17 December 2025
EMA/371701/2025
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 8-11 December 2025

During its December 2025 meeting, the CHMP reviewed 2 recommendations for eligibility to PRIME: 1 was granted and 1 was 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
VGR-R01	Advanced Therapy Medicinal Product	Eye disorders	Treatment of Bietti Crystalline Dystrophy	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

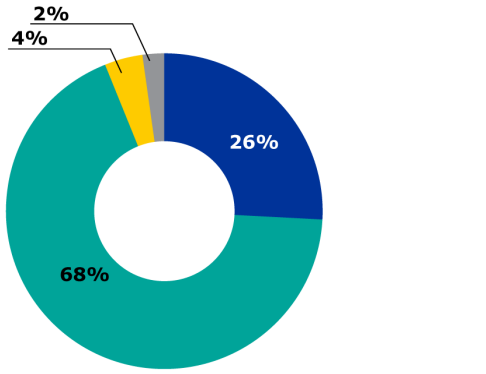
Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy Medicinal Product	Congenital, familial and genetic disorders	Treatment of Duchenne muscular dystrophy	Non-clinical + clinical exploratory	SME

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.

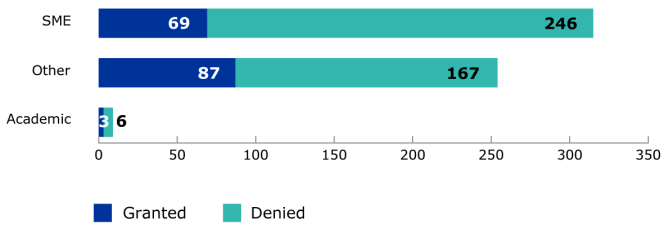
Cumulative overview of PRIME eligibility recommendations adopted by 11 December 2025

Granted Denied Out of scope* Withdrawn

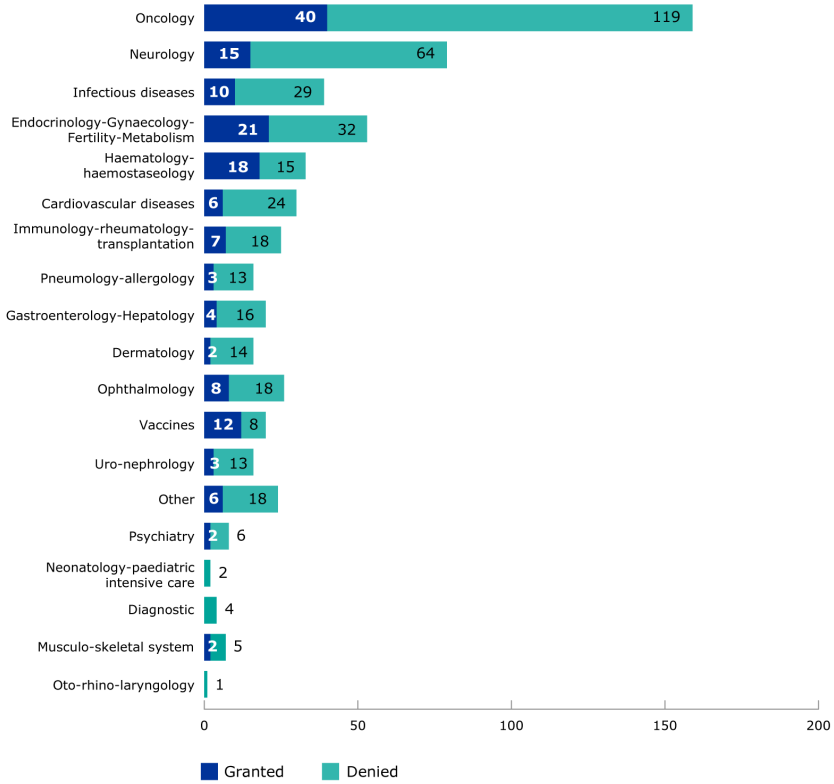
Overall number



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.