20 November 2024
EMA/517347/2024
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 11-14 November 2024

During its November 2024 meeting, the CHMP reviewed 9 recommendations for eligibility to PRIME: 1 was granted and 8 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
NX-5948	Chemical Medicinal Product	Oncology	Treatment of adult patients with relapsed or refractory chronic lymphocytic leukaemia or small lymphocytic lymphoma (CLL/SLL) after at least a BTK inhibitor and a BCL-2 inhibitor	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

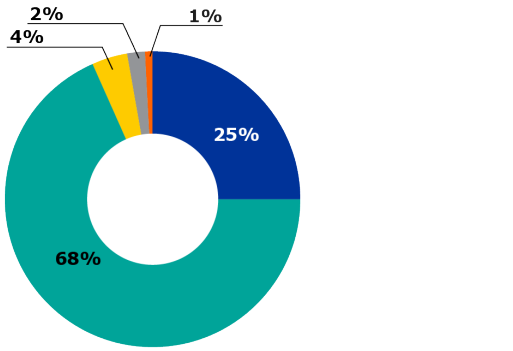
Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy Medicinal Product	Oncology	Treatment of Acute Myeloid Leukemia (AML), Acute Lymphoblastic Leukemia (ALL), Myelodysplastic Syndromes (MDS)	Non-clinical + clinical exploratory	Other
Advanced Therapy Medicinal Product	Oncology	Treatment of Acute Myeloid Leukemia (AML), Acute Lymphoblastic Leukemia (ALL), Myelodysplastic Syndromes (MDS)	Non-clinical + clinical exploratory	Other
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	Cardiac disorders	Treatment of advanced heart failure	Non-clinical + clinical exploratory	SME
Chemical Medicinal Product	Haematology - Haemostaseology	Treatment of lymphatic malformations	Non-clinical + clinical exploratory	SME
Chemical Medicinal Product	Nervous system disorders	Treatment of vanishing white matter disease	Non-clinical + clinical exploratory	Other
Chemical Medicinal Product	Gastrointestinal disorders	Treatment of celiac disease as an adjunct to a gluten-free diet	Non-clinical + clinical exploratory	Other
Chemical Medicinal Product	Nervous system disorders	Adjunctive treatment of seizures associated with developmental and epileptic encephalopathies (DEEs) for patients aged one year and older, adjunctive treatment of seizures in children aged one year and older and adults with Dravet Syndrome	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.

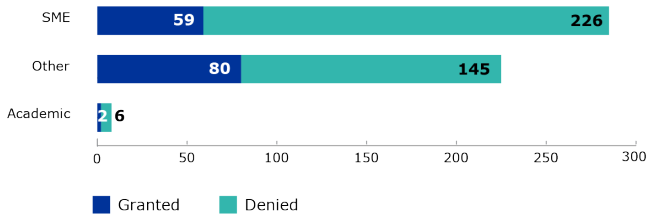
Cumulative overview of PRIME eligibility recommendations adopted by 14 November 2024

Granted Denied Out of scope* Withdrawn Transition**

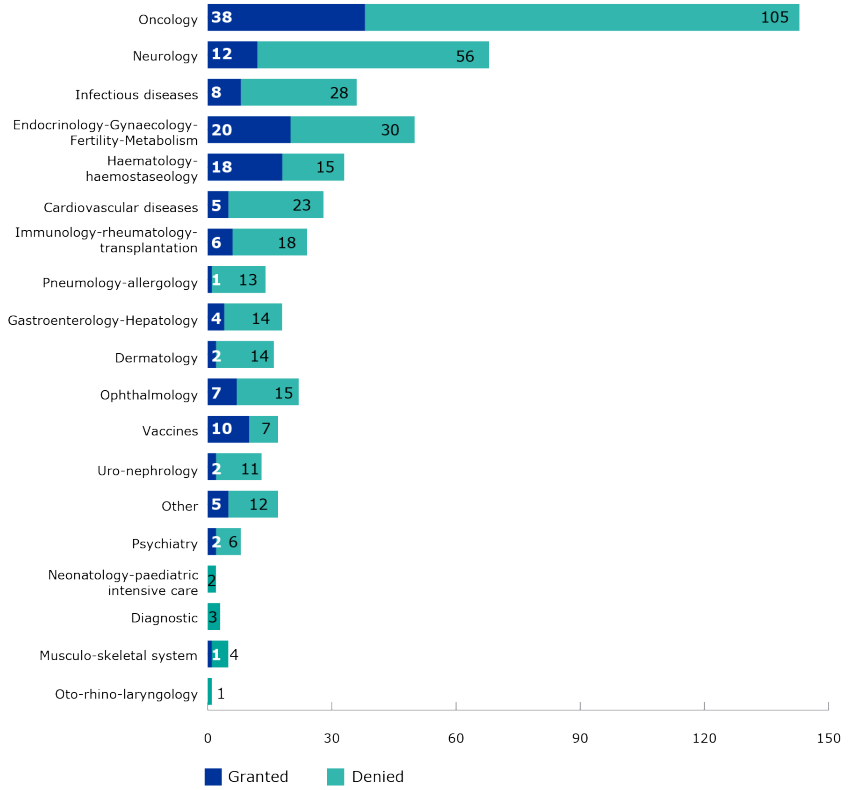
Overall number



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.