



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 October 2024
EMA/457029/2024
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 14-17 October 2024

During its October 2024 meeting, the CHMP reviewed 3 recommendations for eligibility to PRIME: 1 was granted and 2 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
Gallium (68Ga) boclataxafortide	Chemical Medicinal Product	Endocrine disorders	Diagnosis of primary aldosteronism	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

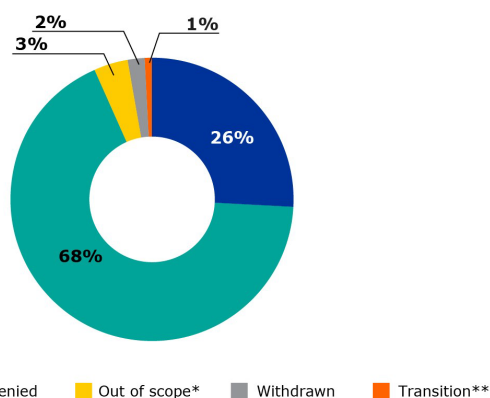
Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Immune system disorders	Primary prophylaxis and treatment of T cell engaging immunotherapy induced cytokine release syndrome (CRS)	Non-clinical + clinical exploratory	SME
Chemical Medicinal Product	Congenital, familial and genetic disorders	Treatment of GM1/GM2 gangliosidosis	Non-clinical + clinical exploratory	SME

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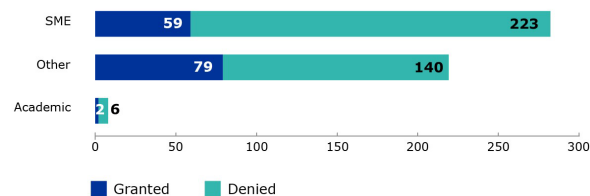
Cumulative overview of PRIME eligibility recommendations adopted by 17 October 2024

■ Granted ■ Denied ■ Out of scope* ■ Withdrawn ■ Transition**

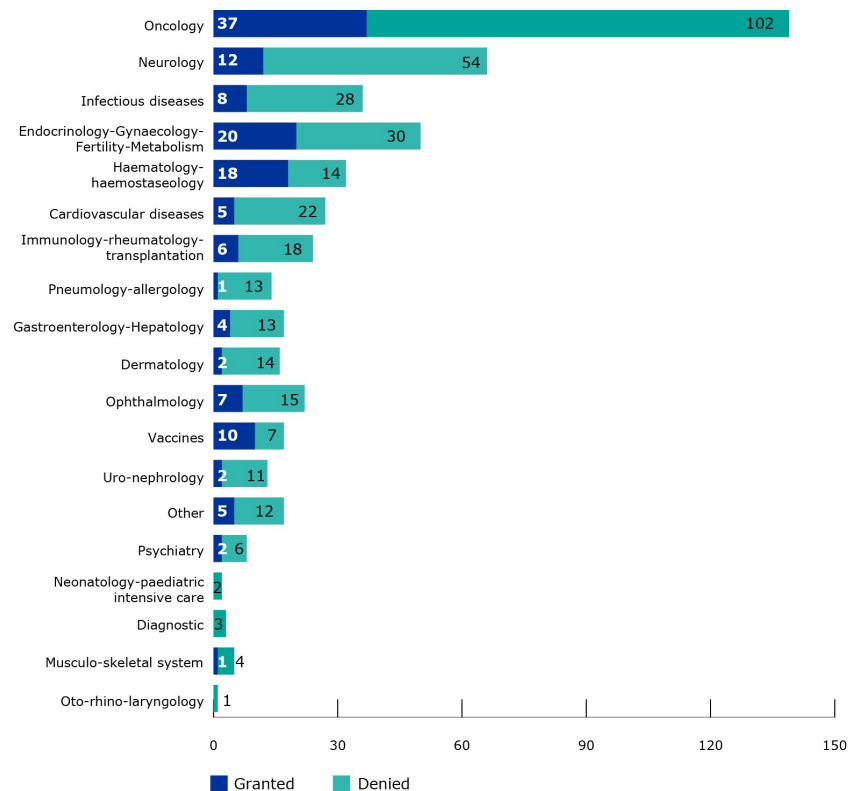
Overall number



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.