



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 June 2019
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Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 27-29 May 2019

During its May 2019 meeting, the CHMP reviewed 5 recommendations for eligibility to PRIME: 1 was 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
Allogeneic EBV-specific Cytotoxic T Lymphocytes	Advanced Therapy	Oncology	Treatment of rituximab refractory Post-Transplant Lymphoproliferative Disorder (PTLD)	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.

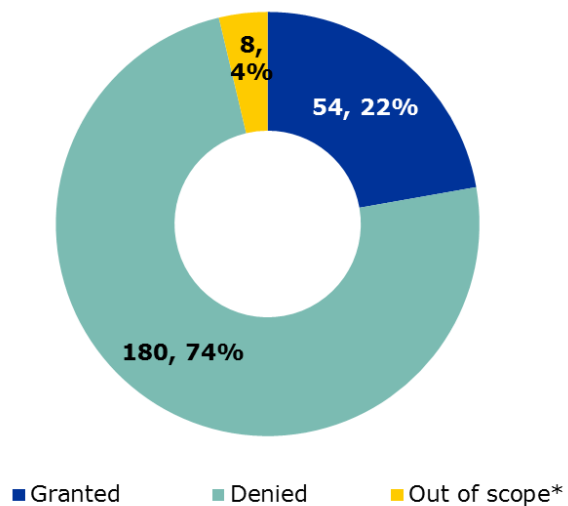
Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Biological	Immunology-Rheumatology-Transplantation	Treatment of Steroid Refractory Gastro-Intestinal predominant acute Graft versus Host Disease (SR-GI-aGvHD)	Nonclinical + Clinical exploratory	SME
Chemical	Cardiovascular diseases	Reduction/prevention of myocardial necrosis following percutaneous coronary intervention for an acute ST-elevation myocardial infarction	Nonclinical + Tolerability first in man	SME
Advanced Therapy	Neurology	Treatment of motor deficits arising from traumatic brain injury	Nonclinical + Clinical exploratory	Other
Chemical	Neurology	Treatment of ataxia telangiectasia	Nonclinical + Clinical exploratory	Other

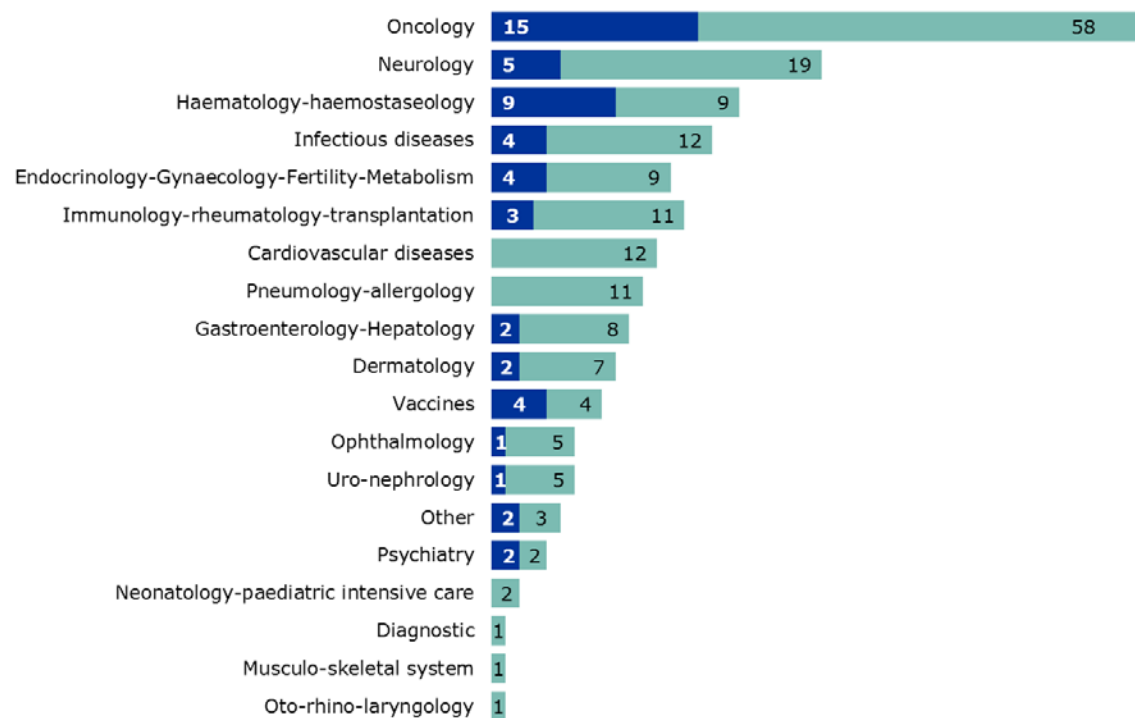
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Cumulative overview of recommendations on PRIME eligibility requests adopted by 29 May 2019

N = 243



By therapeutic area



By type of applicant



* 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.