



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 March 2017
EMA/668812/2016
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 20-23 March 2017

During its March 2017 meeting, the CHMP reviewed 4 recommendations for eligibility to PRIME: 4 were denied. The individual outcomes adopted this month are listed below.

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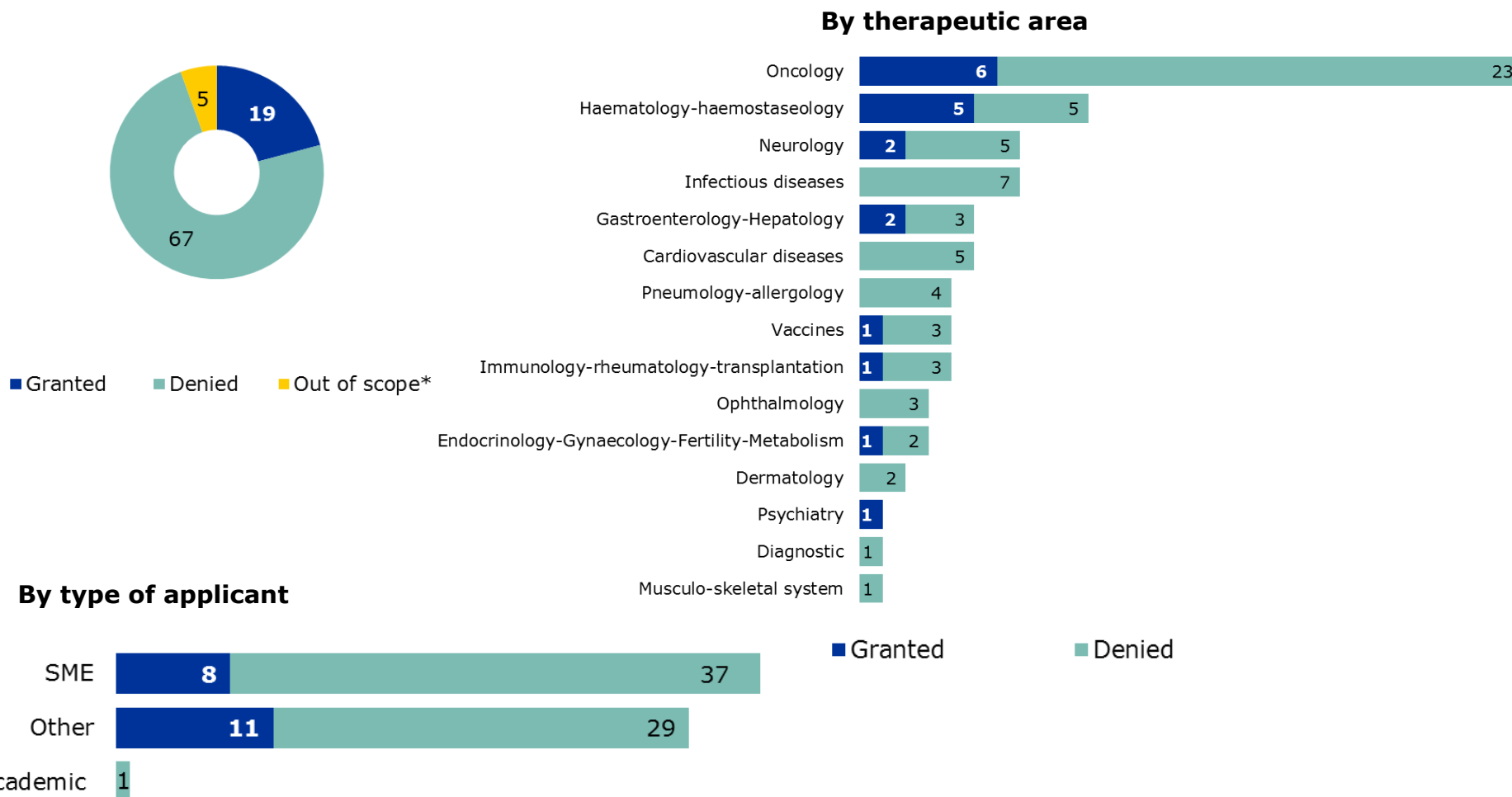


Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Immunological	Oncology	Treatment of metastatic breast cancer	Nonclinical + Clinical exploratory	SME
Chemical	Oncology	Treatment of locally advanced or metastatic HER2+ breast carcinoma	Nonclinical + Clinical exploratory	SME
Chemical	Oncology	Treatment of Ovarian Cancer	Nonclinical + Clinical exploratory	Other
Advanced Therapy	Haematology - haemostaseology	Treatment of Fanconi anaemia type A	Nonclinical + Clinical exploratory	Other

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 March 2017



* One eligible product has subsequently been withdrawn from the scheme at the applicant's request
 Out of scope 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.