



External Guidance – APIMF Post-PQ Change Application Wizard guidance

Document Version Number: 1.1

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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.

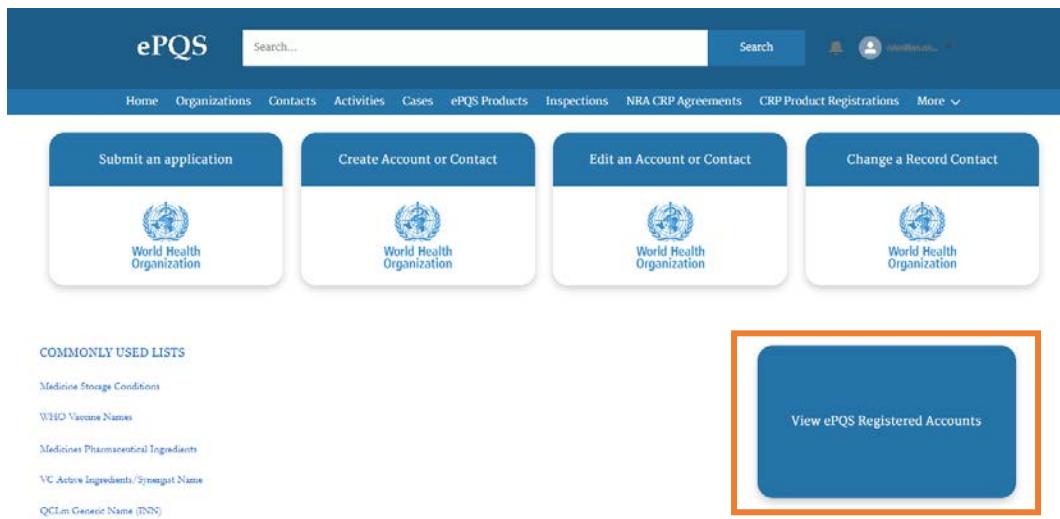


Figure 1. The existence of an Account within the ePQS system can be determined by selecting the indicate - “View ePQS Registered Accounts”

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

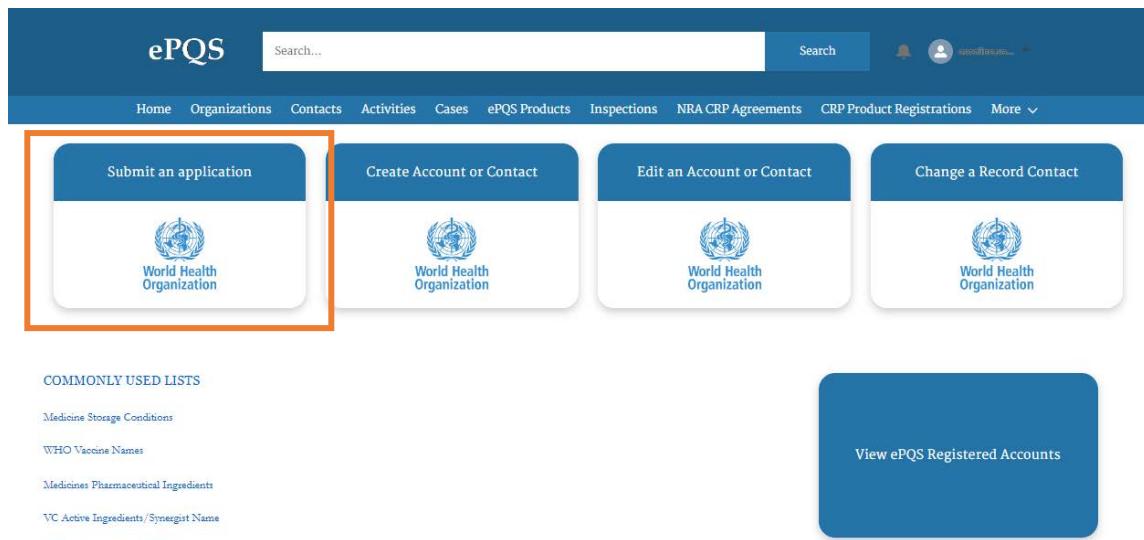


Figure 2. Commence the application process by selecting the Submit an Application tile

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.

