Annex 1. – Updated September 2015

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
**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](#))

**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
```

**Follow Up Measure:**

```
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_fum_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:**

```
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_sda_00xx.zip
```
**Specific Obligation:**
ESUBPXYZ_ESUBPROD_HCxxx123_Wonderpill_sob_00xx.zip

**Paediatric submissions related to a 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

**Worksharing 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

**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.

**Plasma Master File (PMF):**

<table>
<thead>
<tr>
<th>Sender’s Routing ID</th>
<th>Receiver’s Routing ID</th>
<th>PMF Holder Ref. Number</th>
<th>PMF holder or Product name (Abbreviate if the name is longer than 30 characters)</th>
<th>Submission Type</th>
<th>Sequence Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESUBPXYZ</td>
<td>EUBPROD</td>
<td>HPMFxxxxxx-xx</td>
<td>“holdername”</td>
<td>pmf</td>
<td>00xx</td>
</tr>
</tbody>
</table>

e.g. ESUBPXYZ_EUBPROD_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 ASM should have either an EMEA/ASMF number or an EU/ASMF number, depending on the intended use of the ASM 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 ASM 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**

The xxx is the procedure number. If there is no procedure number this can be left out or replaced by 000. The ‘Wonderpill’ in the referral example can be either product name, substance name or class name.

<table>
<thead>
<tr>
<th>Data</th>
<th>Remarks</th>
<th>Case sensitive</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>SenderRoutingId</td>
<td>Routing ID for Sender as registered by the Gateway for identification MDN &amp; acknowledgement messages.</td>
<td>Upper</td>
<td>ESUBPXYZ</td>
</tr>
<tr>
<td>ReceiverRoutingId</td>
<td>Gateway routing ID to differentiate this eSubmission from other application transmissions.</td>
<td>Upper</td>
<td>ESUBPROD</td>
</tr>
<tr>
<td>EMEA</td>
<td>EMEA</td>
<td>Upper</td>
<td>EMEA</td>
</tr>
<tr>
<td>H</td>
<td>Human medicinal product</td>
<td>Upper</td>
<td>H</td>
</tr>
<tr>
<td>XXXXX</td>
<td>Procedure number</td>
<td>Numeric</td>
<td>0011</td>
</tr>
<tr>
<td>C or N</td>
<td>Centrally Authorised Product/</td>
<td>Upper</td>
<td>C</td>
</tr>
</tbody>
</table>
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 Centrally Authorised Products (CAPs):**
- ESUBPXYZ_ESUBPROD_EMEA-H-A-20-xxxx-C_Wonderpill_referral_00XX.zip
- ESUBPXYZ_ESUBPROD_EMEA-H-A-107-xxxx-C_Wonderpill_referral_00XX.zip
- ESUBPXYZ_ESUBPROD_EMEA-H-A-31-xxxx-C_Wonderpill_referral_00XX.zip

**Referrals containing Nationally Authorised Products (NAPs):**
- ESUBPXYZ_ESUBPROD_EMEA-H-A-107-xxxx-N_Wonderpill_referral_00XX.zip
- ESUBPXYZ_ESUBPROD_EMEA-H-A-31-xxxx-N_Wonderpill_referral_00XX.zip

**Other referrals:**
- 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-16C-1-xxxx_Wonderpill_referral_00XX.zip
- ESUBPXYZ_ESUBPROD_EMEA-H-A-16C-4-xxxx_Wonderpill_referral_00XX.zip

**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