



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 February 2025
EMA/4248/2025
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 27-30 January 2025

During its January 2025 meeting, the CHMP reviewed 4 recommendations for eligibility to PRIME: 2 were granted and 2 were denied. The individual outcomes adopted this month are listed below.

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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Eligibility granted

Name*	Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
rVSVdeltaG-LASV-GPC	Biological Medicinal Product	Vaccines	Prevention of Lassa disease	Non-clinical + clinical exploratory	Other
<i>Autologous CD34+ cells transduced with a lentiviral vector containing the human RAG1 gene</i>	<i>Advanced Therapy Medicinal Product</i>	<i>Congenital, familial and genetic disorders</i>	<i>Treatment of RAG1 deficient severe combined immunodeficiency (SCID)</i>	<i>Non-clinical + clinical exploratory</i>	<i>SME</i>

* 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.

Product(s) in italic have been granted eligibility to the scheme at early stages of development (proof of principle/proof of mechanism).

Eligibility denied

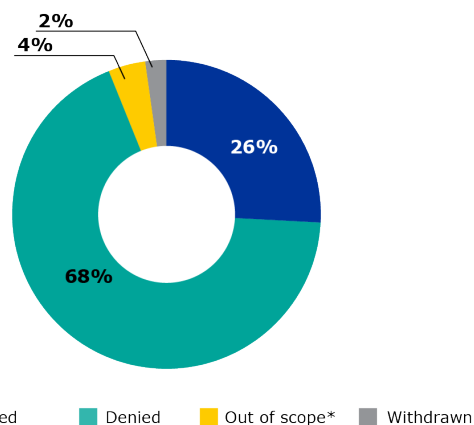
Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy Medicinal Product	Congenital, familial and genetic disorders	Treatment of Duchenne muscular dystrophy	Non-clinical + clinical exploratory	Other
Advanced Therapy Medicinal Product	Nervous system disorders	Treatment of Myasthenia Gravis	Non-clinical + clinical exploratory	Other

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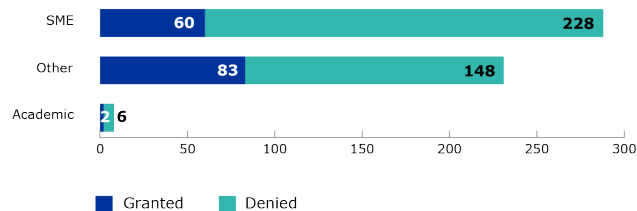
Cumulative overview of PRIME eligibility recommendations adopted by 30 January 2025

■ Granted ■ Denied ■ Out of scope* ■ Withdrawn

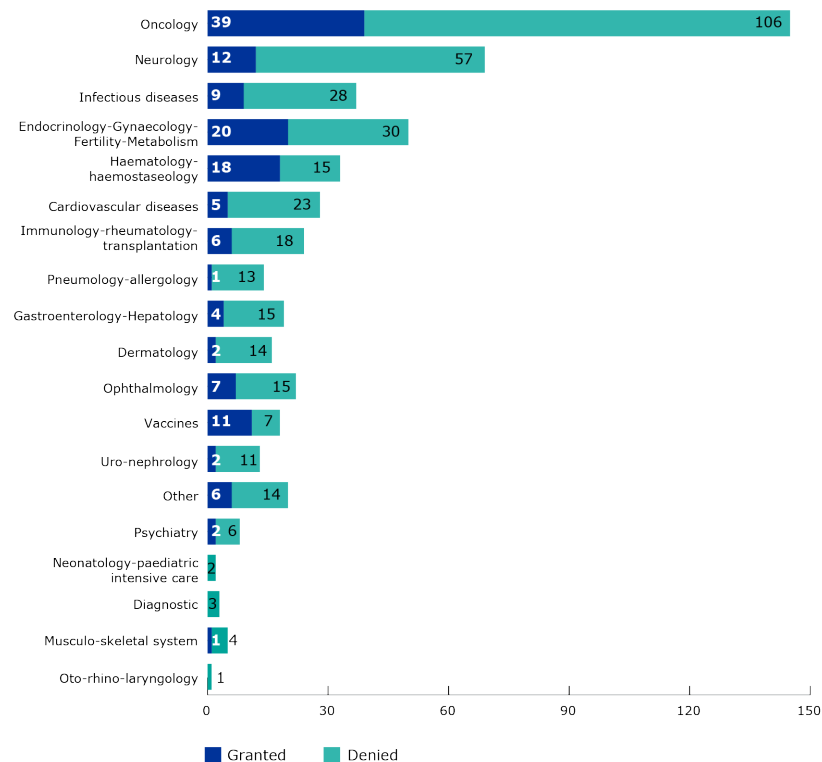
Overall number



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.