



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 September 2021
EMA/324180/2021
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 13-16 September 2021

During its September 2021 meeting, the CHMP reviewed 5 recommendations for eligibility to PRIME: 1 were granted and 4 were denied. In addition, 1 request was received but not started by EMA as it was deemed outside the scope of the scheme. 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
TAK-994	Chemical Medicinal Product	Neurology	Treatment of narcolepsy with cataplexy	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.

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

Eligibility denied

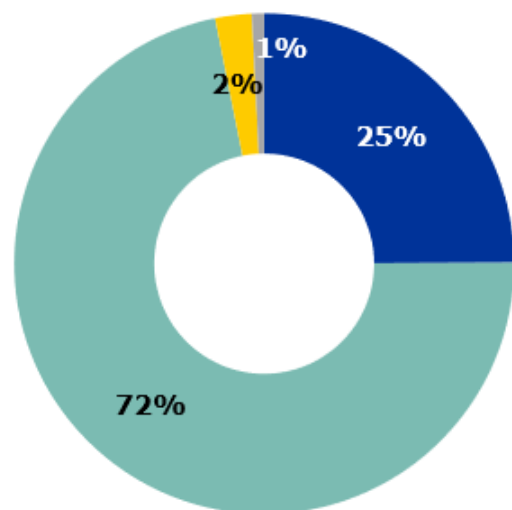
Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Neurology	Treatment of cluster headache	Clinical exploratory	Other
Chemical Medicinal Product	Oncology	Treatment of cutaneous T-cell lymphoma (CTCL)	Nonclinical + Clinical exploratory + Confirmatory	SME
Biological Medicinal Product	Neurology	Treatment of early symptomatic Alzheimer's disease	Nonclinical + Clinical exploratory	Other
Chemical Medicinal Product	Ophthalmology	Treatment of retinitis pigmentosa due to mutations in exon 13 of the USH2A gene	Nonclinical + Clinical exploratory + Literature references	SME

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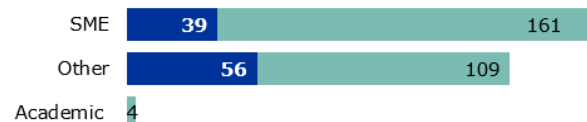
Cumulative overview of PRIME eligibility recommendations adopted by 16 September 2021

■ Granted ■ Denied ■ Out of scope* ■ Withdrawn

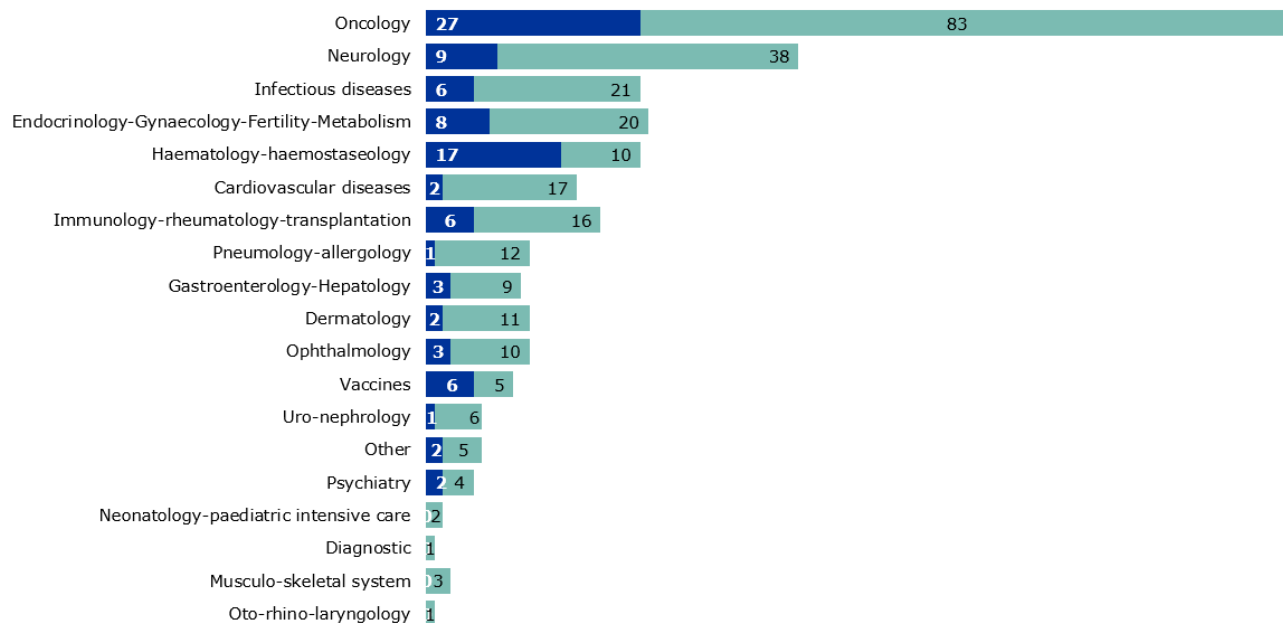
Overall number



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.