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 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

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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.

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

AAN

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Figure 5. Then you will be 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 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.

ePQS Application Wizard

Organization & Contacts Application Info Product Details Documents Finalize

Relevant Products Found

For the specific product type selected, matching relevant prequalified or acceptable status products have been successfully found. You will be asked to link one to this application shortly.

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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

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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.

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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

Organization & Contacts Application Info Product Details Documents Finalize

ePQS Application Wizard

* Select Document Format

eCTD
 Non-eCTD

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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.

ePQS Resume Wizard

Post-PQ Changes

Add Change Information

You will need to list the products that are being changed, and also record the change types that apply

Either

Add products that are the subject of post-prequalification changes

Add one or more pieces of information about the change, including the type

No more at this time

Next

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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.

ePQS Resume Wizard

Organization & Contacts Post-PQ Changes Documents Finalize

Select Products

Choose a product that is the subject of a change
Only those with a status of Prequalified or Acceptable are available.

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

P-12646 UAT - Ritonavir

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

ePQS Resume Wizard

Organization & Contacts Post-PQ Changes Documents Finalize

Add Products

Success
The following product(s) have been linked with your PQC-APIMF-2024-0096 application:
P-12646 UAT

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Figure 12. Confirmation is then received

You can repeat this process to add further APIMFs.

4.5 Indicating the changes announced in the Post-PQ Change application.

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.

Organization & Contacts > Post-PQ Changes > Documents > Finalize

Add Change Information

You will need to list the products that are being changed, and also record the change types that apply

Either

Add products that are the subject of post-prequalification changes

Add one or more pieces of information about the change, including the type

No more at this time

Next

Figure 13. Select the radio button to add change information

On the next screen you will be offered a list of change types to choose from. These correlate to the PQT Amendment guidance categories for APIMFs.

Figure 14. Next select the change type pertinent to the application.

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

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.

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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 Mx API Post-PQ Change	Case Number 00026772	Status Draft	Applicant Organization ePQS Test Account 1 - NonStateActor	Date of Prequalification/Acceptance
---	-------------------------	-----------------	---	-------------------------------------

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	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	PQC-APIMF-2024-0096
10/09/2024, 16:43	WHO Application Number	ePQS External Applicant 1	PQC-APIMF-2024-0096	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

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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

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ePQS Resume Wizard

You are uploading documents to Product#P-12656

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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

2 of 2 items

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

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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):

2 of 2 items

FileNames:

PQC-APIMF-2025-0010_APIMFMZ-2

PQC-APIMF-2025-0010_APIMFZM-1

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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 file should be named. The dossier for each product should be formatted in “.zip” file format.

