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External Guidance – eCTD Submissions via the ePQS Portal	
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ePQS Portal

PQT-related applications, both non-eCTD and eCTD format, are filed via the ePQS Portal (https://who.my.site.com/ePQS/s/login/).

Registration is required to access the portal. More information on the PQS Portal can be located at this webpage https://extranet.who.int/prequal/epqs-portal.

Scope of eCTD submissions

Within the ePQS portal, applications in eCTD format can only be made for the product types: Active Pharmaceutical Ingredients (PQ-APIs), Active Pharmaceutical Ingredient Master Files (APIMFs), Finished Pharmaceutical Products(FPPs), Finished Vaccine Product (FVPs)

A specific Product's dossier may be made in eCTD from the outset, e.g. at the time of initial application for a new prequalified Product. Alternatively, an already prequalified or accepted product maybe converted into eCTD format, by the submission of a Post-Prequalification Change application of subtype "eCTD Baseline".

Continuity of eCTD Submissions

Once a product dossier has been accepted as eCTD compliant, all subsequent submissions (i.e. replacement sections in response to questions raised), and all subsequent applications for the product must be in eCTD format.

Post-Prequalification Change Applications

A single post-prequalification change application (aka Variation) may be related to more than one product.

When creating a post-prequalification change application in the ePQS portal, the applicant will be asked if this application is in eCTD or non-eCTD format. This decision determines which products the application wizard offers to the user for association with the application. If non-eCTD is selected then the wizard will only offer products that are in non-eCTD format, and visa versa.

APIMFs and API PQ

Within ePQS, APIMFs and PQ-APIs are separate products types, with different records add record types for each. Nonetheless, there is a strict relationship between an API PQ product and its related APIMF. The quality information for an API PQ product is completely described by the associated APIMF.

Therefore, within the eCTD repository, an application for prequalification of an API is treated as a sequence of the associated APIMF.

Action	Sequence
Application for a Prequalified API	0000
Response to questions	0001
APIMF Amendment 1	0002
APIMF Amendment 2	0003

Example 1: Application for API PQ made using a new APIMF

Action	Sequence
Application for APIMF Procedure	0000
Response to questions	0001
APIMF Amendment 1	0002
Application for a Prequalified API	0003
APIMF Amendment 2	0004

Example 2: Application for API PQ made using an existing APIMF

Application process

Depending on the application type, at some point in the application wizard the user will be asked to nominate if the submission is in eCTD or non-eCTD format. If the user indicates eCTD format then additional screens will be presented to the user during the document phase of the wizard.

Overall, the process for uploading an eCTD sequence occurs in three parts. Creation of the draft application, gathering of the Module 1 envelope information, and finally uploading of the publishing sequence. See figure 1.

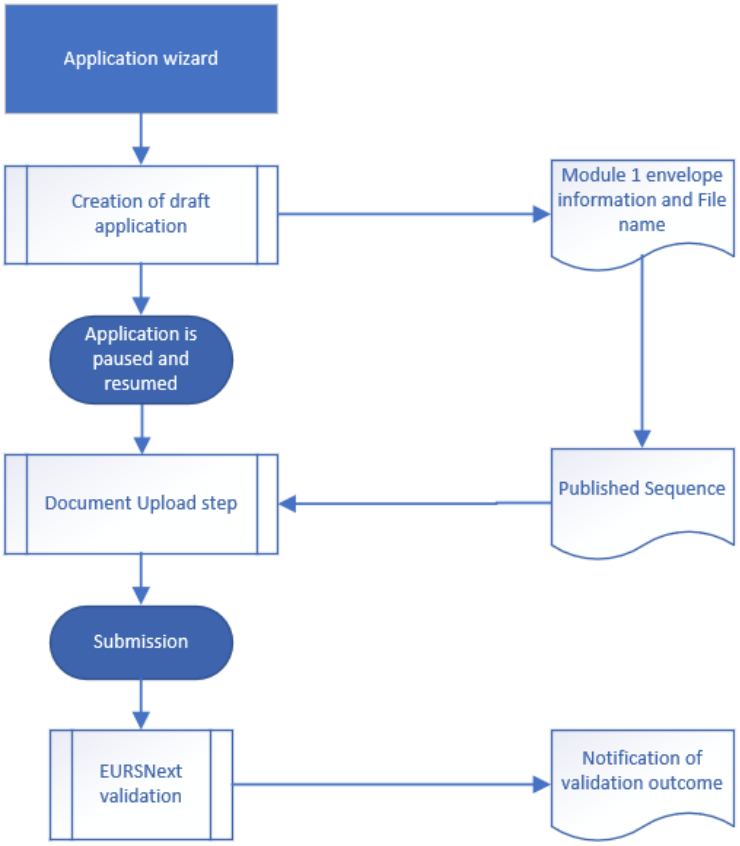

Figure 1. Overall process for completing an e-CTD submission

Module 1 envelope information

During the document upload phase the system will display information that the applicant should use to complete the module 1 envelope for their dossier. In the case of Post-prequalification changes the module 1 information for each of the associated products will be displayed. The wizard may be paused at this stage and resumed once the dossier sequence file has been published with this information.

