

REGULATION AND PREQUALIFICATION DEPARTMENT

Owner: ePQS Manager

Guidance

External Guidance – General Guidance on Wizards

Document Version Number: 1.0

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Scope of Guidance

The guidance is intended to provide uses with a general overview of how application wizards function within the portal, their purposes and common features.

Although wizards follow a similar series of steps, specific information is gathered for different applications. Therefore guidance on each specific wizard should be consulted before commencing.

Prerequisites

Applications wizards are accessed via the ePQS Portal – https://who.my.site.com/ePQS/s/login/. Therefore access to the ePQS portal must be granted first.

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 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"

Should the account not be found, please contact the ePQS administrator at ePQS@who.int. If the account does not exist in the system the user will need to request creation of such Account(s).

What is a wizard, who and when to use it?

Wizards are step-by-step tools that assist and guide applicants to create and submit application records, within the ePQS database. Some wizards involve not only the creation of the application record but also an associated product record.

The system will detect the account (organisation) to which the user belongs and any applications created by the user will be for this Account. If a user is associated with more than one account, the wizard will request the user to select the account to be used.

The application wizards only pertains to the creation and submission of the application. Responses to questions for an existing application are handled differently. User should not create an new application to respond to request for information.

Ownership and rights

Ownership of a record typically provides a user with the ability to edit aspects of that record.

Whilst the application and products records are being created using the wizard, the applicable records have a status of Draft and are owned by the submitting user.

Therefore, until the application is submitted, many details associated with these records can be edited directly on the record. Caution is advised therefore when reviewing draft records, lest unintended changes are made that result in the application failing screening post-submission.

Once the application is submitted, the status changes from Draft to Under Screening (for the majority of applications) and the ownership of the record changes to the appropriate internal PQT team. Therefore, once the applications is submitted the user now has only read access to the record.

Creating a new application with a wizard

ePQS Search		Search	🌲 🙆 motiona. *
Home Organizations Contac	ts Activities Cases ePQS Products	Inspections NRA CRP Agreements CRP Pro	duct Registrations More \checkmark
Submit an application	Create Account or Contact	Edit an Account or Contact	Change a Record Contact
World Health Organization	World Health	World Health Orrapization	World Health Organization
organization	organization	organization	organization
COMMONLY USED LISTS			
Medicine Storage Conditions			
WHO Vaccine Names		v	iew ePQS Registered Accounts
Medicines Pharmaceutical Ingredients			
VC Active Ingredients/Synergist Name			
QCLm Genenic Name (INN)			

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.

During the initial wizard steps no records are created and leaving the wizard leaves no draft record in the system. The wizard will warn the user when a record is about to be created. See section Deleting unwanted records.

Steps in wizard

In general wizards follow the following sequence.

- Selection of applicable product type
- Selection of applicable application for the selected product-type
- Selection of contacts for the application
- Creation and completion of application and related records
- Creation and completion of product and related records (depends on application type)
- Submission of documents
- Submission of application

As records are created these will be visible in the portal under the applicable menu item.

Creation of related records

Many wizards include repeating steps in which related records are created. For instance, the creation of product sites.

Organizatio	on & Contacts	~	\rightarrow	~	Product-H	Related Info	Document
Add Produc	ct Related Infor	mation					
Choose Product	Related Information to A	dd to Application					
Product Site							

Figure 3. An example of a repated step in the wizard where additional related records can be created.

The types of related-records varies between product and application type. Please check the individual wizard guidance

Documents

In the final sequence of the wizard, users will be prompted to upload documents in support of their application. The documents required to be uploaded are indicated on the PQT website. The wizard does not scrutinize the type or completeness of the documents uploaded.

Users submitting medicine or vaccine related applications may be asked to specify if the documents are in eCTD or non-eCTD format. See separate guidance on eCTD submissions.

