend 020 Addition of new site - API SM - ASN
- Amend 020 Addition of new site - API SM - ASN
- Amend 020 Addition of new site - Intermediate - ASN
- Amend 020 Addition of new site - Intermediate - API
- Amend 020 Addition of new site - API - ASN
- Amend 020 Addition of new site - API - API
- Amend 020 Addition of new site - API - API

Note that a complete list of change types can be located from the portal Home page as indicated in figure 15.





*Figure 15. A reference list of Post-Prequalification Changes can be obtained from the indicated list*

On the next page a brief description of the change can be entered, but this is not required for APIMF Post-PQ change applications. Later in the wizard there is the opportunity to summarize the amendment and a full description of the change must be include in the submission documentation.

*Figure 16. The change request is displayed on the next page. There is no need to enter an additional change description.*

ePQS Resume Wizard

Organization & Contacts

✓

✓

Post-PQ Changes
Documents
Finalize

Add Change Info

Success

The change of type "Amend 01b New APIMF version (since 2023) - AIN" has been linked with your PQC-APIMF-2024-0096 application.

Next

About Us
Contact Us
Privacy Policy
Legal Disclaimer

Figure 17. Confirmation of the creation of the change type record

Case

PQC-APIMF-2024-0096

+ Follow
Edit
Resume Application Wizard
New Component(s)

Case Record Type

Case Number

Status

Applicant Organization

Date of Prequalification/Acceptance

Mx API Post-PQ Change

00026772

Draft

ePQS Test Account 1 - NonStateActor

Details
Related
Activities
Preview Document
Document Download
Document Submission

Related Cases (0)

Commitments/Established Conditions (0)

Case History (4)

Date	Field	User	Original Value	New Value
10/09/2024, 17:29	Overall Change Severity Rating	ePQS External Applicant 1		AIN
10/09/2024, 16:43	Created.	ePQS External Applicant 1		
10/09/2024, 16:43	ePQS Case ID	ePQS External Applicant 1		PQC-APIMF-2024-0096
10/09/2024, 16:43	WHO Application Number	ePQS External Applicant 1		PQC-APIMF-2024-0096

View All

Application Changes (1)

Change Ref.	Application Change Type	Change Severity
AC-09450	Amend 01b New APIMF version (since 2023)	AIN

View All

Figure 18. Related tab of the APIMF Post-PQ Change application record

If viewing the record for this application, the related tab a list of the changes applicable to the application can be seen.

You will be again returned to the decision screen where you can add additional related products or change types. Once all information has been entered, choose “no more at this time to move to the next page.

ePQS Resume Wizard

Add Overall Change Info

Enter the following before finalising the application

\* Description of Changes Requested

test

Next

About Us Contact Us Privacy Policy Legal Disclaimer

*Figure 19. A concise summary of the application should be entered.*

Please enter a concise summary of the amendment application. Noting that a full description should be present in the application documentation. You will then move to the document uploading step.

## 5 Document uploading

ePQS Resume Wizard

You are uploading documents to Product#P-12656

Next

About Us Contact Us Privacy Policy Legal Disclaimer

*Figure 20. Initial document upload screen*

### 5.1 eCTD document upload

If an eCTD submission is being made, the system will now display information that the applicant should use to complete the module 1 envelope for their dossier. The wizard may be paused at this stage and resumed once the dossier sequence file has been published.

**ePQS Application Wizard**

**eCTD Submission Module 1 Information**

Below are the Module 1 values required for your eCTD submission envelope. You can select and copy these values before proceeding to the next step to upload your zip file.

Salesforce Case Id : 00028199  
 Application Type : Post-PQ Change  
 Application SubType : AAN  
 Contact-email : epqsmx1+ectduats@proton.me  
 Organization Name : eCTD Mx Account - ZM

Product ID	Product Type	Product SubType	Product Assessment Procedure	Product Name
APIMFMZ-2	Active Pharmaceutical Ingredient Master File	None	Prequalification - Abridged	Rifampicin
APIMEZM-1	Active Pharmaceutical Ingredient Master File	None	Prequalification - Standard	Rifampicin

*Figure 21. Information is provided for the applicant to complete their Module 1 Envelope information*

**ePQS Application Wizard**

File(s) for this application must be uploaded in .zip format.

Please copy and use the following exact name(s) for your submission file(s). This will ensure that your submission(s) can be transmitted to the eCTD repository.

