

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 application 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.



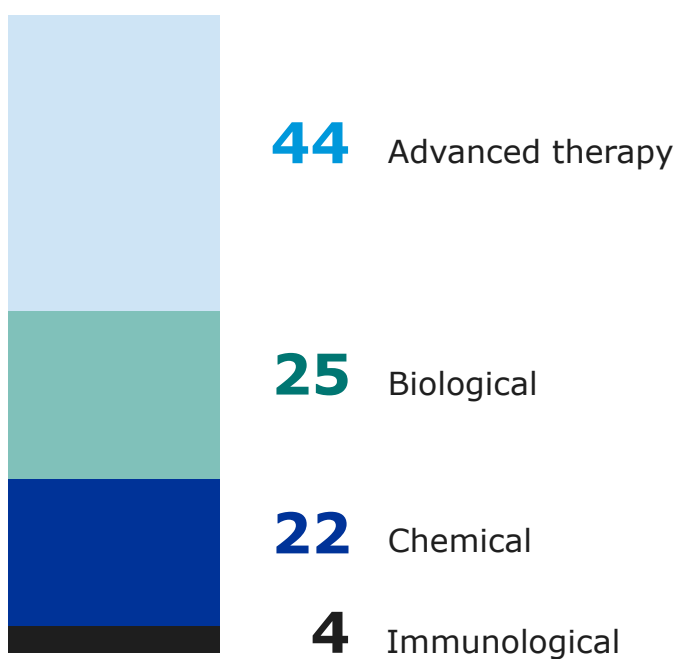
Broad range of **unmet medical needs covered**.

