



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 December 2024
EMA/557312/2024
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 9-12 December 2024

During its December 2024 meeting, the CHMP reviewed 5 recommendations for eligibility to PRIME: 2 were granted and 3 were denied. The individual outcomes adopted this month are listed below.

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Eligibility granted

Name*	Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
GSK5764227	Biological Medicinal Product	Oncology	Treatment of patients with relapsed extensive-stage small cell lung cancer (ES-SCLC)	Non-clinical + clinical exploratory	Other
Tobevibart and Elebsiran	Biological Medicinal Product	Infectious diseases	Treatment of Chronic Hepatitis Delta Virus (HDV) Infection	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

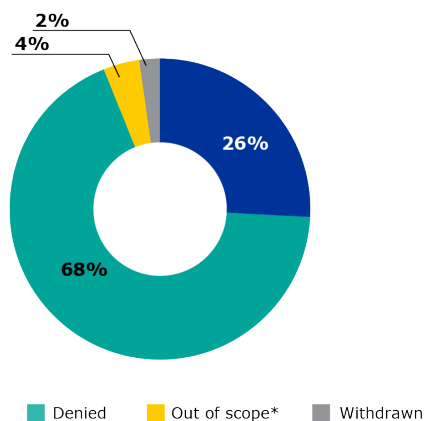
Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy Medicinal Product	Congenital, familial and genetic disorders	Treatment of children and adolescents with hearing loss due to biallelic variants of the OTOF gene	Non-clinical + clinical exploratory	Other
Chemical Medicinal Product	Oncology	Treatment of glioblastoma in combination with radiotherapy	Non-clinical + clinical exploratory	SME
Biological Medicinal Product	Gastrointestinal disorders	Treatment of moderately to Severely Active Ulcerative Colitis	Non-clinical + Tolerability first in man	SME

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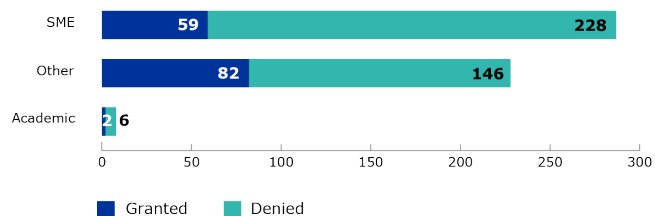
Cumulative overview of PRIME eligibility recommendations adopted by 12 December 2024

■ Granted ■ Denied ■ Out of scope* ■ Withdrawn

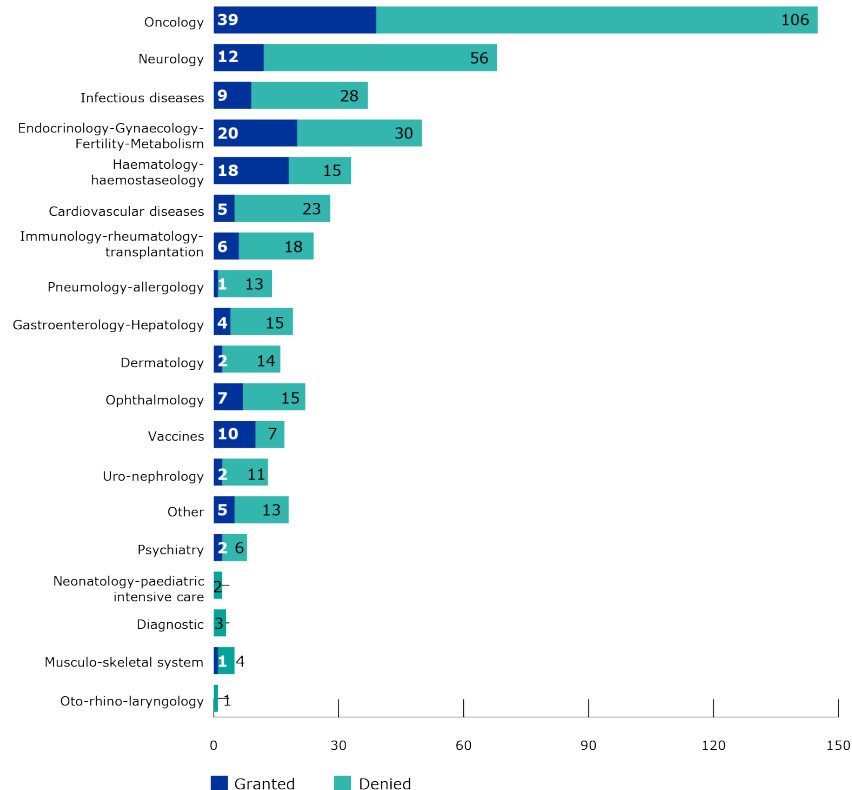
Overall number



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.