



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 July 2020
EMA/254669/2020
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 23 July 2020

During its July 2020 meeting, the CHMP reviewed 7 recommendations for eligibility to PRIME: 2 were granted and 5 were denied. 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 granted

Name*	Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Bomedemstat (IMG-7289)	Chemical	Haematology - Hemostaseology	Treatment of myelofibrosis	Nonclinical+ Clinical exploratory	SME
ADP-A2M4 (transduced CD4+ and CD8+ cells)	Advanced Therapy Medicinal product	Oncology	Treatment of HLA-A*02 positive patients with inoperable or metastatic synovial sarcoma who have received prior chemotherapy and whose tumour expresses the MAGE-A4 tumour antigen	Nonclinical+ Clinical exploratory	Other

* Name of the active substance, INN, common name, chemical name or company code.

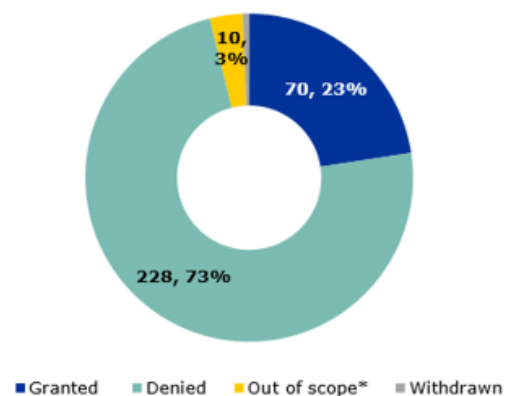
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other types of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

Eligibility denied

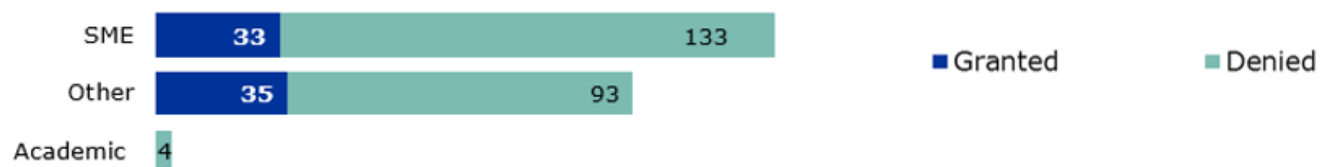
Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical	Ophthalmology	Treatment of non arteritic retinal artery occlusion	Nonclinical+ Clinical exploratory	Other
Advanced Therapy	Ophtalmology	Treatment of X-linked Retinitis Pigmentosa (XLRP)	Nonclinical+ Clinical exploratory	Other
Chemical	Vaccines	Prevention of influenza in healthy adults aged 18–60 years	Nonclinical+ Clinical exploratory	SME
Biological	Cardiovascular Diseases	Treatment of septic shock	Nonclinical+ Clinical exploratory	Other
Advanced Therapy	Oncology	Consolidation treatment in patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation	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.

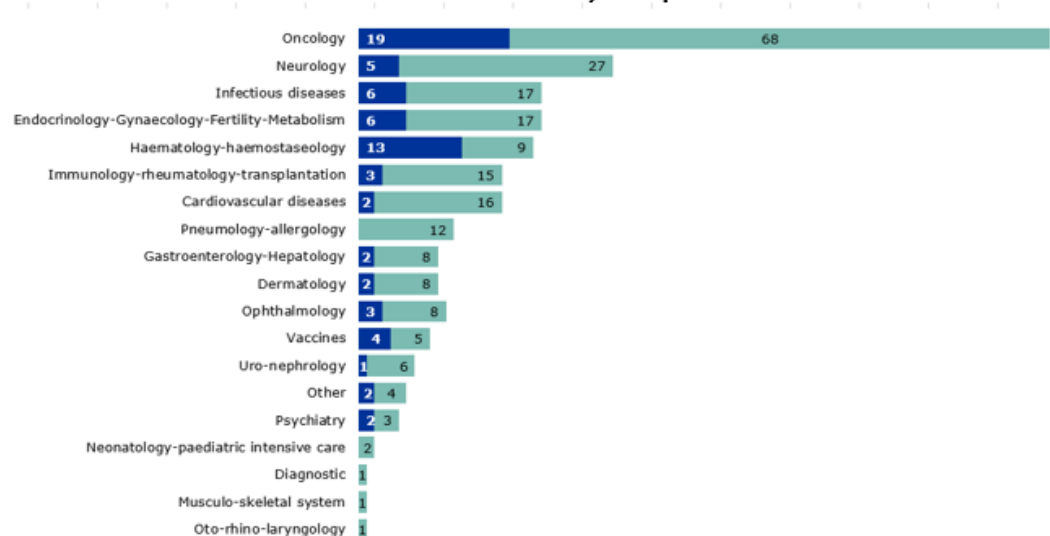
Cumulative overview of recommendations on PRIME eligibility requests adopted by 23 July 2020



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.