Annex 2

Note: XML delivery files should 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, the previously required filenaming conventions should no longer be used.

The filenames are not validated and, in most cases, do not cause rejection/failure of submission. For archiving reasons, the EMA recommends that the package has a meaningful file name 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. Please note that special characters or dashes '-' should not be used as these may lead to a failure.

VCxx1234_Wonderpill.zip or
MAHname_productname.zip

These filenames are used to identify packages sent via the Gateway/Web Client system and are not to be confused with Folder name naming conventions which are used by the VNeeS checker. **The filenaming conventions for the root level folder as per the VNeeS guidance remain in place.**