



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

4 March 2016  
EMA/89921/2016  
Press Office

## Press release

---

# Launch of PRIME – Paving the way for promising medicines for patients

## New scheme supports European Commission priorities

The European Medicines Agency (EMA) launches today its new PRIME (PRIority MEDicines) scheme to strengthen support to medicines that target an unmet medical need. The scheme focuses on medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients with no treatment options. These medicines are considered priority medicines within the European Union (EU).

Through PRIME, EMA offers early, proactive and enhanced support to medicine developers to optimise the generation of robust data on a medicine's benefits and risks and enable accelerated assessment of medicine applications. This will help patients to benefit as early as possible from therapies that may significantly improve their quality of life.

By engaging with medicine developers early, PRIME aims to strengthen clinical trial designs to facilitate the generation of high quality data for the evaluation of an application for marketing authorisation. Early dialogue and scientific advice also ensure that patients participate in trials that are likely to provide the necessary data for an application for marketing authorisation, and help to make best use of limited resources.

"The launch of PRIME is a major step forward for patients and their families that have long been hoping for earlier access to safe treatments for their unmet medical needs, such as rare cancers, Alzheimer's disease and other dementias," says Vytenis Andriukaitis, EU Commissioner for Health and Food Safety. "Through enhanced scientific support this scheme could also help, for example, to accelerate the development and authorisation of new classes of antibiotics or their alternatives in an era of increasing antimicrobial resistance." The Commissioner also highlights that PRIME optimises the use of the current regulatory framework that can contribute to the European Commission's priorities in terms of boosting innovation, jobs, growth and competitiveness.

"Our goal is to foster better planning of medicine development to help companies generate the high quality data we need to assess quality, safety and efficacy of medicines," explains Professor Guido Rasi, EMA's Executive Director. "Patients with no or insufficient treatments could then benefit from scientific progress and cutting edge medicines as soon as possible."



PRIME builds on the existing regulatory framework and available tools such as scientific advice and accelerated assessment. This means that a PRIME medicine is expected to benefit from accelerated assessment at the time of an application for marketing authorisation.

“We want to ensure that breakthroughs in medicines reach patients quicker,” says Dr Tomas Salmonson, Chair of the Committee for Medicinal Products for Human Use (CHMP). “By strengthening collaboration between the scientific committees, and by gaining and sharing knowledge on the medicine throughout the development, we will not only accelerate patients’ access but also ensure an efficient use of available resources.”

To be accepted for PRIME, a medicine has to show its potential to benefit patients with unmet medical needs based on early clinical data. Once a candidate medicine has been selected for PRIME, the Agency:

- appoints a rapporteur from EMA’s CHMP or from the Committee on Advanced Therapies (CAT) in the case of an advanced therapy, to provide continuous support and help to build knowledge ahead of a 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, and provides guidance on the overall development plan and regulatory strategy;
- assigns a dedicated EMA contact point;
- provides scientific advice at key development milestones, involving additional stakeholders such as health technology assessment bodies to facilitate patients’ quicker access to the new medicine;
- confirms potential for accelerated assessment at the time of an application for marketing authorisation.

While PRIME is open to all companies on the basis of preliminary clinical evidence, micro-, small- and medium-sized enterprises (SMEs) and applicants from the academic sector can apply earlier on the basis of compelling non-clinical data and tolerability data from initial clinical trials. They may also request fee waivers for scientific advice. Since SMEs and academia often lack experience with the regulatory framework, they can benefit in particular from earlier scientific and regulatory advice.

### **Strengthened regulatory toolkit for medicines addressing unmet needs**

EMA has released guidance documents on PRIME as well as a comprehensive overview of the EU early access regulatory tools, i.e. accelerated assessment, conditional marketing authorisation and compassionate use. Revised guidelines on the implementation of accelerated assessment and conditional marketing authorisation are also published today. All these tools are reserved for medicines addressing major public health needs. The revised guidelines provide more detailed information based on past experience. They encourage early dialogue between the various stakeholders which is crucial to optimise use of these tools. Although PRIME is specifically designed to promote accelerated assessment, it will also help to make best use of other EU early access tools and initiatives, which can be combined whenever a medicine fulfils the respective criteria.

PRIME was developed in consultation with the Agency's scientific committees, the European Commission and its expert group on Safe and Timely Access to Medicines for Patients (STAMP) as well as the European medicines regulatory network. This network of national competent authorities and its many experts who conduct the scientific evaluations is key to the success of the new scheme.

The main principles of PRIME were released for a two-month public consultation in 2015 and the comments received were taken into account in the final version.

## Notes

---

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the work of the European Medicines Agency can be found on its website:  
[www.ema.europa.eu](http://www.ema.europa.eu)

## Contact our press officer

---

Monika Benstetter

Tel. +44 (0)20 3660 8427

E-mail: [press@ema.europa.eu](mailto:press@ema.europa.eu)

Follow us on Twitter [@EMA\\_News](https://twitter.com/EMA_News)