

EMA/174065/2013 29 August 2019

Annex 1. - Updated August 2019

Note: XML delivery files should now be used for all submissions via the eSubmission Gateway and the eSubmission Gateway Web Client

When a submission is sent via the eSubmission Gateway or the Web Client, to the EMA the submission metadata is provided using XML delivery file. For all submissions, when used in conjunction with the required XML delivery file, the previously required filenaming conventions are no longer necessary; however these can still be used should the applicant wish to continue doing so. The filenames are no longer validated/checked and do not cause rejection/failure of submission. For archiving reasons there is still need to have a meaningful file name for the time being and the following, simplified file names are given here as examples.

It should be noted that there are no special requirements for spaces or underscores `_' between the different parts of the filename as previously.

CAP: HCxxx123 Wonderpill 00xx.zip or HCxxx123_Wonderpill_00xx.zip

NAP for example in a worksharing variation or a referral: *MAHname productname 00xx.zip* or MAHname_productname_00xx.zip

