Active Substance Master File (ASMF) worksharing procedure

Determining the Parent Procedure

Initial ASMFs

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The ASMF assessment worksharing procedure

- The ASMF worksharing procedure is simply a formalised way that Competent Authorities can share assessment reports for the same version of the ASMF

- The procedure is designed to operate with existing legislation and regulatory procedures

- No special “worksharing” timetable
  - the same timetable that is currently followed for DCP/CAP/Variation will apply

- No impact on procedure timings
The ASMF worksharing procedure
Linking CTS to the ASMF repository

The ‘dormant’ ASMF-AR repository record is created on request for EU/ASMF reference number

MAA/MAV is submitted to the Competent Authorities

The CTS record is created for the MAA/MAV

ASMF is submitted to the Competent Authorities

The CTS record is then linked to the ‘activated’ ASMF-AR repository record
The ASMF worksharing procedure
Linking CTS to the ASMF repository – a second procedure

The ‘dormant’ ASMF-AR repository record is created on request for EU/ASMF reference number

MAA is submitted to the Competent Authorities

The CTS record is created for the MAA

ASMF is submitted to the Competent Authorities

The CTS record is then linked to the ‘activated’ ASMF-AR repository record

2nd MAA/MAV is submitted to the Competent Authorities

The CTS record is created for the MAA/MAV
The ASMF worksharing procedure
Linking CTS to the ASMF repository

The CTS record is then linked to the ‘activated’ ASMF-AR repository record

MAAs/MAVs undergo validation

Procedure timetables are confirmed on CTS

CTS timetables automatically* populate timetables in the ASMF repository

* Currently, CAP timetables need to be manually entered
The ASMF worksharing procedure
Linking CTS to the ASMF repository

- **CTS timetables automatically** populate timetables in the ASMF repository
- Timetables are chronologically sorted in order to determine the “Parent Procedure”
- The “Parent Procedure” completes the ASMF-AR repository record

* Currently, CAP timetables need to be manually entered
What is the Parent Procedure?

- The “Parent Procedure” is the lead procedure responsible for preparing the ASMF assessment report first.

- If there is only one procedure using the ASMF, this is automatically designated the “Parent Procedure”.

- If there are more than one procedure using the ASMF, then the procedure timetables should be used to designate the “Parent Procedure”.

- Consequently, other procedures are known as “Daughter Procedures”.

How is the Parent Procedure determined for the first assessment stage? (1)

• For example,
  • IE/H/9690/01/DC Day 70: 17/01/2013
  • UK/H/9878/01/DC Day 70: 28/01/2013
  • FR/H/9798/01/DC Day 70: 24/03/2013
  • EMEA/H/C/123456/00000 Day 80: 31/04/2013

• or,
  • FR/H/9798/01/DC Day 70: 28/08/2016
  • DE/H/9987/II/012/G Day 40: 30/08/2016
  • EMEA/H/C/0004567 Day 80: 03/09/2016
  • IE/H/9690/01/DC Day 70: 17/09/2016
How is the Parent Procedure determined for the first assessment stage? (2)

• Chronologically sorting the timetables, IE/H/9690/01/DC or FR/H/9798/01/DC (depending on the situation) is the first procedure required to produce a Preliminary ASMF Assessment Report – this is the “Parent Procedure”

• The RMS of the parent procedure is responsible for completing the ASMF-AR repository record
The Parent Procedure from the first stage should continue into the second stage of assessment.

Best endeavours by MAH/Applicants, ASMF holder and Competent Authorities should be made to achieve this.

However, this may not be possible in all procedure due to issues unrelated to the ASMF.

Therefore, the worksharing procedure has been specifically designed so that one of the Daughter Procedures can take over as the Parent Procedure.
How is the Parent Procedure determined during the second assessment stage? (2)

- Again, the timetables from the second stage of assessment are used to determine the “Parent Procedure” (as the first stage)
- In the example below, the Applicant of the UK procedure has responded before that of the IE procedure

<table>
<thead>
<tr>
<th>Procedure Code</th>
<th>Response Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK/H/9878/01/DC</td>
<td>Day 120: 16/04/2013</td>
</tr>
<tr>
<td>IE/H/9690/01/DC</td>
<td>Day 120: 31/04/2013</td>
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<tr>
<td>FR/H/9798/01/DC</td>
<td>Day 120: 24/06/2013</td>
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<tr>
<td>EMEA/H/C/123456/00000</td>
<td>Day 150: 31/07/2013</td>
</tr>
<tr>
<td>DE/H/9987/II/012/G</td>
<td>Day 60: 07/12/2016</td>
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<tr>
<td>EMEA/H/C/0004567</td>
<td>Day 150: 15/12/2016</td>
</tr>
<tr>
<td>IE/H/9690/01/DC</td>
<td>Day 120: 22/12/2016</td>
</tr>
<tr>
<td>FR/H/9798/01/DC</td>
<td>Day 120: 04/04/2017</td>
</tr>
</tbody>
</table>
How is the Parent Procedure determined during the second assessment stage? (3)

- UK/H/9878/01/DC or DE/H/9987/II/012/G now becomes the first procedure needing to prepare the Draft ASMF assessment report of the responses, taking over as ‘Parent Procedure’ from IE/H/9690/01/DC and FR/H/9798/01/DC
How is the Parent Procedure determined during the second assessment stage? (4)

- The principle of different assessors preparing the initial assessment report and evaluating responses to deficiency questions has been previously well established at a national level within Agencies and at a European level.

- This practice is facilitated by harmonised European Quality standards.

- Rotating the Parent Procedure ensures that delays encountered in one procedure do not impact any of the other procedures.
End of presentation