15 November 2017
EMA/668793/2016
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 6-9 November 2017

During its November 2017 meeting, the CHMP reviewed 9 recommendations for eligibility to PRIME: 3 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
Autologous T lymphocyte-enriched population of cells transduced with a lentiviral vector encoding a chimeric antigen receptor targeting human B cell maturation antigen with 4-1BB and CD3-zeta intracellular signalling domains (bb2121)	Advanced therapy	Oncology	Treatment of relapsed and refractory multiple myeloma patients whose prior therapy included a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 antibody	Nonclinical + Clinical exploratory	Other
LR12	Chemical	Infectious Diseases	Treatment of Septic Shock	Nonclinical + Tolerability first in man	SME
Recombinant humanised monoclonal IgG2 lambda antibody against human sclerostin (BPS804)	Biological	Other	Treatment of osteogenesis imperfecta types I, III and IV	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.

Product(s) in italic have been granted eligibility to the scheme at early stages of development (proof of principle/proof of mechanism).

Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Biological	Oncology	Treatment of non-muscle invasive bladder cancer	Nonclinical + Clinical exploratory	Other
Chemical	Oncology	Treatment of breast cancer in men	Nonclinical + Clinical exploratory	SME
Biological	Haematology - Hemostaseology	Prevention of bleeding in patients with haemophilia B	Nonclinical + Clinical exploratory	SME
Chemical	Neurology	Treatment of Huntington's disease	Nonclinical + Clinical exploratory	Other
Chemical	Neurology	Treatment of X-linked Adrenoleukodystrophy	Nonclinical + Tolerability first in man	SME
Biological	Immunology-Rheumatology-Transplantation	Treatment of steroid resistant acute Graft-Versus-Host Disease	Nonclinical + Clinical exploratory	SME

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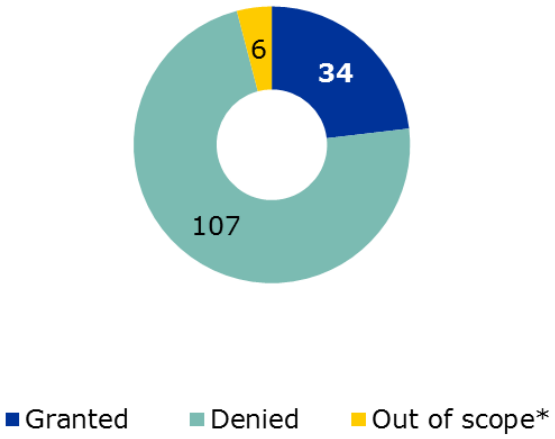
Cumulative overview of recommendations on PRIME eligibility requests adopted by 9 November 2017



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.