29 October 2025
EMA/317115/2025
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 13-16 October 2025

During its October 2025 meeting, the CHMP reviewed 9 recommendations for eligibility to PRIME: 3 were granted and 6 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
NRTX-1001	Advanced Therapy Medicinal Product	Nervous system disorders	Treatment of adults with drug resistant mesial temporal lobe epilepsy (MTLE)	Non-clinical + clinical exploratory	SME
AZD0292	Biological Medicinal Product	Respiratory, thoracic and mediastinal disorders	Prevention of exacerbations in bronchiectasis patients who are chronically colonised with *Pseudomonas aeruginosa*	Non-clinical + clinical exploratory	Other
Taladegib	Chemical Medicinal Product	Respiratory, thoracic and mediastinal disorders	Treatment of idiopathic pulmonary fibrosis	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	Eye disorders	Treatment of patients with Stargardt Disease having severe vision loss	Non-clinical + clinical exploratory	Other
Advanced Therapy Medicinal Product	Eye disorders	Treatment of patients with Retinitis Pigmentosa having severe vision loss	Non-clinical + clinical confirmatory	Other
Biological Medicinal Product	Oncology	Treatment of myelodysplastic syndromes	Non-clinical + clinical exploratory	SME
Biological Medicinal Product	Oncology	Treatment of adult patients with mCRPC previously treated with AR pathway inhibition, two taxane based chemotherapy regimens (if eligible)	Non-clinical + clinical exploratory	Other
Chemical Medicinal Product	Oncology	Treatment of patients with hepatocellular carcinoma (HCC) with FGF19 overexpression who have been previously treated	Non-clinical + clinical exploratory	Other
Chemical Medicinal Product	Diagnostics	Tumor detection and real-time guidance toward complete resection during pancreatic ductal adenocarcinoma (PDAC), extrahepatic cholangiocarcinoma (eCCA), and oral squamous cell carcinoma (OSCC) surgery	Non-clinical + clinical exploratory	SME

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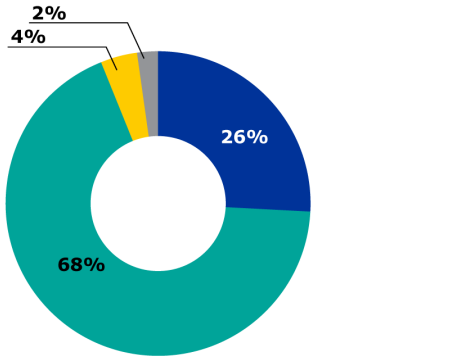
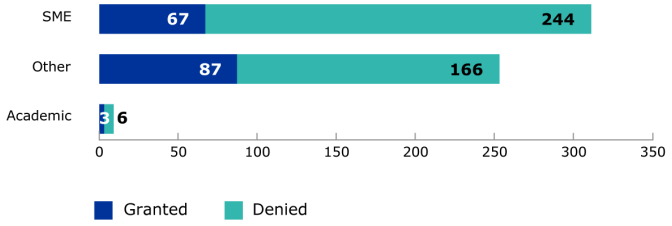
Cumulative overview of PRIME eligibility recommendations adopted by 16 October 2025

Granted Denied Out of scope* Withdrawn

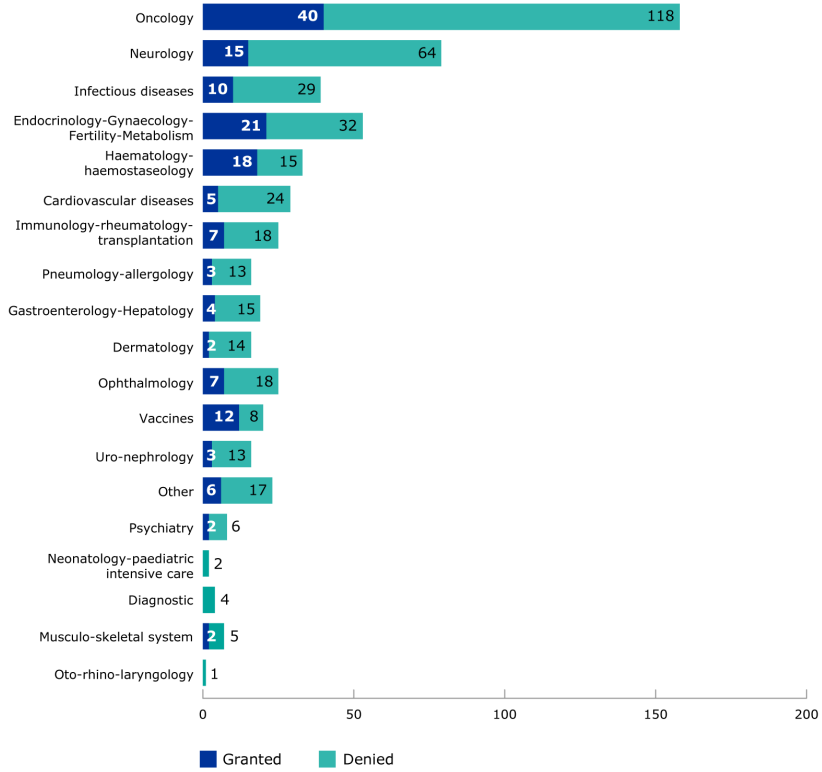
Overall number



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.