



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Early access to medicines



Development support and
regulatory tools



PRIME - PRIORITY MEDICINES

PRIME is a scheme launched by the European Medicines Agency (EMA) to enhance support for the development of medicines that target an unmet medical need. This voluntary scheme is based on enhanced interaction and early dialogue with developers of promising medicines, to optimise development plans and speed up evaluation. This will help patients to benefit as early as possible from therapies that may significantly improve their quality of life.

Through PRIME, the Agency offers early and proactive support to medicine developers to optimise the generation of robust data on a medicine's benefits and risks and enable accelerated assessment of applications.

PRIME builds on the existing regulatory framework and tools already available such as scientific advice and accelerated assessment. This means that developers of a medicine that benefitted from PRIME can expect to be eligible for accelerated assessment at the time of application for a marketing authorisation.

To be accepted for PRIME, a medicine has to show its potential to address an unmet medical need and bring a major therapeutic advantage to patients. Once a candidate medicine has been selected for PRIME, EMA appoints a Rapporteur from the Committee for Medicinal Products for Human Use (CHMP), organises a kick-off meeting with experts from its scientific committees, assigns a dedicated EMA contact point and provides scientific advice at key development milestones.

Accelerated assessment

Accelerated assessment reduces the timeframe for the European Medicine Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) to review a marketing-authorisation application. Applications may be eligible for accelerated assessment if the CHMP agrees the product is of major interest for public health and in particular from the viewpoint of therapeutic innovation.

Evaluating a marketing-authorisation application under the centralised procedure can take up to 210 days, not counting clock stops when applicants have to provide additional information. On request, the CHMP can reduce the timeframe to 150 days if the applicant provides sufficient justification for an accelerated assessment.

Under the PRIME scheme launched in March 2016, it is now possible for applicants to receive confirmation during the clinical development phase that their medicine might be eligible for accelerated assessment.

Any request for accelerated assessment should be made at least two to three months before submitting the marketing authorisation application.

Before submitting a request for accelerated assessment, applicants should seek guidance from the EMA procedure manager to ensure timely submission of their request.

Conditional marketing authorisation

In the interest of public health, applicants may be granted a conditional marketing authorisation for medicines where the benefit of their immediate availability for patients outweighs the risk of less comprehensive data than normally required, based on the scope and criteria defined in the legislation and guidelines.

It is intended for medicines that address an unmet medical need, and that target seriously debilitating or life-threatening diseases, rare diseases or are intended for use in emergency situations in response to a public health threat.

This tool allows for the early approval of a medicine on the basis of less complete clinical data than normally required. However, these medicines are subject to specific post-authorisation obligations that aim to obtain complete data on the medicine.

EMA monitors the fulfilment of these obligations with the aim of ultimately recommending a full marketing authorisation if the complete data confirms that the benefits of the medicine outweigh the risks.

Compassionate use

Compassionate use is a treatment option that allows the use of an unauthorised medicine. Products under development can be made available to groups of patients who have a disease with no satisfactory authorised therapies and who cannot enter clinical trials, but only under strict conditions.

Compassionate use programmes are coordinated and implemented by Member States, which set their own rules and procedures.

Upon request of a Member State, the EMA can provide recommendations through the CHMP on the conditions of use, the conditions for distribution and the patients targeted for the compassionate use of unauthorised new medicines. This is complementary to national legislation and implementation is through the national compassionate-use programmes.

These programmes are only put in place if the medicine is expected to help patients with life-threatening, long-lasting or seriously debilitating illnesses, which cannot be treated satisfactorily with any currently authorised medicine.

The medicine must be undergoing clinical trials or have entered the marketing-authorisation application process and while early studies will generally have been completed, its safety profile and dosage guidelines may not be fully established.



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