



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 December 2023
EMA/898147/2022
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 11-14 December 2023

During its December 2023 meeting, the CHMP reviewed 7 recommendations for eligibility to PRIME: 3 were granted and 4 were denied. 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
ChAdOx1 MERS vaccine	Biological Medicinal Product	Vaccines	Prevention of Middle East Respiratory Syndrome	Non-clinical + Clinical exploratory	SME
Respiratory syncytial virus vaccine	Biological Medicinal Product	Vaccines	Prevention of respiratory syncytial virus (RSV) disease	Non-clinical + Clinical exploratory	Other
RGX-121	Advanced Therapy Medicinal Product	Endocrinology - Gynaecology - Fertility - Metabolism	Treatment of Mucopolysaccharidosis Type II	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

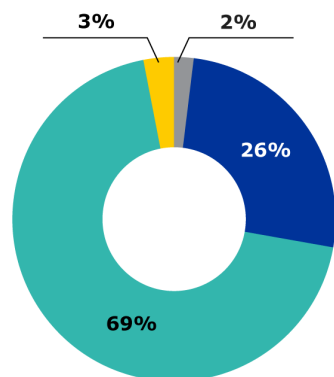
Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Uro-nephrology	Preservation of kidney function after kidney transplantation in adult patients at moderate to high risk of post-transplant kidney graft failure	Non-clinical + Clinical exploratory	SME
Chemical Medicinal Product	Dermatology	Treatment of moderate to severe hidradenitis suppurativa	Non-clinical + Clinical exploratory	Other
Biological Medicinal Product	Uro-nephrology	Treatment of Immunoglobulin A Nephropathy	Non-clinical + Clinical exploratory	Other
Advanced Therapy Medicinal Product	Cardiovascular diseases	Treatment of refractory angina in adult patients who are inadequately controlled and not eligible for revascularization procedures	Non-clinical + Clinical exploratory	SME

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Cumulative overview of PRIME eligibility recommendations adopted by 14 December 2023

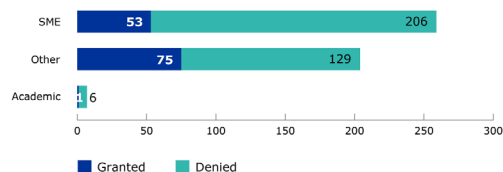
■ Granted ■ Denied ■ Out of scope* ■ Withdrawn

Overall number

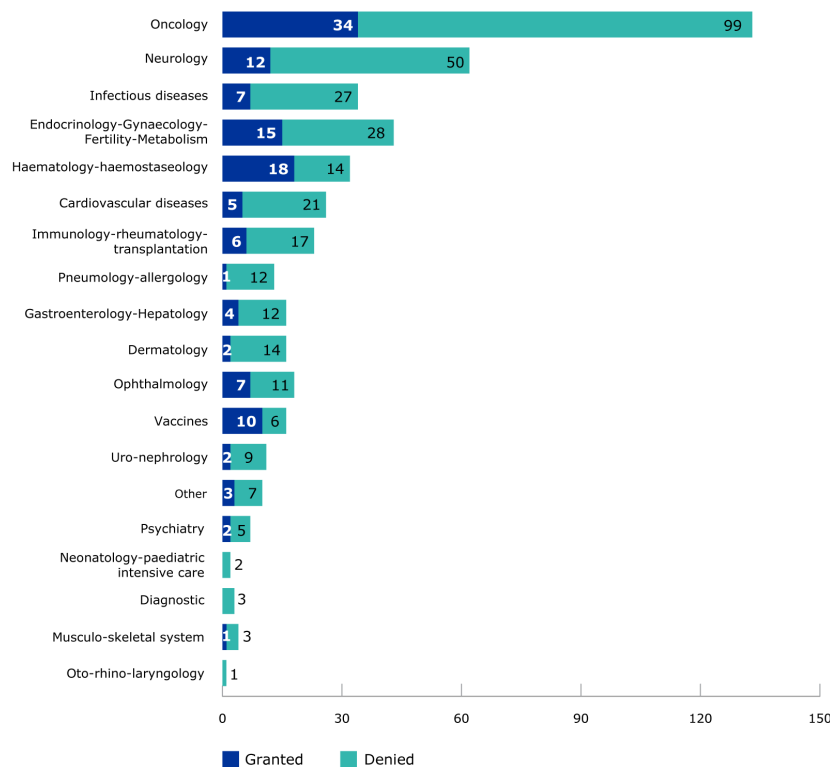


■ Granted ■ Denied ■ Out of scope* ■ Withdrawn

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.