Filename(s):

FileNames:
PQC-APIMF-2025-0010-APIMFMZ-2
PQC-APIMF-2025-0010-APIMEZM-1

*Figure 22. The systems provides the exact name to be used for the uploaded zip file*

Next, the system displays the exact named the submitted filed should be named. The dossier for each product should be formatted in “.zip” file format.

## 5.2 Common document upload steps

The screenshot shows the 'ePQS Resume Wizard' interface. At the top, a progress bar indicates four steps: 'Organization & Contacts' (completed with a checkmark), two intermediate steps (also completed with checkmarks), 'Documents' (the current step, highlighted with a blue border), and 'Finalize' (disabled). Below the progress bar, the title 'Upload Documents' is displayed. The main text area contains instructions: 'Please attach all supporting documentation for your application below. Either drag-and-drop or select one or more files from your desktop, and then click Upload to attach them to this application. You can review the folders for submission in the next page. There you can also rename, tag or remove documents. You can return to this screen to upload additional documents as part of this submission process. If you save the wizard as a draft, when you recommence the wizard you will have the opportunity to upload and review documents once again before final submission. When finished, click Next.' In the center, there is a large blue square icon with a white document and a plus sign, with the text 'Drag and drop files and folders' and 'Browse your device or Select Folders' below it. At the bottom right, there are two buttons: 'Cancel' and 'Upload'. At the very bottom, there are two buttons: 'Previous' and 'Next'.

*Figure 23. 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 24).

ePQS Resume Wizard

Organization & Contacts ✓ ✓ ✓ Documents Finalize

### Upload Documents

Please attach all supporting documentation for your application below. Either drag-and-drop or select one or more files from your desktop, and then click Upload to attach them to this application.

You can review the folders for submission in the next page. There you can also rename, tag or remove documents. You can return to this screen to upload additional documents as part of this submission process. If you save the wizard as a draft, when you recommence the wizard you will have the opportunity to upload and review documents once again before final submission.

When finished, click **Next**.

100MB test folder

✕

Cancel

Upload

Previous

Next

Figure 24. Confirmation of the upload is required

ePQS Resume Wizard

Organization & Contacts ✓ ✓ ✓ Documents Finalize

### Upload Documents

Please attach all supporting documentation for your application below. Either drag-and-drop or select one or more files from your desktop, and then click Upload to attach them to this application.

You can review the folders for submission in the next page. There you can also rename, tag or remove documents. You can return to this screen to upload additional documents as part of this submission process. If you save the wizard as a draft, when you recommence the wizard you will have the opportunity to upload and review documents once again before final submission.

When finished, click **Next**.

✓

Success! Your files have been uploaded.  
[Select More Files](#) or [Select More Folders](#)

Cancel

Upload

Previous

Next

Figure 25. If the documents have uploaded successful a confirmation screen will appear

