Active Substance Master File (ASMF) worksharing procedure

Submitting an initial worksharing ASMF

Dr Elspeth Gray
Joint Working Group on ASMF Procedure & Pharmaceutical Assessor, Medicines and Healthcare Products Regulatory Agency (MHRA), UK
July 2017
The EU/ASMF Repository Number

- The initial version of the worksharing ASMF will be assigned an EU/ASMF/XXXXX/0001 Repository Number

The EU/ASMF Repository Number should be used in ALL correspondence relating to the version of the worksharing ASMF, including the identification of eCTD/NeeS sequences
What (and when) do I submit?

- The ASMF holder should provide each Competent Authority involved in the DCP/CAP or type II variation procedure with:

1. ASMF Submission Details Form
   Annex 3 of CHMP/QWP/227/02 Rev 3 / EMEA/CVMP/134/02 Rev 03
2. Letter of Access*
   Annex 2 of CHMP/QWP/227/02 Rev 3 / EMEA/CVMP/134/02 Rev 03
   Not ASMF version specific and thus valid for the lifetime of that ASMF
3. Complete ASMF
   Applicant’s Part + AP-QOS & Restricted Part + QOS-RP

- Do not submit the ASMF:
  - more than 1 month before…
  - after…

the submission of the MAA or variation procedure
Example Submission Details Form
Page 1 – cover letter

ASMF-Holdings Ltd
100 High Street, London, UK.
www.ASMF-holdings-ltd.com

To: Medicines and Healthcare products Regulatory Agency,
151 Buckingham Palace Road,
Victoria,
London,
SW1W 9SZ

10 October 2013
OZP/Generics Pharmaceuticals Ltd

Dear Sir or Madam:

This Active Substance Master File is submitted in relation to the following product:

<table>
<thead>
<tr>
<th>Medicinal product</th>
<th>Acenocoumarol 2.5mg, 5mg, 7.5mg, 10mg, 15mg and 20mg film-coated tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocated procedure number (as applicable)</td>
<td>UK/IV/99999/01-06/DC</td>
</tr>
<tr>
<td>(Intended) Submission date of the marketing authorisation application or variation (if known)</td>
<td>12/10/2013</td>
</tr>
</tbody>
</table>

Signature, name and function of the ASMF holder’s authorised representative

Dr RA Smith,
Head of Regulatory Affairs,
ASMF-Holdings Ltd

The Submission Details Form should not be amended and all information fields completed.

Competent Authority address
ASMF holder’s headed paper
Active substance & EU/ASMF repository number
Date of letter & ASMF holder’s reference
Medicinal product, procedure number & MAH/Applicant using the ASMF
Signature, name and function of the ASMF holder’s authorised representative
### Administrative details for documents relating to an Active Substance Master file (ASMF)

This submission letter should be used for an Active Substance Master File to be assessed in conjunction with a marketing authorisation application or variation for a medicinal product for human/veterinary use, using either a national or mutual recognition or decentralised or centralised procedure.

<table>
<thead>
<tr>
<th>Distribution list for the ASMF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact details of ASMF holder, including email</td>
</tr>
<tr>
<td>ASMF holder’s version numbers for AP &amp; RP of ASMF</td>
</tr>
</tbody>
</table>

**ASMF-Holdings Ltd**

100 High Street, London, UK. [www.ASMF-holdings-ltd.com](http://www.ASMF-holdings-ltd.com)

**Active substance and ASMF holders internal API code**

<table>
<thead>
<tr>
<th>EU/ASMF repository number</th>
</tr>
</thead>
</table>

The Submission Details Form should not be amended and all information fields completed.

