EMA/174065/2013
27 April 2016

Annex 1. – Updated April 2016

Detailed examples of filenames for different application types

At the time of the Initial MAA submission EMA product number in format Hxxxxxx is to be used. The EMA Product Number must be used in format HC/xxxxxx after the Initial MAA is submitted to the EMA.
In the case of an Article 58 (WHO) submission, please use the number H/W/xxxxxx or prior to submission Hxxxxxx.

The EMA product number is always available on the Eligibility confirmation letter as 'Product Reference'. E.g. if the Eligibility Confirmation Letter indicates Product number H0002271 please eliminate first digit (0) and use H002271 in the filename.

The above 6 digit Product Number (or Product Reference) remains the same throughout the life-cycle of a product and it should be used regardless what type of submission is being transmitted.

There are examples below for different types of submissions for Wonderpill Hxxx123 from MAH:

Initial MAA:
ESUBPXYZ_ESUBPROD_Hxxx123_Wonderpill_initial-maa_0000.zip

Response to LOQ/RSI/LOI:
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_supplemental-info_00xx.zip

Type IA variation application:
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_var-type1a_00xx.zip

Type IB variation application – single:
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_var-type1b_00xx.zip

Type IB variation application – grouping (several scopes):
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_var-type1b_00xx.zip (same as for single)

Type II variation application – single:
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_var-type2_00xx.zip

Type II variation - grouping of several scopes (if it's a mixture of different variation types, the 'highest' is to be applied e.g. one scope is for type IB, two scopes are for type II and a further scope for a type IA):
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_var-type2_00xx.Zip

Extension application:
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_extension_00xx.zip

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An agency of the European Union

PSURs for Article 58 (WHO):
ESUBPXYZ_ESUBPROD_HWxxx123_Wonderpill_psur_00xx.zip

Annual Reassessment:
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_annual-reassessment_00xx.zip

Renewal application:
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_renewal_00xx.zip

Closing (decision) sequence for Type II:
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_ supplemental-info_00xx.zip

Response to Validation Issues:
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_supplemental-info_00xx.zip

Article 61(3) notification:
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_notification-61-3_00xx.zip

Transfer of a Marketing Authorisation:
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_transfer-ma_00xx.zip

Corrigendum:
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_corrigendum_00xx.zip

Post-Authorisation Measure:
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_pam_00xx.zip

Annex II condition:
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_anx_00xx.zip

Legally binding measure:
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_leg_00xx.zip

Additional pharmacovigilance activity in the risk-management plan related to a post-authorisation measures (RMP) (e.g. interim results of imposed/non-imposed interventional/non-interventional clinical or nonclinical studies):
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_mea_00xx.zip

Recommendation related to a post-authorisation measure e.g. quality improvement related to a post-authorisation measure:
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_rec_00xx.zip

Cumulative review following a request originating from a PSUR or a signal evaluation (CAP):
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_sda_00xx.zip

Specific Obligation:
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_sob_00xx.zip

Paediatric submissions related to post-authorisation measures:
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_p46_00xx.zip

Withdrawal of MA or variation application (consolidation sequence):
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_withdrawal_00xx.zip

Referrals containing Centrally Authorised Products (CAPs):
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_A20-xxxx_00xx.zip
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_A31-xxxx_00xx.zip
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_A107i-xxxx_00xx.zip
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_A5(3)-xxxx_00xx.zip

Ancillary medicinal substances in medical device: new

Initial Ancillary medicinal substance application:
ESUBPXYZ_ESUBPROD_Hxxx123_Wonderpill_ema_00xx.zip

Post-authorisation Ancillary medicinal substance applications:
ESUBPXYZ_ESUBPROD_HDxxx123_Wonderpill_ema_00xx.zip

Worksharings and IA Groupings (IG):

For Worksharing and Type IA Grouping (several products affected by the same Type IA changes/scope(s)) applicants are required to obtain a "EMEA/H/C/WSxxxx" or "EMEA/H/C/IGxxxx" number (via email to PA-BUS@ema.europa.eu) in advance of submitting their Work-sharing or IA Grouping.

