March 2022
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Working Group on Active Substance Master File Procedures

Mandate of the Working Group on Active Substance Master File Procedures

1. Background

The documentation for a drug substance (mod 3.2.S or equivalent in the VNees format) can be replaced by an active substance master file (ASMF). Appropriate guidance is given in the CHMP/CVMP guideline on active substance master file procedure (Guideline on the Active Substance Master File Procedure - CHMP/QWP/227/, EMEA/CVMP/134/).

A specific ASMF can be used for multiple marketing authorisation applications (MAAs) and/or marketing authorisation variations in one or more Member States, which may or may not be connected through a European procedure. At the moment, the same ASMF can be assessed by different Member States or Rapporteurs, which can result in duplication of work, inefficient use of assessor resources, and inconsistent decisions being made on the same data.

To deal with the procedural aspects of ASMF assessments, and to consider the development of a guidance paper for efficient worksharing on ASMF assessment, the Working Group on Active Substance Master File Procedures.

2. Mandate

The mandate of the Working Group on Active Substance Master File Procedures is:

- within the current legal framework, to consider the feasibility of a worksharing procedure for ASMF assessments;
- to develop a procedure for a coordinated and harmonised use of ASMF assessments, independent of the licensing procedure being used (centralised procedure, mutual-recognition procedure or decentralised procedure), and prepare a guidance document on procedural rules for a common use of ASMF assessment reports (ARs);
- to develop an EU numbering system for ASMFs;
- to develop a centralised database for all ARs of ASMFs;
- to present proposals to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), Co-ordination Group for Mutual Recognition and Decentralised Procedures for veterinary medicinal products (CMDv), Committee for Medicinal Products for Human Use (CHMP) and Committee for Veterinary Medicinal Products (CVMP) on how the ASMF assessment procedure can be improved and optimised.

3. Composition of the working group

- Chair;
- Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) and Co-ordination Group for Mutual Recognition and Decentralised Procedures for veterinary medicinal products (CMDv);
- Committee for Medicinal Products for Human Use (CHMP) and Committee for Veterinary Medicinal Products (CVMP), including the Chair of the Quality Working Party (QWP);
- European Medicines Agency;
- European Directorate for the Quality of Medicines & HealthCare.

Members who want to bring additional experts should notify the CMDh/CMDv secretariat in advance of the meeting, subject to the agreement of the chairperson.

Members of the Working Group are expected to participate actively in the work and to attend the meetings (either physical or virtually) regularly.

Meeting documentation will be distributed to the Working Group members. The CMDh/CMDv secretariats will ensure that the membership list is up to date.

4. Meeting frequency

Meetings are organised face-to-face at the EMA premises or virtually in the margins of the CMDh/CHMP/CMDv plenary meetings. The frequency of the meetings is reviewed yearly in the CMDh/CMDv plenary meetings. The CMDh/CMDv agrees on the annual CMDh/CMDv meeting schedule.