



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 28-31 May 2018

During its May 2018 meeting, the CHMP reviewed 8 recommendations for eligibility to PRIME: 4 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
Adeno-associated viral vector serotype 8 containing the human MTM1 gene (AT132)	Advanced Therapy	Other	Treatment of X-linked myotubular myopathy	Nonclinical + Clinical exploratory	SME
Allogeneic umbilical cord blood CD34+ cells cultured ex vivo with Notch ligand Delta1 (NLA101)	Advanced Therapy	Immunology- Rheumatology- Transplantation	Treatment in Haematopoietic Stem Cell Transplantation (HSCT)	Nonclinical + Clinical exploratory	SME
Autologous T cells transduced with retroviral vector encoding an anti-CD19 CD28/CD3-zeta chimeric antigen receptor (KTE-C19)	Advanced Therapy	Oncology	Treatment of adult patients with relapsed or refractory mantle cell lymphoma	Nonclinical + Clinical exploratory	Other
MV-CHIK vaccine	Biological	Vaccines	Prevention of Chikungunya fever	Nonclinical + Clinical exploratory	SME

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

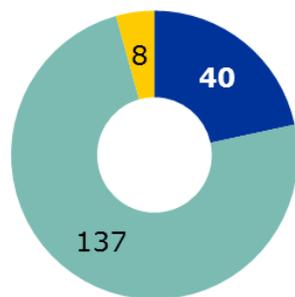
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other types of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy	Oncology	Treatment of adult patients with B-cell precursor relapsed or refractory acute lymphoblastic leukemia	Nonclinical + Clinical exploratory	Other
Chemical	Oncology	Treatment of relapsed / refractory Diffuse Large B-Cell Lymphoma	Nonclinical + Clinical exploratory	Other
Chemical	Dermatology	Treatment of psoriasis	Nonclinical + observational data	SME
Biological	Uro-nephrology	Treatment of Immunoglobulin A nephropathy	Nonclinical + Clinical exploratory	SME

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

Cumulative overview of recommendations on PRIME eligibility requests adopted by 31 May 2018

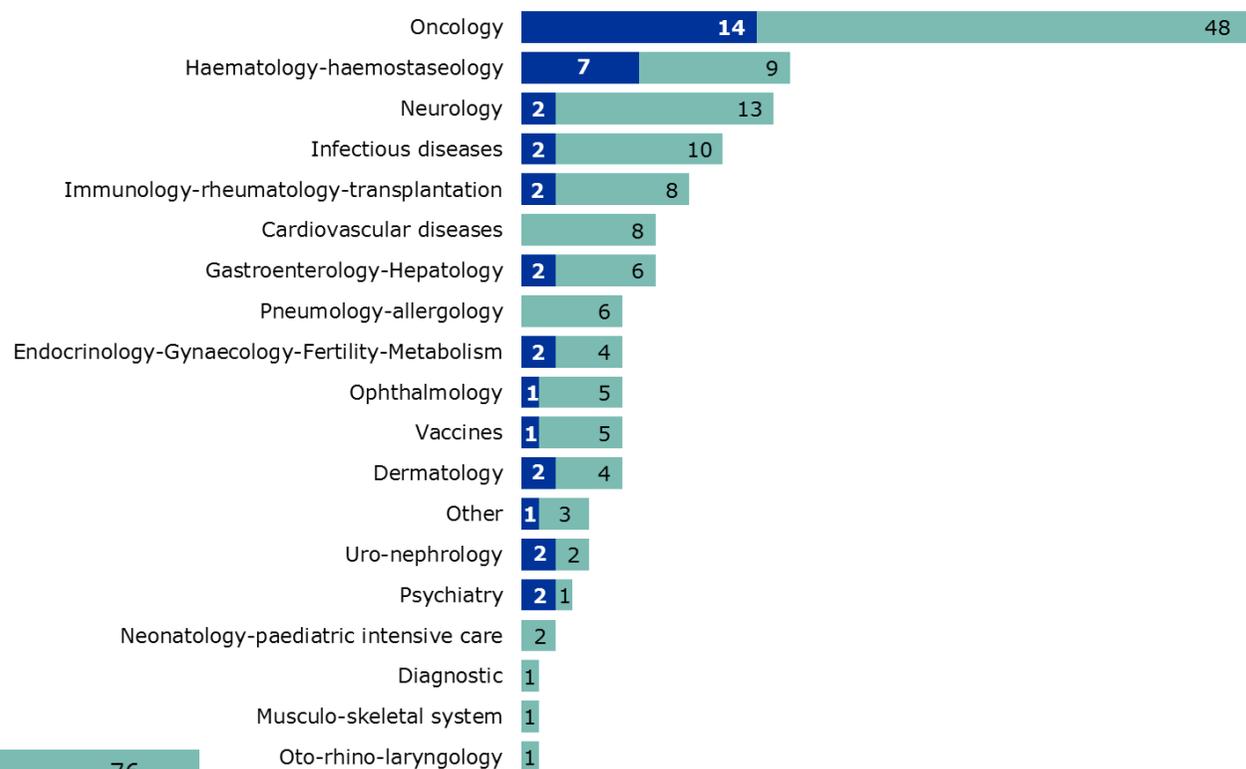


■ Granted ■ Denied ■ Out of scope*

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.