



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 November 2025
EMA/346799/2025
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 10-13 November 2025

During its November 2025 meeting, the CHMP reviewed 3 recommendations for eligibility to PRIME: 1 was granted and 2 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
Autologous blood-derived endothelial progenitor cells, haematopoietic stem/progenitor cells, activated dendritic cells and T helper cells	Advanced Therapy Medicinal Product	Vascular disorders	Treatment of Peripheral arterial disease (PAD) with chronic limb-threatening ischemia (CLTI)	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

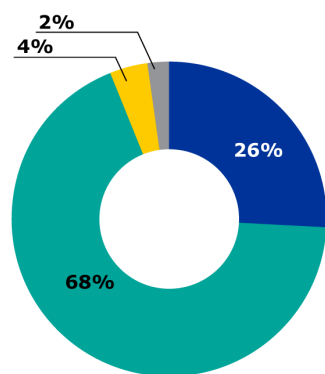
Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Blood and lymphatic system disorders	Treatment of polycythaemia vera	Non-clinical + clinical exploratory	Other
Chemical Medicinal Product	Hepatobiliary disorders	Treatment of paediatric MASH	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 13 November 2025

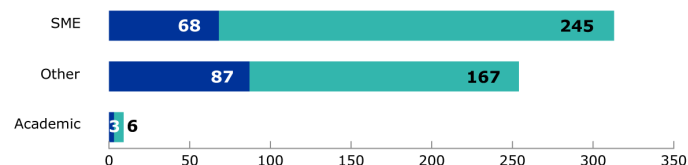
■ Granted ■ Denied ■ Out of scope* ■ Withdrawn

Overall number



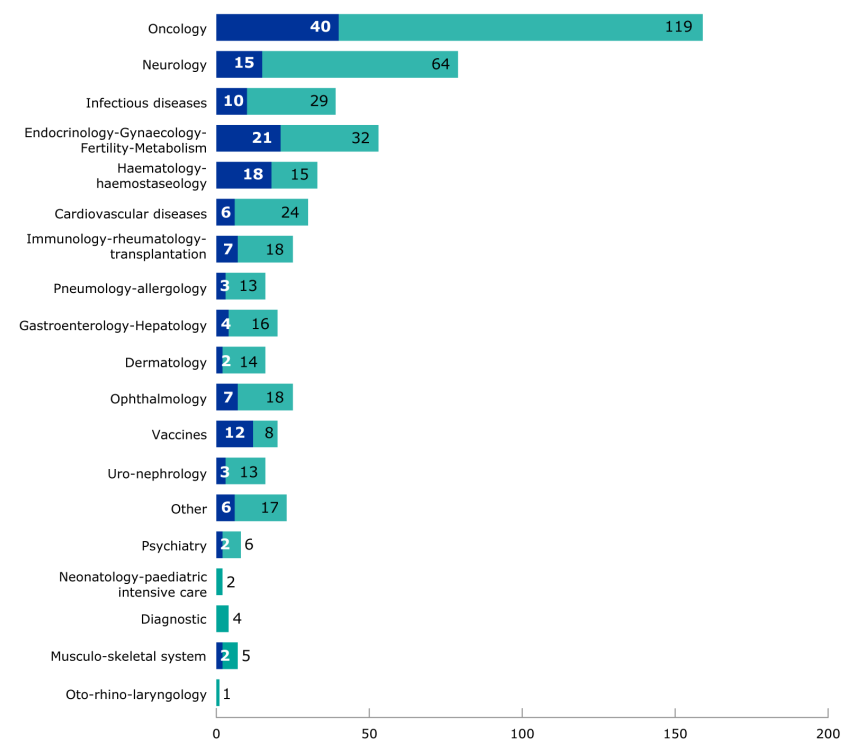
■ Granted ■ Denied ■ Out of scope* ■ Withdrawn

By Applicant Type



■ Granted ■ Denied

By therapeutic area



■ 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.