Active Substance Master File (ASMF) worksharing procedure

Use of an accepted worksharing ASMF in a new Marketing Authorisation Application (MAA) or Variation Application

Dr Elspeth Gray
Joint Working Group on ASMF Procedure & Pharmaceutical Assessor, Medicines and Healthcare Products Regulatory Agency (MHRA), UK
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Proposing an accepted worksharing ASMF in a new MAA

• As with any source of drug substance that is the subject of an ASMF, a worksharing ASMF may be referenced by a new MAA or Variation Application.

• The use of a worksharing ASMF that is already accepted in the context of another MA has significant potential benefits to the Applicant, ASMF Holder and Regulator.
Procedural aspects

- Where the accepted version of the ASMF is referenced in a new procedure, the RMS / Rapporteur of that procedure will review this in the context of the medicinal product that is proposed.

- In the vast majority of cases, the RMS / Rapporteur and other concerned Member States will adopt the final ASMF-AR that is already available in the ASMF repository.

- If this is the case, there is no need to update the assessment report or summary.

- The new procedure should be recorded in the ASMF repository.
If a Potential Serious Risk to Public Health (Major Objection) is raised?

- There may rarely be occasions where the RMS / Rapporteur or CMS for the new procedure may raise a Major Objection or Potential Serious Risk to Public Health (PSRPH) regarding the ASMF.

- Depending upon the circumstances, this may impact all or most of the procedures to which the ASMF is registered.

- These situations will be managed on a case-by-case basis. Appropriate consultation between the relevant Member States may be important.

- Should the ASMF-AR require to be amended under the same ASMF version (YYYY) number, this may be done by the RMS / Rapporteur of the new parent procedure. The updated AR and where necessary, the summary, should be uploaded to the ASMF repository.
End of Presentation