EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Medicines Agency - Science, medicines, health

Clinical efficacy and safety guidelines

This section includes the European Medicines Agency's guidelines on the **clinical efficacy and safety of medicines**.

The Agency's Committee for Medicinal Products for Human Use (CHMP) prepares **scientific guidelines** in consultation with regulatory authorities in the European Union (EU) Member States, to help applicants prepare marketing-authorisation applications for human medicines.

Guidelines provide a basis for practical harmonisation of how the EU Member States and the Agency **interpret** and **apply** the detailed requirements for the demonstration of quality, safety and efficacy that are in the **Community directives**.

The Agency strongly encourages applicants and marketing-authorisation holders to follow these guidelines. Applicants need to justify **deviations from guidelines** fully in their applications at the time of submission. The Agency advises applicants to discuss any proposed deviations with EU regulators during medicine development through scientific advice.

Clinical efficacy and **safety guidelines** are provided for:

- Clinical pharmacology and pharmacokinetics
- Alimentary tract and metabolism
- Blood and blood forming organs
- Blood products (including biotechnological alternatives)
- Cardiovascular system
- Dermatologicals
- Genito-urinary system and sex hormones
- Anti-infectives for systemic use
- Antineoplastic and immunomodulating agents
- Rheumatology/Musculo-skeletal system
- Nervous system
- Respiratory system
- General
- Herbal medicinal products
- Information on medicinal products
- Radiopharmaceuticals and diagnostic agents
- Allergy/Immunology