5.2 Common document upload steps

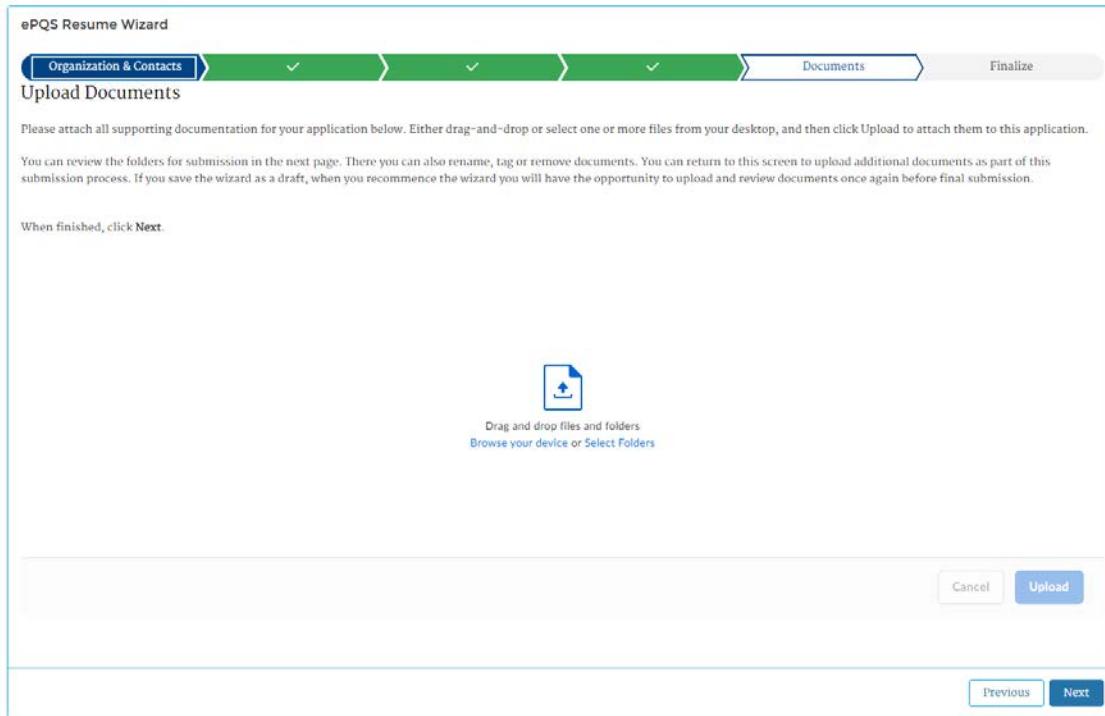


Figure 23. Document upload screen

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).

