

Active Substance Master File (ASMF) worksharing procedure

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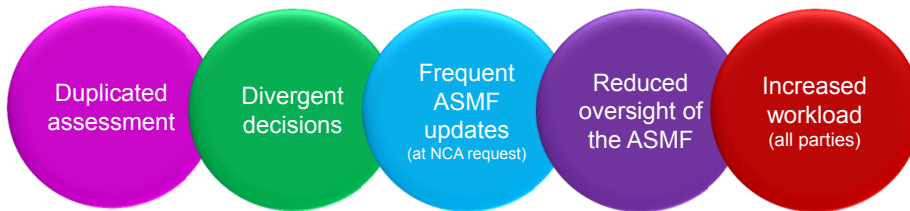
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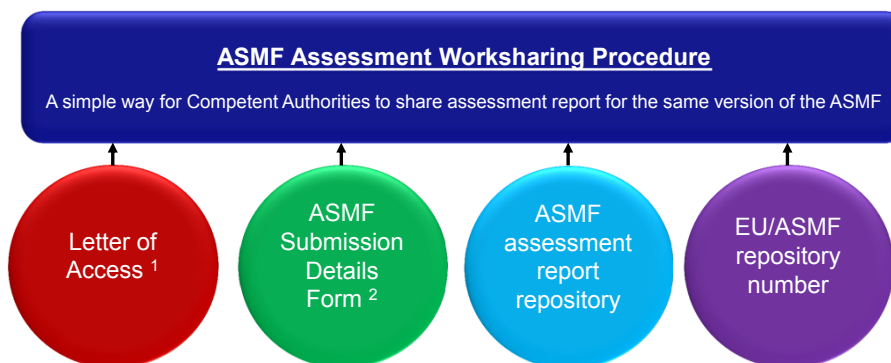
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Why do we need a worksharing procedure for ASMF assessments?

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



What has been done to solve the problem?



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

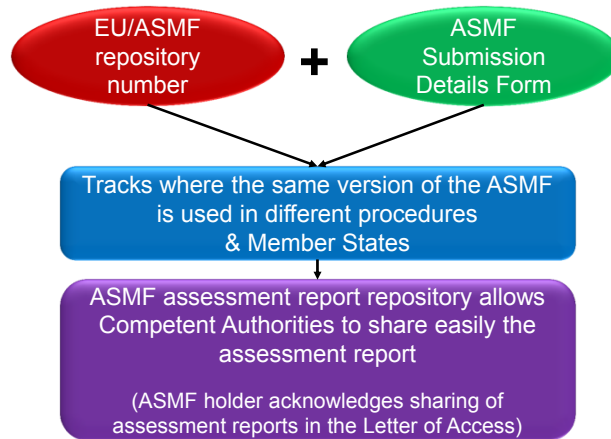
History

- 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

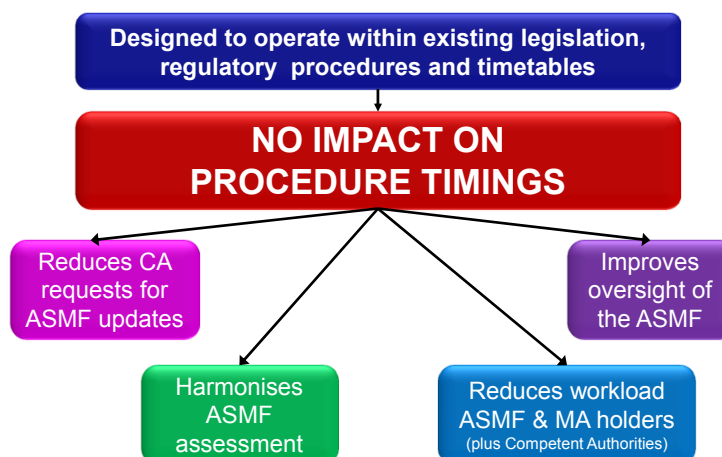
Collaboration

- 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?



How does the ASMF assessment worksharing procedure work?



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

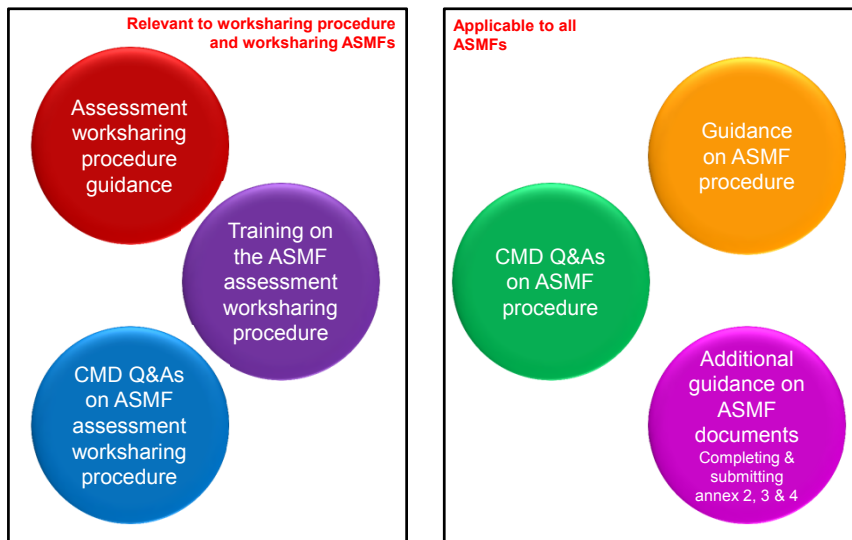
- Assessments of new ASMFs composed of 2 to 3 assessment stages
- ASMF-AR repository uses procedure timetables to identify “parent” procedure
- Other procedures are “Daughter procedures”
- Parent procedure is responsible for drafting assessment report
- QA review of the assessment report by Parent CMS/Daughter 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?



Links to support documents

- Guideline on the ASMF procedure (CHMP/QWP/227/02/Rev3/Corr)
http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500129994
- Additional guidance on documents relating to an active substance master file
http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500133204
- 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”