



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 November 2023
EMA/898143/2022
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 6-9 November 2023

During its November 2023 meeting, the CHMP reviewed 3 recommendations for eligibility to PRIME: 2 were granted and 1 was denied. The individual outcomes adopted this month are listed below.

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Eligibility granted

Name*	Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
PRAX-222	Chemical Medicinal Product	Nervous system disorders	Treatment of SCN2A Developmental and Epileptic Encephalopathy (SCN2A-DEE)	Non-clinical + Tolerability first in man	SME
BI 456906	Chemical Medicinal Product	Gastroenterology - Hepatology	Treatment of NASH/NAFLD with fibrosis	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.

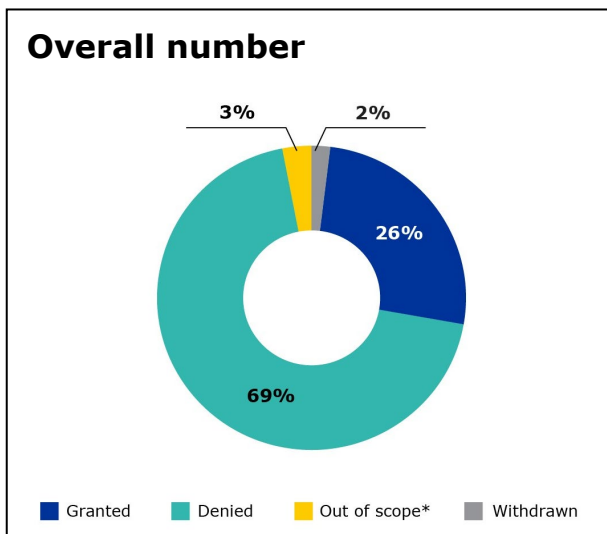
Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Haematology - Haemostaseology	Treatment of Microcystic Lymphatic Malformations	Non-clinical + Clinical exploratory	SME

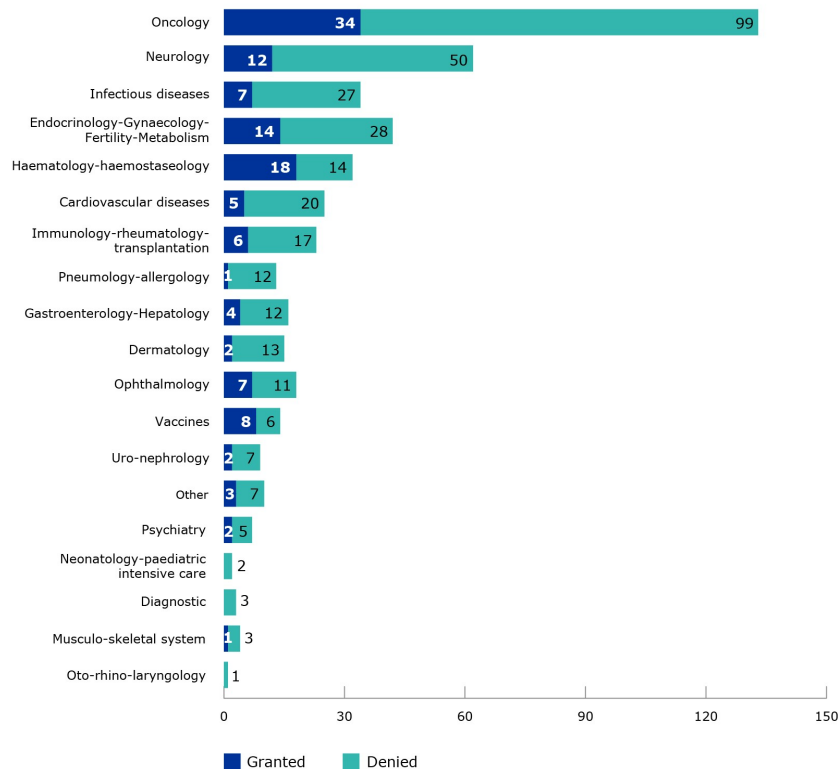
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other type of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

Cumulative overview of PRIME eligibility recommendations adopted by 9 November 2023

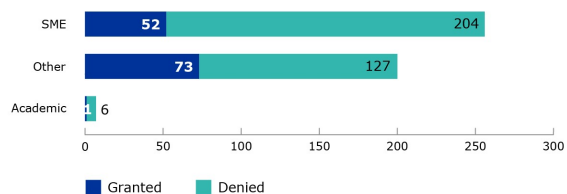
■ Granted ■ Denied ■ Out of scope* ■ Withdrawn



By therapeutic area



By Applicant Type



* 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.