



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 July 2019
EMA/317956/2019
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 22-25 July 2019

During its July 2019 meeting, the CHMP reviewed 2 recommendations for eligibility to PRIME: 1 was granted and 1 was 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
Antisense oligonucleotide complementary to the exonic splicer enhancer sequence at intron 26 of the centrosomal protein 290 pre-mRNA (QR-110)	Chemical	Ophthalmology	Treatment of Leber's congenital amaurosis due to the p.Cys998X mutation in the CEP290 Gene	Nonclinical+ Clinical exploratory	SME

* 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.

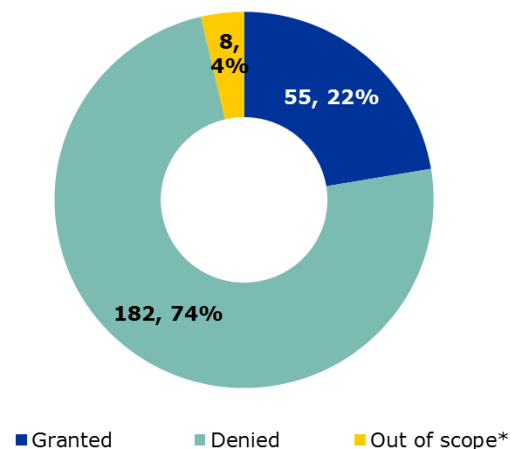
Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Biological	Infectious diseases	Treatment of chronic hepatitis D virus infection	Nonclinical+ Clinical exploratory	SME

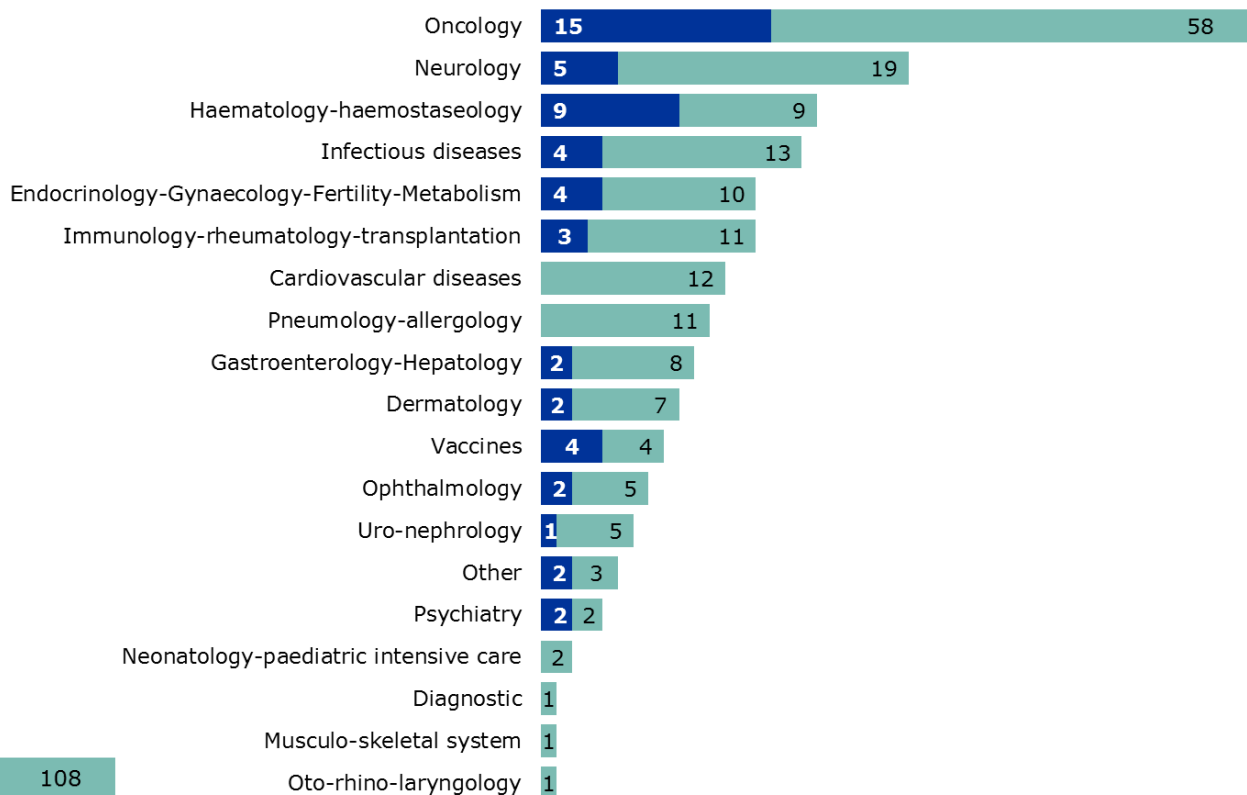
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other type of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

Cumulative overview of recommendations on PRIME eligibility requests adopted by 25 July 2019

N = 246



By therapeutic area



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.