



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 June 2022
EMA/67994/2022
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 20-23 June 2022

During its June 2022 meeting, the CHMP reviewed 8 recommendations for eligibility to PRIME: 3 were granted and 4 were denied. In addition, 1 request was withdrawn. 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
ADVM-022	Advanced Therapy Medicinal Product	Ophthalmology	Treatment of neovascular(wet) age-related macular degeneration	Nonclinical + Clinical exploratory	SME
BNT211	Advanced Therapy Medicinal Product	Oncology	Treatment of testicular germ cell tumours	Nonclinical + Clinical exploratory	Other
MVA-BN-RSV	Immunological Medicinal Product	Vaccine	Active immunization for the prevention of lower respiratory tract disease (LRTD) caused by Respiratory Syncytial Virus (RSV) in adults ≥ 60 years of age	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

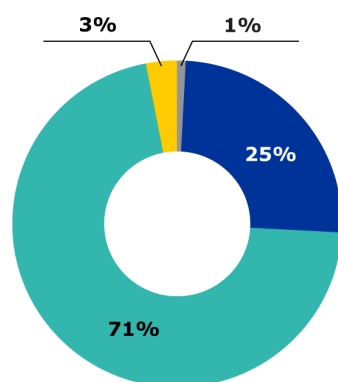
Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy Medicinal Product	Oncology	Treatment of metastatic melanoma	Nonclinical + Clinical exploratory	Academic Sector
Advanced Therapy Medicinal Product	Oncology	Treatment of relapsed/refractory large B cell lymphoma	Nonclinical + Clinical exploratory	Other
Biological Medicinal Product	Endocrinology-Gynaecology-Fertility-Metabolism	Treatment of classical homocystinuria in paediatric and adult patients	Nonclinical + Clinical exploratory	Other
Biological Medicinal Product	Immunology-rheumatology-transplantation	Prevention of graft rejection following solid organ transplantation	Nonclinical + Clinical exploratory	SME

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Cumulative overview of PRIME eligibility recommendations adopted by 23 June 2022

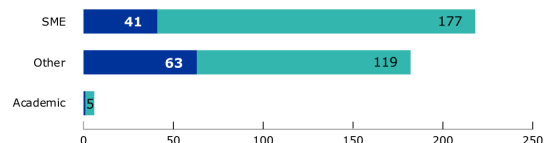
■ Granted ■ Denied ■ Out of scope* ■ Withdrawn

Overall number

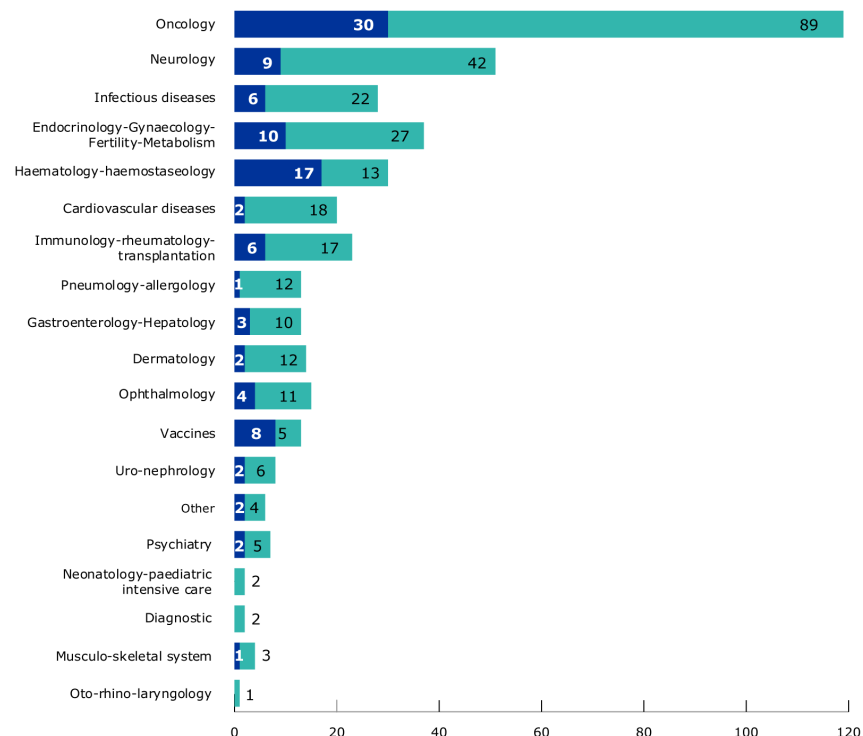


■ Granted ■ Denied ■ Out of scope* ■ Withdrawn

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.