



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 August 2026
EMA/164693/2026
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 20-23 July 2026

During its July 2026 meeting, the CHMP reviewed 7 recommendations for eligibility to PRIME: 2 were granted and 5 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
Adeno-associated virus serotype 8 vector containing the human AIPL1 gene	Advanced Therapy Medicinal Product	Eye disorders	Treatment of AIPL1-associated inherited retinal dystrophy (AIPL1-IRD)	Non-clinical + clinical exploratory	Other
Adeno-associated viral vector serotype 2 encoding glial cell line-derived neurotrophic factor	Advanced Therapy Medicinal Product	Nervous system disorders	Treatment of Parkinson's disease	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

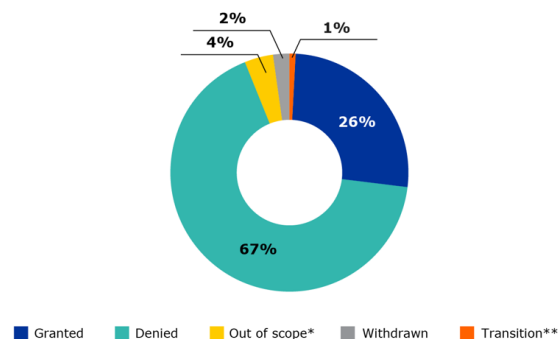
Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy Medicinal Product	Congenital, familial and genetic disorders	Treatment of Primary Hyperoxaluria type 1	Non-clinical + clinical exploratory	SME
Advanced Therapy Medicinal Product	Oncology	Treatment of non- small cell lung cancer (NSCLC)	Non-clinical + clinical exploratory	SME
Chemical Medicinal Product	Oncology	Treatment of SSTR2-positive advanced or metastatic gastroenteropancreatic neuroendocrine tumours (GEP-NETs)	Non-clinical + clinical exploratory	SME
Chemical Medicinal Product	Congenital, familial and genetic disorders	Treatment of Huntington's disease	Non-clinical + clinical exploratory	Other
Chemical Medicinal Product	Congenital, familial and genetic disorders	Treatment of vanishing white matter disease	Non-clinical + clinical exploratory	Other

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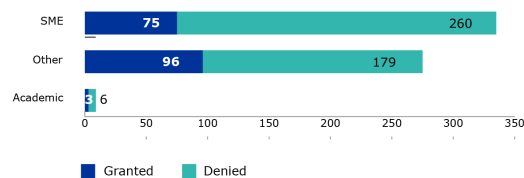
Cumulative overview of PRIME eligibility recommendations adopted by 23 July 2026

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 ■ Withdrawn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

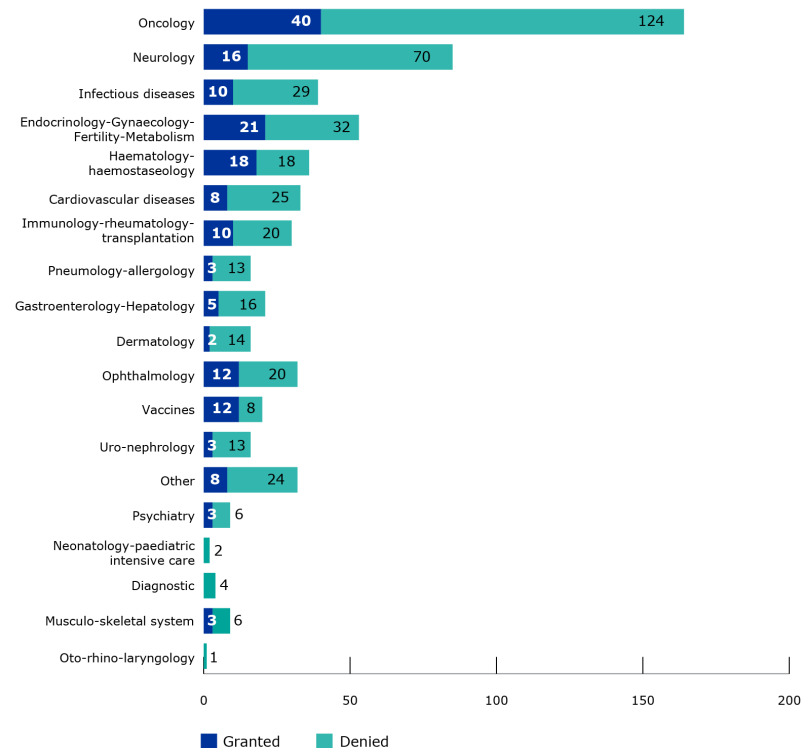
Overall number



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.