



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 24-27 February 2020

During its February 2020 meeting, the CHMP reviewed 5 recommendations for eligibility to PRIME: 1 was granted and 4 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
Adenovirus associated viral vector serotype 5 containing the human RPGR gene	Advanced Therapy	Ophthalmology	Treatment of X linked Retinitis Pigmentosa owing to defects in Retinitis Pigmentosa GTPase Regulator	Nonclinical+ Clinical exploratory	Other

* Name of the active substance, INN, common name, chemical name or company code.

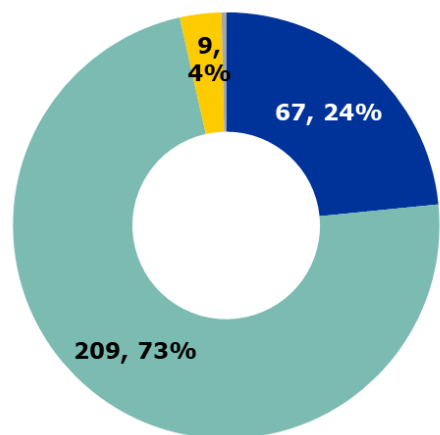
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other types of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical	Cardiovascular diseases	Treatment as an adjunct to diet for the secondary prevention of major adverse cardiac events and congestive heart failure in patients with type 2 diabetes mellitus (T2DM), and recent acute coronary syndrome (ACS) in combination with standard of care including high-intensity statins	Nonclinical+ Clinical exploratory	Other
Chemical	Endocrinology-Gynaecology-Fertility-Metabolism	Treatment of polycystic ovary syndrome in non-obese adolescent girls	Nonclinical+ Clinical exploratory	Academic
Chemical	Endocrinology-Gynaecology-Fertility-Metabolism	Treatment of new-onset type 1 diabetes in patients at risk of imminent loss of the residual β -cell function	Nonclinical+ Clinical exploratory	Other
Chemical	Neurology	Treatment of non-arteritic anterior ischemic optic neuropathy (NAION)	Nonclinical+ Clinical exploratory	Other

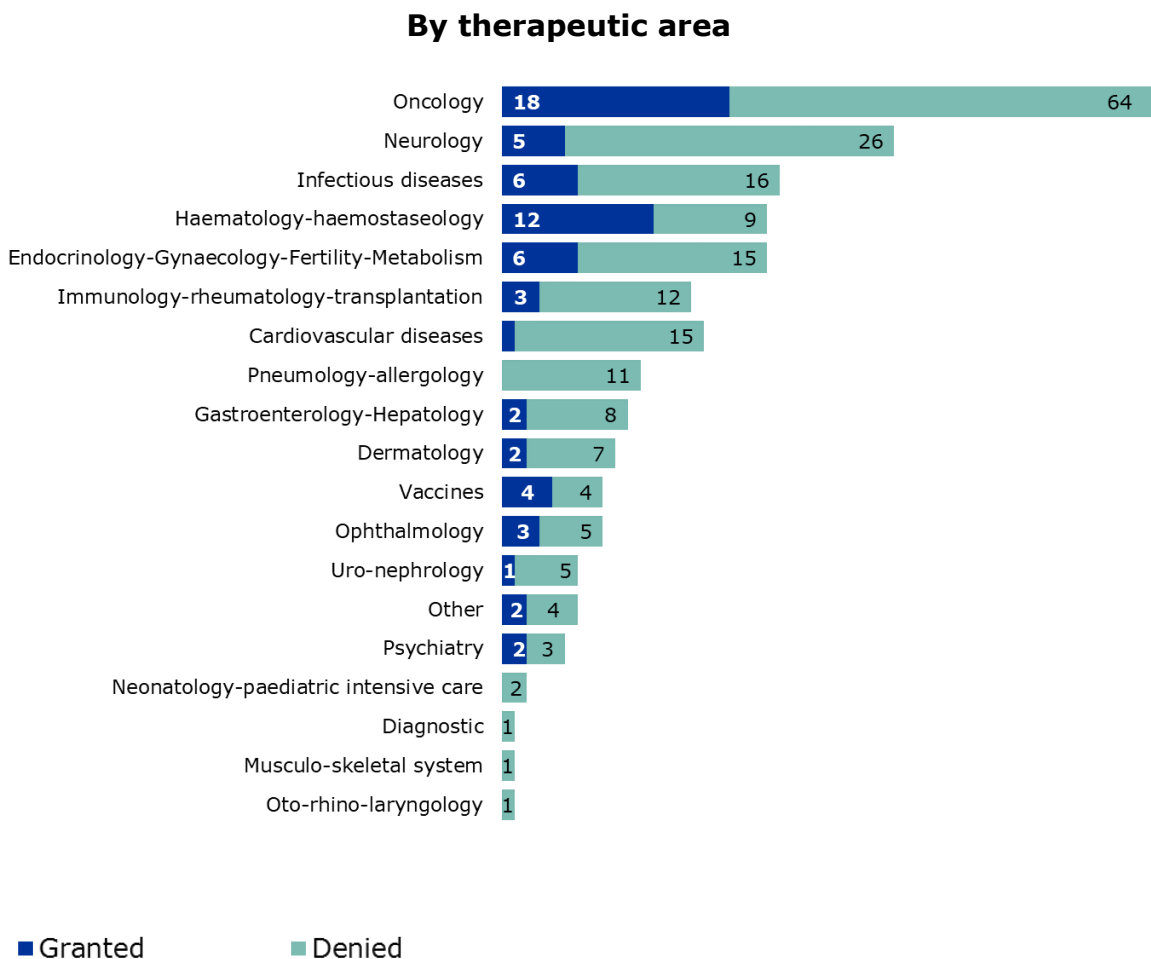
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Cumulative overview of recommendations on PRIME eligibility requests adopted by 24 February 2020



■ Granted ■ Denied ■ Out of scope* ■ Withdrawn

By type of applicant



* 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.