Active Substance Master File (ASMF)
worksharing procedure

ASMF Working Group
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Why do we need a worksharing procedure for ASMF assessments?

When the same ASMF is used in multiple procedures and/or Member States, it can lead to...

- Duplicated assessment
- Divergent decisions
- Frequent ASMF updates (at NCA request)
- Reduced oversight of the ASMF
- Increased workload (all parties)

What has been done to solve the problem?

ASMF Assessment Worksharing Procedure

A simple way for Competent Authorities to share assessment report for the same version of the ASMF

- Letter of Access
- ASMF Submission Details Form
- ASMF assessment report repository
- EU/ASMF repository number

1 Annex 2 and 2 Annex 3 of CHMP/QWP/227/02 Rev 3/Corr Guideline on the ASMF procedure
History

• Goal: There should be 1 procedure for ASMF assessment
  – Used in national, MRP/DCP and CP, variations
  – For human & veterinary products
• April 2010 : discussion in HMA
• June 2010 : first meeting of ASMF-WG
• April 2011 : meeting with interested parties and HMA decision
• December 2013 : start of pilot-phase
• January 2017 : end of pilot-phase, worksharing procedure is business as usual

Collaboration

• Members: All EU national competent authorities
• Observers : EDQM, IGDRP

• Continuous interaction with stakeholders
  – At QWP plenary meetings (Intra-Network)
  – At bimonthly ASMF WG meetings (Intra-Network)
  – ASMF holders taking part in WS and Interested Parties (AESGP, EFPIA, EGA, EUCOPE, APIC/CEFIC, IFAH, EGGVP)
How does the ASMF assessment worksharing procedure work?

- EU/ASMF repository number
- ASMF Submission Details Form

Tracks where the same version of the ASMF is used in different procedures & Member States

ASMF assessment report repository allows Competent Authorities to share easily the assessment report (ASMF holder acknowledges sharing of assessment reports in the Letter of Access)

How does the ASMF assessment worksharing procedure work?

- Designed to operate within existing legislation, regulatory procedures and timetables
- NO IMPACT ON PROCEDURE TIMINGS

- Reduces CA requests for ASMF updates
- Improves oversight of the ASMF
- Harmonises ASMF assessment
- Reduces workload ASMF & MA holders (plus Competent Authorities)
The ASMF assessment worksharing procedure

• Includes…

✓ New ASMFs submitted in DCP, CAP or national marketing authorisation applications and variation applications

✗ Undergoing assessment / previously assessed in a DCP/MRP/CAP

– NB: ASMFs undergoing assessment or have been assessed in national only procedures may still be accepted in the worksharing, but may result in a new evaluation of the ASMF. ASMF holders should list these applications in the Submission Details Form so that the assessment report may be requested and used in the evaluation.

– NB: If the same data have been submitted in a CEP application, ASMF holders should notify Competent Authorities so that the report may be requested from the EDQM

– Updates to a worksharing ASMF can be submitted in a MA or MAV application using any regulatory procedure in order to preserve its lifecycle

• Use of the procedure is strongly recommended, but not mandatory

The ASMF assessment worksharing procedure

• Assessments of new ASMFs composed of 2 to 3 assessment stages
• ASMF-AR repository uses procedure timetables to identify "parent" procedure
• Other procedures are “Daughter procedures”
• Parent procedure is responsible for drafting assessment report
• QA review of the assessment report by Parent CMS/Daughter RMS
• Review of assessment report by Parent CMS
• Only Major Objections raised during reviews
• Procedure repeats as above until assessment is complete
### Current number of ASMF’s in Worksharing

**Status August 2017:**
- Number of ASMF-numbers issued : 128
- Accepted for use (assessment finalised) : 40
- Under evaluation : 58
- Reserved : 26
- ASMFs withdrawn : 4

### What support is available?

**Relevant to worksharing procedure and worksharing ASMFs:**
- Assessment worksharing procedure guidance
- Training on the ASMF assessment worksharing procedure
- CMD Q&As on ASMF assessment worksharing procedure

**Applicable to all ASMFs:**
- Guidance on ASMF procedure
- CMD Q&As on ASMF procedure
- Additional guidance on ASMF documents Completing & submitting annex 2, 3 & 4
Links to support documents

• Guideline on the ASMF procedure (CHMP/QWP/227/02/Rev3/Corr)
• Additional guidance on documents relating to an active substance master file
• CMD Q&As on the ASMF procedure + Q3.4 of the CMD Q&A on Variations (concerning ASMF updates)
  http://www.hma.eu/306.html
• The ASMF assessment worksharing procedure
  http://www.hma.eu/306.html
• Training material on the ASMF assessment worksharing procedure
  http://www.hma.eu/306.html
• CMD Q&As on the ASMF assessment worksharing procedure
  http://www.hma.eu/306.html

What support is available?

• For issues concerning the ASMF assessment work sharing procedure, please contact the CMD Working Group on ASMF procedures
  – H-CMDhSecretariat@ema.europa.eu
  – The subject header of the email should clearly state “ASMF worksharing procedure”