



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 July 2026
EMA/145490/2026
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 22-25 June 2026

During its June 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
C-CAR168	Advanced Therapy Medicinal Product	Immune system disorders	Treatment of Systemic Lupus Erythematosus (SLE), with or without lupus nephritis, refractory to standard therapy	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

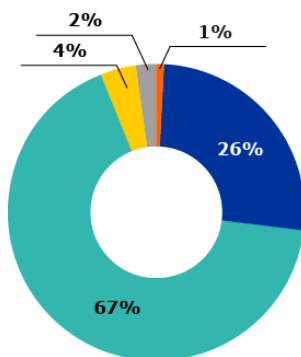
Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy Medicinal Product	Congenital, familial and genetic disorders	Treatment of Aromatic L-amino acid decarboxyase (AADC) deficiency	Non-clinical + clinical exploratory	SME
Biological Medicinal Product	Nervous system disorders	Treatment of acute ischemic stroke with anterior circulation large vessel occlusion in patients receiving mechanical thrombectomy with or without prior intravenous thrombolytic therapy	Non-clinical + clinical exploratory	SME
Chemical Medicinal Product	Nervous system disorders	Treatment of multiple system atrophy	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 25 June 2026

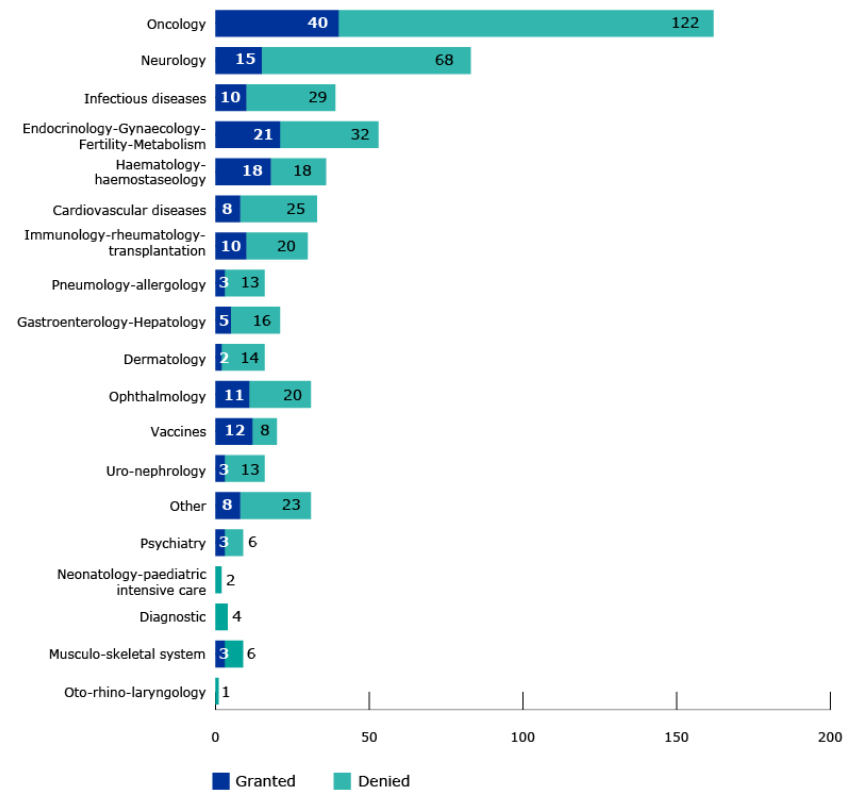
■ Granted
 ■ Denied
 ■ Out of scope*
 ■ Withdrawn
 ■ Transition**

Overall number

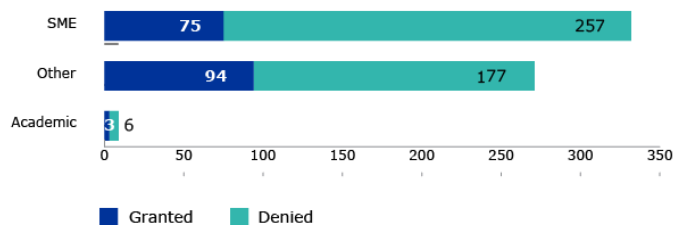


■ Granted
 ■ Denied
 ■ Out of scope*
 ■ Withdrawn
 ■ Transition**

By therapeutic area



By Applicant Type



* 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.