

Ad-hoc group on ASMF assessment (1)



Scope:

- Procedural aspects of ASMF assessment

Goal:

- To investigate the feasibility - practical and legal aspects - of and consider proposals for:
 - one central assessment for ASMF going through CP and DCP
 - a centralised database for all AR of ASMFs
 - an EU numbering system for ASMFs

Composition of the group:

- CMD-h (&v)
- EMA
- EDQM
- Chair of the QWP

Ad-hoc group on ASMF assessment (2)



Progress already in some areas:

- separate AR on the ASMF, separated from AR on medicinal product.
- discussions on high level specifications for a document management system
- early consideration on how to use assessment reports produced in a work sharing procedure.

Future Plans:

- ... a lot
- Meeting with trade associations incl APIC