

# Working Group on Active Substance Master File Assessment Report procedures

Christa Wirthumer-Hoche  
AGES PharmMed  
Vienna, AT

CMDh meeting with IPs  
14 Nov 2011

# Active Substance Master File (ASMF)



The same ASMF is often used in different dossiers for multiple procedures assessed by different assessors.

**Goal:** There should be 1 procedure for ASMF assessment

- Used in national, MRP/DCP and CP
- For human & veterinary products

Discussion started at the HMA meeting April 2010, Sevilla.



Save resources

Increase consistency

# WG of ASMF procedures: Activities



- June 2010:
  - First meeting of ASMF - WG
- April 2011:
  - Meeting with Interested Parties
- April 2011:
  - HMA decision
    - Common repository within CTS
- May 2011:
  - Mandate of the WG on ASMF procedures was adopted by CHMP, CVMP CMD-h & v
  - Mandate published on the EMA and HMA website
- Nov 2011:
  - Discussion at the HMA – endorsement of the working plan of the WG

# Mandate of the WG on ASMF procedures



19 May 2011  
EMA/252320/2011  
Working Party on Active Substance Master File Assessment

Mandate of the Working Group on Active Substance  
Master File Procedures

# Mandate



- Within the current legal framework, to consider the feasibility of a worksharing procedure for ASMF assessment
- To develop a procedure for a coordinated and harmonised use of ASMF assessments, independent of the licensing procedure being used (CP, MRP/DCP, nat.)
- Prepare a guidance document on procedural rules for a common use of ASMF Ars
- To develop an EU numbering system for all ASMFs
- To develop a centralised database for all ARs of ASMF
- To present proposals to the CMD h&v, CHMP & CVMP on how the ASMF assessment procedure can be improved and optimised.

# Masterplan for sharing ASMF AR (1)



- Preparation work – update of the existing guideline
  - Work started already, to be finalised (incl pilot phase on the use of the guideline, and evaluation) Q2/2014
  - Meeting with industry Each year
- Preparation Work – Assessment Reports (AR) Q2- Q3/2012
  - Separation of templates ( interchangeable CP & MRP/DCP)
  - Guidance how to share the ARs
- Development of ASMF AR database in CTS, exchange with EDQM – Q3/2012 Q3/2012
- Development of an EU numbering system Until 2015
  - Stepwise approach Q1/2013
  - Guidance paper, information of industry, training materials for NCAs

# Masterplan for sharing ASMF AR (2)



Elaboration of models for sharing the assessment reports of the Active Substance Master File

- Informal system to share ASMF ARs
- Option 1 – development of a formal „Floating Rapp“ ASMF worksharing
  - o Stepwise approach
- Option 2 - development of a „Fixed Rapp“ ASMF worksharing

→ Implications have to be evaluated further

Timeframe: until 2018

# Assigning an ASMF number



At present - no defined EU-wide numbering system for ASMFs.

- ASMFs numbering currently at a pure national level
- No harmonised format
- No consistent approach to assign version numbers

## New numbering system

- Proposal  
*mandatory for all new ASMFs?*
- submitted as part of a new application or variation?

# EU ASMF number - proposal



EU/ASMF/xxxxx/Versionyyyy

Encourage ASMF holder

- to apply for an EU number for existing ASMFs
  - immediately prior to the submission of a significant regulatory case in relation to an existing ASMF
    - Registration of an existing ASMF as part of a new MAA
    - Variation to an existing ASMF

Who is issuing the EU ASMF number?

- RMS controlled or
- ASMF holder to retrieve from an IT-DB?

# ASMF Guideline – revision (1)



- Revised **Annex 2** – Letter of Access
  - The ASMF holder hereby is informed of and accepts that the EEA NCAs, the EMA including all CHMP and CVMP Members and their experts, and the Certification of Substances Division of the EDQM may share the ARs of the above mentioned ASMF amongst themselves.

Allows MSs to share ASMF ARs ,  
– basis for Worksharing

# ASMF Guideline – revision (2)



- Revised **Annex 3** – Submission letter and administrative details for documents relating to an ASMF
  - Include the 5 most recently submitted medicinal products or all medicinal products submitted under National or European procedures – Centralised, Decentralised and Mutual Recognition under the last 2 years, whichever is greater
- New **Annex 4** – Withdrawal of Access letter
  - The ASMF holder also hereby confirms that they have previously informed [Name of MAH/Applicant] of this decision at least 6 months from the date of this letter.

# Next steps



- Update of the ASMF guideline in respect to the Annexes (no further changes at the moment) –
  - Publication Q1/Q2 2011
- „Fill-In“ – guideline for the Annexes – to be published until Q2/2011
- Information of industry
- Development of further practical procedural guidance:
  - „Issuing of the ASMF number“
  - „How to use the ASMF-AR“

**Thank you!**

