27 March 2024
EMA/97338/2024
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 18-21 March 2024

During its March 2024 meeting, the CHMP reviewed 9 recommendations for eligibility to PRIME: 3 were granted and 6 were denied. In addition, 1 request was 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.

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Eligibility granted

Name*	Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Esepapogene zalarnarepvec	Advanced Therapy Medicinal Product	Oncology	Recurrent or metastatic human-papillomavirus 16 positive, PD-L1 CPS ≥20, oropharyngeal squamous cell carcinoma	Non-clinical + Clinical exploratory	SME
BJT-778	Biological Medicinal Product	Infectious diseases	Treatment of Chronic Hepatitis D virus infection	Non-clinical + Clinical exploratory	SME
Pegozafermin	Biological Medicinal Product	Metabolism and nutrition disorders	Treatment of adults with metabolic dysfunction-associated steatohepatitis (MASH) with liver fibrosis and for the treatment of adults with MASH with compensated cirrhosis	Non-clinical + Clinical exploratory	SME

* 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
Advanced Therapy Medicinal Product	Endocrine disorders	Treatment of Chronic Diabetic Foot Ulcers (DFUs)	Non-clinical + Tolerability first in man	SME
Advanced Therapy Medicinal Product	Congenital, familial and genetic disorders	Treatment of Canavan disease	Non-clinical + Clinical exploratory	Other
Chemical Medicinal Product	Ophthalmology	Treatment of Geographic Atrophy Secondary to Age-Related Macular Degeneration	Non-clinical + Clinical exploratory	SME
Chemical Medicinal Product	Ophthalmology	Treatment of Dry age-related macular degeneration	Non-clinical + Clinical exploratory	SME
Chemical Medicinal Product	Psychiatric disorders	Treatment of Treatment-Resistant Depression	Non-clinical + Clinical exploratory	SME
Biological Medicinal Product	Nervous system disorders	Treatment of Parkinson's Disease	Non-clinical + Clinical exploratory	SME

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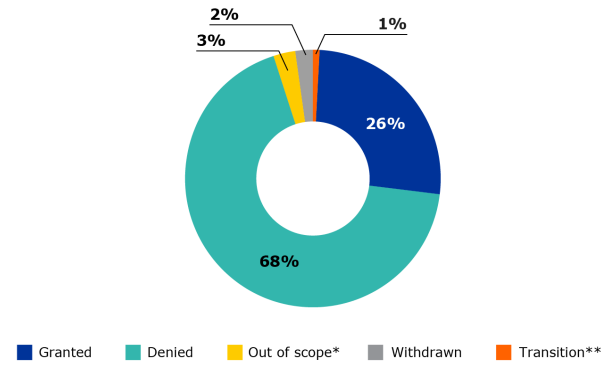
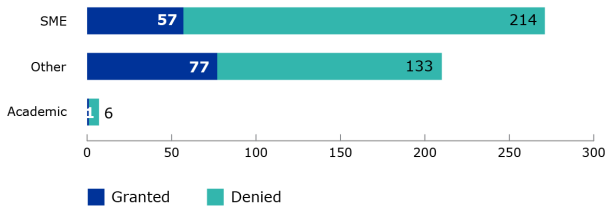
Cumulative overview of PRIME eligibility recommendations adopted by 21 March 2024

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

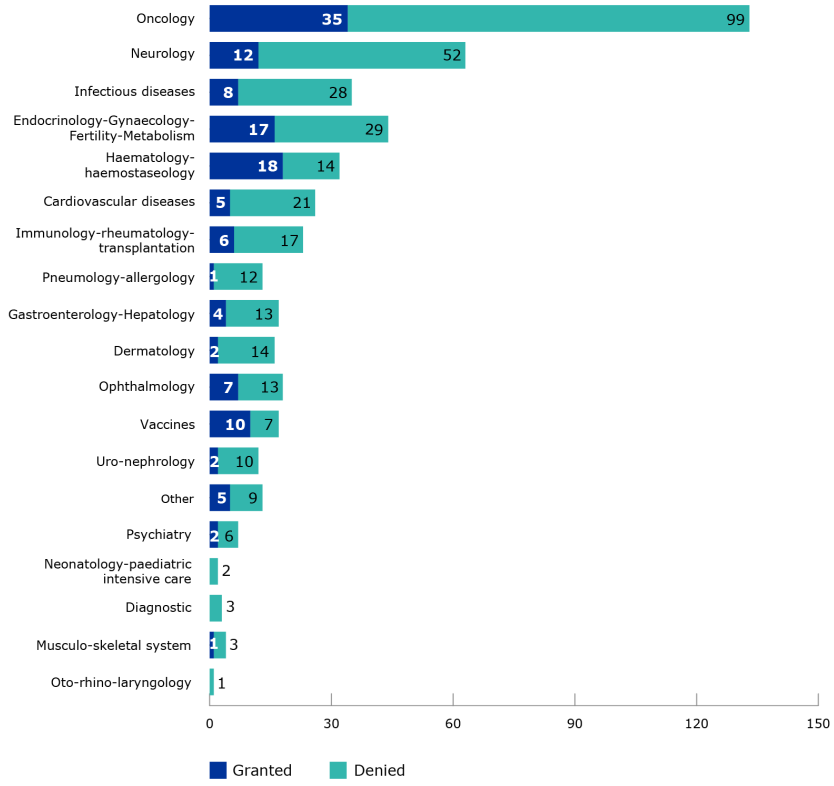
Overall number



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.