



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 May 2017
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Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 15-18 May 2017

During its May 2017 meeting, the CHMP reviewed 12 recommendations for eligibility to PRIME: 5 were granted and 7 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
Asunercept	Biological	Oncology	Treatment of glioblastoma	Nonclinical + Clinical exploratory	Other
Olipudase alfa	Biological	Endocrinology- Gynaecology-Fertility- Metabolism	Treatment of non-neurological manifestations of acid sphingomyelinase deficiency	Nonclinical + Clinical exploratory	Other
Rapastinel	Chemical	Psychiatry	Adjunctive treatment of major depressive disorder	Nonclinical + Clinical exploratory	Other
Recombinant IgG degrading enzyme of <i>Streptococcus pyogenes</i>	Biological	Immunology- Rheumatology- Transplantation	Prevention of graft rejection following solid organ transplantation	Nonclinical + Clinical exploratory	SME
Synthetic 47-amino-acid N-myristoylated lipopeptide, derived from the preS region of hepatitis B virus	Chemical	Infectious Diseases	Treatment of chronic hepatitis D infection	Nonclinical + Clinical exploratory	SME

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

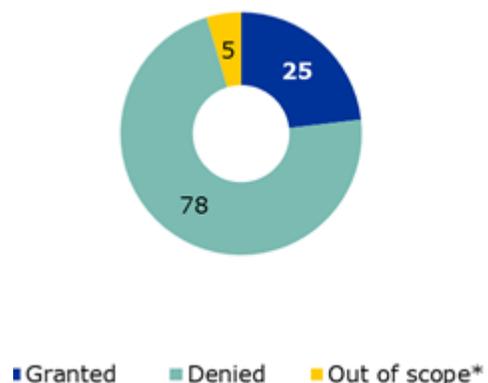
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other types of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Biological	Oncology	Treatment of metastatic uveal melanoma	Clinical exploratory	Other
Chemical	Oncology	Treatment of acute myeloid leukaemia	Nonclinical + Clinical exploratory	Other
Immunological	Oncology	Treatment of pancreatic cancer	Nonclinical + Clinical exploratory	SME
Chemical	Infectious Diseases	Treatment of cystic fibrosis exacerbations	Nonclinical + Clinical exploratory	SME
Chemical	Immunology-Rheumatology-Transplantation	Treatment of diffuse cutaneous systemic sclerosis	Nonclinical + Clinical exploratory	Other
Biological	Neonatology-Paediatric Intensive Care	Prevention of necrotising enterocolitis	Nonclinical + Clinical exploratory	SME
Chemical	Uro-nephrology	Treatment of calciphylaxis	Nonclinical + Clinical exploratory	Other

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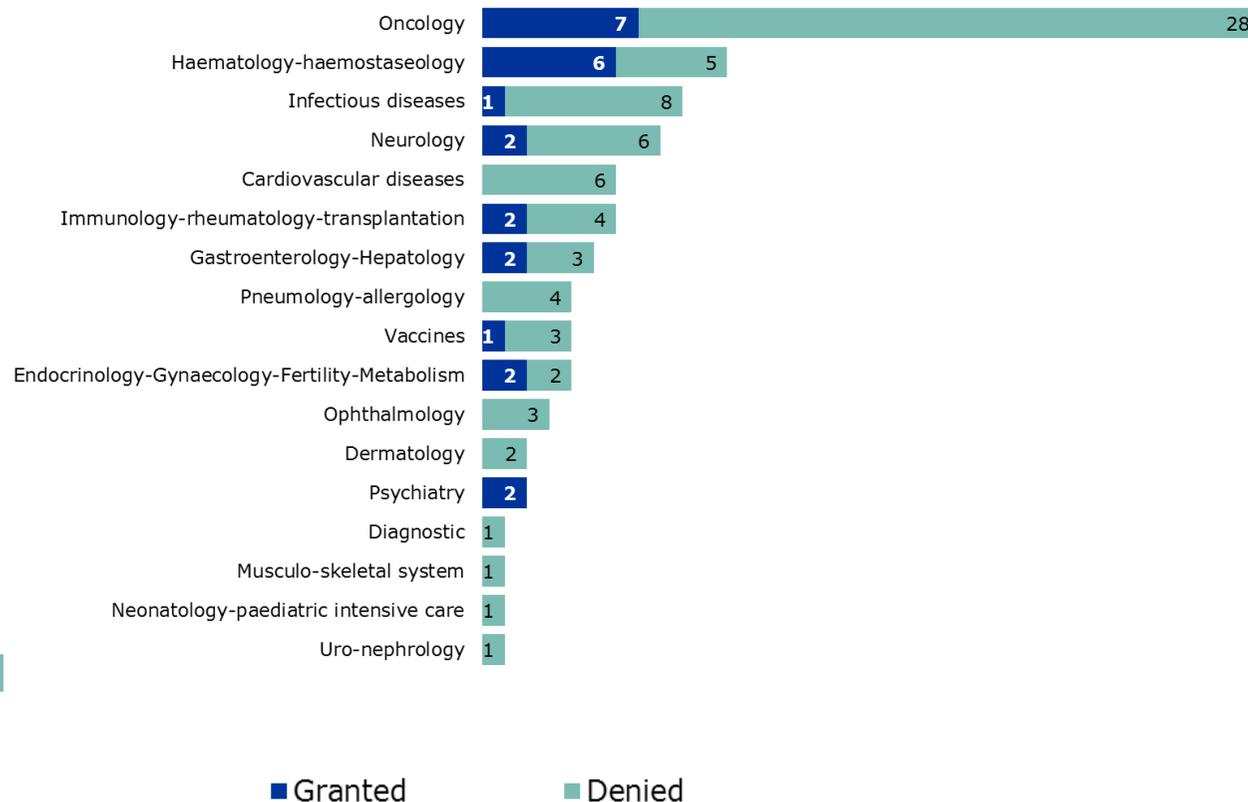
Cumulative overview of recommendations on PRIME eligibility requests adopted by 18 May 2017



By type of applicant



By therapeutic area



* One eligible product has subsequently been withdrawn from the scheme at the applicant's request
 Out of scope 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.