



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 June 2017
EMA/668842/2016
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 19-22 June

During its June 2017 meeting, the CHMP reviewed 10 recommendations for eligibility to PRIME: 2 were granted and 8 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
2-hydroxy-6-((2-(1-isopropyl-1H-pyrazol-5-yl)pyridin-3-yl)methoxy)benzaldehyde (GBT440)	Chemical	Haematology - Hemostaseology	Treatment of Sickle Cell Disease	Nonclinical + Clinical exploratory	Other
Polatuzumab vedotin	Biological	Oncology	Treatment of relapsed and refractory patients with diffuse large B cell lymphoma	Clinical exploratory	Other

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

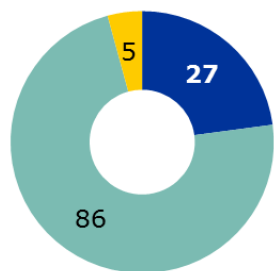
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other types of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical	Gastroenterology-Hepatology	Treatment of Diabetic Gastroparesis	Nonclinical+ Clinical exploratory	Other
Biological	Oncology	Treatment of acute myeloid leukaemia (AML)	Non-clinical + Clinical exploratory	Other
Chemical	Neurology	Treatment of autism spectrum disorder	Clinical exploratory	Other
Immunological	Neurology	Treatment of myasthenia gravis	Non-clinical + Clinical exploratory	SME
Biological	Oncology	Treatment of soft tissue sarcoma	Nonclinical + Clinical exploratory	Other
Biological	Oncology	Treatment of mesothelioma	Nonclinical + Clinical exploratory	SME
Biological	Infectious Diseases	Treatment of HIV infection	Nonclinical + Clinical exploratory	SME
Advanced Therapy	Dermatology	Treatment of partial deep dermal and full thickness burns	Nonclinical + Clinical exploratory	SME

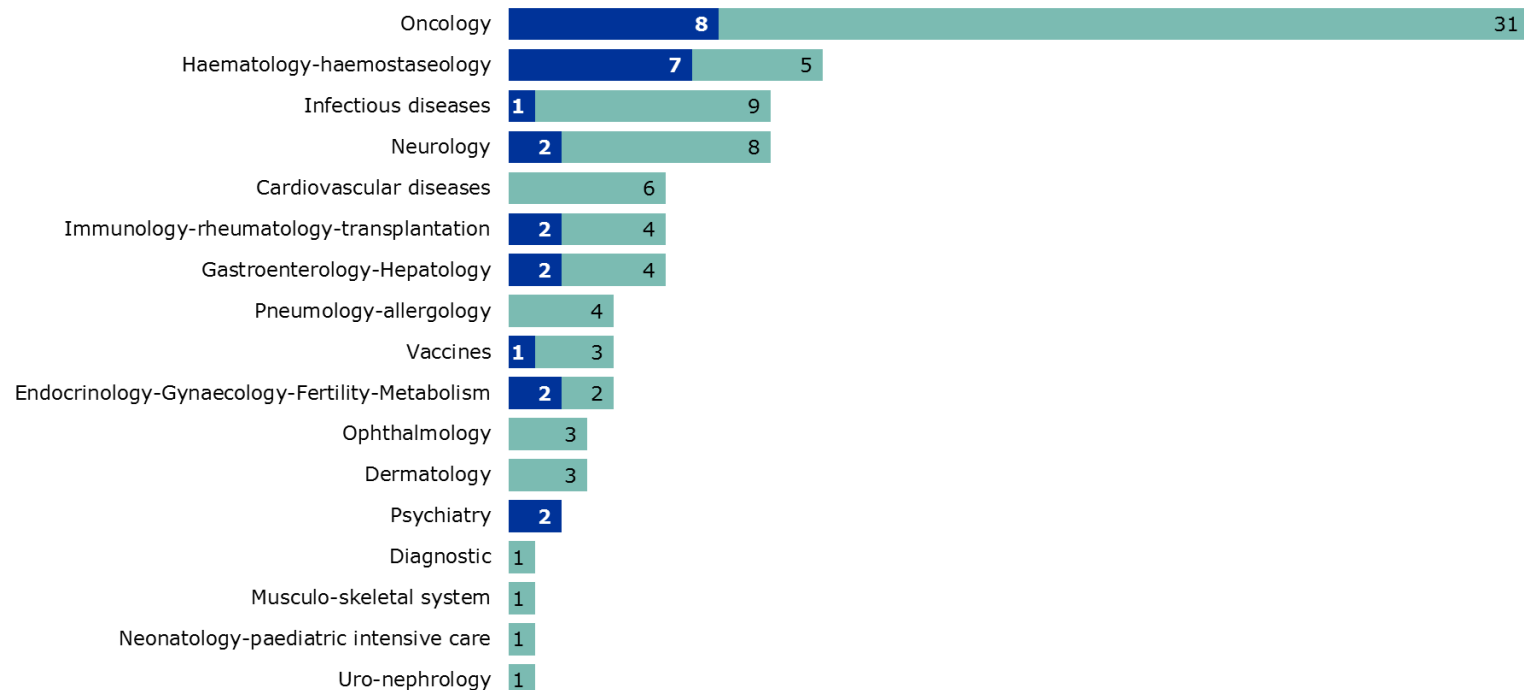
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other type of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

Cumulative overview of recommendations on PRIME eligibility requests adopted by 22 June 2017

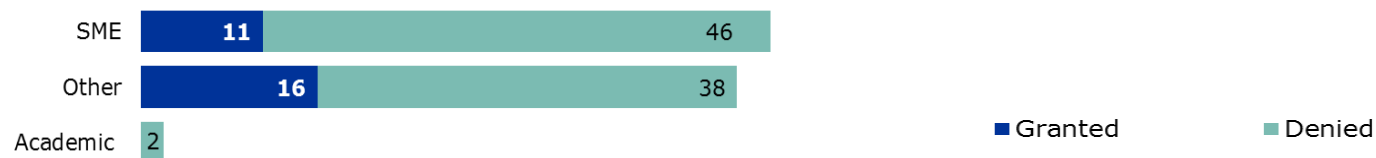


■ Granted ■ Denied ■ Out of scope*

By therapeutic area



By type of applicant



* One eligible product has subsequently been withdrawn from the scheme at the applicant's request
 Out of scope 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.