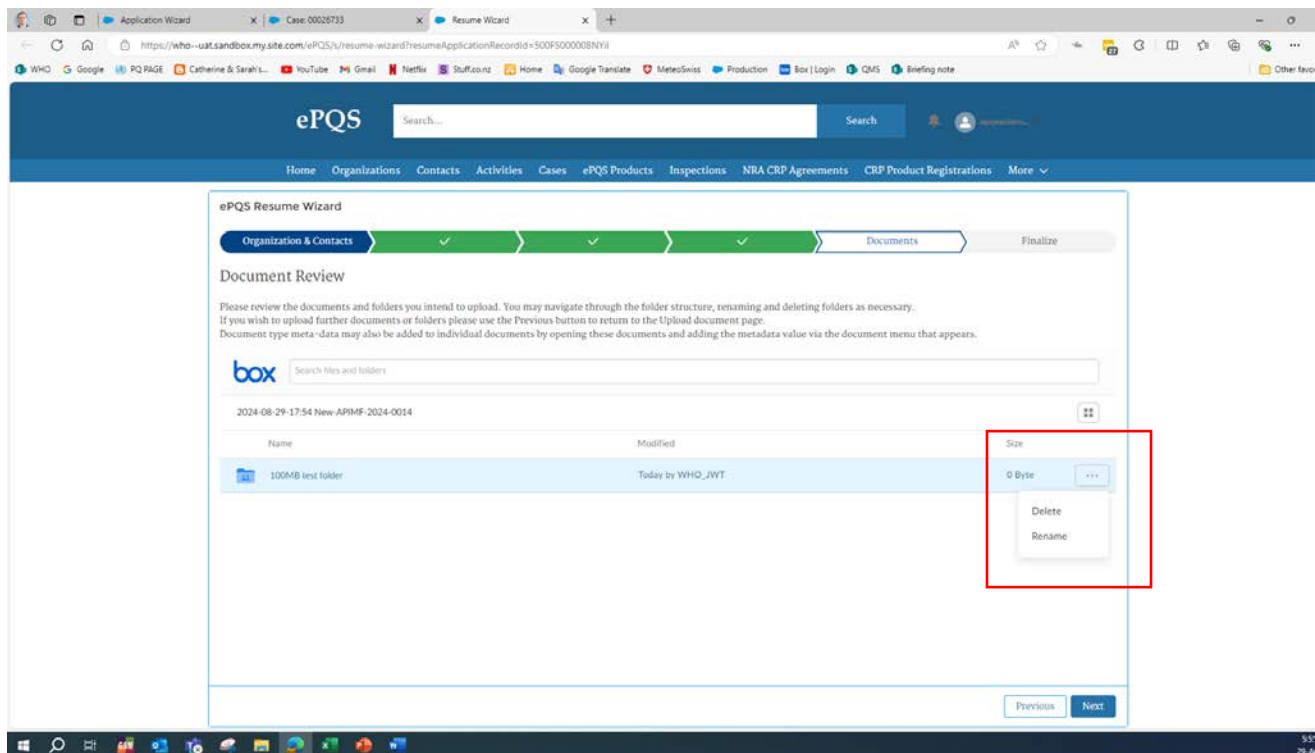


Figure 26. Document review screen where the uploaded files can be adjusted if necessary

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

ePQS Application Wizard

Organization & Contacts

Review Application

It is important that you review your application prior to submission. Use the link provided to open it in a new tab and look at the information entered, and also review the related records (click on the Related sub-tab) of which you should be able to open those records too.

Case ID: New-APIMF-2025-0007

Product or Laboratory ID: P-13429

**Submit, Save or Discard**

Please choose whether you are ready to submit this application, if you need more time then save the existing draft, or discard if made in error.

Ready to submit?

☐ Yes

☐ No, save existing draft application and product (if applicable)

☐ No, discard this draft application and product (if applicable)

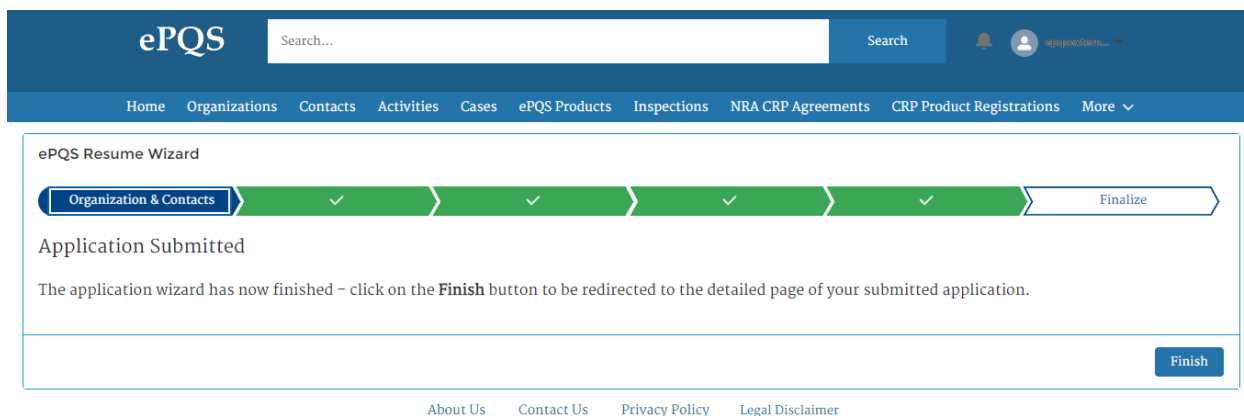
Your application cannot be submitted. eCTD submissions require all files to be .zip format and named as specified in previous steps. Please click 'Previous' to correct your file(s) before submitting.

