3 April 2019
EMA/101446/2019
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 25-28 March 2019

During its March 2019 meeting, the CHMP reviewed 7 recommendations for eligibility to PRIME: 3 were granted and 4 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
Purified Inactivated Zika Virus vaccine (TAK-426)	Immunological	Vaccines	Active immunization for the prevention of disease caused by Zika virus	Nonclinical+ Clinical exploratory	Other
Autologous human T cells genetically modified ex-vivo with a lentiviral vector encoding a chimeric antigen receptor (CAR) for B-cell maturation antigen (BCMA) (JNJ-68284528)	Advanced therapy	Oncology	Treatment of adult patients with relapsed or refractory multiple myeloma, whose prior regimens included a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 antibody and who had disease progression on the last regimen	Nonclinical+ Clinical exploratory	Other
Genetically modified replication-incompetent herpes simplex virus-1 expressing collagen VII (KB103)	Advanced therapy	Dermatology	Treatment of Dystrophic Epidermolysis Bullosa	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	Endocrinology-Gynaecology-Fertility-Metabolism	Treatment of recent onset Type 1 autoimmune diabetes (T1D) patients with evidence of residual β-cell function	Nonclinical+ Clinical exploratory	Other
Chemical	Endocrinology-Gynaecology-Fertility-Metabolism	Increase the chance of an ongoing pregnancy in women undergoing fresh single blastocyst transfer following in vitro fertilization (IVF)	Nonclinical+ Clinical exploratory	SME
Chemical	Gastroenterology-Hepatology	Treatment of primary biliary cholangitis (PBC) in patients with an inadequate response to ursodeoxycholic acid (UDCA) or unable to tolerate UDCA	Nonclinical+ Clinical exploratory	SME
Chemical	Uro-Nephrology	Treatment of chronic kidney disease -associated pruritus in patients on haemodialysis	Nonclinical+ Clinical exploratory	Other

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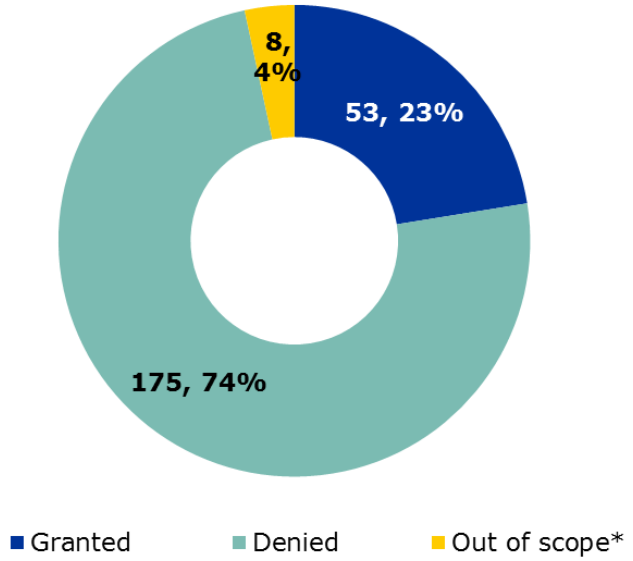
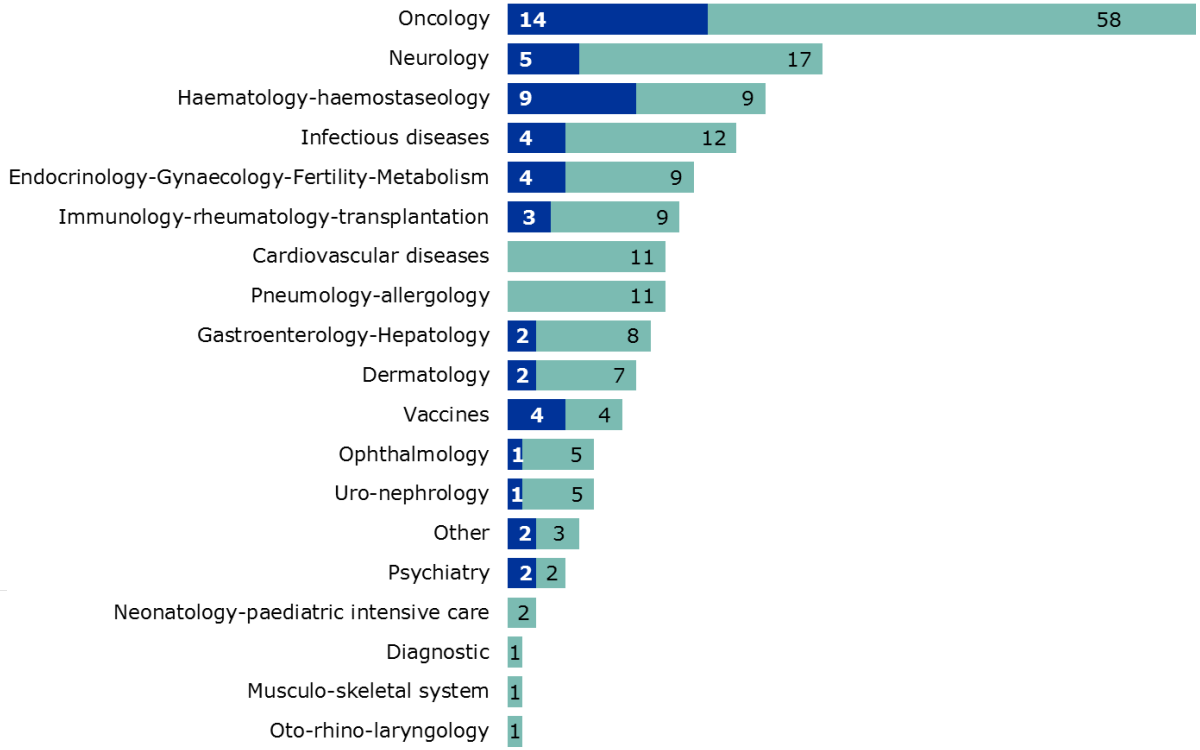
Cumulative overview of recommendations on PRIME eligibility requests adopted by 28 March 2019

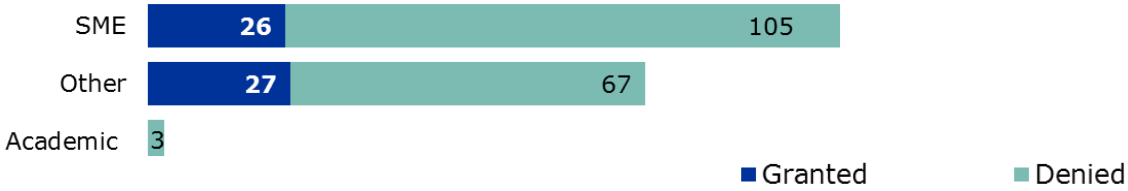
N = 236



By therapeutic area



By type of applicant



* 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.