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 authorization.
- Accelerated assessment confirmed at the time of marketing authorization 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 authorization applications.
- Broad range of unmet medical needs covered.

**PRIME eligibility**

- 95 Requests granted by type of medicines: 44 Advanced Therapy, 25 Biological, 22 Chemical, 4 Immunological
- 56% Orphan medicines

**Impact on marketing authorisation applications**

- 18 PRIME medicines received a marketing authorisation
  - 10 Conditional Marketing Authorizations
  - 7 Advanced Therapies
  - 89% Orphan medicines
  - 89% Started their evaluation under accelerated assessment
  - 1 in 3 Applications have been submitted by SMEs

**Average evaluation time**

- Evaluation time for EMA products which started under accelerated assessment
- Average evaluation time for PRIME medicines, which started under accelerated assessment
- Average evaluation time for PRIME advanced therapies
- Average evaluation time for all new active substances (in 2020)

![Graph showing evaluation times with average times indicated](image)