Home	Organizations	Contacts	Activities	Cases	ePOS Products	Inspections	NRA CRP Agreements	Application Wizard	More V
	Leave the second se								
ePQS Application	Wizard								
* Select Document Type									
Non-eCTD									
									a

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Figure 4. During some medicine or vaccine related applications, users will be asked if eCTD formatted documents are being submitted.

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	l then click Upload to	o 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 submission process. If you save the wizard as a draft, when you recommence the wizard you will have the opportunity to upload and review docu	to upload additional aments once again be	documents as part of this efore final submission.
When finished, click Next.		
Drag and drop files and folders		
promise your derive or select inducts		
		Cancel Upload
		Previous Next

Figure 5. Individual files or folders can be uploaded using the options indicated from this page in the wizard.

Individual files or folders can be uploaded using the options indicated, as indicated in figure 5. Once the upload has been completed there is an opportunity to review the uploaded documents.

The uploaded folders and files can be renamed or deleted on the next screen as indicated in figure 6. All documents can be deleted and the user can return to the upload screen by using the "Previous" button.

Organization & Contacts	~ >	\sim	×		Documents	- Fi	inalize
ument Review							
e review the documents and folders you in	tend to upload. You may na	vigate through the folder stru	cture, renaming and	deleting folder	rs as necessary.		
ment type meta-data may also be added to	individual documents by o	pening these documents and a	adding the metadata	value via the d	ocument menu that ap	pears.	
Search files and tolders							
							1
024-06-28-12-23 New-APIMF-2024-0018							
Name		Modified				Size	
100MB test folder		Today by WH	TWL_OH			96.42	MB
							Delete
							Rename

Organization & Contacts Documents Finalize crument Review Documents and folders you intend to upload. You may navigate through the folder structure, renaming and deleting folders as necessary. within to upload further documents or folders please use the Previous button to return to the Upload document page. ment type meta-data may also be added to individual documents by opening these documents and adding the metadata value via the document menu that appears. Oxec Search files and folders Modified Size 024-06-28-12-23 New-APIIMF-2024-0018 > 100MB text folder If Modified Size If Medicac file download - Copy (2).docx If Modified Size 1 15-MB-docx file download - Copy (3).docx Today by WHO_JWT 22.14 MB Preview 1 15-MB-docx file download - Copy (4).docx Today by WHO_JWT Delete Download 1 15-MB-docx file download - Copy (4).docx Today by WHO_JWT Delete Download 1 15-MB-docx file download - Copy (4).docx Today by WHO_JWT Delete Download	S Res	sume Wiz	ard										
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Figure 6. Folders and their contents can be renamed and deleted.

Saving and restarting a draft application

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

Home Organizations Contacts Activities Cases ePQS Product	Inspections NRA CRP Agreements CRP Product Registrations More \checkmark					
Case New-APIMF-2024-0018	+ Follow Edit Resume Application Wizard New Component(s)					
Case Record Type Case Number Status Applicant Organization Mx APIMF Application 00027852 Draft	Date of Prequalification/Acceptance Case Owner					
tails Related Activities Preview Document Document Download D	ocument Submission					
lew-APIMF-2024-0018	0					
WHO Application Number New-APIME-2024-0018	Status Draft					
WHO Product ID	Applicant Organization					
La source Froduct Type Active Pharmaceutical Ingredient Master File	Applicant Organization (Legal)					
Application Type	Applicant Primary Contact					
Application Subtype Sandard	Applicant Secondary Contact					
Product Assessment Procedure APIME Procedure - Standard	Alternative Applicant Secondary Contact					

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

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

Submitting the application



When the user is ready to submit they can do so. The ownership of the record reverts to PQT and therefore the records become non-editable. An email notification will be sent to the Applicant's primary contact.

Note

It can be observed via the portal that the status of the records will have also changed, normally to Under Screening.

Deleting unwanted records

In case a draft application is no longer wanted, or if other interventions are needed then the ePQS manager should be contacted at ePQS@who.int for assistance.

Post-submission

Notifications for requests for information, submission of documents is covered in other guidance.