EUROPEAN MEDICINES AGENCY

SCIENCE MEDICINES HEALTH

Applying for EU marketing authorisation

For medicinal products for human use

An agency of the European Union

Medicines can be authorised throughout the EU by means of a single application procedure.

The centralised procedure

The European Medicines Agency is responsible for the scientific evaluation of applications for centralised marketing authorisations.

Once granted by the European Commission, the centralised marketing authorisation is valid in all EU and EEA-EFTA states (Iceland, Liechtenstein and Norway). This allows the marketing-authorisation holder to market the medicine and make it available to patients and healthcare professionals throughout the EEA.

How long does it take?

Upon submission of a valid application, the evaluation takes up to 210 days, at the end of which the Committee for Medicinal Products for Human Use (CHMP) must issue a scientific opinion on whether the medicine may be authorised or not.

This opinion is then transmitted to the European Commission, which has the ultimate authority for granting the marketing authorisation within 67 days after receipt of the CHMP opinion.

Which products *must* be centrally authorised?

All human medicines derived from biotechnology and other high-tech processes must be evaluated by the Agency via the centralised procedure. The same applies to all advanced-therapy medicines and medicinal products containing new active substances intended for

the treatment of HIV/AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions, and viral diseases, as well as to all designated orphan medicines intended for the treatment of rare diseases.

Which products may *optionally* be centrally authorised?

For medicines that do not fall under any of the above-mentioned categories, companies can submit an application to the Agency, provided the medicine is a new active substance, constitutes a significant therapeutic, scientific or technical innovation, or is in any other respect in the interest of patients at EU level.

Also, generics of centrally authorised products and applications for certain medicinal products for paediatric use may be authorised in this way.

Therefore, the Agency does not evaluate all medicines currently in use across Europe. For medicines falling outside the scope of the centralised procedure, the decentralised procedure, mutual-recognition procedure or purely national authorisation procedures should be used, depending on the number of countries in which authorisation is sought.

To find out whether a product can be evaluated under the centralised procedure, companies should submit to the CHMP an 'eligibility request', accompanied by a justification that the product falls under one of the categories described above.

Can I get pre-submission advice from the Agency?

Companies should inform the Agency in writing approximately 7 months in advance of their intended submission date. About the same time, a pre-submission meeting with the Agency's product team may be requested. It is strongly recommended that applicants take this opportunity to obtain procedural, regulatory and legal advice from the Agency.

A successful pre-submission meeting and use of the pre-submission guidance available on the Agency's website should enable applicants to submit applications which conform to the legal and regulatory requirements, and this can speed up the validation process.

Pre-submission meetings also enable applicants to establish contact with the Agency staff closely involved with the application as it proceeds.

How is my product evaluated?

The evaluation of centrally authorised products is done by the CHMP, with input from the Pharmacovigilance Risk Assessment Committee (PRAC) on aspects of the risk-management plan and the Committee for Advanced Therapies (CAT) for advanced-therapy medicines. The committees are composed of members from each of the 28 EU Member States and from Iceland and Norway, plus co-opted members who provide additional expertise in particular scientific areas.

For each product, the CHMP/PRAC/CAT appoints (co-)rapporteurs to lead and coordinate the evaluation. The appointment is usually initiated at the earliest 7 months before submission, following receipt of the letter of intention to submit a marketing-authorisation application.

Steps involved in obtaining an EU marketing authorisation

1. Submission of eligibility request.
   (At the earliest 18 months and at the latest 7 months in advance of submission.)
2. Notification of intention to submit an application.
   (Approx. 7 months in advance of submission.)
3. Appointment of rapporteurs.
   (Approx. 7 months in advance of submission.)
4. Pre-submission meeting.
   (Approx. 7 months in advance of submission.)
5. Submission of the application.
6. Scientific evaluation.
   (210 days of assessment.)
7. CHMP scientific opinion.
8. European Commission decision on the marketing authorisation.

Useful information

On the European Medicines Agency's website: Regulatory > Human Medicines > Pre-authorisation

'EMA pre-submission procedural advice for users of the centralised procedure' (EMA/339324/2007).

Regulation (EC) No 726/2004.

'The rules governing medicinal products in the European Union', Notice to Applicants, Volume 2A, Chapter 4: Centralised Procedure.

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Further information

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