1 March 2017
EMA/668803/2016
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 20-23 February 2017

During its February 2017 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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Eligibility granted

Name*	Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Adeno-associated viral vector containing factor IX gene variant (PF-06838435/SPK-9001)	Advanced therapy	Haematology - Hemostaseology	Treatment of haemophilia B	Nonclinical + Clinical exploratory	Other
Givosiran	Chemical	Endocrinology-Gynaecology-Fertility-Metabolism	Prevention of acute attacks of hepatic porphyria	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
Radiopharmaceutical	Oncology	Conditioning treatment for haematopoietic stem cell transplantationin patients with Acute myeloid leukaemia	Nonclinical + Clinical exploratory	SME
Immunological	Infectious Diseases	Prevention of postoperative invasive disease caused by Staphylococcus aureus	Nonclinical + Clinical exploratory	Other
Chemical	Immunology-Rheumatology-Transplantation	Treatment of antiphospholipid syndrome	Nonclinical + Clinical exploratory	Academic

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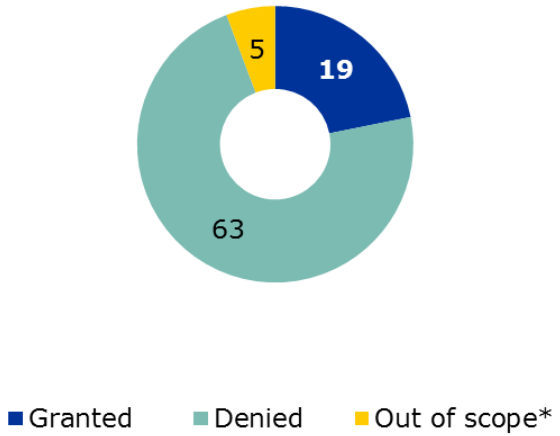
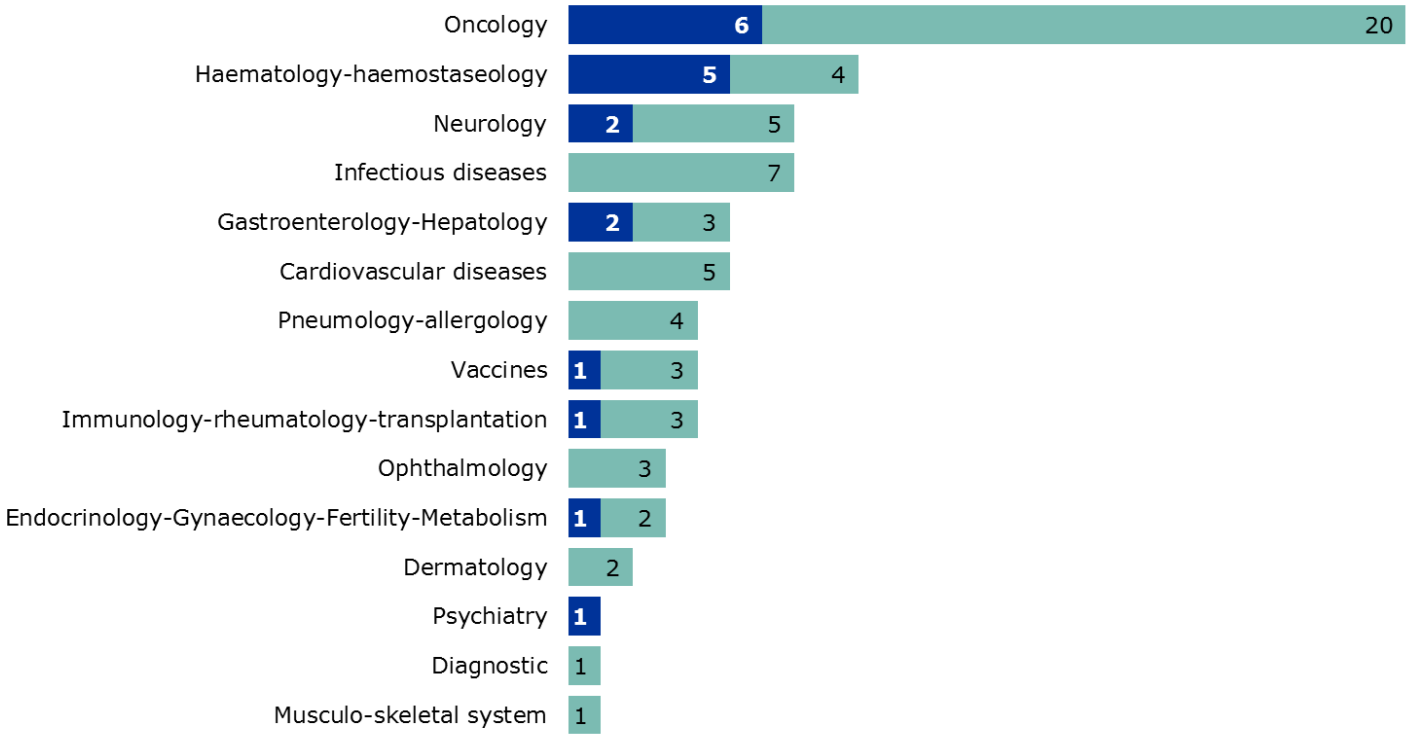
Cumulative overview of recommendations on PRIME eligibility requests adopted by 23 February 2017



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.