



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 September 2018
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Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 17-20 September 2018

During its September 2018 meeting, the CHMP reviewed 4 recommendations for eligibility to PRIME: 1 was granted and 3 were denied. The individual outcomes adopted this month are listed below.

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5550

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Eligibility granted

Name*	Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Autologous CD34+ cells transduced with lentiviral vector encoding the human beta globin gene (OTL-300)	Advanced therapy	Haematology-haemostaseology	Treatment of transfusion-dependent β -thalassemia	Nonclinical + Clinical exploratory	SME

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

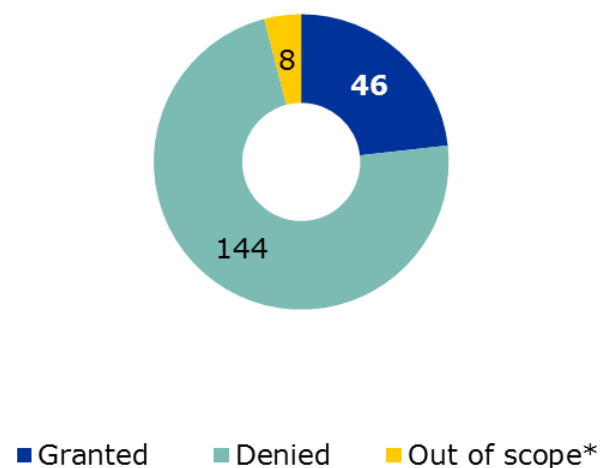
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other types of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Biological	Oncology	Treatment of primary choroidal melanoma	Nonclinical + Clinical exploratory	SME
Chemical	Oncology	Treatment of patients with solid tumours with a specific biomarker fusion-positive or mutant variants	Nonclinical + Clinical exploratory	Other
Biological	Infectious Diseases	Treatment of recurrent Clostridium difficile infection	Nonclinical + Clinical exploratory	SME

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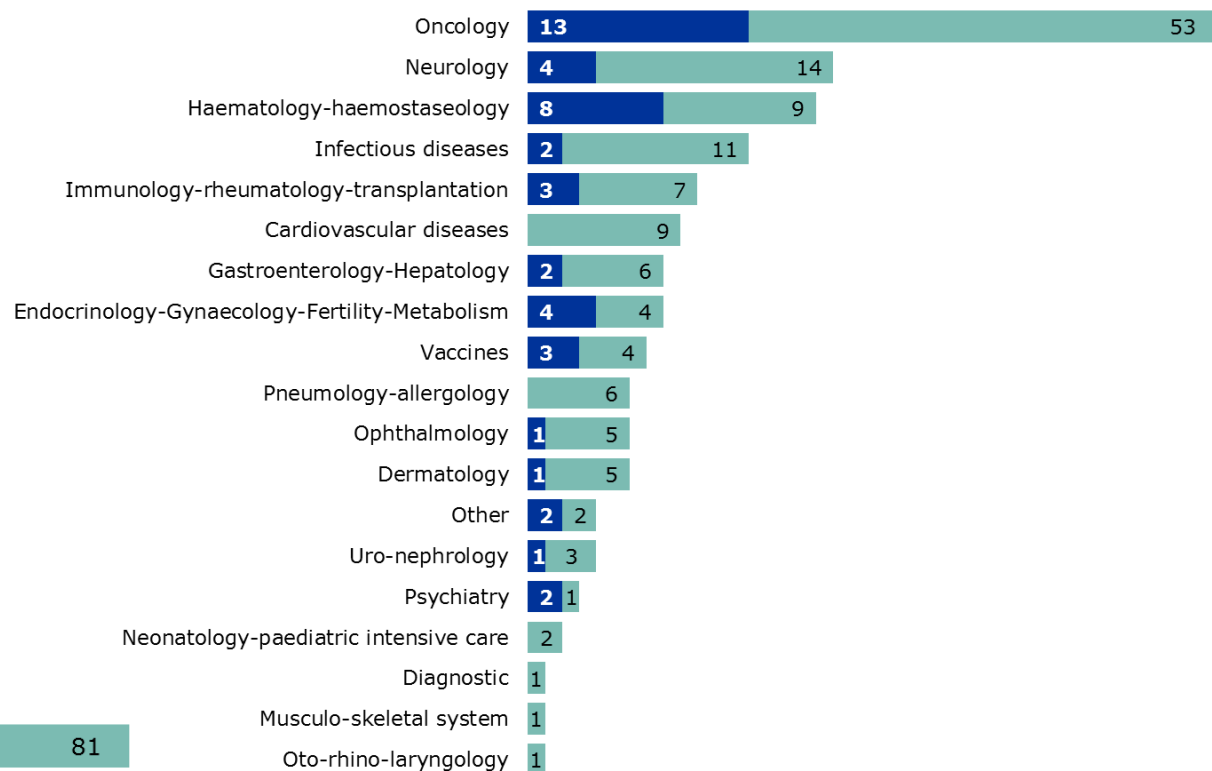
Cumulative overview of recommendations on PRIME eligibility requests adopted by 20 September 2018



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.