



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/174065/2013
4 April 2017

Annex 1. – Updated April 2017

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

Examples of filenames for those submission types for which the XML delivery files are not currently available

Ancillary medicinal substances in medical device:

Initial Ancillary medicinal substance application:

ESUBPXYZ_ESUBPROD_Hxxx123_Wonderpill_ema_00xx.zip

Active Substance Master File (ASMF):

XML delivery files can be used for majority of ASMF submissions. **In the exceptional case** where the relevant ASMF number is not available in the XML delivery file user interface the ASMF may be sent using filenaming conventions.

ASMF holders are advised to apply for EMA/ASMF/xx123 number and follow the eASMF submission rules. A valid ASMF should have either an EMEA/ASMF number or an EU/ASMF number, depending on the intended use of the ASMF by its holder. When applying for EMEA or EU ASMF numbers, or submitting any documentation quoting these, please note that they are not inter-changeable. Only **one** ASMF number should be quoted. You can apply for this number by submitting the [EMEA/ASMF request form](#) available on the [eASMF webpage](#)

ASMF for Centralised Procedures eCTD format ASMF:

ESUBPXYZ_ESUBPROD_EMEA-ASMF-xx123_Activesubstance_asmf_00xx.zip

EU ASMF Assessment Worksharing submission:

ESUBPXYZ_ESUBPROD_EU-ASMF-xx123_Activesubstance_asmf_00xx.zip

