



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 February 2017
EMA/668882/2016
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 23-26 January 2017

During its January 2017 meeting, the CHMP reviewed 10 recommendations for eligibility to PRIME: 2 were granted and 8 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
Adeno-associated viral vector serotype 9 containing the human SMN gene (AVXS-101)	Advanced therapy	Neurology	Treatment of paediatric patients diagnosed with spinal muscular atrophy Type 1	Nonclinical + Clinical exploratory	SME
Adeno-associated viral vector serotype 5 containing a B-domain deleted variant of human coagulation factor VIII gene (BMN 270)	Advanced therapy	Haematology - Hemostaseology	Treatment of haemophilia A	Nonclinical + Clinical exploratory	Other

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

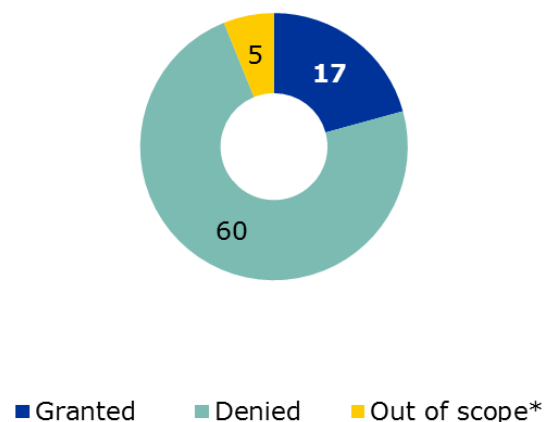
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other types of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical	Oncology	Treatment of hepatocellular carcinoma	Nonclinical + Clinical exploratory	SME
Chemical	Endocrinology-Gynaecology-Fertility-Metabolism	Treatment of Alström Syndrome	Nonclinical + Clinical exploratory	Other
Biological	Dermatology	Treatment of moderate to severe atopic dermatitis	Nonclinical + Clinical exploratory	Other
Advanced Therapy	Cardiovascular Diseases	Treatment of ischaemic stroke	Nonclinical + Clinical exploratory	SME
Chemical	Oncology	Treatment of oral mucositis in head and neck cancer patients receiving chemoradiation therapy	Nonclinical + Clinical exploratory	SME
Advanced Therapy	Haematology-haemostaseology	Treatment of cytomegalovirus-associated viremia or disease after transplant	Nonclinical + Clinical exploratory	SME
Biological	Cardiovascular Diseases	Prevention of arteriovenous access dysfunction in haemodialysis patients	Nonclinical + Clinical exploratory	SME
Chemical	Infectious diseases	Treatment of cystic fibrosis exacerbations	Nonclinical + Clinical exploratory	SME

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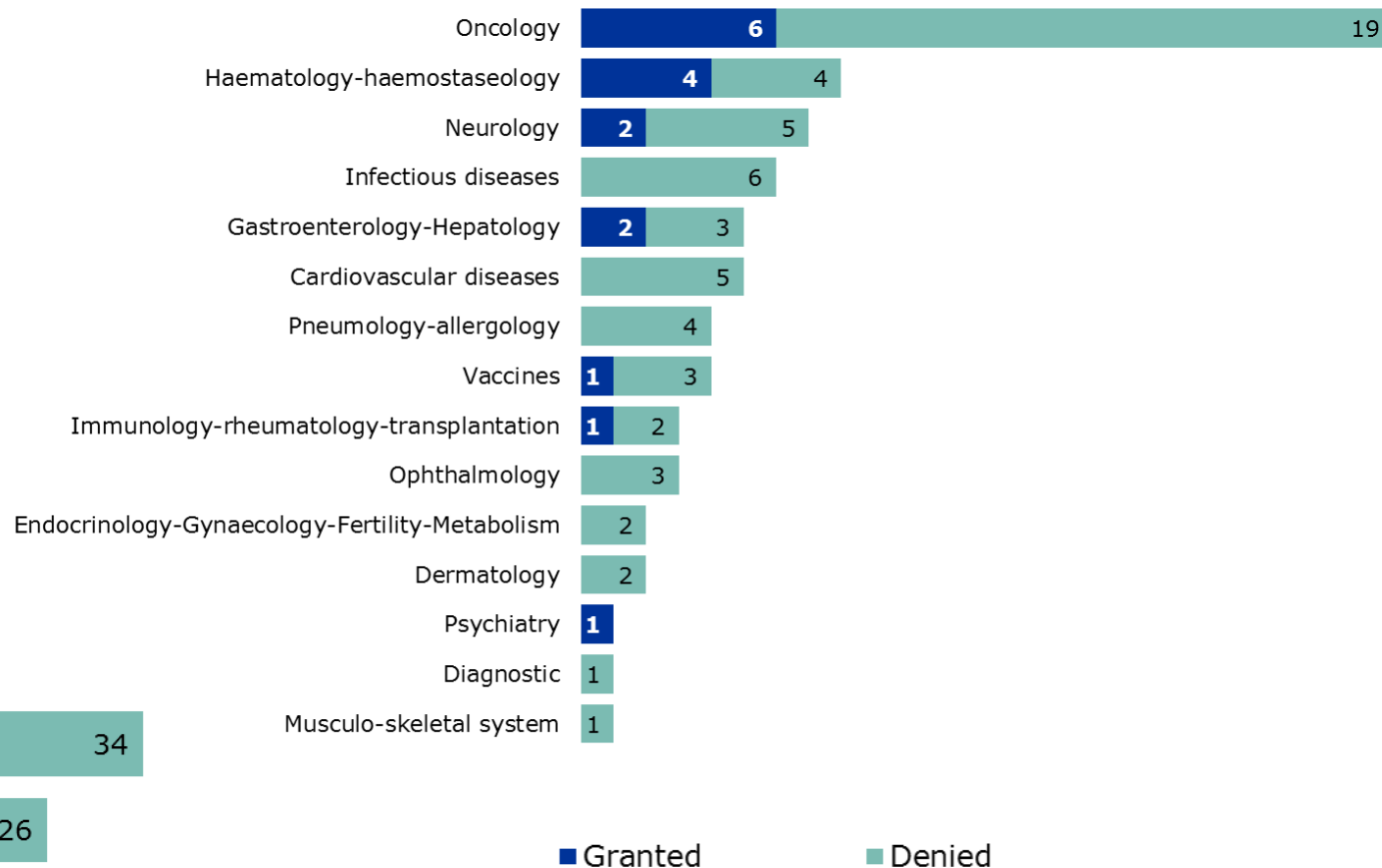
Cumulative overview of recommendations on PRIME eligibility requests adopted by 26 January 2017



By type of applicant



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.