31 January 2024
EMA/35288/2024
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 22-25 January 2024

During its January 2024 meeting, the CHMP reviewed 6 recommendations for eligibility to PRIME: 2 were granted and 4 were denied. The individual outcomes adopted this month are listed below.

Additionally, the CHMP reviewed data on progress to proof of concept and confirmed eligibility for MTBVAC, Mycobacterium tuberculosis, live attenuated in the prevention of tuberculosis disease in newborns, and adolescent and adults, which was initially granted eligibility to the scheme at early stages of development (proof of principle/proof of mechanism) on 28 June 2018.

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Eligibility granted

Name*	Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Isaralgagene civaparvovec	Advanced Therapy Medicinal Product	Congenital, familial and genetic disorders	Treatment of Fabry disease	Non-clinical + Clinical exploratory	Other
GTX 102	Chemical Medicinal Product	Congenital, familial and genetic disorders	Treatment of Angelman syndrome	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

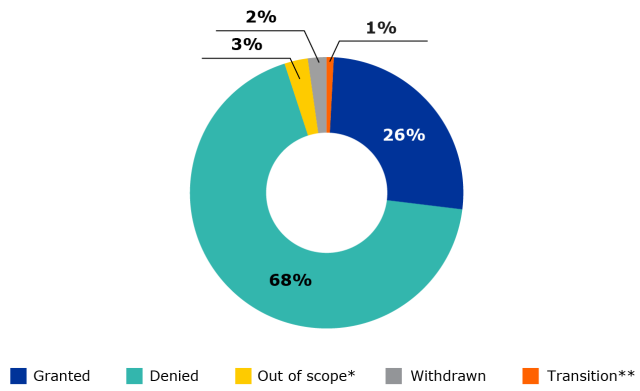
Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy Medicinal Product	Nervous system disorders	Treatment of Parkinson's disease	Non-clinical + Clinical exploratory	Other
Biological Medicinal Product	Vaccines	Prevention of pneumococcal disease	Non-clinical + Clinical exploratory	Other
Biological Medicinal Product	Congenital, familial and genetic disorders	Treatment of Myotonic Dystrophy Type 1	Non-clinical + Clinical exploratory	SME
Chemical Medicinal Product	Renal and urinary disorders	Treatment of chronic kidney disease in adults with CKD and high albuminuria and/or high proteinuria	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.

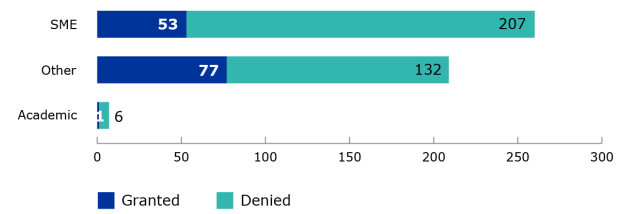
Cumulative overview of PRIME eligibility recommendations adopted by 25 January 2024

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

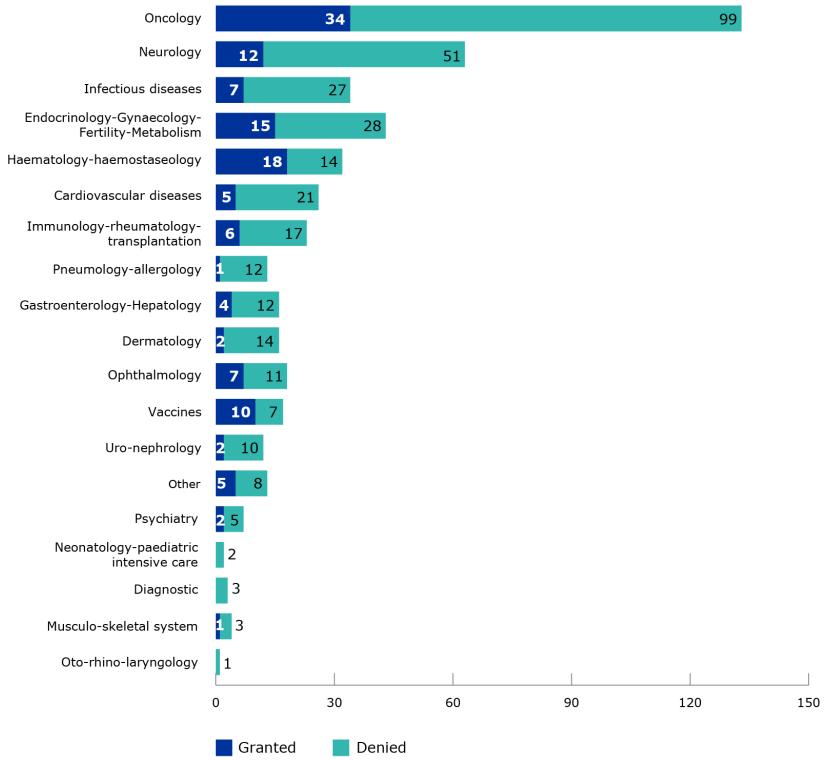
Overall number



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.