19 October 2016
EMA/571987/2016
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 10-13 October 2016

During its October 2016 meeting, the CHMP reviewed 9 recommendations for eligibility to PRIME: 3 were granted and 6 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
A4250	*Chemical*	*Gastroenterology-Hepatology*	*Treatment of Progressive Familial Intrahepatic Cholestasis*	*Nonclinical + Tolerability first in man*	*SME*
Allogeneic Epstein-Barr virus-specific cytotoxic T lymphocytes (ATA129)	Advanced therapy	Haematology - Hemostaseology	Treatment of patients with Epstein-Barr Virus-associated Post Transplant Lymphoproliferative Disorder in the allogeneic hematopoietic cell transplant setting who have failed on rituximab.	Nonclinical + Clinical exploratory	Other
MBX-8025	Chemical	Gastroenterology-Hepatology	Treatment of Primary Biliary Cholangitis	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
Advanced therapy	Oncology	Hematopoietic reconstitution of patients who are medically indicated for allogeneic hematopoietic stem cell transplantation	Nonclinical + Clinical exploratory	SME
Biological	Oncology	Treatment of patients with acute myeloid leukaemia (AML)	Nonclinical + Clinical exploratory	Other
Chemical	Oncology	Treatment of patients with advanced or metastatic ALK-positive non-small cell lung cancer	Nonclinical + Clinical exploratory	Other
Biological	Haematology - Hemostaseology	Treatment of paroxysmal nocturnal haemoglobinuria	Nonclinical + Clinical exploratory	SME
Medicinal product derived from Human Blood or Human Plasma	Musculo-skeletal system	Relief of pain and improvement of joint function in osteoarthritis of the knee	Nonclinical + literature	SME
Advanced therapy	Endocrinology-Gynaecology-Fertility-Metabolism	Treatment of Type 1 Diabetes with Residual Beta Cell Function	Clinical exploratory	SME

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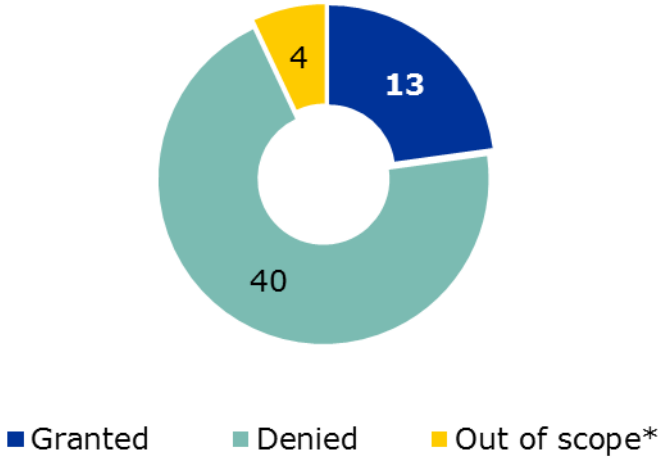
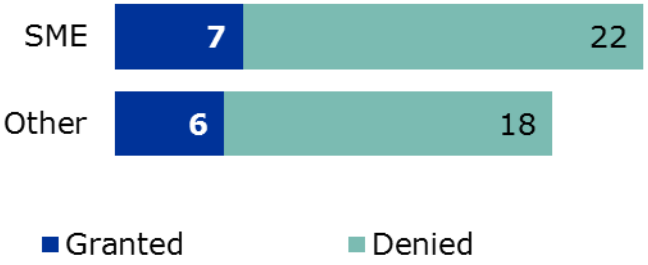
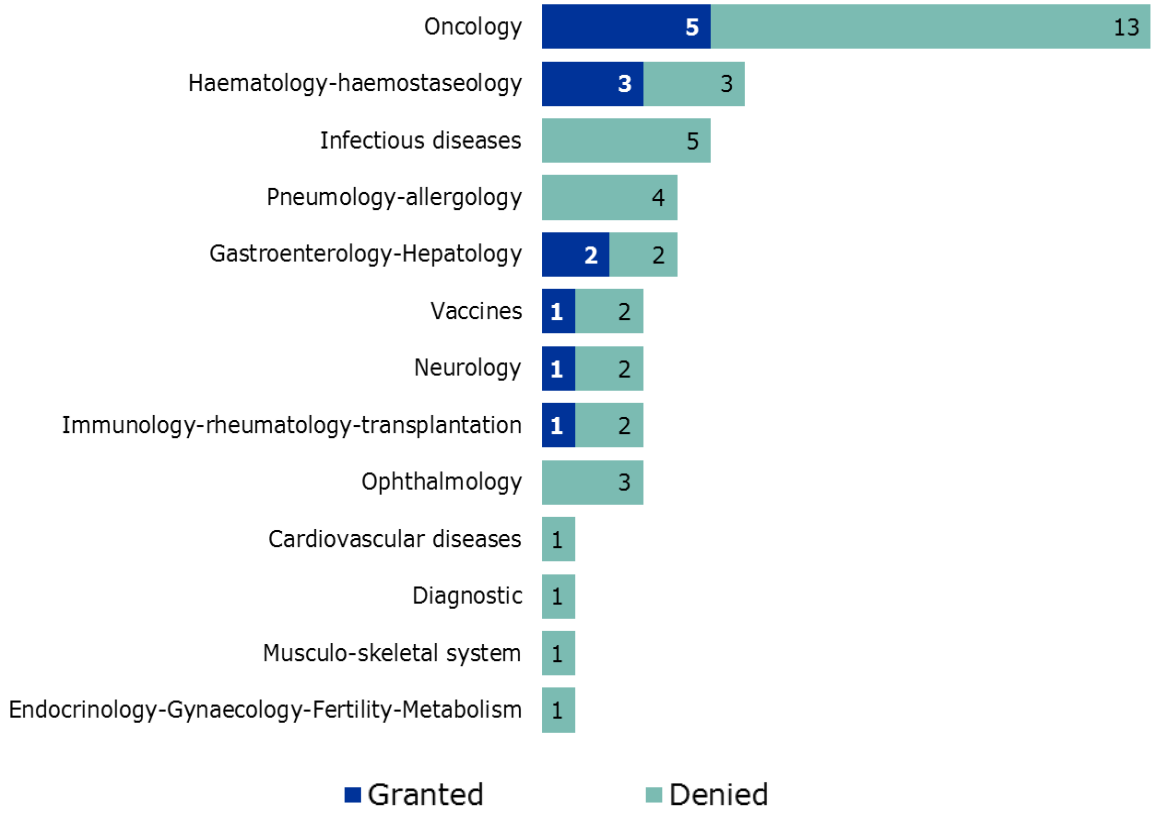
Cumulative overview of recommendations on PRIME eligibility requests received as of 24 August2016



By type of applicant



By therapeutic area



* 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.