



EMA/51022/2015

## Annex 3. January 2015

### Examples of filenames for Periodic Safety Update Report (PSUR) submissions to the PSUR repository

When a submission is sent via the eSubmission Gateway or the Web Client, **to the PSUR repository** the **submission metadata** is provided using [XML delivery file](#).

For PSUR submissions, **when used in conjunction** with the **required XML delivery file**, the previously required filenaming conventions are no longer required; 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 proposed for PSUR submissions.

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

#### **PSURs for all CAPs single CAP or CAP included in the EU Single Assessment procedure - where the substance is contained in both CAPs and NAPs:**

HCxxx123\_Wonderpill\_00xx.zip *or*  
HCxxx123 Wonderpill 00xx.zip

#### **PSURs for all NAPs included in the EU Single Assessment procedure -where the substance is contained in both CAPs and NAPs or in NAPs only:**

MAHname\_00000000\_YYYYMM\_00xx.zip *or*  
MAHname 00000000 YYYYMM 00xx.zip

#### **PSURs for single, pure NAPs not included in the EU Single Assessment procedure -where the substance is authorised in one Member State only:**

MemberStatename\_YYYYMM\_SubstanceName\_00xx.zip *or*  
MemberStatename YYYYMM SubstanceName 00xx.zip

The 8 digit unique (PSUSA) number shown as 00000000 in the above examples and the -YYYYMM-format Data Lock Point, can be found in the published [EURD list](#)

Folders inside the zip containing submissions (e.g. Sequence 0001, 0002 etc.) should follow the eCTD or NeS guidelines.



Details of simplified filename proposals

<b>Data</b>	<b>Remarks</b>	<b>Case sensitive</b>	<b>Example</b>
<b>H</b>	Human medicinal product	no	H
<b>XXXXXX</b>	Procedure number	Numeric	000111
<b>C</b>	Centrally Authorised Product	no	C
<b>MAH/Company name</b>	MAH name	No	DrugCompany
<b>Product Name/Substance name</b>	product short name or substance short name	Upper / Lower	Wonderpill
<b>Member State name</b>	country name in 2 digit format	No	UK
<b>00XX</b>	Sequence Number (range from 0000 to 9999)	Numeric	0020
<b>.zip</b>	.zip	Lower	.zip

The last part of the filename 00XX.zip is the eCTD sequence number. In case the submission is not in eCTD format this should be the sequence number of submission related to that particular procedure; for example, the very first submission of a referral procedure would be sequence 0000, the following for example supplemental information sequence would be 0001 etc.

**Note:**

Please note that during a pilot period, PSUR submissions can be made via the eSubmission Gateway / Web Client without the use of XML delivery file in which case the **existing** filenaming conventions from [Annex 1](#) **must** be used. In this case the PSUR submissions **are not** included in the PSUR Repository.