



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 May 2025
EMA/135852/2025
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 22-25 April 2025

During its April 2025 meeting, the CHMP reviewed 2 recommendations for eligibility to PRIME and 2 were denied. The individual outcomes adopted this month are listed below.

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Eligibility denied

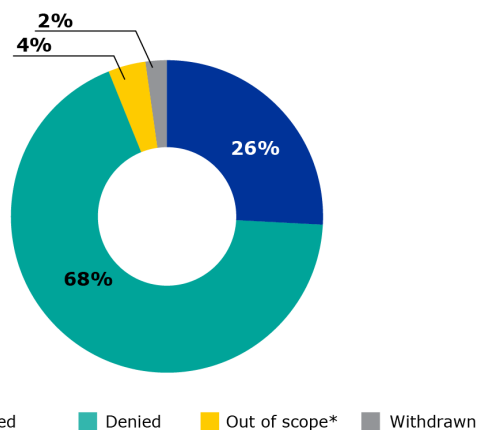
Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Biological Medicinal Product	Oncology	Treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC)	Non-clinical + clinical exploratory	Other
Chemical Medicinal Product	Endocrine disorders	Treatment of type 2 diabetes	Non-clinical + 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.

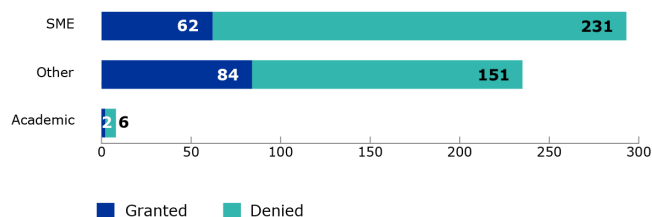
Cumulative overview of PRIME eligibility recommendations adopted by 25 April 2025

■ Granted ■ Denied ■ Out of scope* ■ Withdrawn

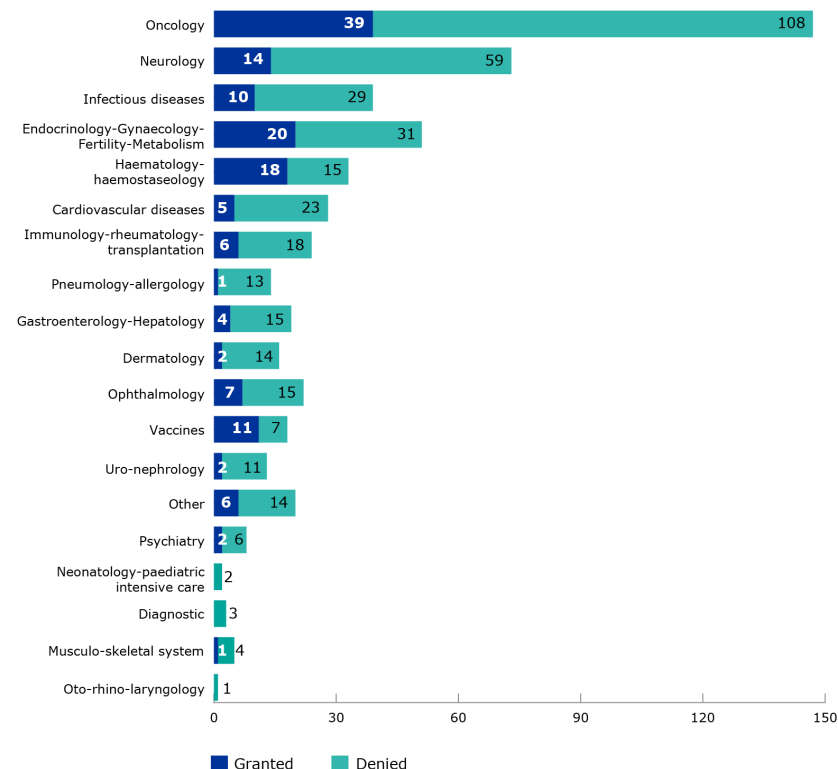
Overall number



By Applicant Type



By therapeutic area



* 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.