



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 June 2023
EMA/898122/2022
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 22-25 May 2023

During its May 2023 meeting, the CHMP reviewed 7 recommendations for eligibility to PRIME: 2 were granted and 5 were 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
ABSK021	Chemical Medicinal Product	Oncology	Treatment of tenosynovial giant cell tumor (TGCT)	Nonclinical + Clinical exploratory	Other
RP-A501	Advanced Therapy Medicinal Product	Cardiovascular Diseases	Treatment of Danon disease	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

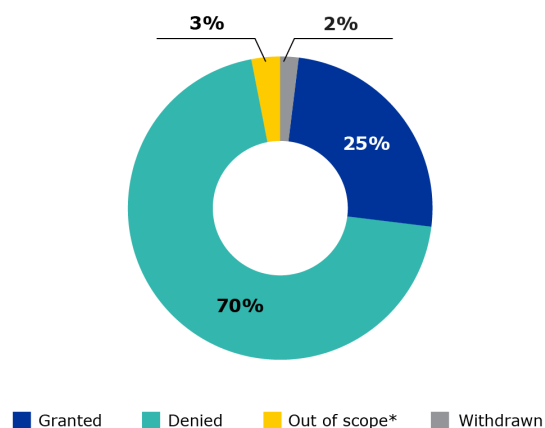
Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Biological Medicinal Product	Critical care	Treatment of Sepsis	Nonclinical + Clinical exploratory	SME
Biological Medicinal Product	Infectious Diseases	Adjunct treatment of <i>S. aureus</i> pneumonia	Nonclinical + Clinical exploratory	SME
Advanced Therapy Medicinal Product	Oncology	Treatment of B Cell Lymphoma	Nonclinical + Clinical exploratory	SME
Biological Medicinal Product	Oncology	Treatment of primary indeterminate lesions and small choroidal melanoma	Nonclinical + Clinical exploratory	SME
Biological Medicinal Product	Vaccines	Prevention of LRTI caused by RSV or hMPV in infants and children aged 6 weeks to < 5 years, and children and adolescents from 5 years to < 18 years of age with certain chronic conditions	Nonclinical + Clinical exploratory	Other

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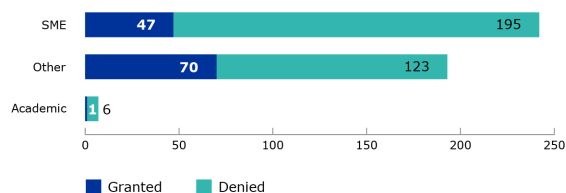
Cumulative overview of PRIME eligibility recommendations adopted by 25 May 2023

■ Granted ■ Denied ■ Out of scope* ■ Withdrawn

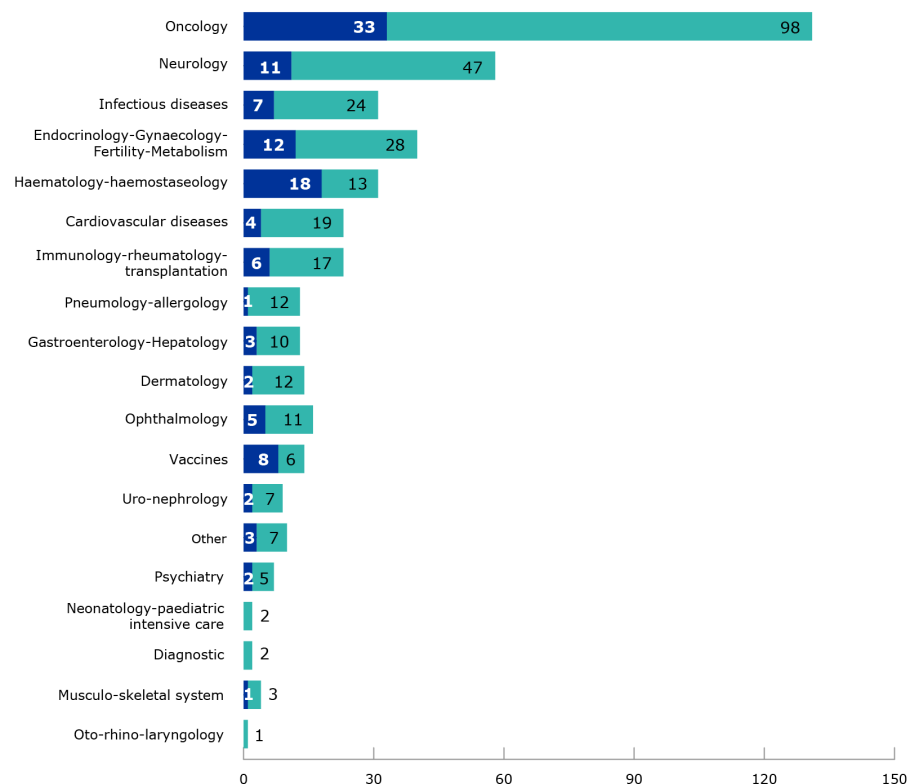
Overall number



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.