4 July 2024
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Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 24-27 June 2024

During its June 2024 meeting, the CHMP reviewed 4 recommendations for eligibility to PRIME and 4 were denied. The individual outcomes adopted this month are listed below.

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Eligibility denied

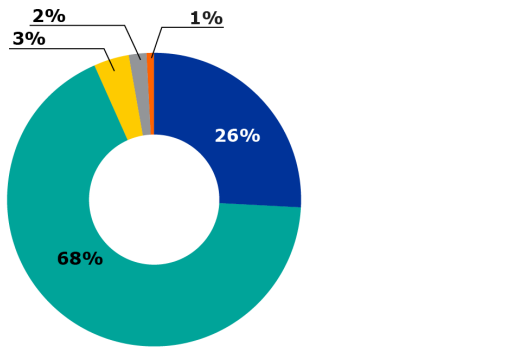
Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Biological Medicinal Product	Respiratory, thoracic and mediastinal disorders	Prevention of bronchopulmonary dysplasia	Non-clinical + clinical exploratory	Other
Biological Medicinal Product	Cardiac disorders	Treatment of cardiogenic shock	Non-clinical + clinical exploratory	SME
Chemical Medicinal Product	Congenital, familial and genetic disorders	Treatment of Becker muscular dystrophy	Non-clinical + clinical exploratory	SME
Chemical Medicinal Product	Blood and lymphatic system disorders	Treatment of adult patients with relapsed/refractory NPM1m or KMT2Ar Acute Myeloid Leukemia (AML)	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 27 June 2024

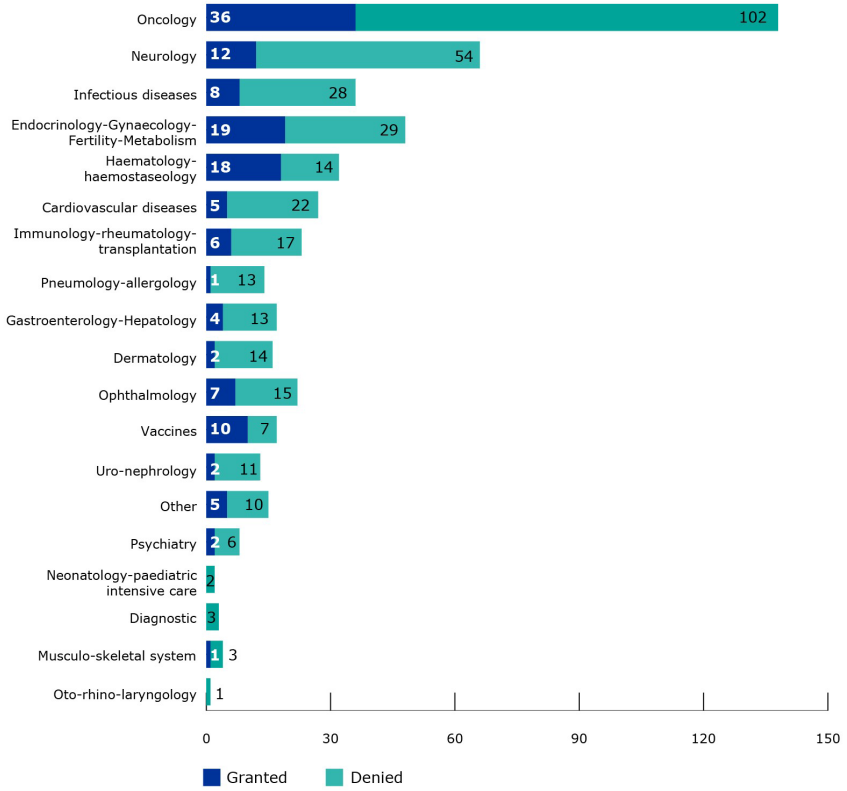
Granted Denied Out of scope* Withdrawn Transition**

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.