



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 January 2018
EMA/777015/2017
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 22-25 January 2018

During its January 2018 meeting, the CHMP reviewed 9 recommendations for eligibility to PRIME: 9 were denied. In addition, 1 request was received but not started by EMA as it was deemed outside the scope of the scheme.

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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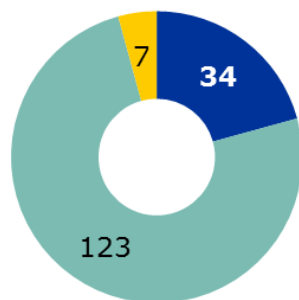


Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy	Oncology	Treatment of patients with first recurrence of advanced ovarian cancer	Nonclinical + Clinical exploratory	Other
Advanced Therapy	Oncology	Treatment of patients with newly diagnosed advanced ovarian cancer	Nonclinical + Clinical exploratory	Other
Biological	Oncology	Treatment of glioblastoma multiforme	Nonclinical + Clinical exploratory	Other
Biological	Oncology	Treatment of patients with relapsed or refractory diffuse large B-Cell lymphoma who are not eligible for high-dose chemotherapy and autologous stem-cell transplantation	Nonclinical + Clinical exploratory	Other
Chemical	Immunology-Rheumatology-Transplantation	Treatment of lupus nephritis	Nonclinical + Clinical exploratory	SME
Chemical	Gastroenterology-Hepatology	Treatment of idiopathic gastroparesis	Nonclinical + Clinical exploratory	Other
Advanced Therapy	Ophthalmology	Treatment of retinal dystrophy associated with defects in RPE65 (Leber congenital amaurosis LCA2)	Nonclinical + Clinical exploratory	SME
Biological	Neonatology-Paediatric Intensive Care	Prevention of chronic lung disease in extremely premature infants (<28 weeks gestational age)	Nonclinical + Clinical exploratory	Other
Chemical	Other	Treatment of Proteus Syndrome	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 25 January 2018

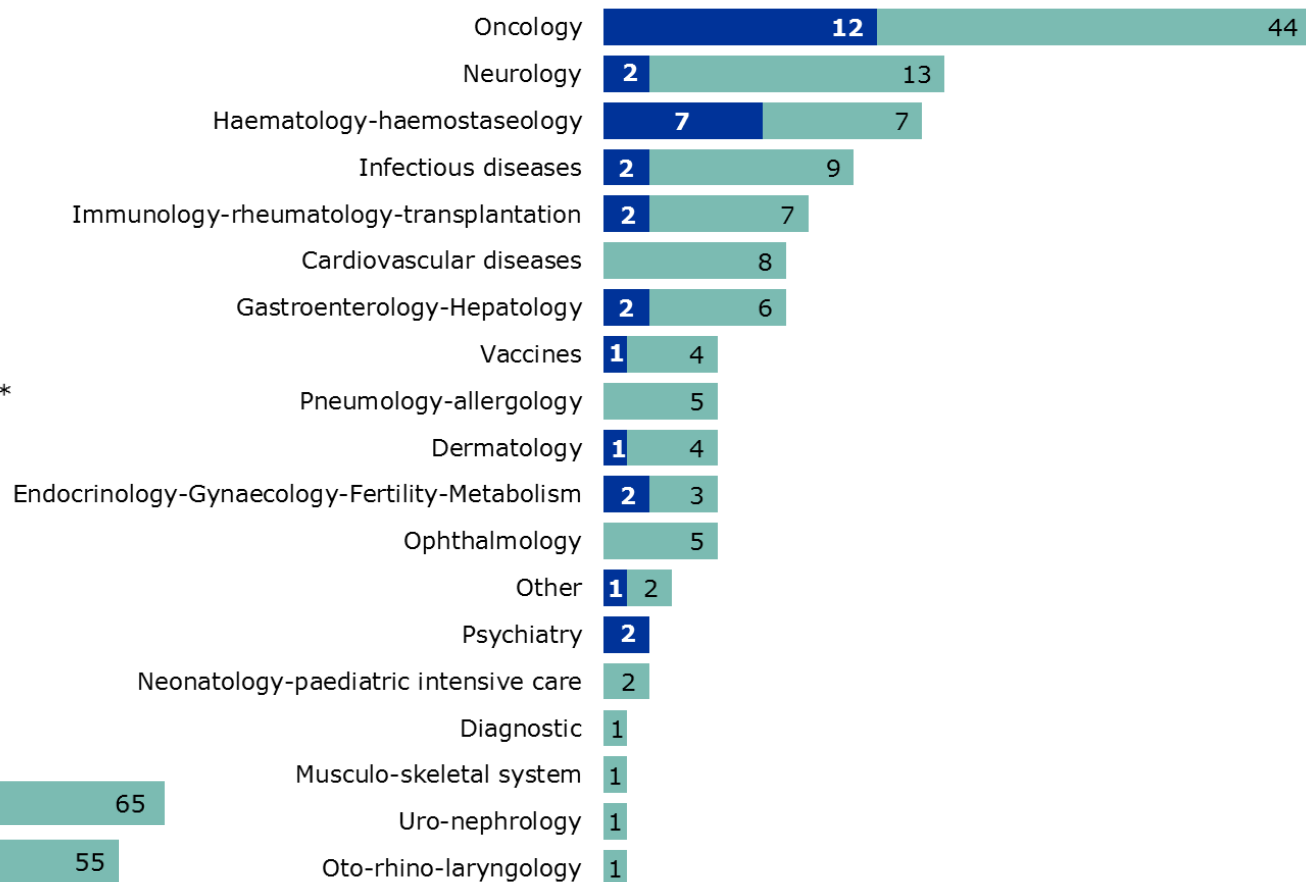


■ Granted ■ Denied ■ Out of scope*

By type of applicant



By therapeutic area



■ Granted ■ Denied

* 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.