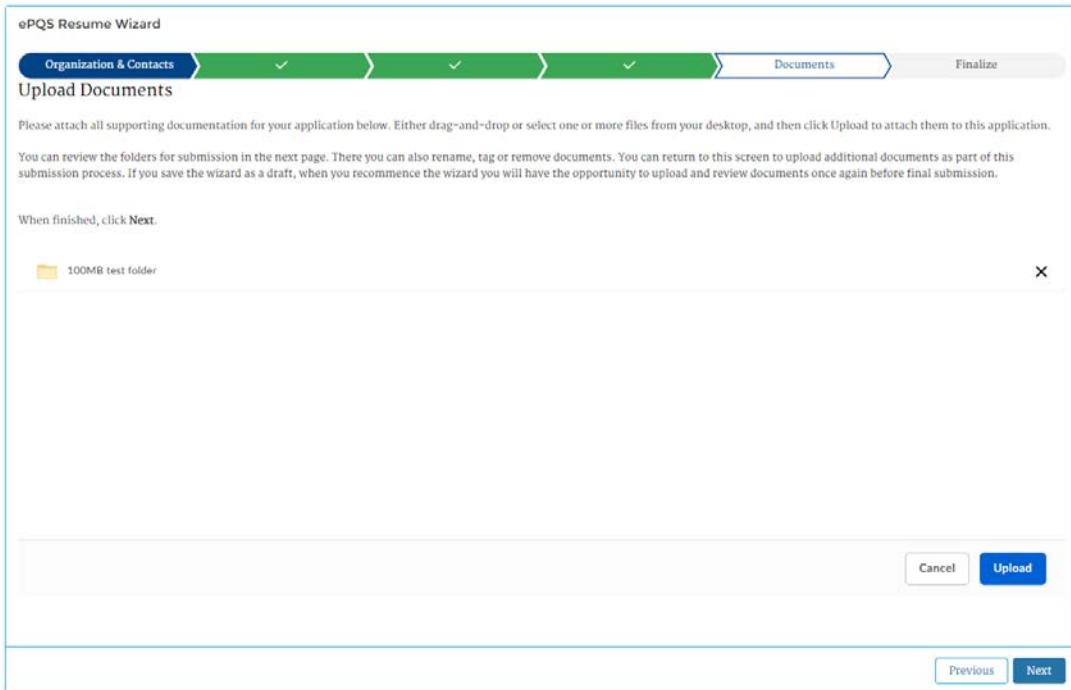


Figure 24. Confirmation of the upload is required

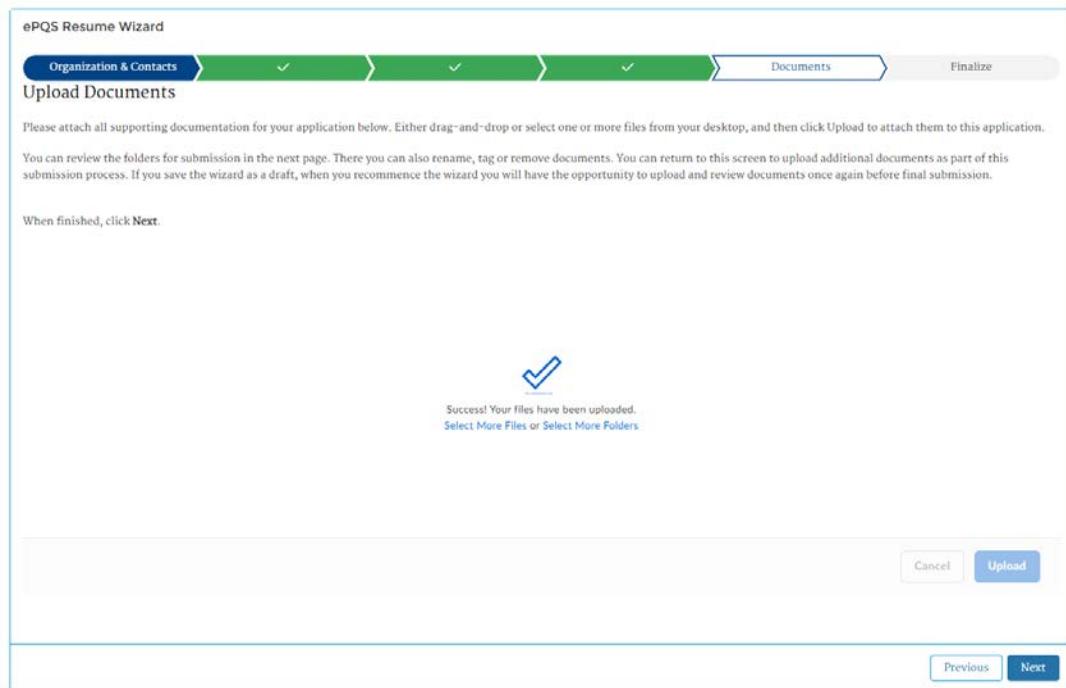


Figure 25. If the documents have uploaded successful a confirmation screen will appear

