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EMA/120761/2014 Rev.3

Annex 2

Note: XML delivery files should now be used for all submissions via the eSubmission Gateway. In the exceptional case where the relevant data is not available in the XML delivery file user interface, the submission may be sent using filenaming conventions.

Detailed examples of filenames for e-Submission Gateway/Web Client submissions for those veterinary application types for which the XML delivery files are currently not available

Centrally Authorised Product (CAP) submissions:

Filename example for submission for Vetpill VCxxxx123:

ESUBPXYZ_ESUBPROD_VCxxxx123_Vetpill_VNeeS_mmdd.zip

Active Substance Master File (ASMF):

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.

ASMF for Centralised Procedures CTD or VNeeS format ASMF:

ESUBPXYZ_ESUBPROD_EMEA-ASMF-xx123_Activesubstance_VNeeS_mmdd.zip

EU ASMF Assessment Worksharing submission:

ESUBPXYZ_ESUBPROD_EU-ASMF-xx123_Activesubstance_VNeeS_mmdd.zip

The filename is broken down into different parts as described in the table below:

Data	Remarks	Case sensitive	Example
SenderRoutingId	Routing ID for Sender as registered by the Gateway, to route MDN receipt and Acknowledgement messages back to the sender.	Upper	ESUBPXYZ



ReceiverRoutingId	Routing ID for EMA's eSubmission Gateway Community, it's required for routing a transmission to its intended destination e.g. eSubmission Test and Production environments use "ESUBVAL" and "ESUBPROD" respectively.	Upper	ESUBPROD
EMA Product No (or procedure No) for Centrally Authorised Veterinary Products	e.g. EMEA/VC/0000999 (This must be a 7 digit number)	Upper	VC0000999
Product Name	Maximum 30 characters.	No	Vetpill
VNeeS	To identify that this is a submission in the VNeeS format	No	VNeeS
Submission Date	Must be a four digit numeric value in the format "mmdd", for example 15 th of March is 0315	N/A (should be numeric)	0315
.zip	.zip	Lower	.zip

Additional information on Veterinary Centralised Procedure submissions:

For Centrally Authorised Products, the EMA product number is available in the Eligibility confirmation letter as 'Product Reference'. The Eligibility Confirmation Letter indicates product number in format V000xxxx. The **7** digit product number remains the same throughout the life-cycle of a product and it should be used regardless what type of submission is being transmitted. For veterinary submissions there is no need to differentiate initial MAA submission and subsequent submissions in the filename of the gateway package.

In case of a submission that does not have EMA product number (e.g. referral), or submission including several products (e.g. worksharing) the product number can be replaced by using the procedure number.

The fourth part of the filename (**highlighted in yellow**) cannot have more than 30 characters, so if a product has got a long name and the filename is likely to be over 30 characters, the name of the product should be shortened. This might be particularly relevant for vaccines.

Please note that the last part (sixth part) of the filename should be in the form of the date format mmdd. So for example for an application submitted on the 30th November 2014, the last part will show "1130".

These filenames are used to by the Gateway/Web Client system to direct the submission to correct destination within EMA 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.**