

3 July 2019
EMA/212625/2019
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 24-27 June 2019

During its June 2019 meeting, the CHMP reviewed 1 recommendation for eligibility to PRIME: 1 was denied. The individual outcomes adopted this month are listed below.



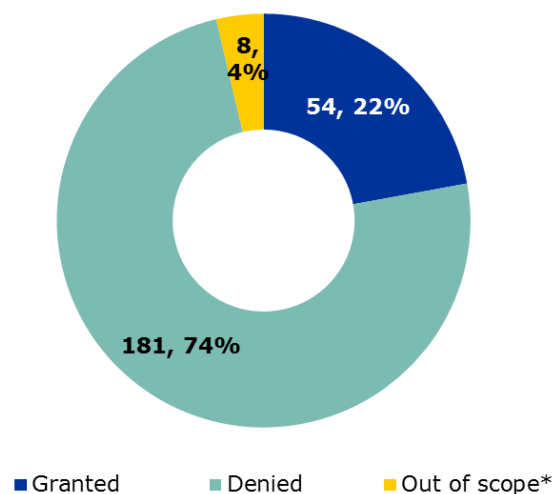
Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced therapy	Endocrinology-Gynaecology-Fertility-Metabolism	Treatment of glycogen storage disease type Ia	Nonclinical + clinical exploratory	Other

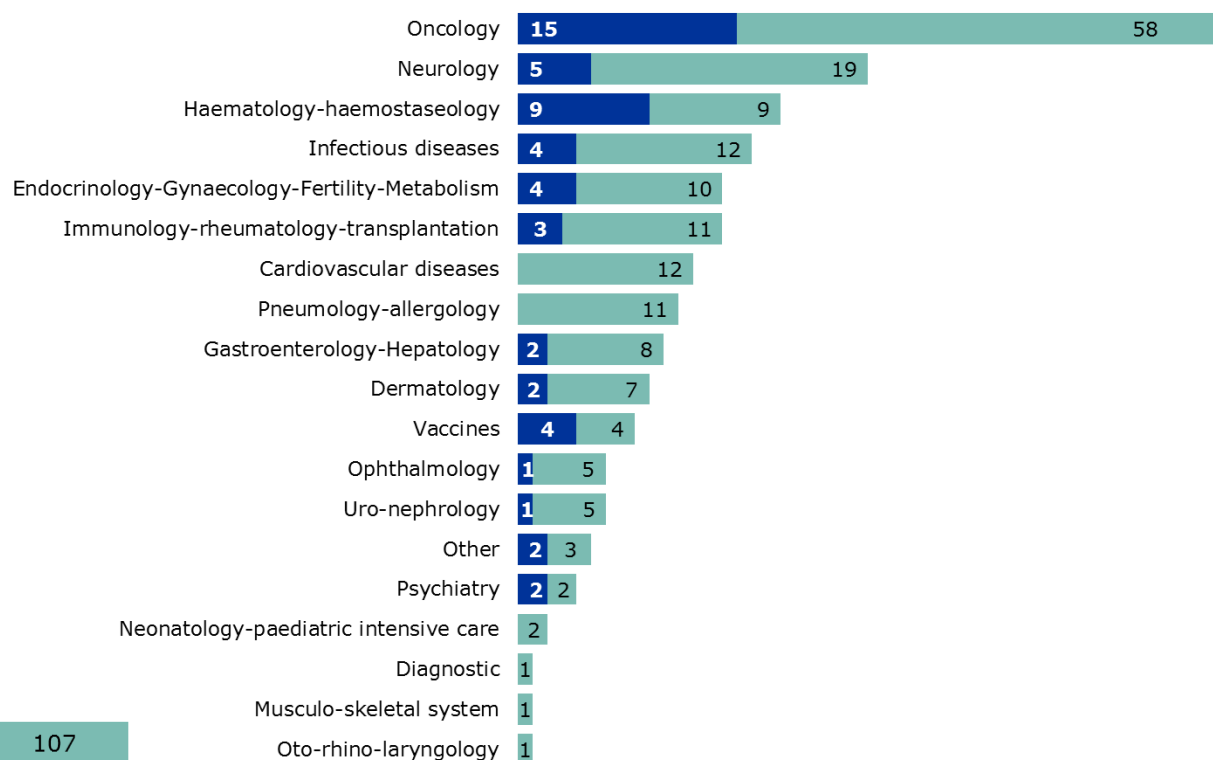
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other type of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

Cumulative overview of recommendations on PRIME eligibility requests adopted by 29 May 2019

N = 244



By therapeutic area



By type of applicant



■ 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.