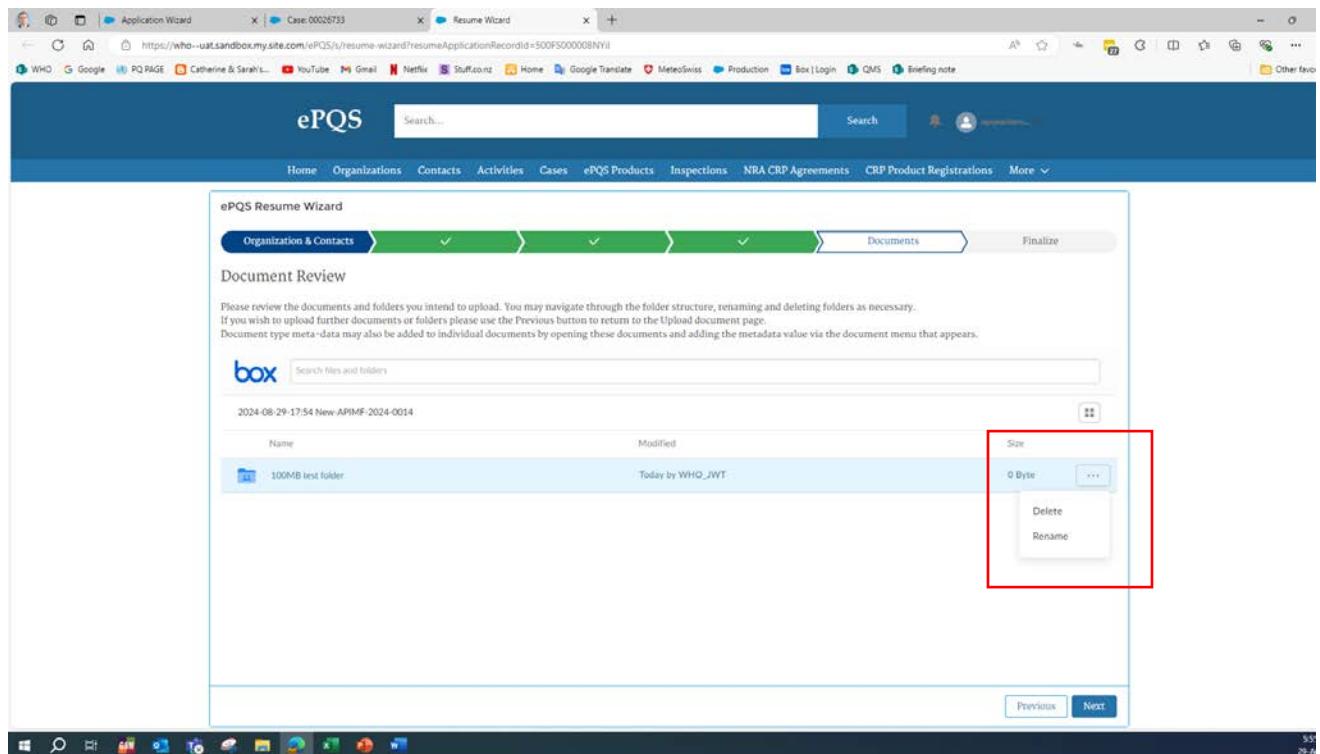


Figure 26. Document review screen where the uploaded files can be adjusted if necessary

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

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.

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.

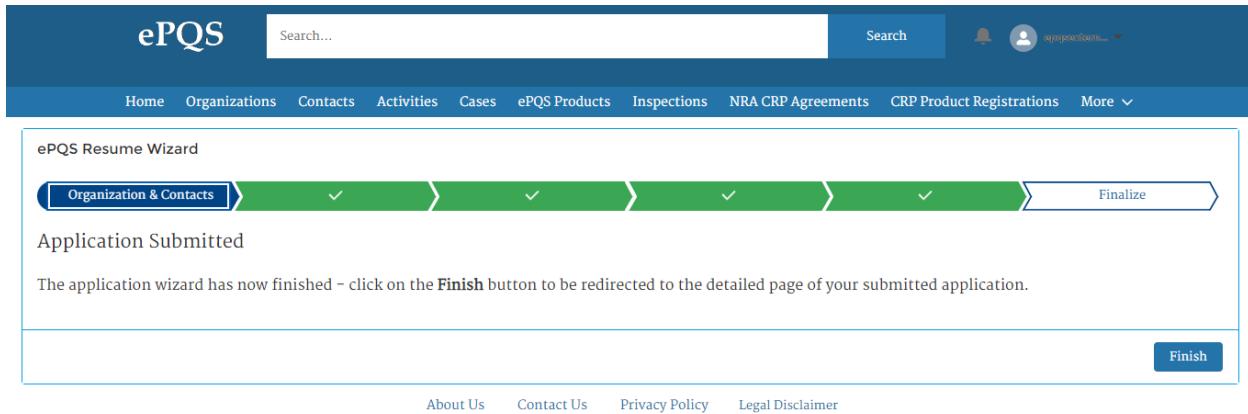


Figure 28. Confirmation screen

Currently there is a bug that displays “Invalid” once finished is selected. This can be disregard. 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

