24 September 2025
EMA/290349/2025
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 15-18 September 2025

During its September 2025 meeting, the CHMP reviewed 13 recommendations for eligibility to PRIME: 2 were granted and 11 were denied. The individual outcomes adopted this month are listed below.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

Eligibility granted

Name*	Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Resecabtagene autoleucel	Advanced Therapy Medicinal Product	Musculoskeletal and connective tissue disorders	Treatment of treatment-resistant Idiopathic Inflammatory Myopathy	Non-clinical + clinical exploratory	SME
Udonitrectag lysine	Chemical Medicinal Product	Endocrine Disorders	Treatment of Diabetic Foot Ulcer	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 Pancreatic cancer	Non-clinical + clinical exploratory	SME
Advanced Therapy Medicinal Product	Oncology	Treatment of CD70 Positive Advanced or Metastatic Clear Cell Renal Cell Carcinoma	Non-clinical + clinical exploratory	Other
Advanced Therapy Medicinal Product	Congenital, familial and genetic disorders	Treatment of propionic acidaemia	Non-clinical + clinical exploratory	Other
Biological Medicinal Product	Oncology	Treatment of neuroblastoma	Non-clinical + clinical exploratory	SME
Biological Medicinal Product	Oncology	Treatment of relapse or refractory B-cell Acute Lymphoblastic Leukaemia (B-ALL)	Non-clinical + clinical exploratory	Other
Biological Medicinal Product	Cardiac disorders	Treatment of cardiogenic shock	Non-clinical + clinical exploratory	SME
Chemical Medicinal Product	Neurodevelopmental disorder	Treatment of Angelman syndrome	Non-clinical + clinical exploratory	Other
Chemical Medicinal Product	Surgical and medical procedures	Treatment of acute pain after instrumented spinal surgery	Non-clinical + clinical exploratory	SME
Chemical Medicinal Product	Nervous system disorders	Treatment of Alzheimer's disease	Non-clinical + clinical exploratory	SME
Chemical Medicinal Product	Neurology	Treatment of fragile X syndrome	Non-clinical + clinical exploratory	SME

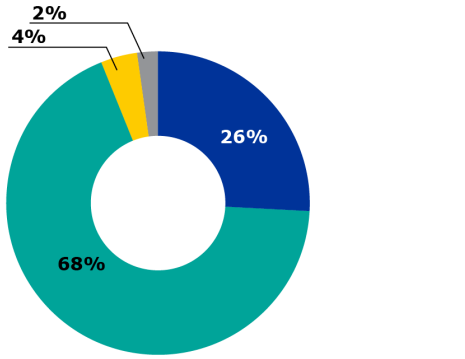
Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Neurology	Treatment of amyotrophic lateral sclerosis	Non-clinical + clinical exploratory	SME

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.

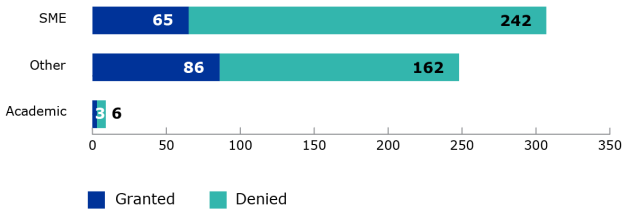
Cumulative overview of PRIME eligibility recommendations adopted by 18 September 2025

Granted Denied Out of scope* Withdrawn

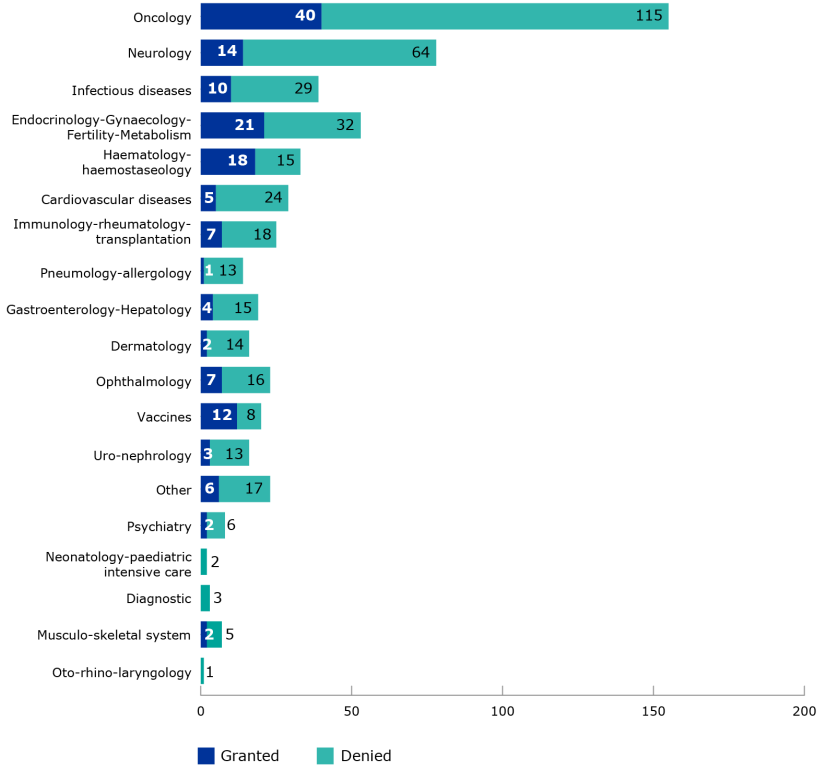
Overall number



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.