Previous Next

Figure 27. Final screen before submitting

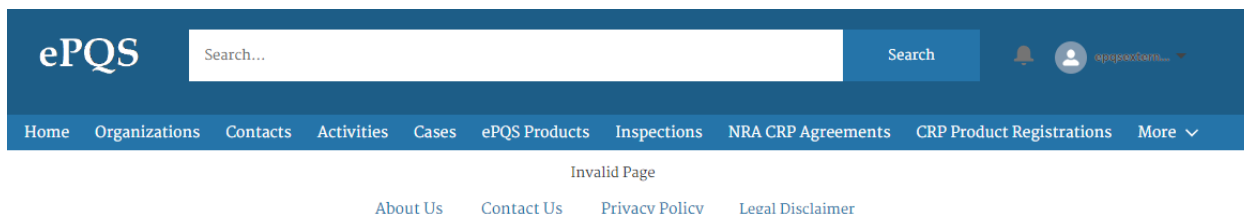
The final screen before submitting has three options. Save as a draft (see section 8), submitting, or discarding the application. If you discard the application, the application and product record will no longer be visible in the application and product lists. It can still be found via the global search 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 documents to be uploaded.



*Figure 28. 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 29. 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 30). Second, the status of the application changes from Draft to Under Screening. Finally, the Date Application Submitted is entered or updated by the system.



Case

New-APIMF-2024-0013

+ Follow

Edit

Resume Application Wizard

New Component(s) ▼

Case Record Type

Case Number

Status

Applicant Organization

Date of Prequalification/Acceptance

Mx APIMF Application

00026722

Under Screening

ePQS Test Account 1 - NonStateActor

Details

Related

Activities

Preview Document

Document Download

Document Submission

▼ General Details

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)

*Figure 30. Record ownership and status changes once submitted*

If an eCTD submission has been submitted, the eCTD compliance field on the application record 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 31.

Case

PQC-APIMF-2024-0144

+ Follow

Edit

Resume Application Wizard

New Component(s) ▼

Case Record Type

Case Number

Status

Applicant Organization

Date of Prequalification/Acceptance

Case Owner

Mx API Post-PQ Change

00027971

Under Screening

eCTD Mx Account - ZM

ePQS Mx API Queue

Details

Related

Activities

Preview Document

Document Download

Document Submission

box

Search files and folders

PQC-APIMF-2024-0144

Name	Modified	Size
Correspondence (External)	Thu Dec 19 2024	226.88 KB

*Figure 31. 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.

The screenshot shows the ePQS application record page for Case New-APIMF-2024-0018. The top navigation bar includes links for Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. Below the navigation bar, the case details are displayed, including Case Record Type (Mx APIMF Application), Case Number (00027852), Status (Draft), Applicant Organization, Date of Prequalification/Acceptance, and Case Owner. A red box highlights the 'Resume Application Wizard' button, which is located next to the 'Edit' button. Below the case details, there are tabs for Details, Related, Activities, Preview Document, Document Download, and Document Submission. The 'Details' tab is selected, showing General Details for the case, including ePQS Case ID, WHO Application Number, WHO Product ID, Product Type, Application Type, Application Subtype, Product Assessment Procedure, and Reference Authority.

Figure 32. 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](mailto: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

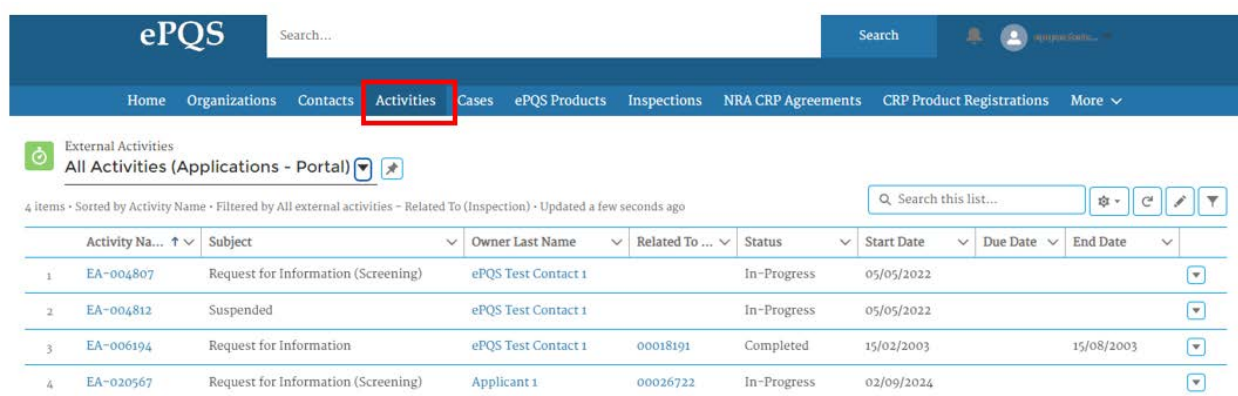
Receiving and uploading documents in response to screening or assessment queries occurs in the same manner.