Case Record Type: Mx APIMF Application Case Number: 00026722 Status: Under Screening Applicant Organization: [ePQS Test Account 1 - NonStateActor](#) Date of Prequalification/Acceptance

Details Related Activities Preview Document Document Download Document Submission

General Details

ePQS Case ID: New-APIMF-2024-0013 WHO Application Number: New-APIMF-2024-0013 WHO Product ID: P-12650 Product Type:

Case Owner: ePQS Mx API Queue
Status: Under Screening
Applicant Organization: [ePQS Test Account 1 - NonStateActor](#)
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

Case Record Type: Mx API Post-PQ Change Case Number: 00027971 Status: Under Screening Applicant Organization: [eCTD Mx Account - ZM](#) Date of Prequalification/Acceptance Case Owner: ePQS Mx API Queue

Details Related Activities Preview Document Document Download Document Submission

box

Search files and folders

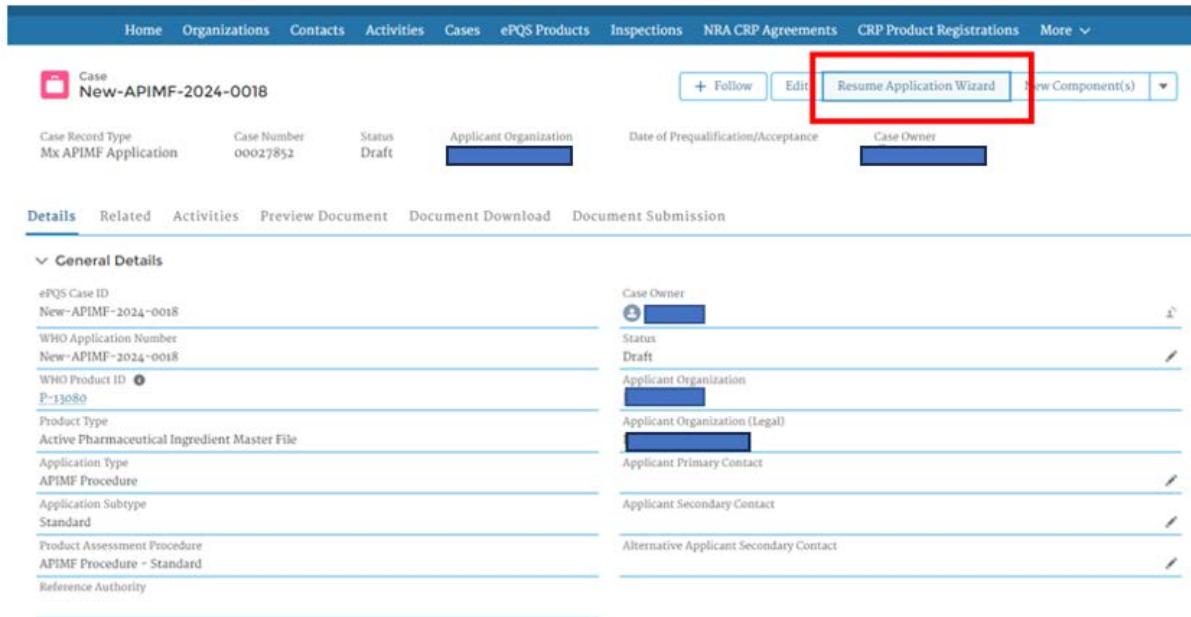
PQC-APIMF-2024-0144

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 for case New-APIMF-2024-0018. The top navigation bar includes Home, Organizations, Contacts, Activities, Cases, ePQS Products, Inspections, NRA CRP Agreements, CRP Product Registrations, and More. The main content area shows the case details: Case Type Mx APIMF Application, Case Number 00027852, Status Draft, and Applicant Organization (redacted). The 'Resume Application Wizard' button in the top right is highlighted with a red box. Below the case details, there are tabs for Details, Related, Activities, Preview Document, Document Download, and Document Submission. The 'General Details' section is expanded, showing fields like ePQS Case ID, WHO Application Number, WHO Product ID, Product Type, Application Type, Application Subtype, and Reference Authority. To the right of these fields are corresponding 'Case Owner' and 'Status' fields, both of which are redacted.

