7 April 2025
EMA/96923/2025
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 24-27 March 2025

During its March 2025 meeting, the CHMP reviewed 5 recommendations for eligibility to PRIME: 2 were granted and 3 were denied. The individual outcomes adopted this month are listed below.

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Eligibility granted

Name*	Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Radiprodil	Chemical Medicinal Product	Nervous system disorders	Treatment of GRIN-related neurodevelopmental disorder	Non-clinical + clinical exploratory	Other
MEM-ANT3310	Chemical Medicinal Product	Infections and infestations	Treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment options	Non-clinical + clinical exploratory	SME

* Name of the active substance, INN, common name, chemical name or company code.

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

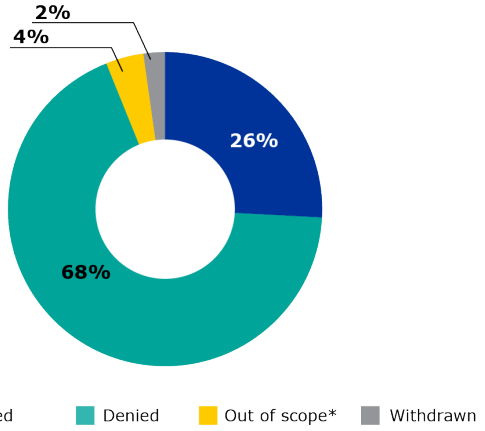
Eligibility denied

Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Biological Medicinal Product	Infections and infestations	Treatment of sepsis	Non-clinical + clinical exploratory	SME
Biological Medicinal Product	Oncology	Treatment of adult patients with advanced clear cell renal cell carcinoma (ccRCC) following progression on or after 2 prior lines of systemic therapies	Non-clinical + clinical exploratory	Other
Advanced Therapy Medicinal Product	Congenital, familial and genetic disorders	Treatment of Huntington's disease	Non-clinical + clinical exploratory	Other

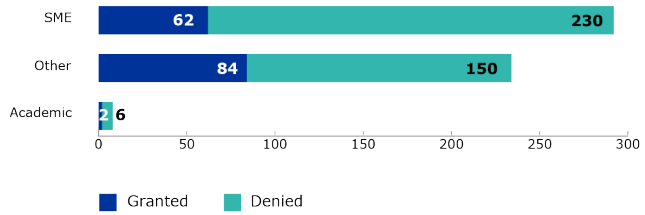
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other type of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

Cumulative overview of PRIME eligibility recommendations adopted by 27 March 2025

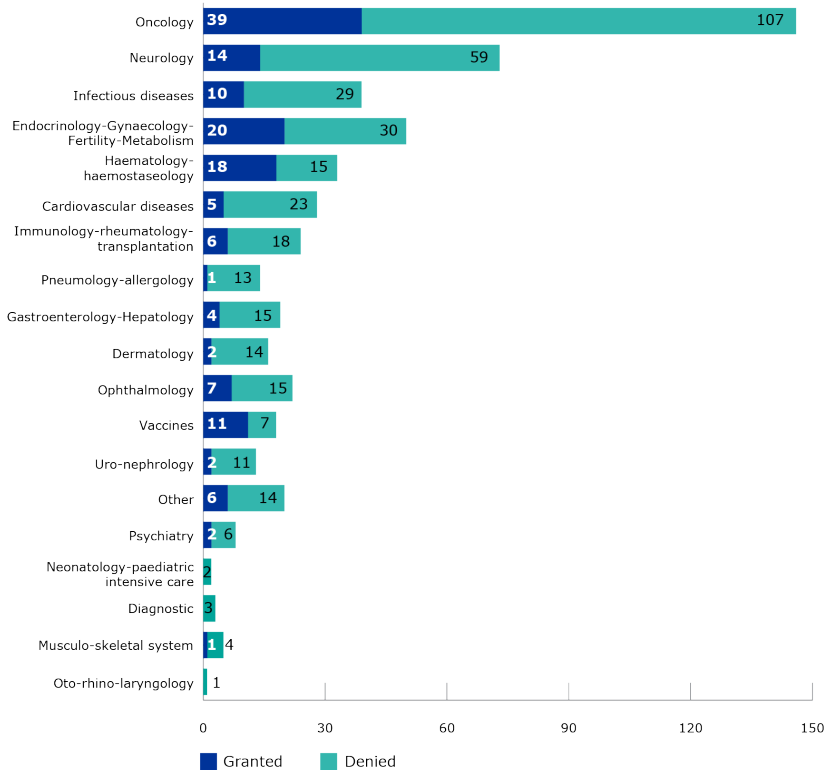
Overall number



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.