EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Active substance master file procedure

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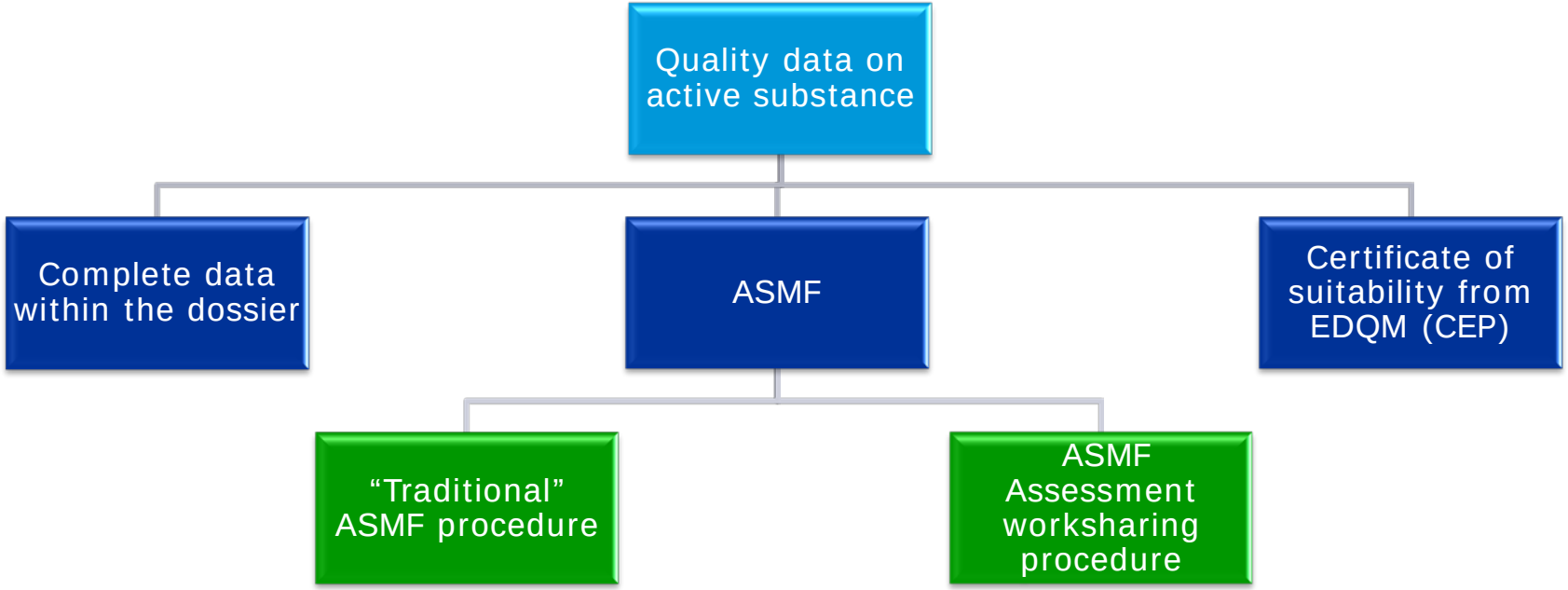
General concepts



General concepts

What is an ASMF?

Document (independent from the marketing authorisation dossier) by which the information relating to the development, manufacture and control of the active substance is supplied.

Structure

- Administrative information.
- Expert's summaries.
- Applicant's part (AP) – open part.
- Restricted part (RP) – closed part.

ASMF procedure

Purpose

To allow confidential intellectual property or 'know-how' of the manufacturer of the active substance to be protected, while at the same time allowing the applicant or marketing authorisation holder (MAH) to take full responsibility for the medicinal product and the quality and quality control of the active substance.

Participants

- ASMF holder: owner of the ASMF dossier.
- Applicant/MAH: owner of the veterinary medicinal product dossier.

ASMF procedure (*cont.*)

Scope

- Well-defined active substances:
  - Chemical or herbal.
  - New active substance.
  - Existing active substance: with or without a monograph in the Ph. Eur. or a pharmacopoeia of a member state.

Restrictions

- Not applicable to biological substances (e.g. vaccines), excipients or finished products.
- ASMFs are submitted in support of marketing authorisation/line extension applications or variations. Never assessed on their own!

Pre-submission

A reference number should be allocated for ASMFs submitted to the EMA:

- Reference number structure:
  EMEA/ASMF/XXXXX (traditional ASMF procedure) or EU/ASMF/XXXXX (ASMF assessment WS procedure).
- Specific request forms available on public websites (EMA or HMA).
- ASMF holder should complete the request form and send it to PA-BUS@ema.europa.eu
- ASMF reference number should be included in the letter of access (ASMF holder), submission letter and administrative details (ASMF holder) and application form (applicant).

Submission

Data

- **ASMF holder:**
  - Complete ASMF dossier:
    - Administrative documents: letter of access (annex 2 ASMF guideline), submission letter and administrative details (annex 3 ASMF guideline), expert's CV and signature.
    - Expert's summaries of AP and RP: quality overall summary structure (if ASMF in CTD format) or detailed and critical summary structure (if ASMF in NtA format).
    - Applicant's part: non-confidential information on the manufacture and control of the active substance.
    - Restricted part: confidential information on the manufacture and control of the active substance.

Submission (*cont.*)

Data

- **Applicant / MAH**: within the dossier of the medicinal product
  - Copy of letter of access.
  - Copy of the applicant's part of the ASMF.

Timelines

- Ideally at the same time as the MAA/variation.
- Acceptable: One month before submission of MAA/variation.
- Co-ordination also required for submission of responses!

ASMF assessment worksharing procedure

Purpose:

Harmonised assessment throughout Europe, minimise the workload of ASMF holders, applicants and competent authorities.

Principle:

Mutual recognition of assessment of the same ASMF between EEA Competent Authorities (CAs).

ASMF assessment worksharing procedure (*cont.*)

Eligibility:

- 'new ASMF' submitted via CP or DCP only.
- 'new ASMF': an ASMF that has not been previously assessed by a Competent Authority as part of a CP, DCP or MRP. May have been assessed as part of a national application.
- Other ASMFs will be eligible at a later stage.

Status:

- Not mandatory.
- Pilot phase: extended to December 2015.

ASMF assessment worksharing procedure (*cont.*)

Status:

- Total: 66 (3 veterinary)
- EU numbers reserved: 10
- Under evaluation: 55 (3 veterinary)
- Withdrawn: 1

Practicalities

- **Co-ordination in submission is essential for a smooth MAA/variation procedure.**
- **Proactively request the ASMF reference number to the ASMF holder.**

To avoid potential delay in the MAA/variation procedure (at validation, start or re-start of procedure).

CONSTANTLY LIAISE AND COMMUNICATE WITH THE ASMF HOLDER

Useful links

ASMF guideline and annexes templates

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000495.jsp&mid=WC0b01ac05803a36d0

Q&A on ASMF

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000059.jsp&mid=WC0b01ac058002d9ad

Working Group on Active Substance Master File Procedures

http://www.hma.eu/306.html

Thank you for your attention

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