



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 July 2021
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Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 19-22 July 2021

During its July 2021 meeting, the CHMP reviewed 5 recommendations for eligibility to PRIME: 1 was granted and 4 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
MB-107	Advanced Therapy Medicinal Product	Immunology-rheumatology-transplantation	Treatment of X-linked severe combined immunodeficiency (XSCID) in newly diagnosed infants	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.

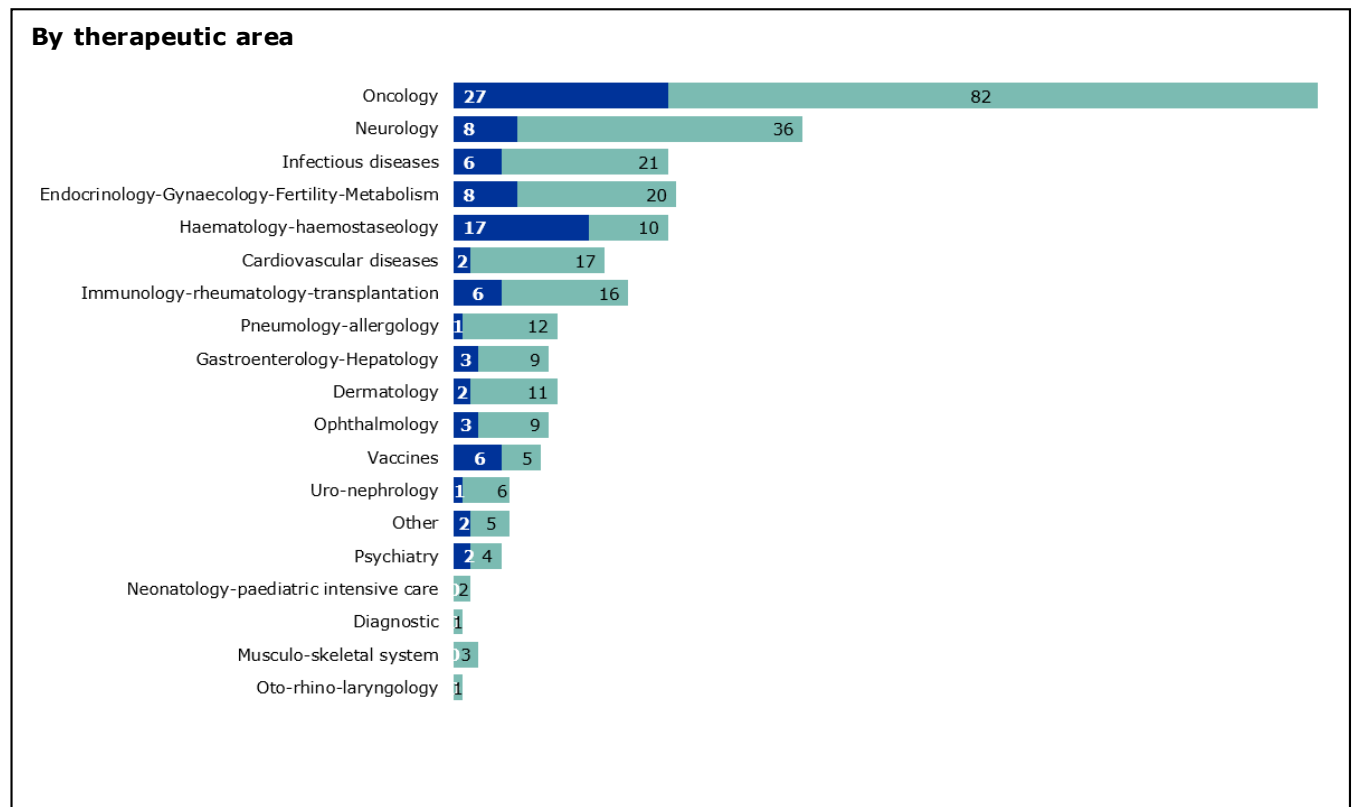
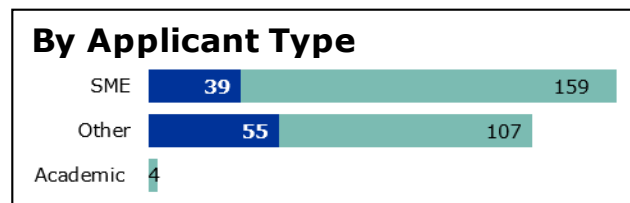
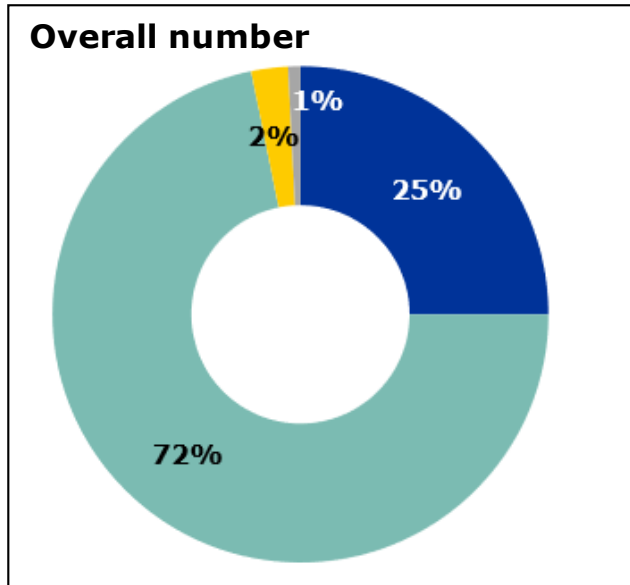
Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Oncology	Treatment of Merkel Cell Carcinoma	Nonclinical + Clinical exploratory	SME
Advanced Therapy Medicinal Product	Oncology	Treatment of relapsed and refractory Multiple Myeloma	Nonclinical + Clinical exploratory	SME
Chemical Medicinal Product	Haematology - Hemostaseology	Treatment of essential thrombocythaemia	Nonclinical + Clinical exploratory	SME
Chemical Medicinal Product	Neurology	Treatment of dementia with Lewy Bodies	Nonclinical + Clinical exploratory	SME

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Cumulative overview of PRIME eligibility recommendations adopted by 22 July 2021

■ Granted ■ Denied ■ Out of scope* ■ Withdrawn



* 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.