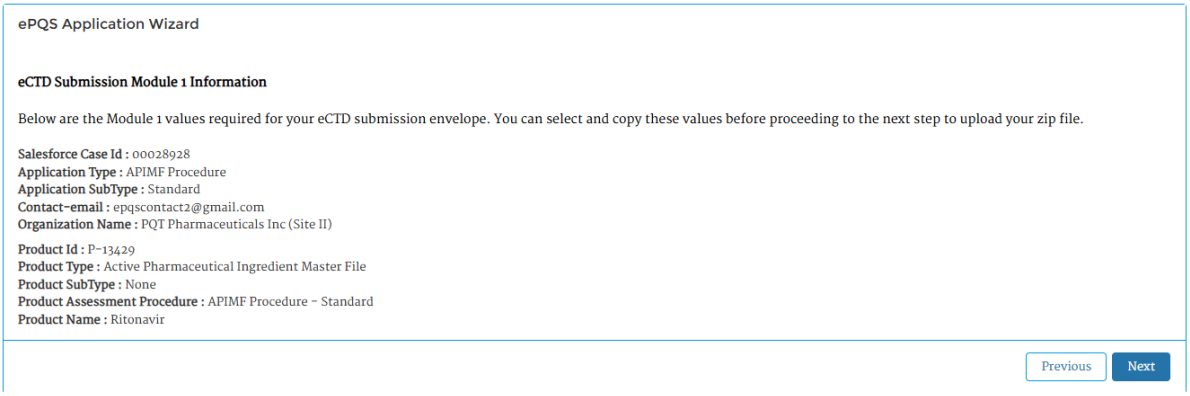

Figure 1: Information is provided to complete their Module 1 Envelope information

File names

On the subsequent page the system also indicates the exact name the submitted file, or files should be named. The dossier for a single product should be formatted in a single ".zip" file. Post-prequalification change applications will require one zip file for each related product.

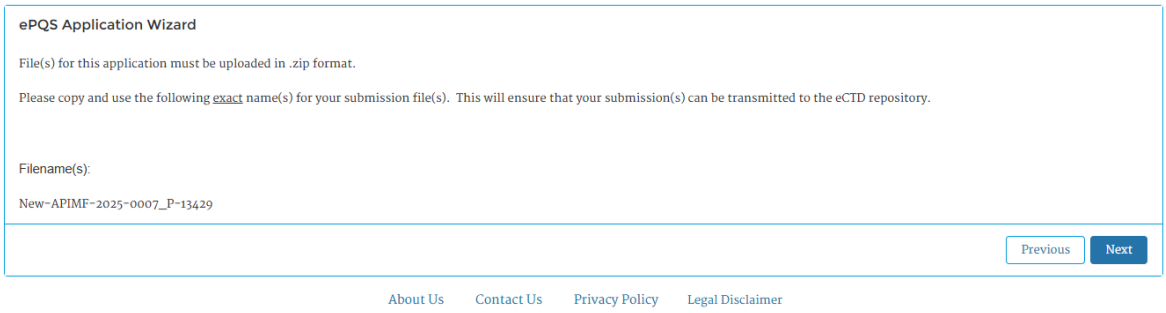

Figure 2: The systems provides the exact name to be used for the uploaded zip file

Compiling the Zip file

The compiled dossier sequence must be uploaded in Zip format. Applicants should Zip the sequence folder directly and then rename the zipped file. When unzipped the sequence folder should be immediately available as indicated in Figure 3

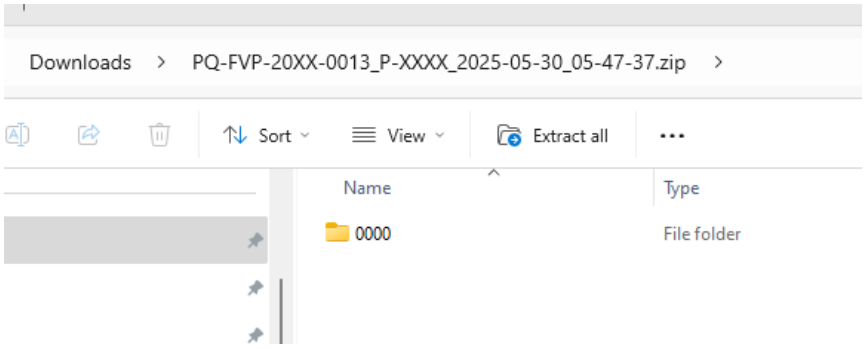

Figure 3: The dossier sequence folder should be immediately available when the file is decompressed.

Notifications

If an eCTD application has been submitted, an eCTD 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 for review by the applicant, as seen in figure 4.

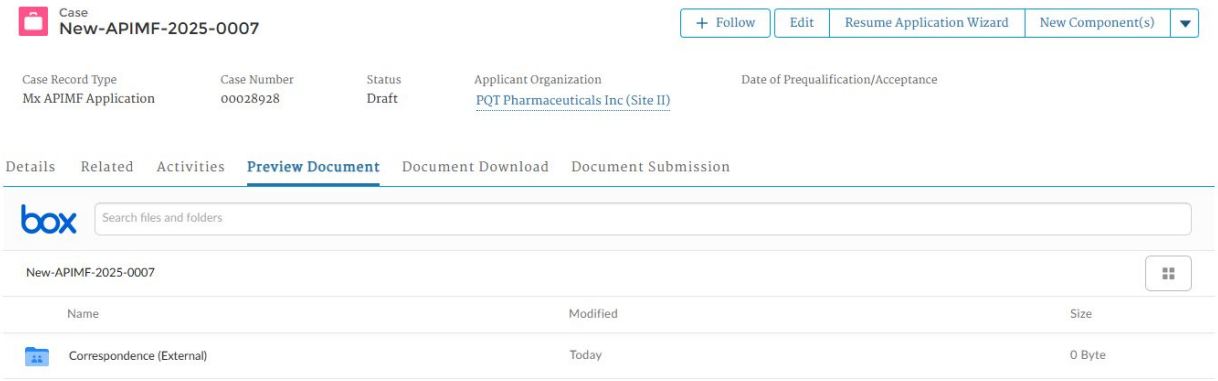

Figure 4: eCTD validation reports are placed in the Correspondence (External) folder of the application.