



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 17-20 July 2023

During its July 2023 meeting, the CHMP reviewed 4 recommendations for eligibility to PRIME: 1 was granted and 3 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*	Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
RP-L301	Advanced Therapy Medicinal Product	Endocrinology- Gynaecology-Fertility- Metabolism	Treatment of pyruvate kinase deficiency	Nonclinical + 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.

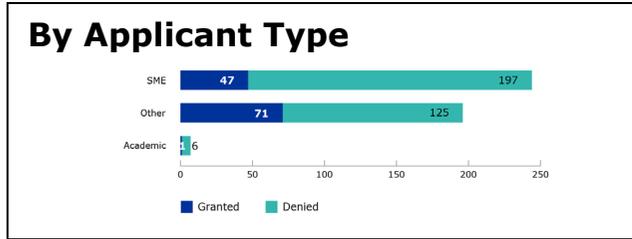
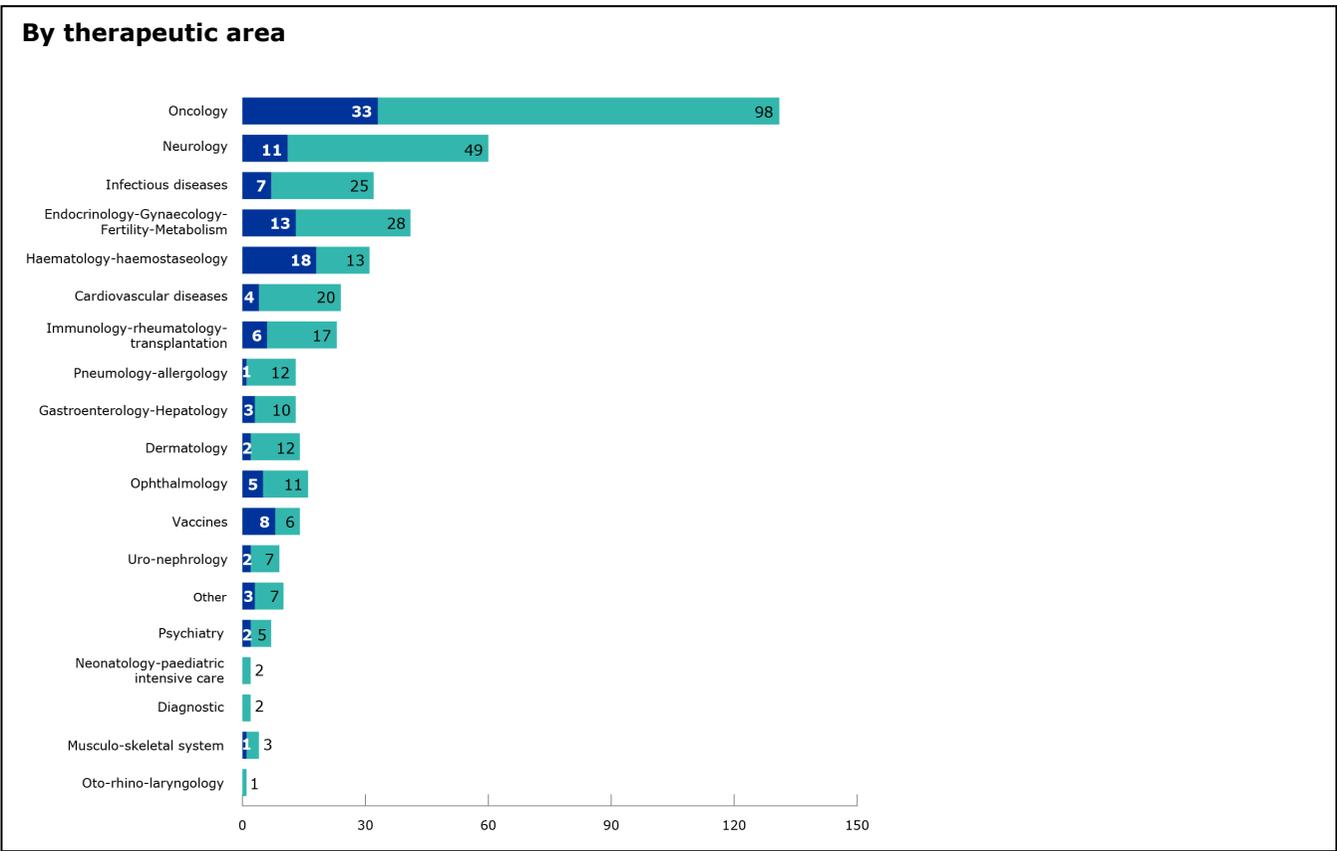
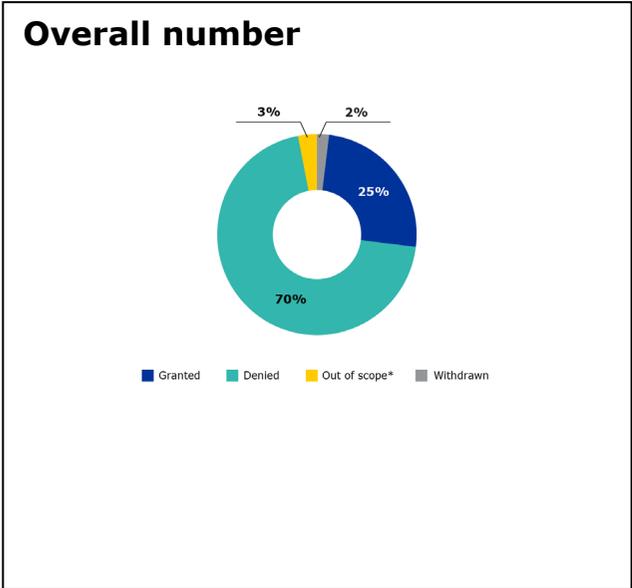
Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Immunological Medicinal Product	Infectious Diseases	Prevention of pneumococcal disease	Nonclinical + Clinical exploratory	Other
Chemical Medicinal Product	Neurology	Treatment of narcolepsy with cataplexy	Nonclinical + Clinical exploratory	Other
Chemical Medicinal Product	Neurology	Treatment of Alzheimer's Disease	Nonclinical + Clinical exploratory	SME

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Cumulative overview of PRIME eligibility recommendations adopted by 20 July 2023

■ Granted ■ Denied ■ Out of scope* ■ Withdrawn



* 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.