



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

4 February 2026  
EMA/18748/2026  
Press office

## Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 26-29 January 2026

During its January 2026 meeting, the CHMP reviewed 6 recommendations for eligibility to PRIME: 1 was 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
Autologous T-cells transduced with lentiviral vector expressing a chimeric antigen receptor directed against CD19	Advanced Therapy Medicinal Product	Immune system disorders	Treatment of Systemic Lupus Erythematosus (SLE) either with or without renal involvement (Lupus Nephritis, LN)	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

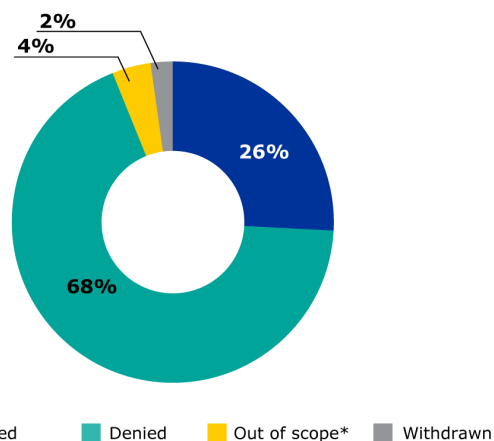
Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy Medicinal Product	Congenital, familial and genetic disorders	Treatment of inherited retinal dystrophies due to dysfunction in the ABCA4 gene	Non-clinical + clinical exploratory	SME
Advanced Therapy Medicinal Product	Cardiac disorders	Treatment of advanced heart failure	Non-clinical + clinical exploratory	SME
Advanced Therapy Medicinal Product	Oncology	Treatment of mantle cell lymphoma	Non-clinical + clinical exploratory	Other
Chemical Medicinal Product	Congenital, familial and genetic disorders	Treatment of spinal and bulbar muscular atrophy	Non-clinical + clinical exploratory	Other
Chemical Medicinal Product	Nervous system disorders	Treatment of acute ischaemic stroke	Non-clinical + clinical exploratory	Other

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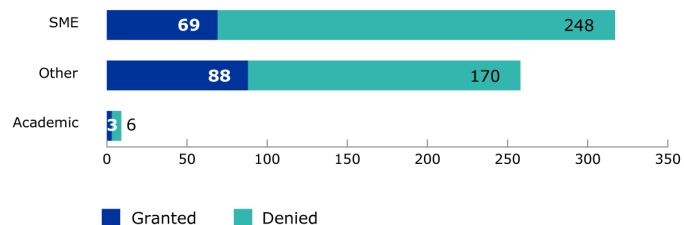
## Cumulative overview of PRIME eligibility recommendations adopted by 29 January 2026

■ Granted ■ Denied ■ Out of scope\* ■ Withdrawn

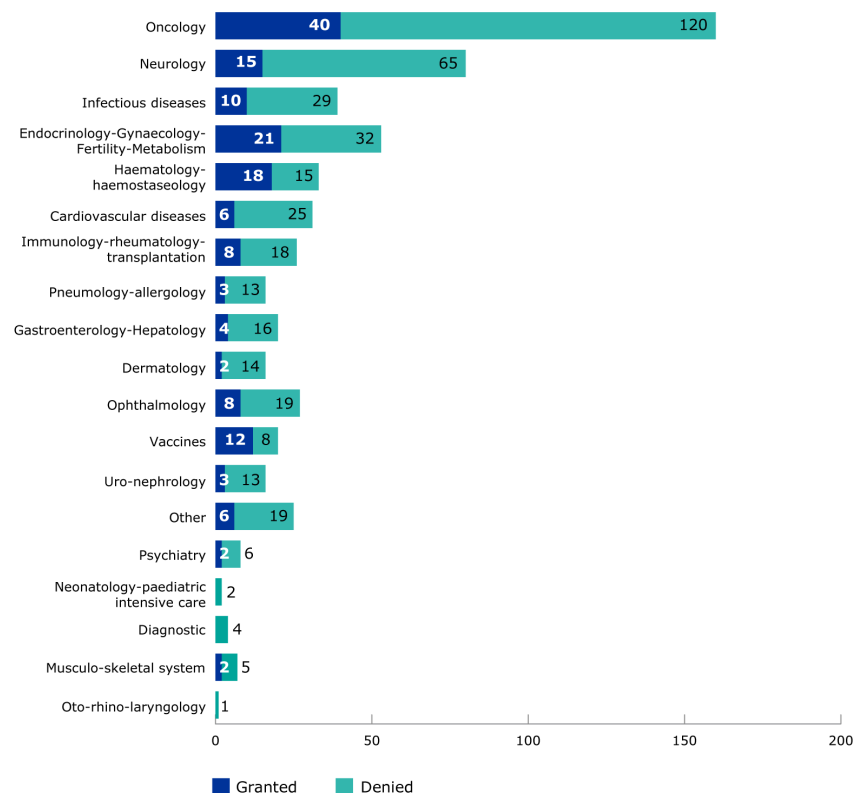
### Overall number



### 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.