



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 June 2020
EMA/194047/2020
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 25-28 May 2020

During its May 2020 meeting, the CHMP reviewed 2 recommendations for eligibility to PRIME: 2 were denied. In addition, 1 request was withdrawn at the request of the applicant before the start of the procedure.

The individual outcomes adopted this month are listed below.

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union

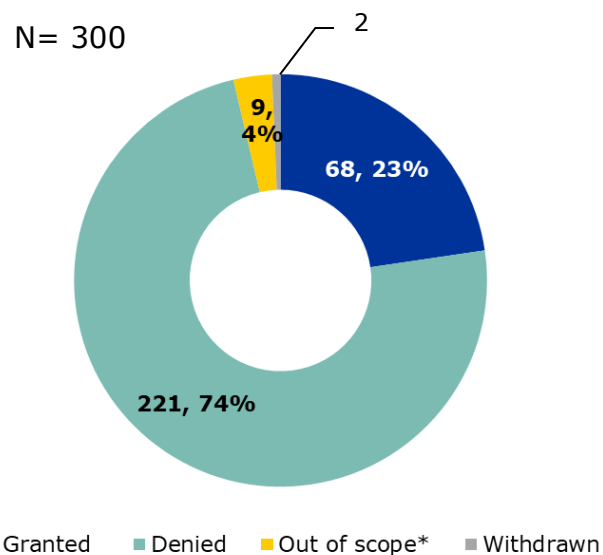


Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy	Immunology-Rheumatology-Transplantation	Treatment of cerebral adrenoleukodystrophy where hematopoietic stem cell transplantation is indicated	Nonclinical+ Clinical exploratory	SME
Biological	Pneumology-Allergology	Treatment of Loculated Pleural Effusions	Nonclinical+ Clinical exploratory	SME

SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other type of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

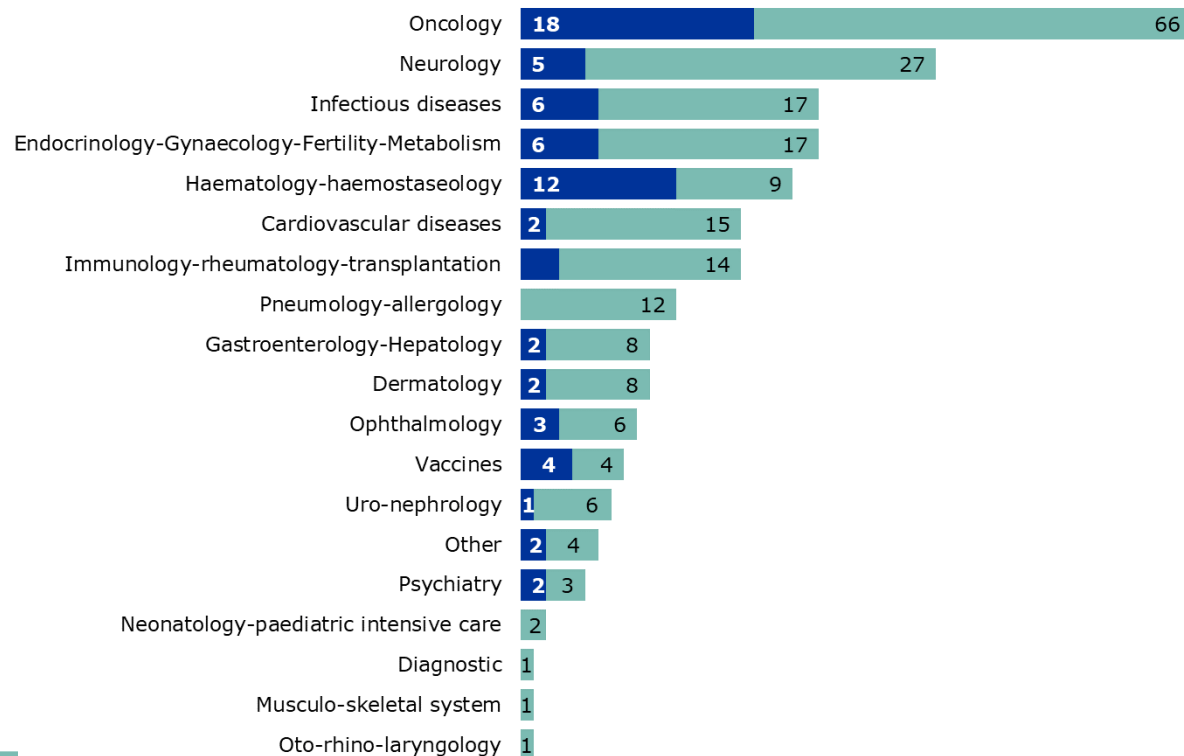
Cumulative overview of recommendations on PRIME eligibility requests adopted by 28 May 2020



By type of applicant



By therapeutic area



* This indicates eligibility requests received but not started by EMA as they were deemed outside the scope of the scheme or with a format and content inadequate to support their review. These are not included in the breakdown by type of applicant or by therapeutic area.