EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Medicines Agency - Science, medicines, health

Multidisciplinary guidelines

This section includes the European Medicines Agency's guidelines that apply to **more than one specific area** or have been prepared through the collaboration of **several working parties**.

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.

Multidisciplinary guidelines are provided for:

- Paediatrics
- Cell therapy and tissue engineering
- Vaccines
- Biosimilars
- Gene therapy
- Herbal medicinal products
- Nanomedicines
- Pharmacogenomics
- Miscellaneous

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