MARCH 2016 – JUNE 2021

PRIME: 5 years experience

The European Medicines Agency's PRIority MEdicines (PRIME) scheme was set up in March 2016 to provide early and enhanced scientific and regulatory support to medicines that have the potential to significantly address patients' unmet medical needs.

How has PRIME helped patients benefit from new treatment options since its launch?

Supported the medicines evaluation process and **reduced time to marketing authorisation**.

Accelerated assessment confirmed at the time of marketing authorisation and increased chance to keep it until opinion.

Benefitted **more complex medicines** and/or applications with smaller datasets (advanced therapies, medicines for rare diseases).

Enhanced regulatory support and compliance with scientific advice led to higher success rate of marketing authorisation applications.

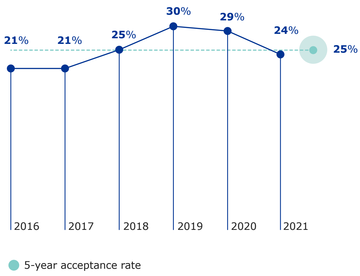
Broad range of **unmet medical needs covered**.

PRIME eligibility

95 **Requests granted**
by type of medicines:

56% **Orphan medicines**

PRIME acceptance rate
(1 March 2016 - 30 June 2021)



Impact on marketing authorisation applications

18 **PRIME medicines received a marketing authorisation**

Among these:

10 Conditional Marketing Authorisations

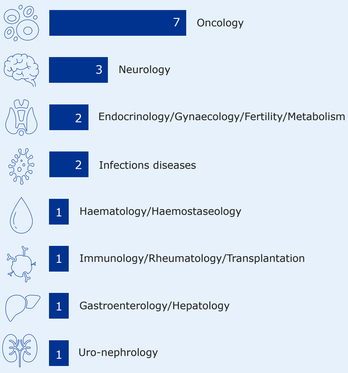
7 Advanced therapies

89% Orphan medicines

89% Started their evaluation under accelerated assessment

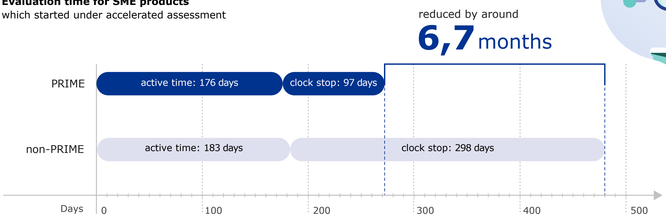
1 in 3 Applications have been submitted by SMEs

Therapeutic areas of unmet medical needs:



Average evaluation time

Evaluation time for SME products
which started under accelerated assessment



257 days
average evaluation time for **PRIME medicines**, which started under accelerated assessment

310 days
average evaluation time for **PRIME advanced therapies**

333 days
average evaluation time for all **new active subtances** (in 2020)

For the five-year report on PRIME, visit the EMA website

CLICK HERE

The cut-off date for data collection is 30 June 2021.