



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 December 2016
EMA/668748/2016
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 12-15 December 2016

During its December 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.



Eligibility granted

Name*	Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Autologous CD4+ and CD8+ T cells Expressing a CD19-Specific Chimeric Antigen Receptor (JCAR017)	Advanced therapy	Oncology	Treatment of relapsed / refractory diffuse large B-cell lymphoma (DLBCL)	Nonclinical + Clinical exploratory	Other

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

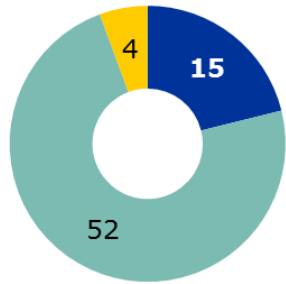
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other types of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical	Oncology	Treatment of leptomeningeal carcinomatosis	Nonclinical + Clinical exploratory	Other
Immunological	Oncology	Treatment of Malignant Pleural Mesothelioma	Nonclinical + Clinical exploratory	SME
Radiopharmaceutical	Oncology	Treatment of paediatric neuroblastoma patients	Nonclinical + Clinical exploratory	Other
Chemical	Neurology	Treatment of Spinal Muscular Atrophy	Nonclinical + Clinical exploratory	Other
Chemical	Neurology	Treatment of Alzheimer's disease	Nonclinical + Clinical exploratory	Other
Immunological	Vaccines	Prevention of disease caused by dengue virus	Nonclinical + Clinical exploratory	Other

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Cumulative overview of recommendations on PRIME eligibility requests received until 19 October 2016



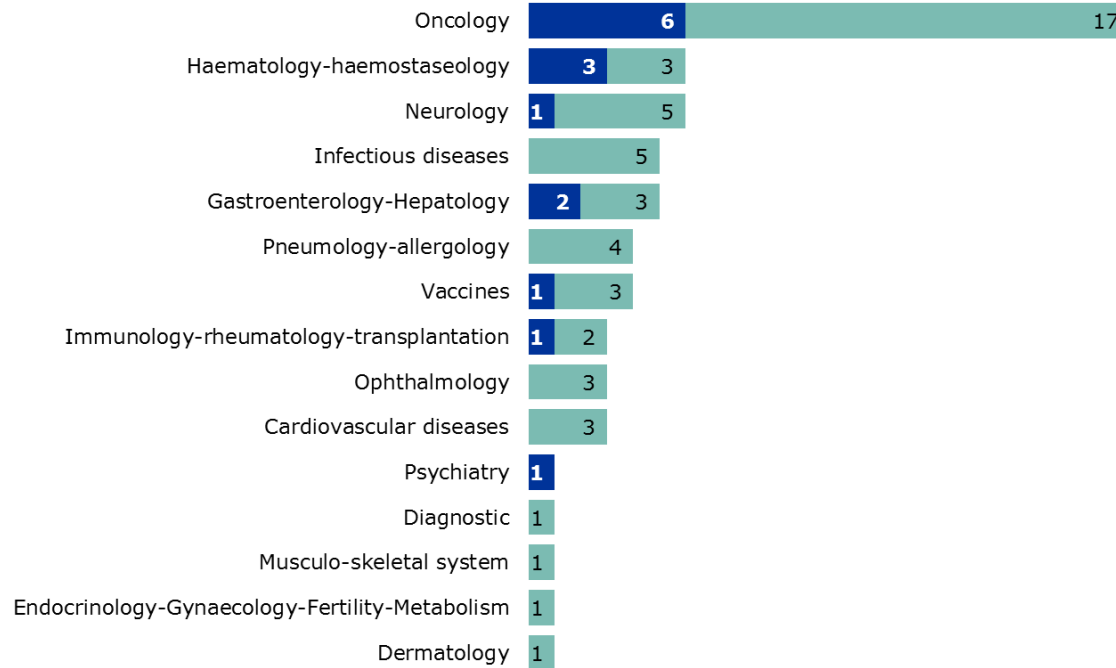
■ Granted ■ Denied ■ Out of scope*

By type of applicant



■ Granted ■ Denied

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.