



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 December 2017
EMA/668784/2016
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 11-14 December 2017

During its December 2017 meeting, the CHMP reviewed 7 recommendations for eligibility to PRIME: 7 were denied. The individual outcomes adopted this month are listed below.

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Send a question via our website www.ema.europa.eu/contact

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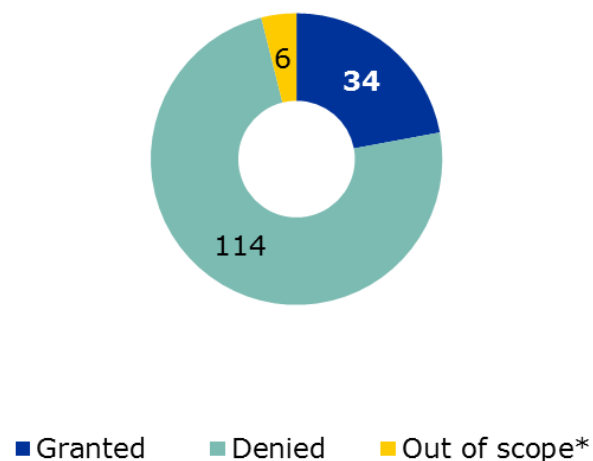


Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical	Oncology	Treatment of familial adenomatous polyposis	Nonclinical + Clinical exploratory	SME
Chemical	Oncology	Treatment of acute myeloid leukaemia	Nonclinical + Clinical exploratory	SME
Chemical	Oncology	Treatment of acute myeloid leukaemia	Nonclinical + Clinical exploratory	Other
Chemical	Oncology	Treatment of patients with unresectable or metastatic tumours with a specific gene fusion/translocation	Nonclinical + Clinical exploratory	Other
Chemical	Neurology	Treatment of acute sudden sensorineural hearing loss	Nonclinical + Clinical exploratory	SME
Chemical	Immunology-Rheumatology-Transplantation	Treatment of Pemphigus	Nonclinical + Clinical exploratory	SME
Advanced Therapy	Endocrinology-Gynaecology-Fertility-Metabolism	Treatment and prevention of progression of Type I Diabetes Mellitus in paediatric patients	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.

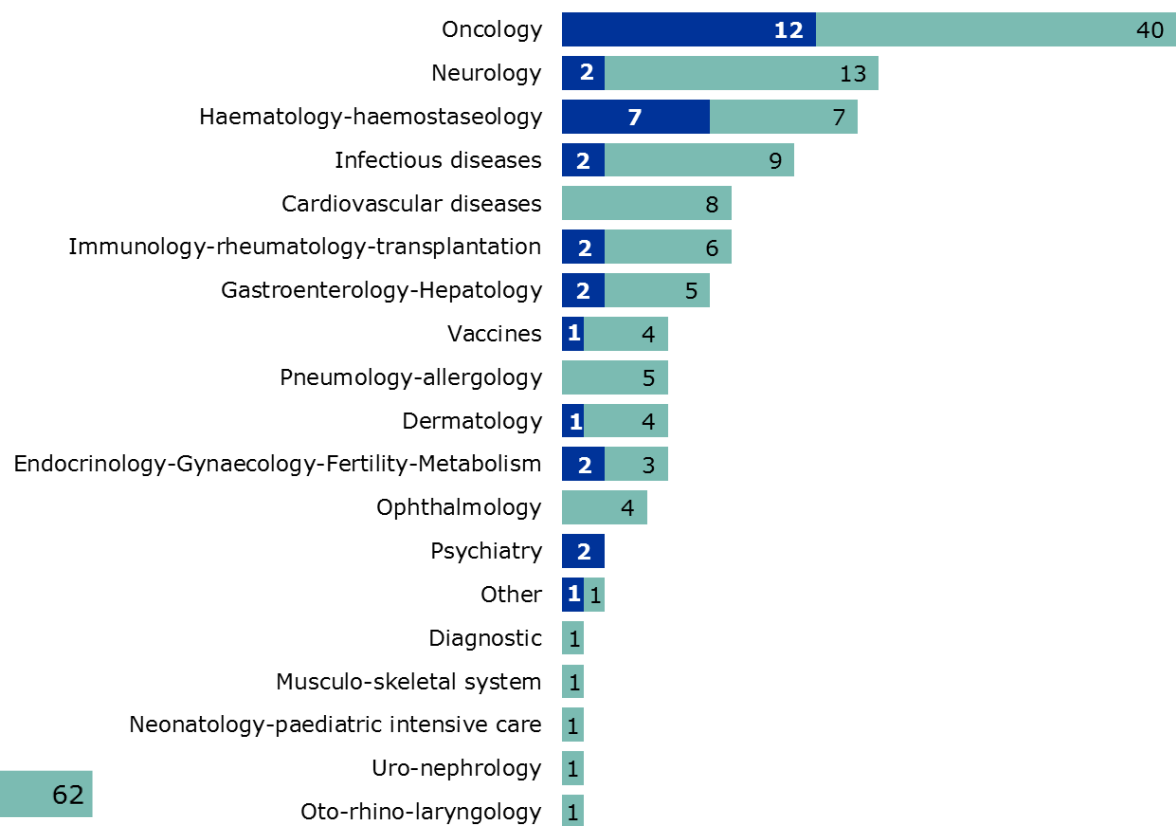
Cumulative overview of recommendations on PRIME eligibility requests adopted by 14 December 2017



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.