



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 June 2021
EMA/235088/2021
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 21-24 June 2021

During its June 2021 meeting, the CHMP reviewed 4 recommendations for eligibility to PRIME: 4 were denied. The individual outcomes adopted this month are listed below.

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Eligibility denied

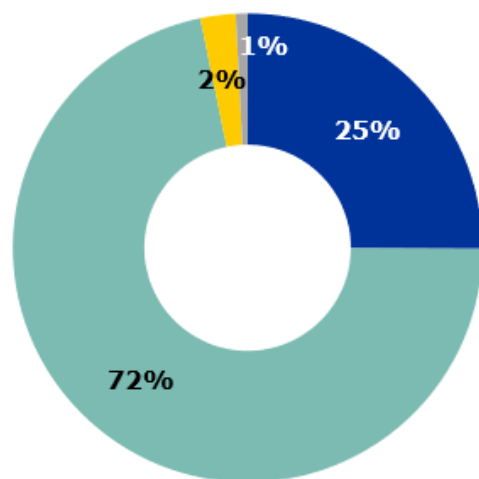
Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Infectious Diseases	Treatment of chronic hepatitis B	Nonclinical + Clinical exploratory	Other
Biological Medicinal Product	Cardiovascular Diseases	Treatment of acute ischemic stroke	Nonclinical + Tolerability first in man	SME
Chemical Medicinal Product	Oncology	Treatment of myelofibrosis	Nonclinical + Clinical exploratory	Other
Chemical Medicinal Product	Neurology	Treatment of acute agitation associated with dementia	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.

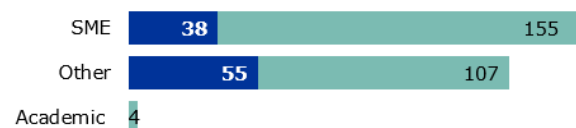
Cumulative overview of PRIME eligibility recommendations adopted by 24 June 2021

■ Granted ■ Denied ■ Out of scope* ■ Withdrawn

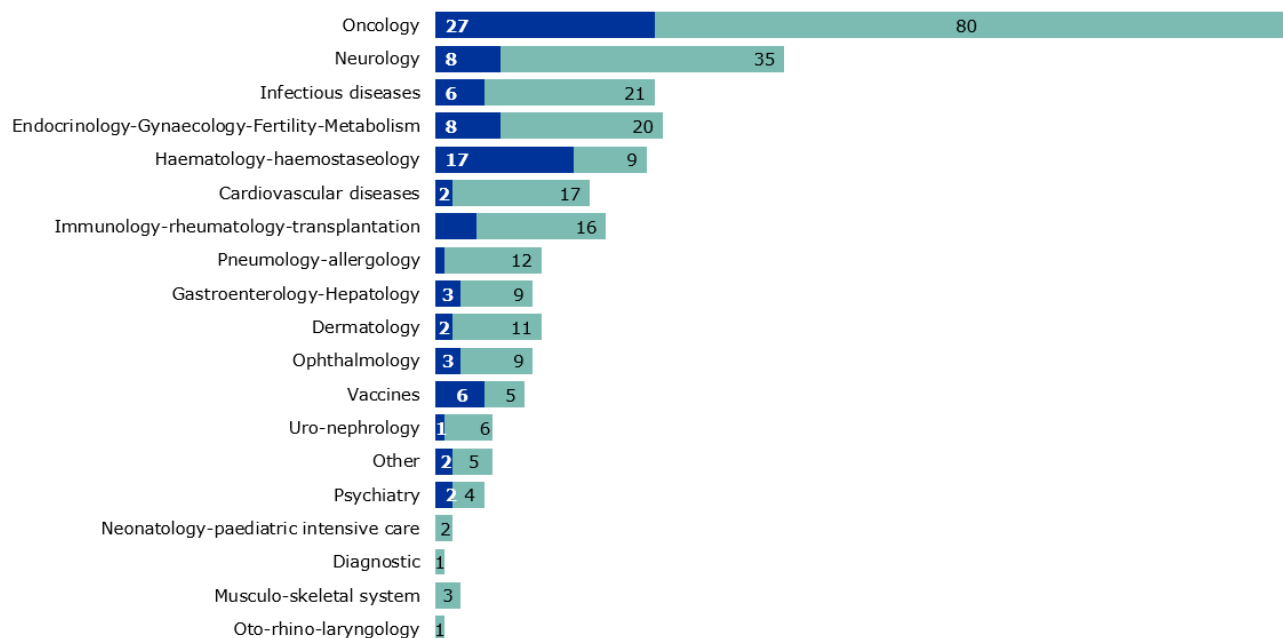
Overall number



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.