EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PRIME – PRIORITY MEDICINES

Paving the way for promising medicines for patients

Why PRIME is needed

Many patients with serious diseases have no or only unsatisfactory therapeutic options and should be able to benefit from scientific advancement and cutting edge medicines as early as possible.

The European Medicines Agency (EMA) developed PRIME in line with the European Commission's priorities and the common strategy to 2020 for the European medicines regulatory network. The goal is to foster research on and development of medicines for patients whose diseases cannot be treated or who need better treatment options to help them live healthier lives.

Benefits of PRIME

FOR PATIENTS

- PRIME is driven by patients' needs.
- It focuses on medicines that **address an unmet medical need**, i.e. offer a major therapeutic advantage over existing treatments, or benefit patients with no current treatment options for their disease.
- It helps to translate research into the development of medicines while meeting regulatory requirements.
- It aims to **bring promising treatments to patients earlier**, without compromising high evaluation standards and patient safety.

FOR MEDICINE DEVELOPERS

- PRIME helps developers of promising new medicines to optimise development plans.
- It fosters early dialogue with EMA to facilitate robust data collection and high quality marketing authorisation applications.
- It speeds up evaluation so that medicines can reach patients earlier.
- It encourages developers to focus resources on medicines likely to make a real difference to patients' lives.

"PRIME aims to bring promising innovative medicines to patients faster by optimising and supporting medicine development."

PRIME: in brief

Medicines eligible for PRIME must address an unmet medical need.

Preliminary data must be available showing the potential to address this need and bring a major therapeutic advantage to patients.

EMA will provide early and enhanced support to optimise the development of eligible medicines, speed up their evaluation and contribute to timely patients' access.

Which medicines are NOT eligible for PRIME?

Medicines that do not address an unmet medical need.

Medicines that do not bring a major therapeutic advantage to patients.

Medicines that are already on the market.

"EMA provides early, proactive and strengthened scientific and regulatory support to PRIME candidate medicines."

How does PRIME work?

PRIME builds on the existing regulatory framework, including the provision of scientific advice and the accelerated assessment procedure used for innovative medicines that address an unmet medical need and bring a major therapeutic advantage to patients.

Once a candidate medicine has been selected for PRIME, the Agency:

- appoints a rapporteur from the Committee for Medicinal Products for Human Use (CHMP) or from the Committee for Advanced Therapies (CAT), to provide continuous support and help to build knowledge ahead of marketing authorisation application;
- organises a kick-off meeting with the CHMP/CAT rapporteur and a multidisciplinary group of experts from relevant EMA scientific committees and working parties;
- offers a dedicated EMA contact person;
- provides scientific advice at key development milestones, involving additional stakeholders as needed – e.g. health technology assessment bodies and patients;
- expects regular updates (development tracker);
- organises a submission readiness meeting 9-12 months ahead of the intended marketing authorisation application submission.

Medicines eligible for PRIME are also potentially eligible for accelerated assessment at the time of application for a marketing authorisation.

How to apply for PRIME

- Complete the electronic application form through the secure IRIS platform;
- Include data* to demonstrate that the medicine addresses an unmet medical need;
- EMA responds after 40 days.

Special support for SMEs and academia

Micro-, small- and medium-sized enterprises (SMEs) and applicants from the academic sector can apply for PRIME at an earlier stage of development when they have compelling non-clinical data and tolerability data from initial clinical trials. They may also request a fee waiver for scientific advice.

SMEs and academia can particularly benefit from earlier scientific and regulatory support since they often lack experience with the regulatory framework.

*Exploratory trial data showing clinical response efficacy and safety data in patients (prior to phase III/confirmatory clinical studies).

More information
www.ema.europa.eu > Human regulatory >Support for early access > PRIME
PRIME webpage
Contact: prime@ema.europa.eu

The European Medicines Agency (EMA) is an EU Agency that provides independent, science-based recommendations on the quality, safety and efficacy of medicines to protect human and animal health.
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