<table>
<thead>
<tr>
<th>Active substance and ASMF holders internal API code</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Contact details of each manufacturing site, including email, GPS co-ordinates &amp; D-U-N-S number (if applicable)</th>
</tr>
</thead>
</table>

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**ASMF Holder**

ASMF-Holdings Ltd

100 High Street, London, UK.

Contact person: RA Smith

Telephone: +44 (0)20 7040 9026

e-mail: asmin@asmf-holdings.com

<table>
<thead>
<tr>
<th>Active Substance Manufacturer Manufacturing site(s)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>ASMF-Holdings Pvt Ltd, India</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 2a, Verna, Goa</td>
</tr>
<tr>
<td>15-040 3702</td>
</tr>
<tr>
<td>Lat: 15.350</td>
</tr>
<tr>
<td>Long: 73.917</td>
</tr>
</tbody>
</table>

Contact person: Dr R Patel

Telephone: (92-22) 662953656

e-mail: rpatel@asmf-holdings.com
Submission type is marked as new submission. Other options are ASMF update, response to deficiency letter & administrative change.

Submission format, in this case eCTD. However, see national submission requirements.

List of documents provided, additional to the ASMF.

The Submission Details Form should not be amended and all information fields completed.
Example Submission Details Form
Page 4

Table of changes from present to proposed version of the ASMF. This is not completed for a new submission.

Confirmation that the ASMF has not been previously submitted in Europe.

List of procedures using the ASMF - this is not completed as the ASMF has not been previously submitted in Europe.

The Submission Details Form should not be amended and all information fields completed.
Example of a Letter of Access

Medicinal product, procedure number & MAH/Applicant using the ASMF

ASMF holder’s headed paper

EU/ASMF/XXXXX reference number

Active substance, internal API code and ASMF holder’s contact details

ASMF holder acknowledges sharing of ASMF assessment reports

Signature, name and function of the authorised representative of the ASMF holder

No amendments should be made to the Letter of Access template
Additional guidance on completing the Submission Details Form, as well as the Letter of Access to the ASMF and the EU numbering system for ASMF is published on the HMA and EMA websites:


http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/CMD_subgroups_working_groups/ASMF_WG/CMDh_308_2013_Rev.2_2018_04_clean.pdf
What do I submit if the ASMF is used in another procedure?

• The ASMF holder should provide each Competent Authority involved in the DCP/CAP or type II variation procedure with:

1. An updated ASMF Submission Details Form
Annex 3 of CHMP/QWP/227/02 Rev 3 / EMEA/CVMP/134/02 Rev 03

2. Letter of Access
Annex 2 of CHMP/QWP/227/02 Rev 3 / EMEA/CVMP/134/02 Rev 03

• An updated Submission Details Form is used to update the ASMF-AR repository, provides up-to-date information on the ASMF (particularly contact details), and helps track where the ASMF is referenced in Europe

• The same version of the ASMF does not need to be re-submitted, if previously submitted to the Competent Authority
Confirmation that the ASMF has been previously submitted in Europe

List of procedures using the ASMF. The first procedure using the ASMF is now listed
What do I need to submit for responses to a deficiency letter?

- The ASMF holder should provide each Competent Authority involved in the DCP/CAP or type II variation procedure with:

  1. An updated ASMF Submission Details Form
     Annex 3 of CHMP/QWP/227/02 Rev 3 / EMEA/CVMP/134/02 Rev 03
  2. Responses to deficiency questions on both the Applicant’s and Restricted Parts
     See CMD Questions & Answers on the ASMF Procedure
  3. Updated sections of the Applicant’s and Restricted Parts of the ASMF

- The ASMF holder should provide each MAH/Applicant with a copy of the Applicant’s Part responses for inclusion in their responses
  - Ensures the MAH/Applicant retains responsibility for the active substance in the medicinal product
    - See CMD Questions & Answers on the ASMF Procedure
The version numbers of the AP & RP of the ASMF have not been changed or updated.

The responses did not trigger a change in the content of the ASMF.

The responses provided further explanation of the existing data.

Updated contact person and email.
Submission type is marked as response to a deficiency letter.

Copy of the deficiency letter has been provided.

eCTD sequence has been updated to account for the response submission.
End of Presentation