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 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

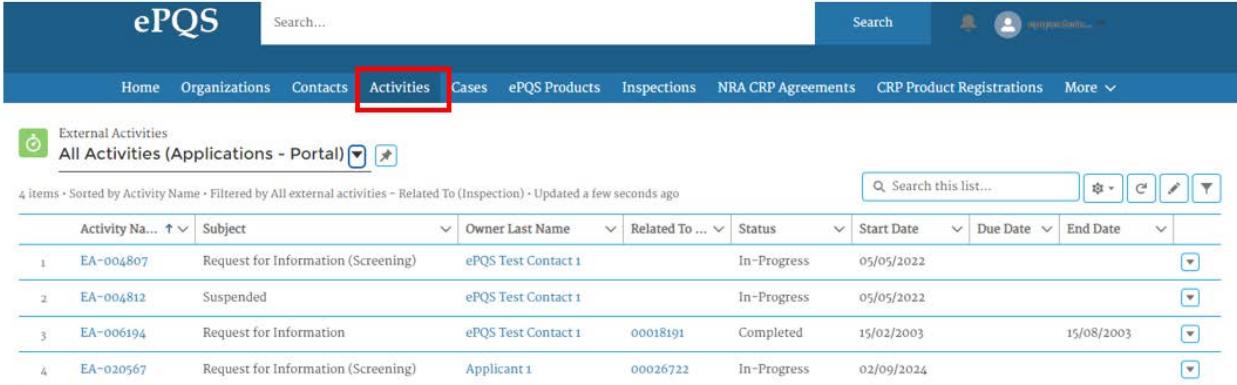
Receiving and uploading documents in response to screening or assessment queries occurs in the same manner.

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).



Activity Na...	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 33. Outstanding tasks can be viewed via the activity list

Please note that the activity described below has been assigned 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

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 shows a web-based application interface for a case record. At the top, there is a header with a 'Case' icon, the case number 'New-APIMF-2024-0012', and several buttons: '+ Follow', 'Edit', 'Resume Application Wizard', 'New Component(s)', and a dropdown menu. Below the header, there are several data fields: 'Case Record Type' (Mx APIMF Application), 'Case Number' (00026721), 'Status' (Under Screening), 'Applicant Organization' (ePQS Test Account 1 - NonStateActor), and 'Date of Prequalification/Acceptance'. Below these fields is a navigation bar with tabs: 'Details', 'Related', 'Activities', 'Preview Document', 'Document Download', and 'Document Submission'. The 'Document Submission' tab is highlighted with a red box. Underneath the navigation bar, there is a section titled 'Case Submission Wizard' with the sub-instruction 'Welcome to Document Submission Wizard. Please click on Next to proceed for Case#00026721'. At the bottom of the page are links for 'About Us', 'Contact Us', 'Privacy Policy', and 'Legal Disclaimer', followed by a 'Next' button.

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 APassessment@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.

Information

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

Case Information

Case Record Type

This field is calculated upon save

WHO Product ID

This field is calculated upon save

System Information

Created By

Kingsley Abuegje AWURU, 05/05/2022, 14:26

Last Modified By

Kingsley Abuegje AWURU, 26/05/2022, 13:54

Cancel Save

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.

Information

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

ePQS External Applicant 1

Time Assignment

Manufacturer

Status

Completed

Activity Outcome

Received

Activity Phase

Under Screening

Response Date

02/09/2024

Case Information

Case Record Type

Mx APIMF Application

WHO Product ID

P-12650

Component Type

Cancel Save

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.