

## **WHO-PQT eCTD FAQ Document**

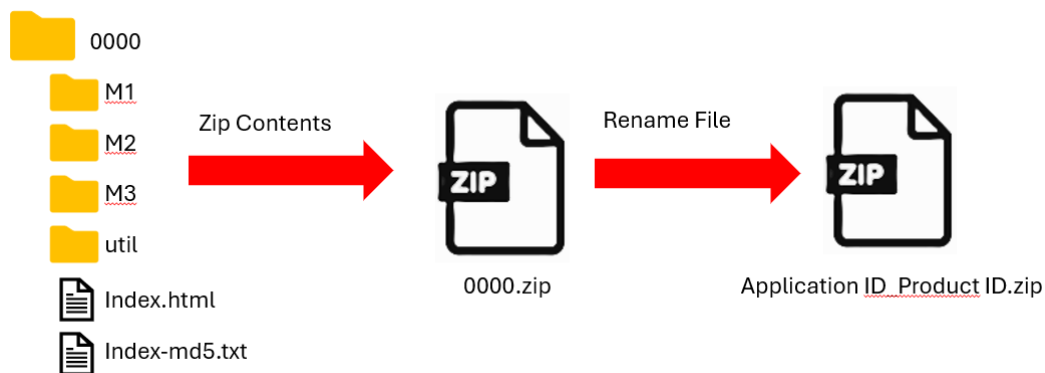
This document will be updated regularly in response to questions received. At various times, advice in this document may then be incorporated into a guidance document and removed from the document.

### **Question 1 - How to submit information or correspondence not strictly related to an application or application response?**

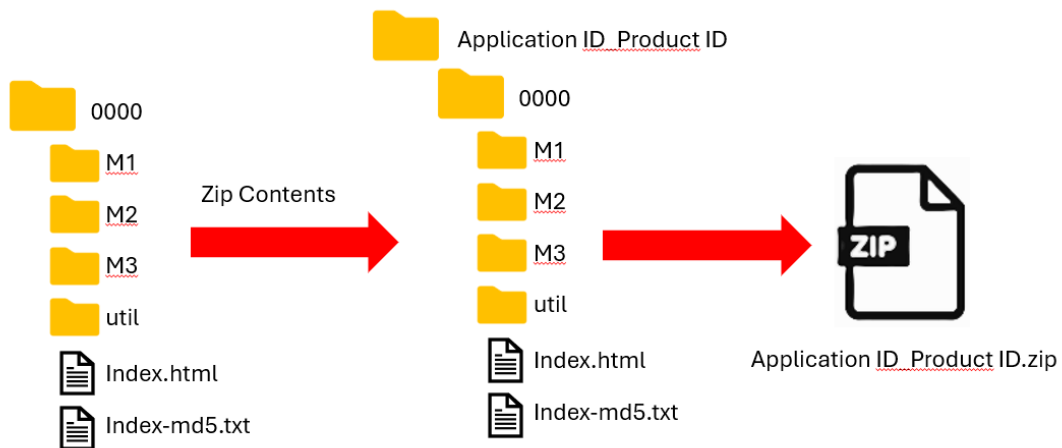
The ePQS Portal does allow the submission of documents outside of the application process. Each user and each Organisation (Account) has access via the portal to a folder where miscellaneous information can be uploaded.

### **Question 2 – My eCTD dossier failed to trigger the eCTD validation tool in EURSNext**

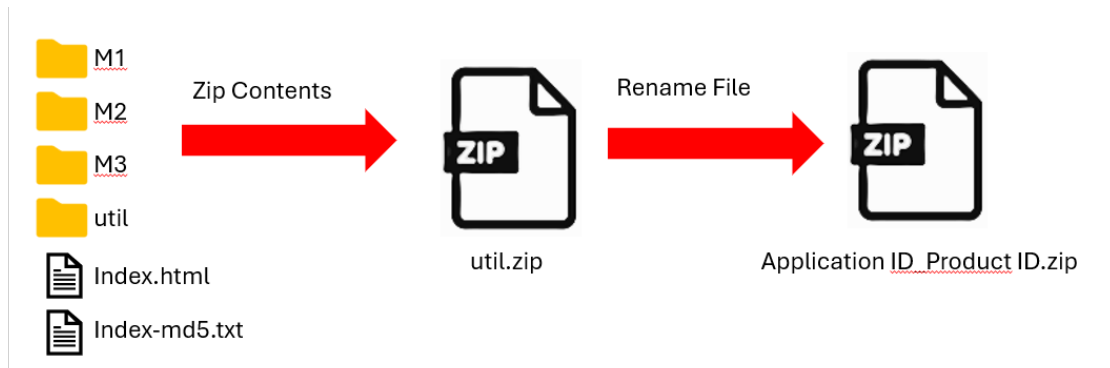
We have noted that several applications for eCTD add an unnecessary folder layer to the submission before zipping. The sequence folder should be zipped and then renamed (Figure 1). Do not place the sequence sequence folder inside another folder with the ePQS naming convention and then zip (Figure 2).



**Figure 1: Correctly prepared Zip file**



**Figure 2: Incorrectly prepared Zip file**



**Figure 2: Incorrectly prepared Zip file**

**Question 3 – I encountered a validation error F.06 with my APIMF submission.**

Attributes for specific sections 2.3.S and 3.2.S should contain 'op ' or 'rp ' as prefix". The prefix should be separated from the substance name by a space. Some manufacturers have encountered errors because they have used instead a hyphen in the specific section name attribute for "substance".

END