01 February 2023
EMA/898113/2022
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 23-26 January 2023

During its January 2023 meeting, the CHMP reviewed 6 recommendations for eligibility to PRIME: 2 were granted and 4 were denied. In addition, 2 requests were received but not started by EMA as it was deemed outside the scope of the scheme.
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*	Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
ApTOLL	Chemical Medicinal Product	Cardiovascular diseases	Treatment of Acute Ischemic Stroke	Nonclinical + Clinical exploratory	SME
GNT0003	Advanced Therapy Medicinal Product	Other, congenital, familial and genetic disorders	Treatment of severe Crigler-Najjar syndrome in adults and children >10 years old, requiring phototherapy	Nonclinical + 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.

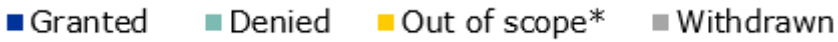
Product(s) in italic have been granted eligibility to the scheme at early stages of development (proof of principle/proof of mechanism).

Eligibility denied

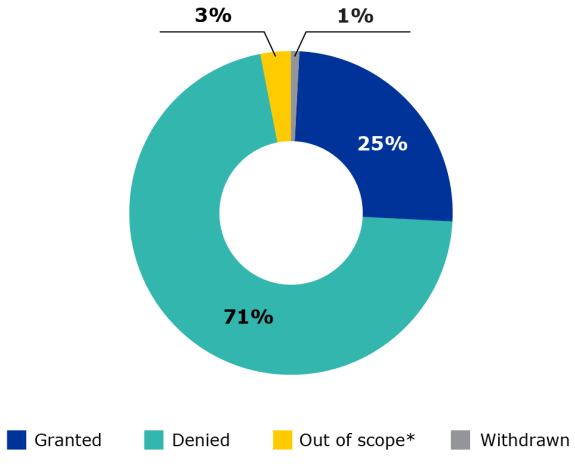
Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Oncology	Treatment of non-muscle Invasive Bladder Cancer	Nonclinical + Clinical exploratory	Other
Immunological Medicinal Product	Oncology	Treatment of patients with stage IIIB or stage IV non-small cell lung cancer (NSCLC) not amenable to EGFR/ALK/ROS based therapy, who are treatment-naïve for advanced/metastatic disease (1st line NSCLC)	Nonclinical + Clinical exploratory	SME
Chemical Medicinal Product	Oncology	Treatment of prostate cancer	Nonclinical + Clinical exploratory	SME
Chemical Medicinal Product	Oncology	Indicated for patients with locally advanced squamous cell carcinoma of the head and neck	Nonclinical + Clinical exploratory	Other

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.

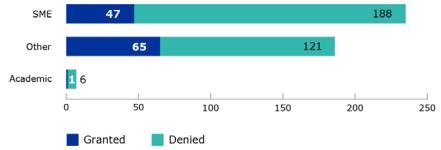
Cumulative overview of PRIME eligibility recommendations adopted by 26 January 2023



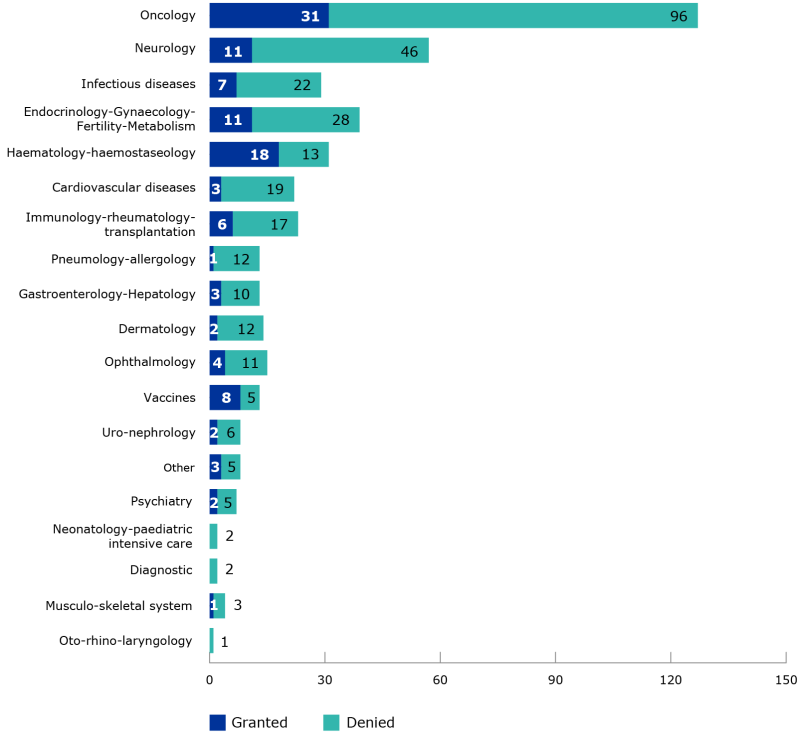
Overall number



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.