Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

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BEST PRACTICE GUIDE

for

Active substance master file (ASMF) in the mutual recognition and decentralised procedures

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1. INTRODUCTION

In accordance with the Directive 2009/9/EC (Annex I of Directive 2001/82/EC[1]), Title I, Part 2C1.1, for well defined active substances, the active substance manufacturer or the applicant may arrange for detailed information related to the manufacturing process of active substance (the detailed description of the manufacturing method, quality control during manufacture and process validation) to be supplied in a separate document directly to the competent authorities by the manufacturer of the active substance as an Active Substance Master File (ASMF).

2. AIM AND SCOPE

This Best Practice Guide is intended to assist Applicants/MA holders in the management of the Active Substance Master File procedure in the mutual recognition procedure (MRP) and in the decentralised procedure (DCP).

3. REFERENCES AND RELATED DOCUMENTS

- Guideline on Active Substance Master File Procedure (ASMF) – EMEA/CVMP/134/02
- Directive 2009/9/EC (Annex I of Directive 2001/82/EC[1])
- CMDv Best Practice Guide on Mutual Recognition Procedure (CMDv/BPG/001)
- CMDv Best Practice Guide on Decentralised Procedure (CMDv/BPG/002)

4. DESCRIPTION OF PROCEDURE

At all times during the procedures when comments relating to the restricted section of the ASMF are sent by CMS or RMS, they must be clearly identified as confidential.

4.1 Submission to the Concerned Member States

The active substance manufacturer should submit complete and current version of the ASMF (the Applicants Part, the Restricted Part and the Expert report (in case of NTA format) or the Detailed and Critical Summaries/Quality Overall Summary (in case of CTD format) accompanied by a covering letter and the letter of access) to all the Concerned Member States (CMSs).
If a CMS has received the same version of the complete ASMF previously, only the letter of access may be provided. In this case, the CMS should be informed about the ASMF version number used in the MRP or in the DCP. However, the CMSs can still ask for a complete version of the ASMF if required.

[1] As amended by Directive 2004/28/EC and Directive 2009/53/EC.

The manufacturer of the active substance should confirm to the RMS that the same version of the ASMF has been submitted to all CMSs and should specify the version number of the ASMF.

In the case of an MRP, at day -14, the RMS sends at the same time an assessment report of the dossier (including comments on the Applicants Part of the ASMF) and an assessment report for the restricted part of the ASMF to the CMSs.

4.2 Validation

The CMSs will check the receipt of the additional documents mentioned below. In the case of the absence of one of them the application will be not validated :

- the complete ASMF
- the assessment report of the closed part of the ASMF (MRP only)

4.3 Before Day 70 and Day 105 of the DCP

By day 70, the RMS prepares a preliminary assessment report (PAR) of the dossier (including comments on the Applicant's part of the ASMF) and an assessment report for the restricted part of the ASMF. These are sent to the CMSs.

By day 105, the RMS finalizes the preliminary assessment report and list of questions. The assessment report and the list of questions on the veterinary medicinal product including comments on the Applicant's part of the ASMF are sent to all CMSs and to the Applicant. The report on the restricted part of the ASMF is only sent to the CMS.
The list of questions (if any) based on the PAR of the Restricted part of the ASMF is sent to all CMSs and directly to the ASMF holder.

4.4 Before day 54 of the MRP and day 145 of the assessment step II of the DCP

The CMSs send their questions on the dossier and the ASMF to the RMS. If a CMS has a question regarding the restricted section of the ASMF it is identified as a confidential document separate from the other CMS' comments.

4.5 Consolidated list of questions (DCP: day 150 of the assessment step II, MRP: day 57)

The RMS will prepare the list of questions (LOQ) excluding all questions related to the restricted part of the ASMF. However the fact that question are raised on the restricted part of the ASMF should be specified in the appropriate sections. This LOQ is sent to the CMSs and the applicant.
If necessary, the RMS prepares a separate LOQ regarding the restricted part of the ASMF. This LOQ is sent directly to the ASMF holder and the CMSs and the applicant is informed that questions have been sent directly to the ASMF holder.

4.6 The Applicant and ASMF holder responses (DCP Day 106 and Day 170, MRP Day 65)

The Applicant and the open parts ASMF holder responses to the list of questions should be sent, after consolidation by the Applicant, to the RMS and this is forwarded to the CMSs in the usual fashion.
The ASMF holder forwards copies of any supporting data relating to their answers on the restricted part of the ASMF directly to the RMS and the CMSs.