Worksharing:
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_WSxxxx_00xx.zip

Response to Worksharing:
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_WSxxxx_supplemental-info_00xx.zip

Worksharing NAPs: new
ESUBPXYZ_ESUBPROD_NAP-WSxxxx_Wonderpill_ema_00xx.zip

Type IA Groupings (IGs):
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_IGxxxx_00xx.zip

Response to IA Groupings:

ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_IGxxxx_supplemental-info_00xx.zip

Applicants are required to ensure that each product for the same Worksharing is sent in separate zips. The Worksharing number should be always correctly referred to. Additionally, it is imperative that all products within Worksharing /IA Grouping (IG) are sent on the same day to ensure timely start of the procedure.

If one product in the Worksharing/IA Grouping (IG) fails during the transmission, only this part of the Worksharing /IA Grouping (IG) has to be re-sent. Content validation will only start when ALL parts of the Worksharing / IA Grouping (IG) have reached the Agency. The submission date of the Worksharing / IA Grouping (IG) will be the date of the last submitted product.

Example:

ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_WSxxxx_00xx.zip - technically valid submission on 01-01-20xx

ESUBPXYZ_ESUBPROD_HCxxx124_Wonderpill_WSxxxx_00xx.zip - technically valid submission on 01-01-20xx

ESUBPXYZ_ESUBPROD_HCxxx125_Wonderpill_WSxxxx_00xx.zip - technically valid submission on 01-01-20xx

ESUBPXYZ_ESUBPROD_HCxxx126_Wonderpill_WSxxxx_00xx.zip - technically **invalid** submission on 01-01-20xx

ESUBPXYZ_ESUBPROD_HCxxx127_Wonderpill_WSxxxx_00xx.zip - technically valid submission on 01-01-20xx

Resubmission:

ESUBPXYZ_ESUBPROD_HCxxx126_Wonderpill_WSxxxx_00xx.zip - technically valid submission on 10-01-20xx

This means that the official submission date for this Work Sharing procedure will be **10**-01-20xx. This also means that if the re-submitted element will arrive after the submission deadline, it will follow the applicable timetable and not the missed one.

Periodic Safety Update reports for CAPs and NAPs **– all PSUR submissions** (with the exception of PSURs for Art. 58 products) **must contain xml delivery file. The zip package should be given a meaningful name. For more information on how to submit PSUR can be found from the PSUR Repository webpage.**

Periodic Safety Update reports for CAPs -included in the EU Single Assessment procedure - where the substance is contained in both CAPs and NAPs:
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_00000000_Substance_MAH_YYYYMM_psusa_00xx.zip
(in these cases, the 8 digit unique (PSUSA) number, in the above example shown as 00000000 as well as the -YYYYMM- format Data Lock Point, can be found in the published EURD list)

Periodic Safety Update reports for NAPs -included in the EU Single Assessment procedure - where the substance is contained in both CAPs and NAPs:
ESUBPXYZ_ESUBPROD_00000000_NAP Product_MAH_YYYYMM_psusa_00xx.zip
(in these cases, the 8 digit unique (PSUSA) number, in the above example shown as 00000000 as well as the -YYYYMM- format Data Lock Point, can be found in the published EURD list)

Plasma Master File (PMF):

Sender's Routing ID	**Receiver's Routing ID**	**PMF Holder Ref. Number**	**PMF holder or Product name** (Abbreviate if the name is longer than 30 characters)	**Submission Type**	**Sequence Number**
ESUBPXYZ	EUBPROD	HPMFxxxxxx-xx	“holdername”	pmf	00xx

e.g. ESUBPXYZ_ESUBPROD_HPMF000003-04_holdername_pmf_00xx.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. 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

Referral Submissions containing Nationally Authorised Products (NAPs):

The xxxx is the procedure number. If there is no procedure number this can be left out or replaced by 0000. The 'Wonderpill' in the referral example can be either product name, substance name or class name.

Data	Remarks	Case sensitive	Example
SenderRoutingId	Routing ID for Sender as registered by the Gateway for identification MDN & acknowledgement messages.	Upper	ESUBPXYZ
ReceiverRoutingId	Gateway routing ID to differentiate this eSubmission from other application transmissions.	Upper	ESUBPROD
EMEA	EMEA	Upper	EMEA
H-A-XX	Human medicinal product-Arbitration-Article number	Upper	H-A-XX
XXXX	Procedure number	Numeric	0011
Product Name/Substance name/Class name	maximum 30 characters	Upper / Lower	Wonderpill
Referral	Procedure type	Lower	referral
00XX	Sequence Number (range from 0000 to 9999)	Numeric	0020
.zip	.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.

