



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 May 2026
EMA/117263/2026
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 18-21 May 2026

During its May 2026 meeting, the CHMP reviewed 4 recommendations for eligibility to PRIME: 1 was 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
Sutacimig	Biological Medicinal Product	Congenital, familial and genetic disorders	Treatment of Glanzmann thrombasthenia	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

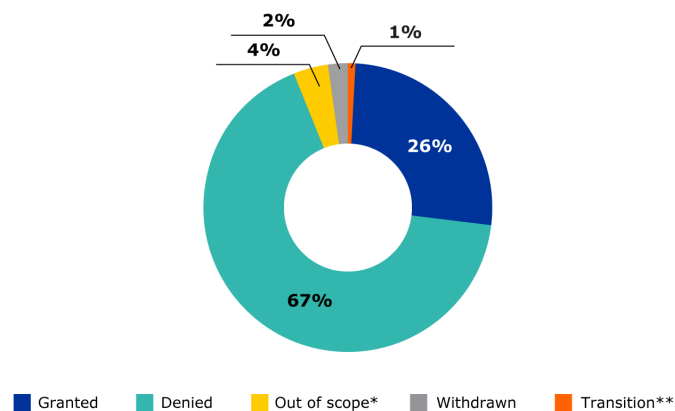
Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy Medicinal Product	Oncology	Treatment of Acute Myeloid Leukemia (AML), Myelodysplastic Syndromes (MDS)	Non-clinical + clinical exploratory	SME
Advanced Therapy Medicinal Product	Oncology	Treatment of acute lymphoblastic leukaemia	Non-clinical + clinical exploratory	Other
Advanced Therapy Medicinal Product	Congenital, familial and genetic disorders	Treatment of osteogenesis imperfecta	Non-clinical + clinical exploratory	SME

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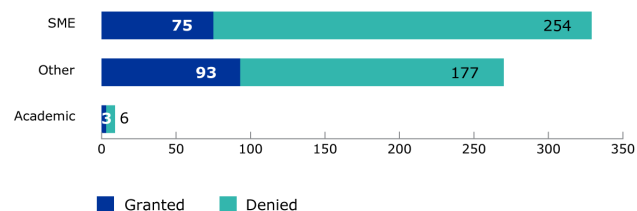
Cumulative overview of PRIME eligibility recommendations adopted by 21 May 2026

■ Granted ■ Denied ■ Out of scope* ■ Withdrawn ■ Transition**

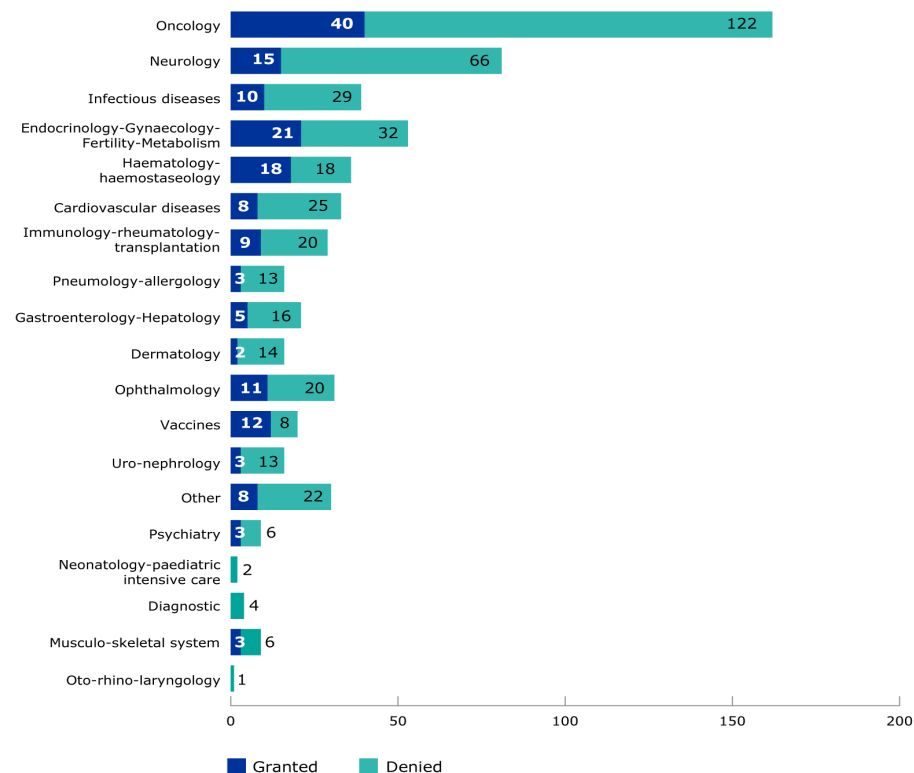
Overall number



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.

** Application for transition from Early Entry to Full PRIME eligibility.