

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 folder inside another folder with the ePQS naming convention and then zip (Figure 2).

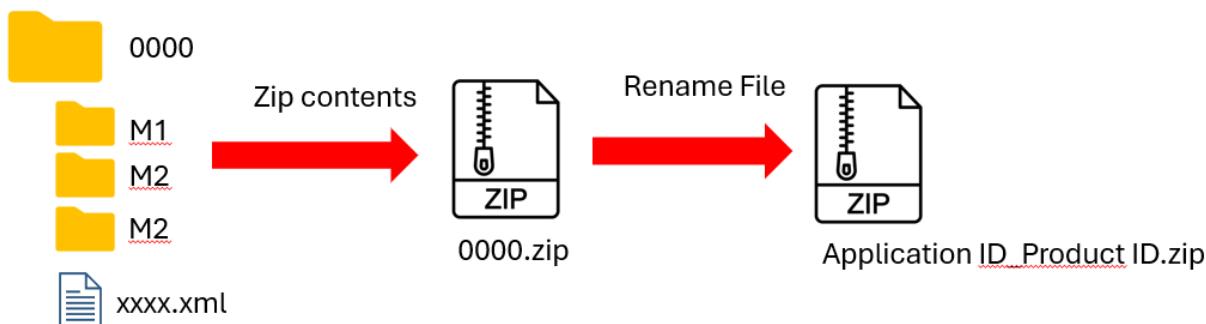


Figure 1: Correctly prepared Zip file

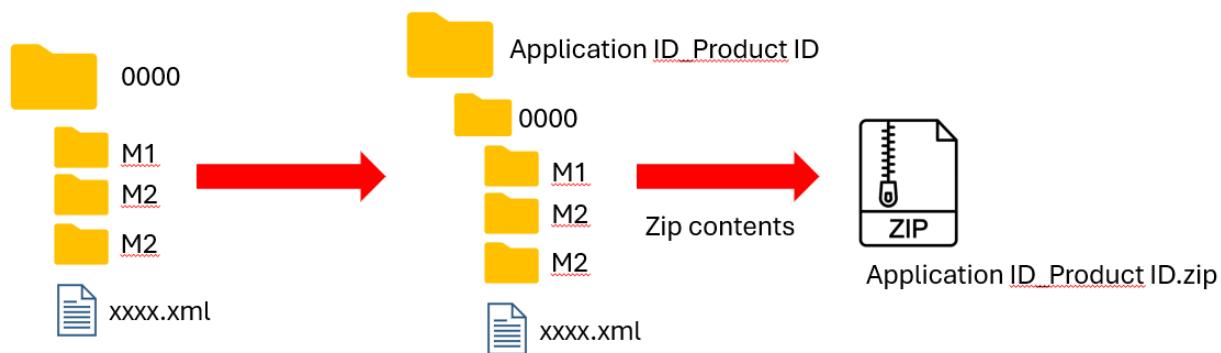


Figure 2: Incorrectly prepared Zip file