



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 August 2018
EMA/387634/2018
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 23-26 July 2018

During its July 2018 meeting, the CHMP reviewed 5 recommendations for eligibility to PRIME: 2 were granted and 3 were denied. The individual outcomes adopted this month are listed below.

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Send a question via our website www.ema.europa.eu/contact

An agency of the European Union



Eligibility granted

Name*	Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chimeric 2'-O-(2-methoxyethyl) modified oligonucleotide targeted to huntingtin RNA (RO7234292)	Chemical	Neurology	Treatment of Huntington's Disease	Nonclinical + Clinical exploratory	Other
Autologous haematopoietic stem cells transduced with lentiviral vector Lenti-D encoding the human ATP-binding cassette, sub-family D (ALD), member 1 (ABCD1) from cDNA	Advanced therapy	Neurology	Treatment of cerebral adrenoleukodystrophy	Nonclinical + Clinical exploratory	Other

* Name of the active substance, INN, common name, chemical name or company code.

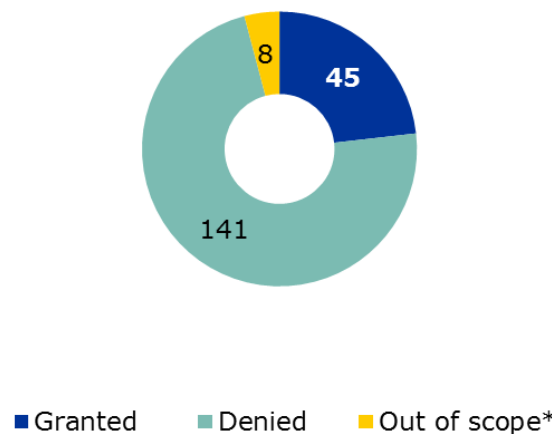
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other types of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

Eligibility denied

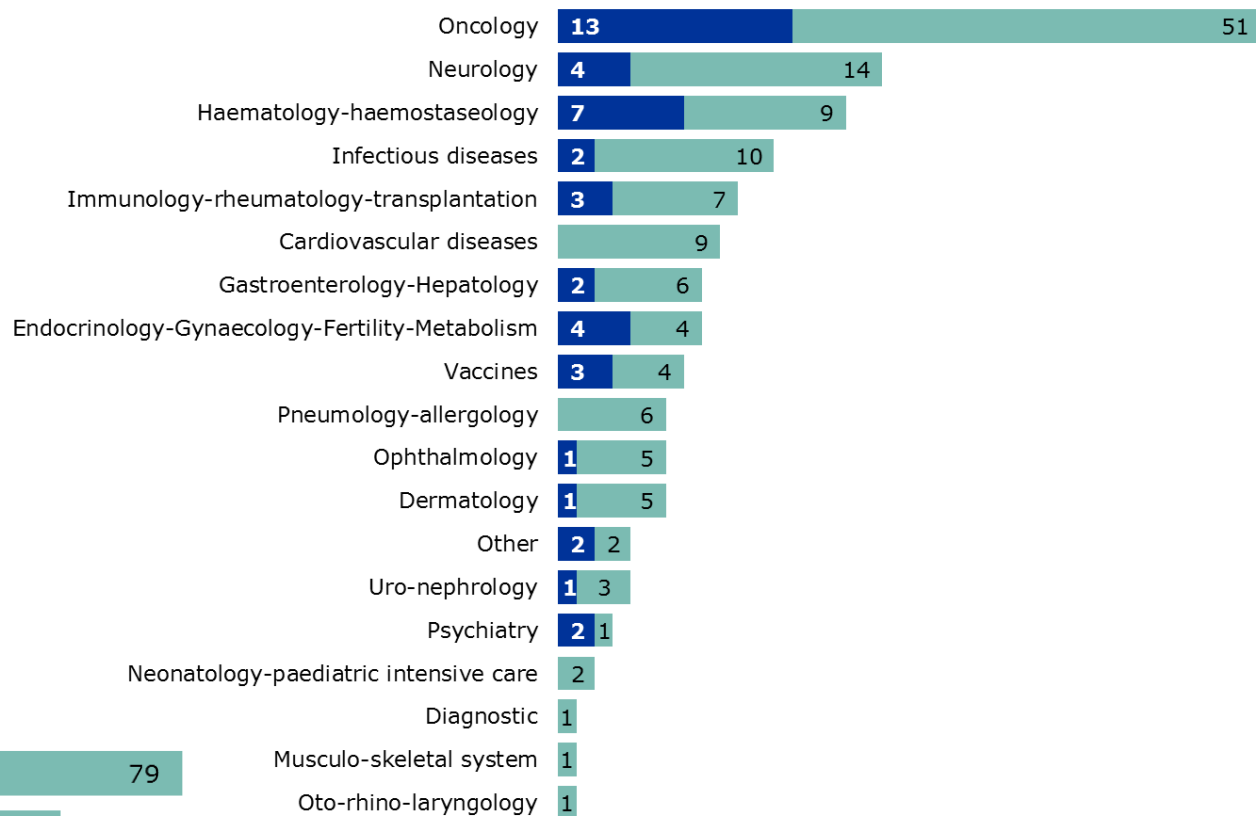
Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced therapy	Cardiovascular diseases	Treatment of refractory angina	Nonclinical + Clinical exploratory	SME
Chemical	Oncology	Treatment of patients with relapsed/refractory acute myeloid leukaemia	Nonclinical + Clinical exploratory	SME
Chemical	Neurology	Treatment of patients with Early Alzheimer's Disease (AD), defined patients with either Mild Cognitive Impairment due to AD or mild Dementia due to AD	Nonclinical + Clinical exploratory	SME

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Cumulative overview of recommendations on PRIME eligibility requests adopted by 26 July 2018



By therapeutic area



By type of applicant



■ Granted ■ Denied

* 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.