PRIME eligibility



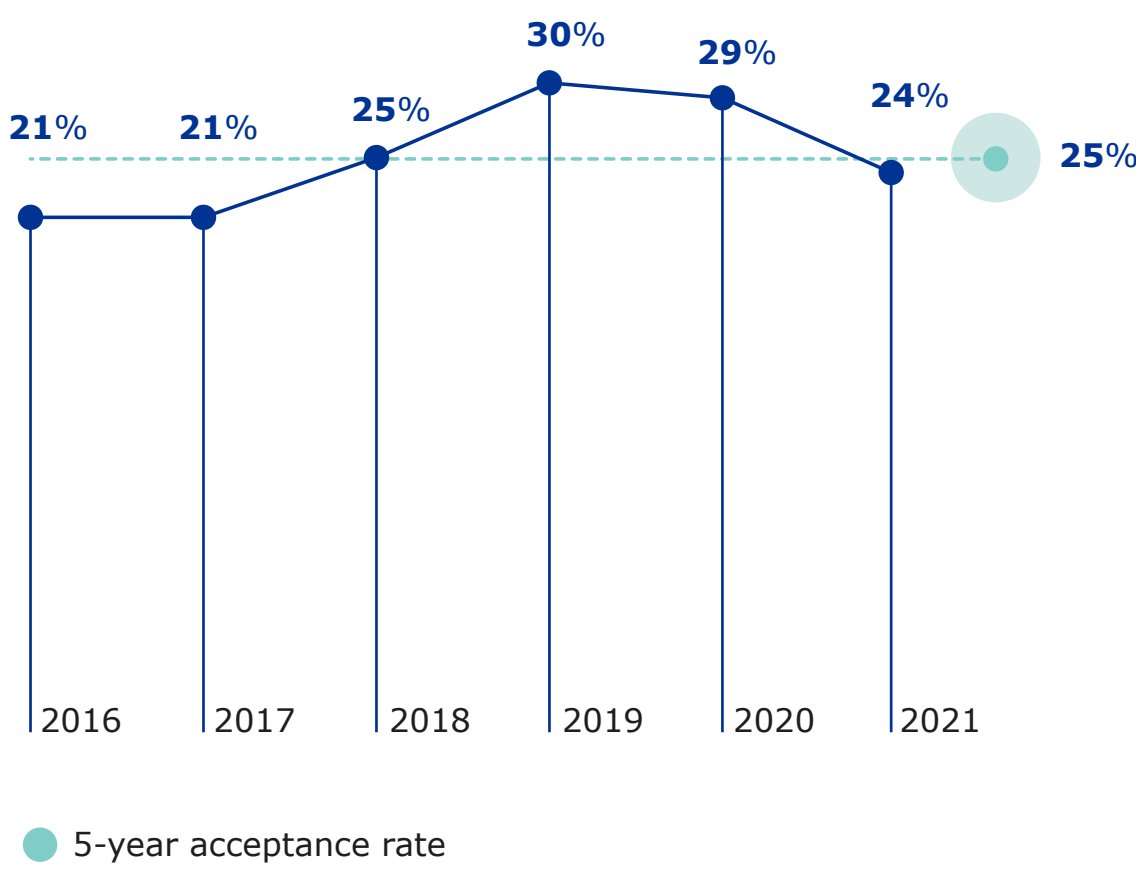
95

Requests granted by type of medicines:



56% Orphan medicines

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



Impact on marketing authorisation applications

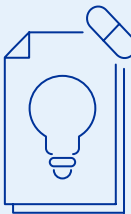
18

PRIME medicines received a marketing authorisation

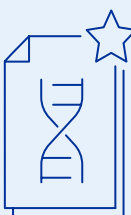
Among these:



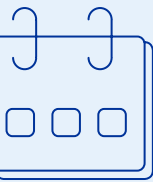
10 Conditional Marketing Authorisations



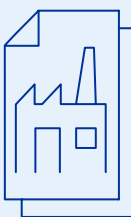
7 Advanced therapies



89% Orphan medicines

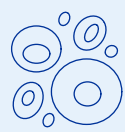


89% Started their evaluation under accelerated assessment



1 in 3 Applications have been submitted by SMEs

Therapeutic areas of unmet medical needs:



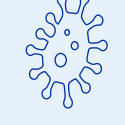
7 Oncology



3 Neurology



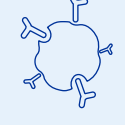
2 Endocrinology/Gynaecology/Fertility/Metabolism



2 Infections diseases



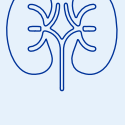
1 Haematology/Haemostaseology



1 Immunology/Rheumatology/Transplantation



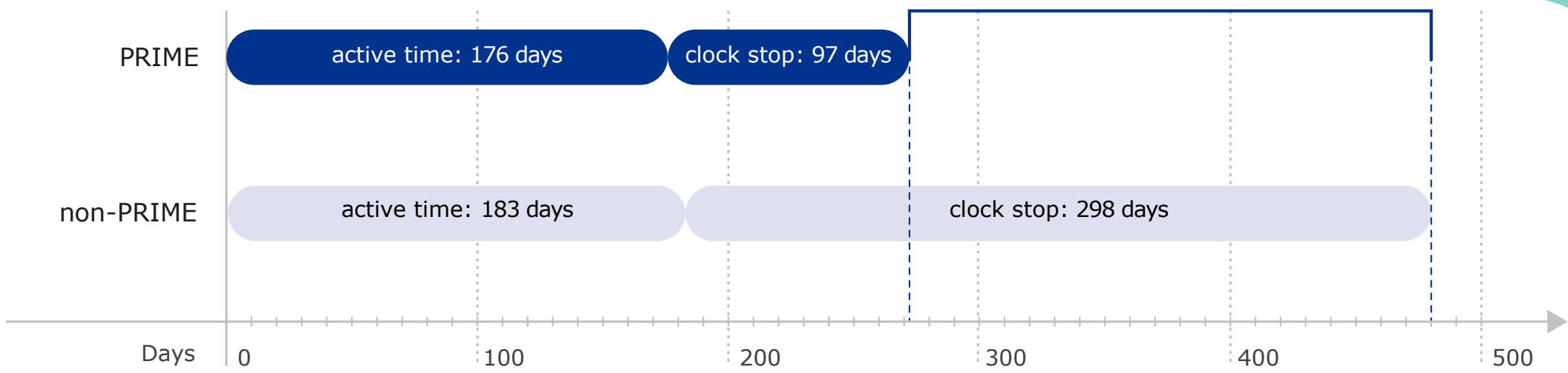
1 Gastroenterology/Hepatology



1 Uro-nephrology

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 substances** (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.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

