



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Scientific advice and protocol assistance

For medicines for human use

An agency of the European Union



Scientific Advice Working Party (SAWP)

- A permanent working party of the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP).
- A multidisciplinary group comprising 28 members, including members of the Committee for Orphan Medicinal Products (COMP), the Paediatric Committee (PDCO), the Committee for Advanced Therapies (CAT) and the Pharmacovigilance Risk Assessment Committee (PRAC).
- Assures expertise in: non-clinical pharmacology and toxicology; pharmacokinetics; methodology and statistics; therapeutic fields including HIV, anti-infectives, immunology, respiratory diseases, cardiology, oncology, diabetes, neurodegenerative disorders, ophthalmology and psychiatry; biomarkers and pharmacogenomics; cell and gene therapy, registries and pharmacovigilance, or other areas as needed.
- Coordinates the provision of scientific advice and protocol assistance, and brings forward to the CHMP, the CAT and the COMP an integrated view on quality, non-clinical, clinical, safety and efficacy aspects of the development of medicinal products, and on significant benefit relating to orphan medicinal products.
- Meets 11 times a year at EMA for a 3-4 day meeting, generally set two weeks before the CHMP meeting.

The European Medicines Agency (EMA) offers scientific advice and protocol assistance to facilitate the development and availability of high-quality, effective and acceptably safe medicines, for the benefit of patients.

Scientific advice

At any stage of the lifecycle, and irrespective of eligibility to use the centralised marketing-authorisation procedure, sponsors can request scientific advice from the Agency.

This helps the sponsor to ensure that the appropriate tests and studies are performed, so that no or fewer major objections regarding the design of the tests are likely to be raised during the evaluation of the marketing-authorisation application.

Such objections can significantly delay the marketing of a product and, in certain cases, result in refusal of the marketing authorisation. Therefore, following the Agency's advice increases the probability of a positive outcome.

Protocol assistance

'Protocol assistance' is scientific advice for orphan-designated medicinal products.

In addition to the scope of scientific advice, protocol assistance may relate to:

- the demonstration of significant benefit within the scope of the designated orphan indication;

- similarity/clinical superiority in cases where other potentially similar orphan products have market exclusivity in the concerned therapeutic indication.

How to request scientific advice or protocol assistance

Companies can request scientific advice or protocol assistance either during the initial development of a medicine (before submission of a marketing-authorisation application) or later on, during the post-authorisation phase.

Information on the required documents, timelines, fees and regulatory procedures is available on the Agency's website via:

Home > Regulatory > Human medicines > Scientific advice and protocol assistance

Parallel EMA/HTA scientific advice

Applicants can seek CHMP scientific advice/protocol assistance in parallel with advice from health-technology-assessment (HTA) bodies.

Applicants for these procedures are welcome to arrange a discussion by sending a request by e-mail to: scientificadvice@ema.europa.eu

Qualification of novel methodologies

Biomarkers and innovative drug-development methods play an increasingly important role at the global level for a more informed development of new medicines, and it is expected that they will contribute to an increased rate of success in making new medicines available to patients.

The Agency's qualification process is a voluntary scientific pathway leading to two main types of scientific advice from the CHMP:

- a CHMP qualification opinion on the acceptability of a specific use of the proposed method (e.g. use of a biomarker) in a research and development (R&D) context (non-clinical or clinical studies), based on assessment of the submitted data;
- a CHMP qualification advice on future protocols and methods for further method development towards qualification, based on evaluation of the scientific rationale and on preliminary data submitted.

Applications are welcome from consortia, networks, public/private partnerships, learned societies or pharmaceutical industry for a specific intended use in pharmaceuticals R&D.

Parallel EMA/FDA advice

EMA and the United States Food and Drug Administration (FDA) have a joint programme to provide parallel scientific advice to exchange views on scientific issues during the development phase of new medicinal products (i.e. new human medicines and biologics).

Medicines for non-EU markets

Scientific-advice requests for medicinal products intended to be marketed exclusively outside the European Union, in the context of WHO collaboration as defined in Article 58(2) of Regulation (EC) No 726/2004, are also possible.



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Further information

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