Referrals containing Nationally Authorised Products (NAPs):

ESUBPXYZ_ESUBPROD_EMEA-H-A-29-P-xxxx_Wonderpill_referral_00XX.zip
ESUBPXYZ_ESUBPROD_EMEA-H-A-13-xxxx_Wonderpill_referral_00XX.zip
ESUBPXYZ_ESUBPROD_EMEA-H-A-29-4-xxxx_Wonderpill_referral_00XX.zip
ESUBPXYZ_ESUBPROD_EMEA-H-A-30-xxxx_Wonderpill_referral_00XX.zip
ESUBPXYZ_ESUBPROD_EMEA-H-A-5-3-xxxx_Wonderpill_referral_00XX.zip
ESUBPXYZ_ESUBPROD_EMEA-H-A-31-xxxx_Wonderpill_referral_00XX.zip
ESUBPXYZ_ESUBPROD_EMEA-H-A-107-xxxx_Wonderpill_referral_00XX.zip
ESUBPXYZ_ESUBPROD_EMEA-H-A-16C-1-C-xxxx_Wonderpill_referral_00XX.zip
ESUBPXYZ_ESUBPROD_EMEA-H-A-16C-4-xxxx_Wonderpill_referral_00XX.zip

PASS 107 initial submission: new
ESUBPXYZ_ESUBPROD_PASS-107_Wonderpill_ema_00xx.zip

PASS 107 supplemental information submissions: new
ESUBPXYZ_ESUBPROD_PASS-107-xxxx_Wonderpill_ema_00xx.zip

Data	Remarks	Case sensitive	Example
SenderRoutingId	Routing ID for Sender as registered by the Gateway for identification MDN & acknowledgement messages.	Upper	ESUBPXYZ
ReceiverRoutingId	Gateway routing ID to differentiate this eSubmission from other application transmissions.	Upper	ESUBPROD
Initial PASS 107 submission: **PASS-107**	Procedure type description for PASS protocol 107	Upper / Numeric	PASS-107
Supplemental-information PASS 107 submission: **PASS-107-XXXX**	Procedure number is only available for supplemental-information PASS submissions. It must be used with dash – as a part of procedure name	Numeric	PASS-107-0404
Product Name/Substance name	maximum 30 characters	Upper / Lower	Wonderpill
EMA	EMA procedure identifier	Lower	ema
00XX	Sequence Number (range from 0000 to 9999)	Numeric	0020
.zip	.zip	Lower	.zip

Signal detection (non-CAP): **new**
ESUBPXYZ_ESUBPROD_EPITTxxxx-SDA_Wonderpill_ema_00xx.zip

Sender's Routing ID	**Receiver's Routing ID**	**Procedure type description**	**Product/Substance name** (Abbreviate if the name is longer than 30 characters)	**Submission Type**	**Sequence Number**
ESUBPXYZ	EUBPROD	EPITT number and the signal detection procedure identifier: EPITT12345-SDA	Wonderpill	ema	00xx

Publication of Clinical Data for Medicinal Products – Redacted version: new
ESUBPXYZ_ESUBPROD _HCxxx123_wonderpill_Redacted-Proposal_00xx.zip

Publication of Clinical Data for Medicinal Products – Final version: new
ESUBPXYZ_ESUBPROD _HCxxx123_wonderpill_Final-version_00xx.zip

Sender's Routing ID	**Receiver's Routing ID**	**EMA CAP number**	**Product name** (Abbreviate if the name is longer than 30 characters)	**Submission Type**	**Sequence Number**
ESUBPXYZ	EUBPROD	HC001234	Wonderpill	redacted-proposal	00xx
ESUBPXYZ	EUBPROD	HC001234	Wonderpill	final-version	00xx

Paediatric Submissions:

The six digit number is the PIP number. The four digit number at the last part of the filename should be month and year, for example February 2014 is: 0214. This part must only contain 4 numerical digits.

ESUBPXYZ_ESUBPROD_000000_paediatrics_00xx.zip