### 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, a copy of this letter can be located in the Correspondence (External folder), which is accessible via the application record as indicated in figure 31.

In addition, you will notice that an Activity has been opened in the name of the primary contact (figure 33). And, you will have been sent an email alerting you to this (figure 34).



The screenshot shows the ePQS web interface. The 'Activities' tab is highlighted in the top navigation bar. Below the navigation bar, there is a section for 'External Activities' with a sub-header 'All Activities (Applications - Portal)'. A table lists 4 items, sorted by Activity Name. The table has columns for Activity Name, Subject, Owner Last Name, Related To, Status, Start Date, Due Date, and End Date. The first two items are 'Request for Information (Screening)' and 'Suspended', both with status 'In-Progress'. The third item is 'Request for Information' with status 'Completed'. The fourth item is 'Request for Information (Screening)' with status 'In-Progress'.

Activity Na...	Subject	Owner Last Name	Related To ...	Status	Start Date	Due Date	End Date
EA-004807	Request for Information (Screening)	ePQS Test Contact 1		In-Progress	05/05/2022		
EA-004812	Suspended	ePQS Test Contact 1		In-Progress	05/05/2022		
EA-006194	Request for Information	ePQS Test Contact 1	00018191	Completed	15/02/2003		15/08/2003
EA-020567	Request for Information (Screening)	Applicant 1	00026722	In-Progress	02/09/2024		

Figure 33. Outstanding tasks can be viewed via the activity list

Please note that the activity described below has been assign to you.

- Activity Name: Request for Information (Screening)
- Component case Type:
- Component Case:
- Case number: 00026722
- WHO Product ID: P-12650

Should you require further information please log into ePQS, If you are unable to do so or should not be receiving these emails, please contact [contactepqs@who.int](mailto:contactepqs@who.int)

Figure 34. When an activity is assigned an accompanying email is also sent

## 10.2 Responding to requests

To upload documents in response to questions raised, proceed to the application and select the document submission tab.

The screenshot displays the APIMF application interface. At the top, a case header shows 'Case New-APIMF-2024-0012' with buttons for '+ Follow', 'Edit', 'Resume Application Wizard', and 'New Component(s)'. Below this, a table lists case details: Case Record Type (Mx APIMF Application), Case Number (00026721), Status (Under Screening), Applicant Organization (ePOS Test Account 1 - NonStateActor), and Date of Prequalification/Acceptance. A navigation bar includes tabs for Details, Related, Activities, Preview Document, Document Download, and Document Submission (which is highlighted with a red box). The Document Submission Wizard is active, displaying a welcome message: 'Welcome to Document Submission Wizard. Please click on Next to proceed for Case#00026721'. A 'Next' button is located at the bottom right of the wizard. At the very bottom of the page, there are links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer'.

*Figure 35. 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 21 and 22).

The system does not currently alert internal or external users when additional information is uploaded. This is being fixed. In the meantime, please ensure an email is sent to [APlassessment@who.int](mailto:APlassessment@who.int) alerting them that documents have been uploaded.

In addition to any correspondence you might undertake with the assessment team, you can also signal the uploading of your response by changing the status of the activity to “actioned” as indicated in figure 36.

<b>Information</b> Related To (Case) Related To (Inspection) Activity Name Request for Information (Screening) Due Date Start Date 05/05/2022 End Date		Owner User16482068782195409890 Time Assignment Manufacturer *Status Actioned Activity Outcome Activity Phase Under Screening Response Date
<b>Case Information</b> Case Record Type <i>This field is calculated upon save</i> WHO Product ID <i>This field is calculated upon save</i>		Component Type <i>This field is calculated upon save</i>
<b>System Information</b> Created By Kingsley Aboagye AWURU, 05/05/2022, 14:26		Last Modified By Kingsley Aboagye AWURU, 26/05/2022, 13:51
<div> <div>Cancel</div> <div>Save</div> <div> <a href="#">Print</a> <a href="#">Download</a> </div> </div>		

**Figure 36.** 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, then assessment team will change the status and outcome of the activity, and enter the end date.

<b>Information</b> Related To (Case) 00026722 Related To (Inspection) Activity Name Request for Information (Screening) Due Date Start Date 02/09/2024 End Date 03/09/2024		Owner ePOS External Applicant 1 Time Assignment Manufacturer Status Completed Activity Outcome Received Activity Phase Under Screening Response Date 02/09/2024
<b>Case Information</b> Case Record Type Mx APIMF Application WHO Product ID P-12650		Component Type

**Figure 37.** 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.