



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 June 2024
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Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 27-30 May 2024

During its May 2024 meeting, the CHMP reviewed 5 recommendations for eligibility to PRIME and 5 were denied. The individual outcomes adopted this month are listed below.

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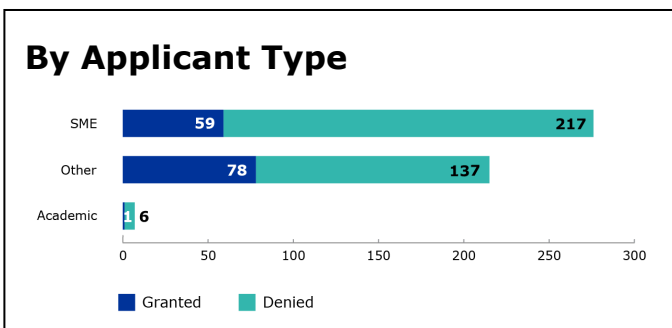
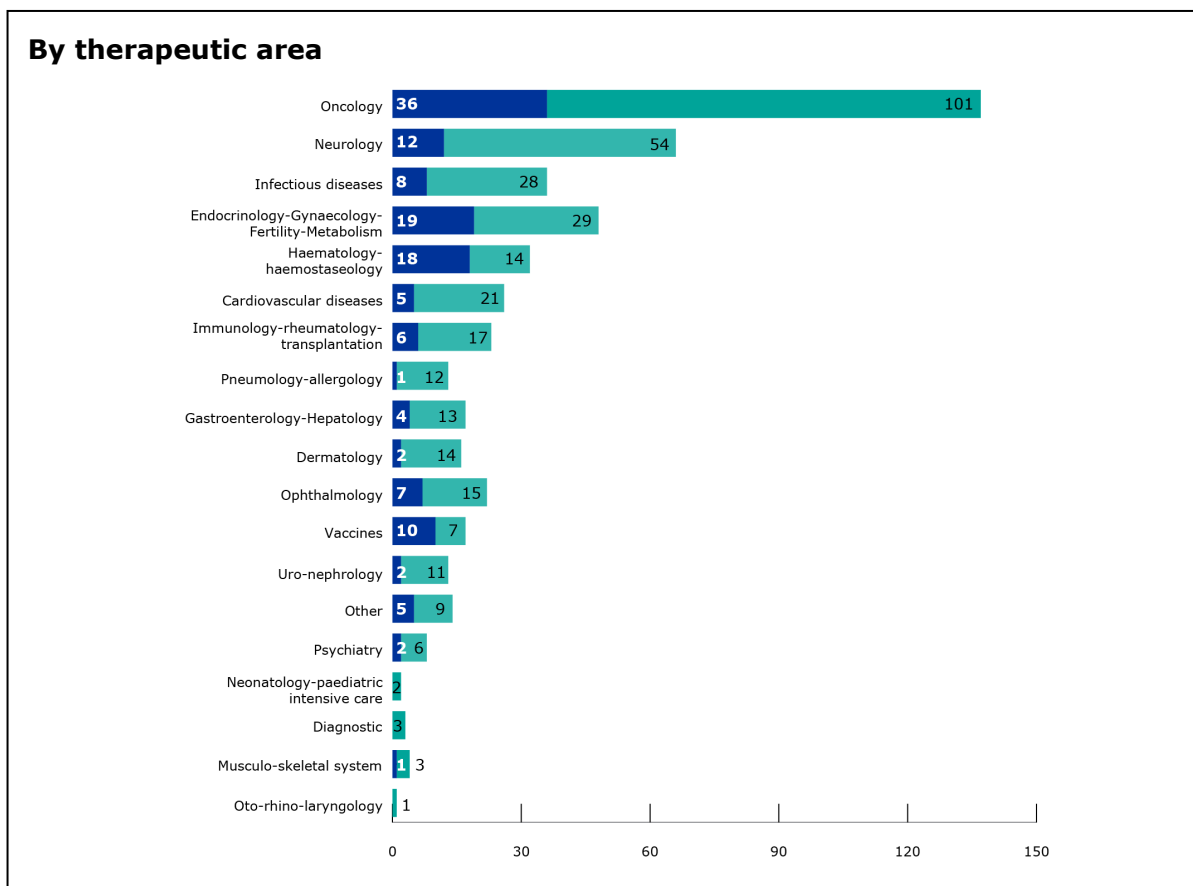
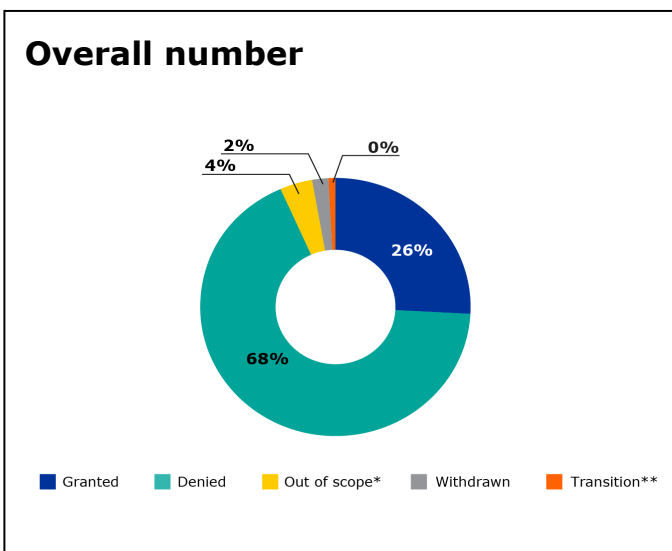
Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Nervous system disorders	Treatment of Parkinson's Disease (Advanced Stage)	Non-clinical + Clinical exploratory	SME
Chemical Medicinal Product	Oncology	Treatment of metastatic Castration-Resistant Prostate Cancer	Non-clinical + Clinical exploratory	Other
Chemical Medicinal Product	Oncology	Treatment of unresectable or metastatic, FGFR-altered, previously treated cholangiocarcinoma	Non-clinical + Clinical exploratory	Other
Biological Medicinal Product	Renal and urinary disorders	Reducing the risk of an irreversible loss of kidney function following open-chest cardiac surgery in patients who are at increased risk for acute kidney injury	Non-clinical + Clinical exploratory	SME
Advanced Therapy Medicinal Product	Eye disorders	Treatment of Bietti Crystalline Dystrophy	Non-clinical + 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 30 May 2024

■ Granted
 ■ Denied
 ■ Out of scope*
 ■ Withdrawn
 ■ Transition**



* 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.