



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 February 2022
EMA/519982/2021
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 24-27 January 2022

During its January 2022 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

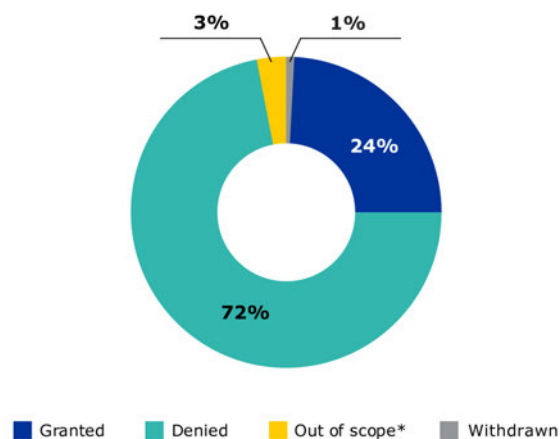
Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Psychiatry	Treatment of Major Depressive Disorder (MDD)	Nonclinical + Clinical exploratory	SME
Biological Medicinal Product	Endocrinology-Gynaecology-Fertility-Metabolism	Treatment of type 1 diabetes mellitus (T1D)	Nonclinical + Clinical exploratory	SME
Biological Medicinal Product	Other: Auto-inflammatory diseases	Haemophagocytic lymphohistiocytosis	Nonclinical + Clinical exploratory	SME
Advanced Therapy Medicinal Product	Oncology	Treatment of paediatric patients with diffuse intrinsic pontine glioma	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.

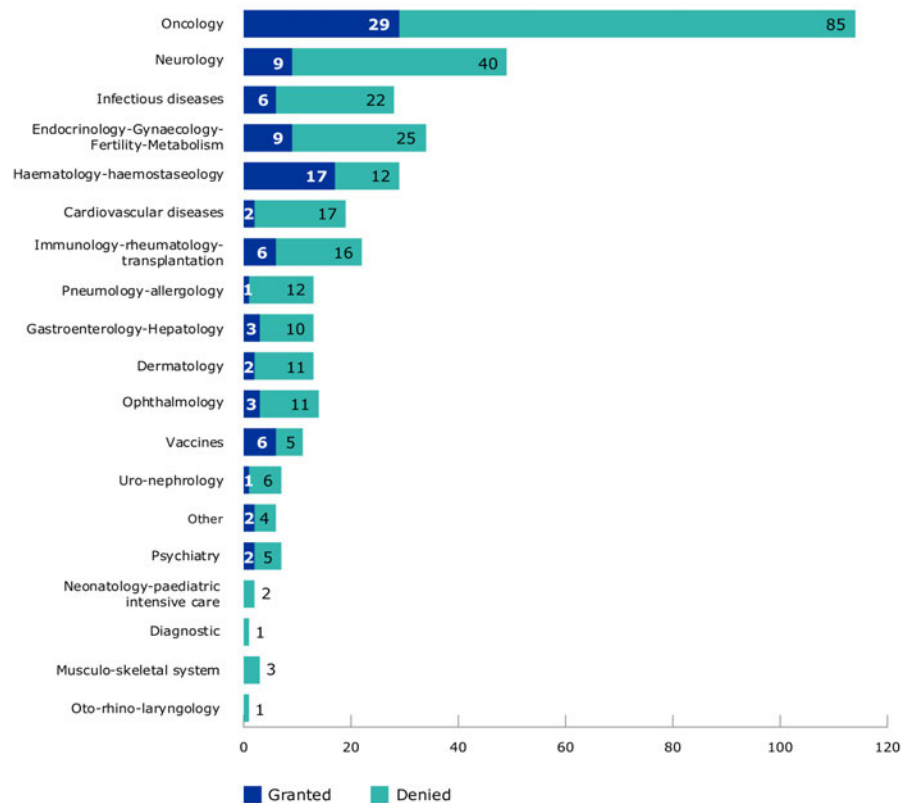
Cumulative overview of PRIME eligibility recommendations adopted by 27 January 2022

■ Granted ■ Denied ■ Out of scope* ■ Withdrawn

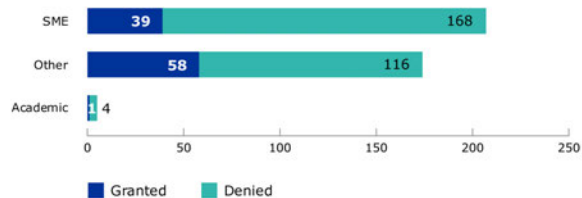
Overall number



By therapeutic area



By Applicant Type



* 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.