



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 15-18 October 2018

During its October 2018 meeting, the CHMP reviewed 6 recommendations for eligibility to PRIME: 6 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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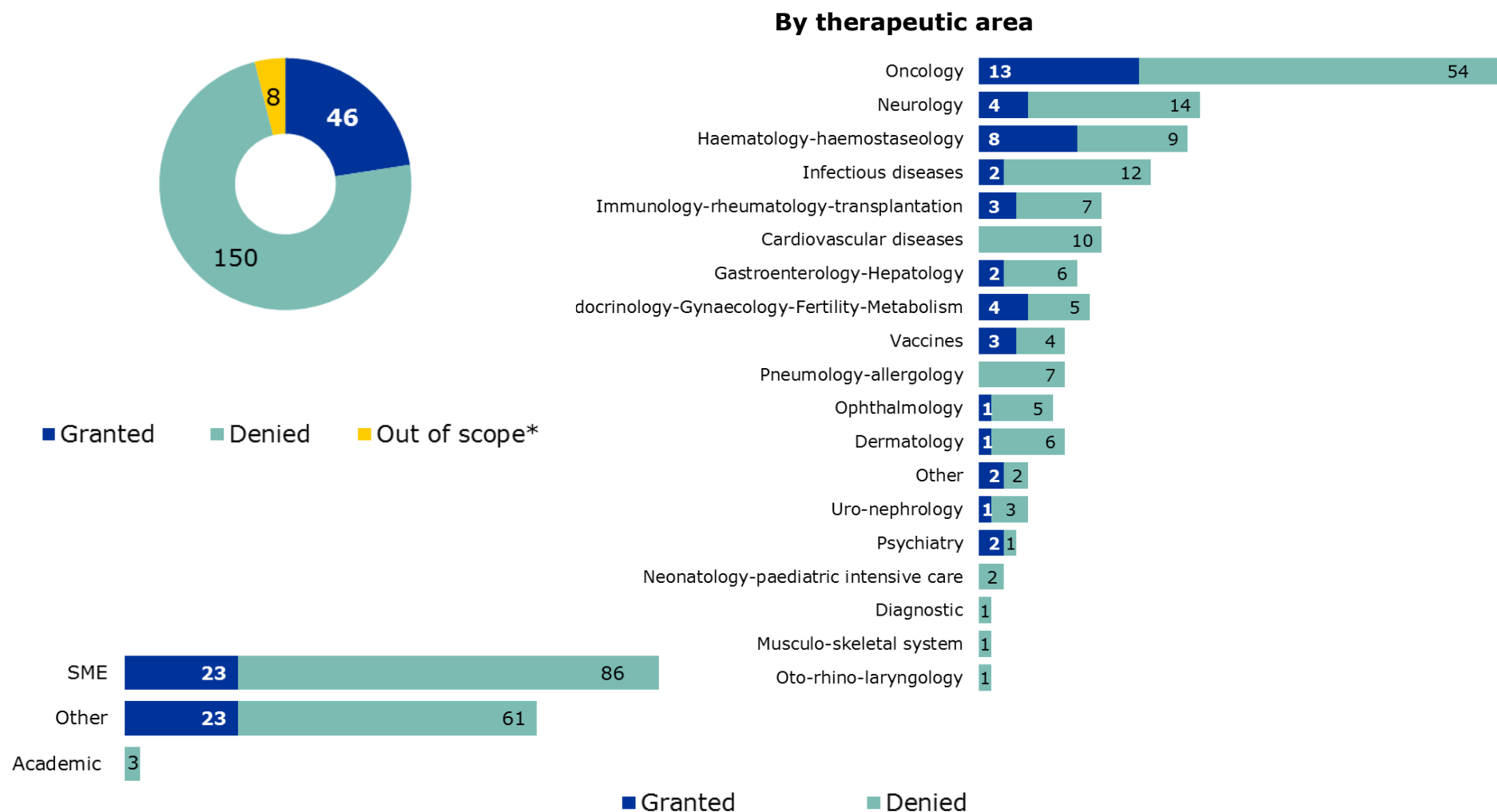


Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Biological	Pneumology-Allergology	Treatment of peanut allergy	Nonclinical+ Clinical exploratory	SME
Chemical	Infectious diseases	Treatment of cytomegalovirus infection	Nonclinical+ Clinical exploratory	Other
Advanced Therapy	Oncology	Treatment of patients with unresectable or metastatic melanoma who have previously been treated with at least two systemic therapies, including a PD-1 blocking antibody and if BRAF V600 mutation positive, a BRAF inhibitor.	Nonclinical+ Clinical exploratory	SME
Chemical	Endocrinology-Gynaecology-Fertility-Metabolism	Treatment of Hutchinson-Gilford Progeria Syndrome and Progeroid Laminopathies	Nonclinical+ Clinical exploratory	SME
Biological	Cardiovascular diseases	Treatment of acute ischemic stroke	Nonclinical + Tolerability first in man	SME
Chemical	Dermatology	Treatment of Epidermolysis Bullosa	Nonclinical + other	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 18 October 2018



* 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.