



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 June 2016
EMA/424592/2016
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 20-23 June 2016

During its June 2016 meeting, the CHMP reviewed 8 recommendations for eligibility to PRIME: 2 were granted and 6 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
CTL019	Advanced Therapy	Oncology	Treatment of paediatric patients with relapsed or refractory B cell acute lymphoblastic leukaemia	Nonclinical + Clinical exploratory	Other
Recombinant Vesicular Stomatitis Virus with Envelope Glycoprotein replaced by Zaire ebolavirus (Kikwit Strain) Glycoprotein	Immunological	Vaccines	Vaccination against Ebola (Zaire strain)	Nonclinical + Clinical exploratory	Other

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

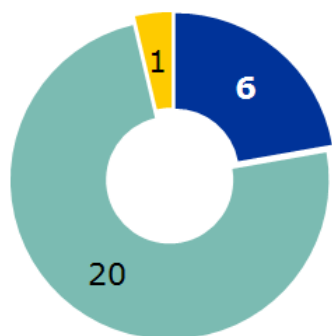
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other types of applicants are those not qualifying or not registered as SME.

Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Biological	Oncology	Treatment of small cell lung cancer	Nonclinical + Clinical exploratory	SME
Chemical	Oncology	Prevention/treatment of oral mucositis in head and neck cancer patients receiving radiation- and/ or chemo-therapy	Nonclinical + Clinical exploratory	SME
Advanced Therapy	Oncology	Treatment of metastatic renal carcinoma (mRCC)	Nonclinical + Clinical exploratory	SME
Chemical	Oncology	Treatment of symptomatic tenosynovial giant cell tumour	Nonclinical + Clinical exploratory	Other
Immunological	Infectious diseases	Treatment of HIV infection	Nonclinical + Clinical exploratory	SME
Chemical	Gastroenterology- Hepatology	Treatment of non-alcoholic steatohepatitis	Nonclinical + Clinical exploratory	Other

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Cumulative overview of recommendations on PRIME eligibility requests received as of 3 May 2016



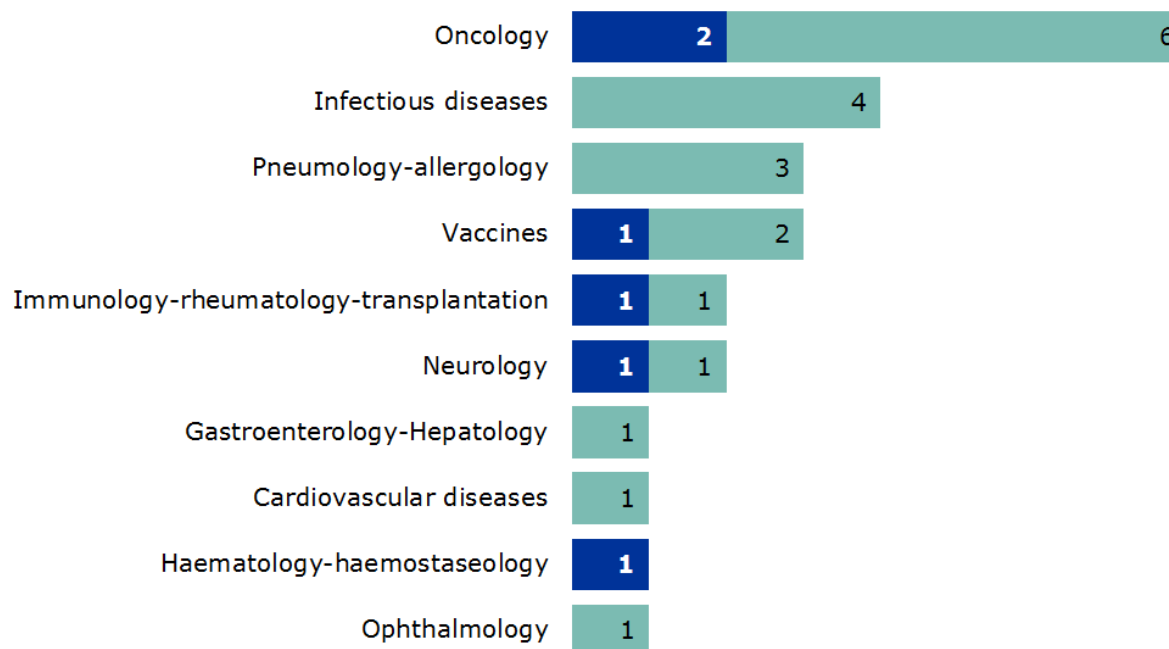
■ Granted ■ Denied ■ Out of scope*

By type of applicant



■ Granted ■ Denied

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.