EMEA guidelines

- **Procedure for European Guidelines and Related Documents within the Pharmaceutical Legislative Framework (EMEA/P/24143/2004 Rev 1)**
- **“Soft-law“ non-legally binding, however, sound justification in case of deviation**

What is a guideline

- A community document with explicit legal basis to fulfill an obligation laid down in the community pharmaceutical legislation
- Provides advice to applicants or marketing authorisation holders, competent authorities or other interested parties
- Harmonised EU position, e.g. on scientific issues, that facilitates development, assessment, approval and control of medicinal products in the EU
- “Living Document”, developed and updated in the view of ongoing experience and evolution of science

Terminology

- Guideline
- Note for guidance
- Position Paper
- Points to consider

GUIDELINES

Types of Guidelines within the pharmaceutical legislative framework

Scientific Guidelines related to Quality, Safety and Efficacy (published by the EMEA on its website):

give guidance for overall pharmaceutical product development, as well as clinical and non-clinical tests to facilitate the Application for marketing authorisation

- Regulatory Guidelines
- GMP,GCP,GLP,GDP Guidelines
- Pharmacovigilance Guidelines
- Orphan medicinal Products Designation Guidelines
- Herbal Medicinal Product Guidelines
- /.../

Procedure for Drafting a Guideline

1. Selection of a topic and inclusion in the relevant work programme(s)
2. Appointment of rapporteur and (if necessary) co-rapporteur
3. Development of concept paper and release for consultation
4. Preparation of draft guideline
5. Release for external consultation of draft guideline
6. Collection of Comments
7. Preparation of final guideline
8. Adoption of final guideline and publication
9. Implementation

1.Selection of topics and inclusion in EMEA work programme

The need for a new guideline may be triggered by

- Frequently encountered problems with established products (e.g. need for clearer guidance on dossier requirements for certain indications/classes of products or harmonised requirements covering all EU Member States)
- Questions brought forward within the framework of scientific advice (e.g. PMDD)
- Development of new technologies, new practices or new therapeutic areas (e.g. JIA)
- PDCO

2. Appointment of Rapporteur

- Once a topic has been selected a rapporteur (and co-rapporteur if appropriate) is appointed by the relevant working party, scientific advisory group or EMEA
- Rapporteurs are responsible for drafting the concept paper and subsequent guideline with support of the relevant working party, group or committee

3. Development of a concept paper

- Should point out the key issues to be covered in the guideline, no elaboration on solutions
- Reference to relevant literature and guidelines
- Adoption by the Committee
- Release for external Consultation (EMEA website) to relevant interested parties through publication on the EMEA website for a period of 2 to 3 months
- Comments collected on the concept paper will be considered in the development of the future guideline
- Concept paper becomes a historical document and will be archived

4. Preparation of draft guideline

Guideline structure follows a preset template

- Cover (title) page
- Table of contents
- Executive summary
- Introduction (background)
- Scope
- Legal basis
- Proposed timetable (on the cover page)
- Definitions
- References (Scientific or legal including reference to the concept paper)

Internal discussion within the working party or other working parties

If indicated, specific SAG may be involved

5. Release for consultation of Draft guideline

- Submission to the appropriate body (Scientific Committee/European Commission/European Pharmacopoeia) for adoption of the draft guideline for release for external consultation
- Usually 6 months
- Specific template for submission of comments of interested parties

6. Collection and treatment of comments

Depending on the subject, comments are expected from

- Member States of the EEA/EEFTA countries
- Other regulatory authorities (e.g. FDA, Health Canada, European Pharmacopoeia, other ICH partners)
- European industry associations (e.g. EFPIA)
- European scientific/academic societies and patient/consumer groups/health care professionals
- Other interested parties

→ Rapporteur prepares an overview of the main comments that explains the rationale behind their acceptance or non-acceptance,

to be published on the EMEA website (with guideline)

7./8. Preparation of final guideline and adoption

- Preparation of final version:

  External comments are considered by the working party, revision of the text
- Adoption of final guideline:

  The committee and/or European Commission adopt the final guideline, normally at a plenary meeting
- The guideline is published on the relevant website, previous drafts and the concept paper are archived

9. Implementation

- Guidelines come into operation 6 months after their adoption
- Training for assessors to ensure consistent application of guidelines organised in association with relevant working parties

Maintenance and revision of adopted guidelines

- Normally guidelines will be considered for revision after five years of application
- Earlier revision in case of limited experience, fast evolving knowledge, major problems, major changes in scientific knowledge
- Triggers (e.g. scientific advice, PDCO)

Amendment of JIA Guideline (EMEA/CHMP/EWP/392476/2006)

Draft proposal for changes by PDCO

- Classification of JIA
- Design of studies (withdrawal/active comparator)
- Validated outcome measures (primary endpoints)
- Outcome predictors
- Extrapolation from adults
- Age groups
- Follow-up registries