



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4 August 2025
EMA/223988/2025
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 21-24 July 2025

During its July 2025 meeting, the CHMP reviewed 5 recommendations for eligibility to PRIME: 1 was granted and 4 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
BGB-16673	Chemical Medicinal Product	Oncology	Treatment of Waldenstrom's macroglobulinemia (WM) previously treated with a BTK inhibitor	Non-clinical + clinical exploratory	Other

* 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

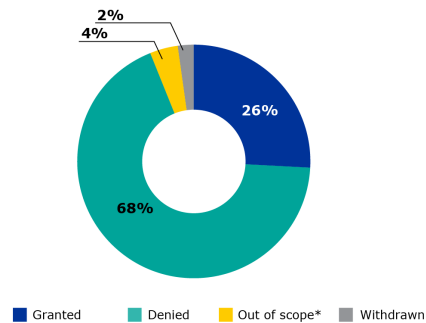
Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Renal and urinary disorders	Treatment of focal segmental glomerular sclerosis (FSGS)	Non-clinical + clinical exploratory	Other
Chemical Medicinal Product	Nervous system disorders	Treatment of Huntington's Disease	Non-clinical + clinical	Other
Biological Medicinal Product	Oncology	Treatment of myelodysplastic syndromes	Non-clinical + clinical exploratory	SME
Advanced Therapy Medicinal Product	Renal and urinary disorders	Treatment of female stress urinary incontinence	Non-clinical + clinical exploratory	SME

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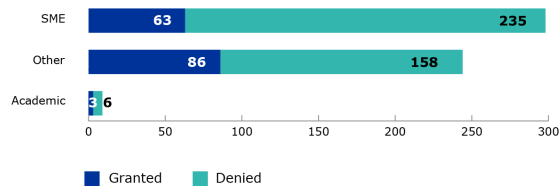
Cumulative overview of PRIME eligibility recommendations adopted by 24 July 2025

■ Granted ■ Denied ■ Out of scope* ■ Withdrawn

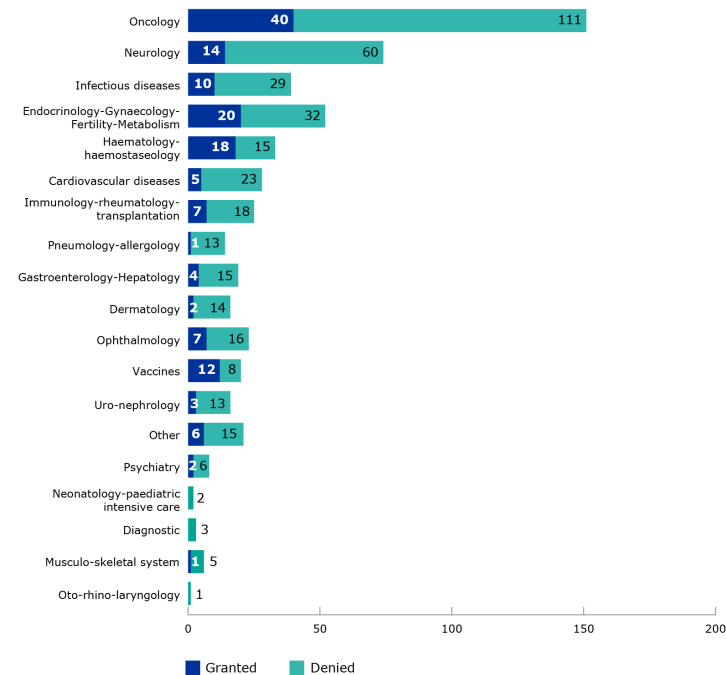
Overall number



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.