



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 7-10 November 2016

During its November 2016 meeting, the CHMP reviewed 7 recommendations for eligibility to PRIME: 1 was granted and 6 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

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Eligibility granted

Name*	Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Allopregnanolone (SAGE-547)	Chemical	Psychiatry	Treatment of Postpartum depression	Nonclinical + Clinical exploratory	Other

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

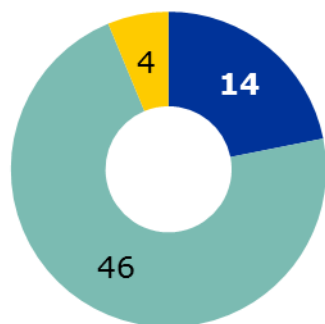
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other types of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced therapy	Oncology	Treatment of mesothelioma	Nonclinical + Clinical exploratory	SME
Chemical	Gastroenterology- Hepatology	Treatment of patients with non-alcoholic steatohepatitis	Nonclinical + Clinical exploratory	SME
Chemical	Neurology	Treatment of tics associated with Tourette syndrome	Nonclinical + Clinical exploratory	Other
Chemical	Dermatology	Treatment of systemic sclerosis	Nonclinical + Tolerability first in man	SME
Advanced therapy	Cardiovascular Diseases	Treatment of Critical Limb Ischemia in subjects with Diabetes Mellitus	Nonclinical + Clinical exploratory	SME
Advanced therapy	Cardiovascular Diseases	Adjunct therapy for adult heart failure patients undergoing coronary arterial bypass graft (CABG)	Nonclinical + Clinical exploratory	SME

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Cumulative overview of recommendations on PRIME eligibility requests received until 21 September 2016

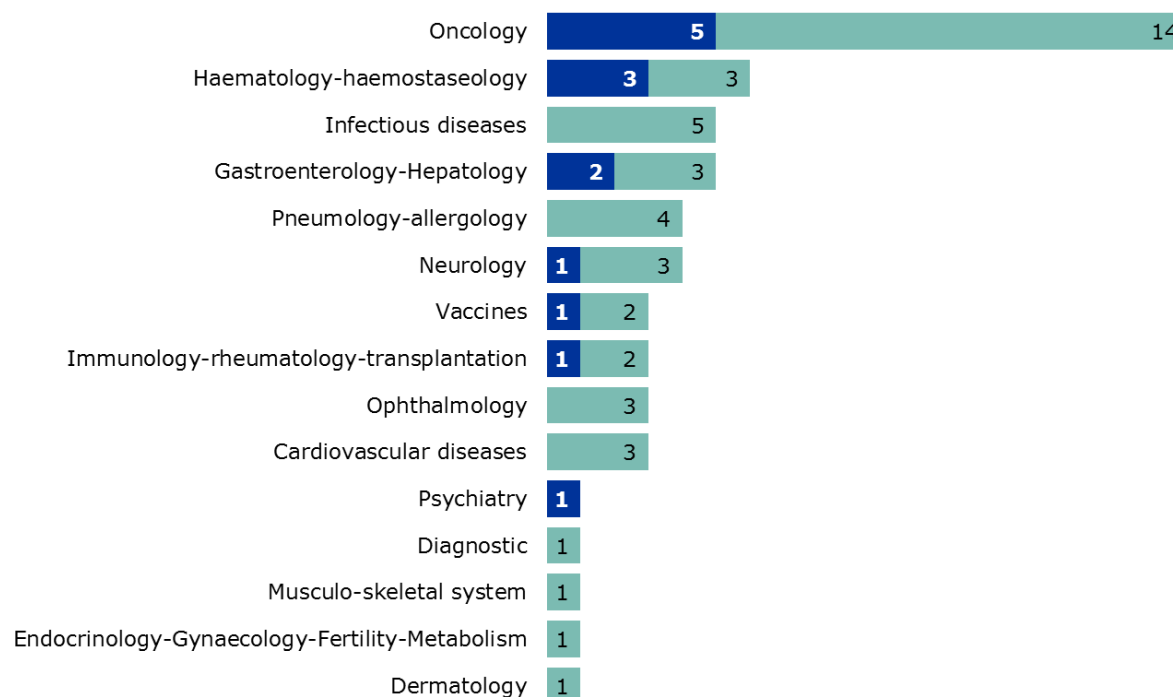


■ Granted ■ Denied ■ Out of scope*

By type of applicant



By therapeutic area



■ 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.