



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

27 July 2016  
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Press office

## Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 18-21 July 2016

During its July 2016 meeting, the CHMP reviewed 9 recommendations for eligibility to PRIME: 2 were granted and 7 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 CD4 and CD8 T cells transduced with lentiviral vector containing an affinity-enhanced T cell receptor to target the cancer-testis tumour antigen NY-ESO-1 (NY-ESO-1c259T)	Advanced Therapy	Oncology	Treatment of HLA-A*0201, HLA-A*0205, or HLA-A*0206 allele positive patients with inoperable or metastatic synovial sarcoma who have received prior chemotherapy and whose tumour expresses the NY-ESO-1 tumour antigen.	Nonclinical + Clinical exploratory	SME
Adenovirus serotype 5 containing partial E1A deletion and an integrin-binding domain (DNX-2401)	Advanced Therapy	Oncology	Treatment of recurrent glioblastoma in patients for which a gross total resection is not possible or advisable, or for those who refuse further surgery.	Nonclinical + Clinical exploratory	Other

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

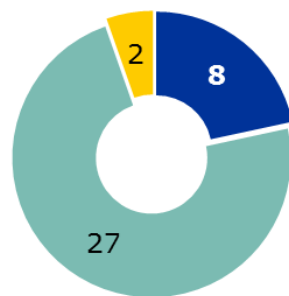
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other types of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

## Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Biological	Oncology	Treatment of relapsed and refractory multiple myeloma.	Nonclinical + Clinical exploratory	Other
Biological	Oncology	Treatment of diffuse intrinsic pontine glioma (DIPG)	Nonclinical + Clinical exploratory	SME
Biological	Haematology - Hemostaseology	Treatment of hemophilia A	Clinical exploratory	Other
Chemical	Haematology - Hemostaseology	Treatment of iron overload in patients with beta thalassaemia	Nonclinical + Clinical exploratory	SME
Advanced Therapy	Gastroenterology- Hepatology	Treatment of active moderate to severe Crohn's Disease (CD) patients	Nonclinical + Clinical exploratory	SME
Chemical	Infectious Diseases	Treatment of invasive fungal infections	Non clinical + tolerability first in man	SME
Biological	Pneumology-Allergology	Treatment of peanut allergy	Clinical exploratory	Other

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 received as of 1 June 2016



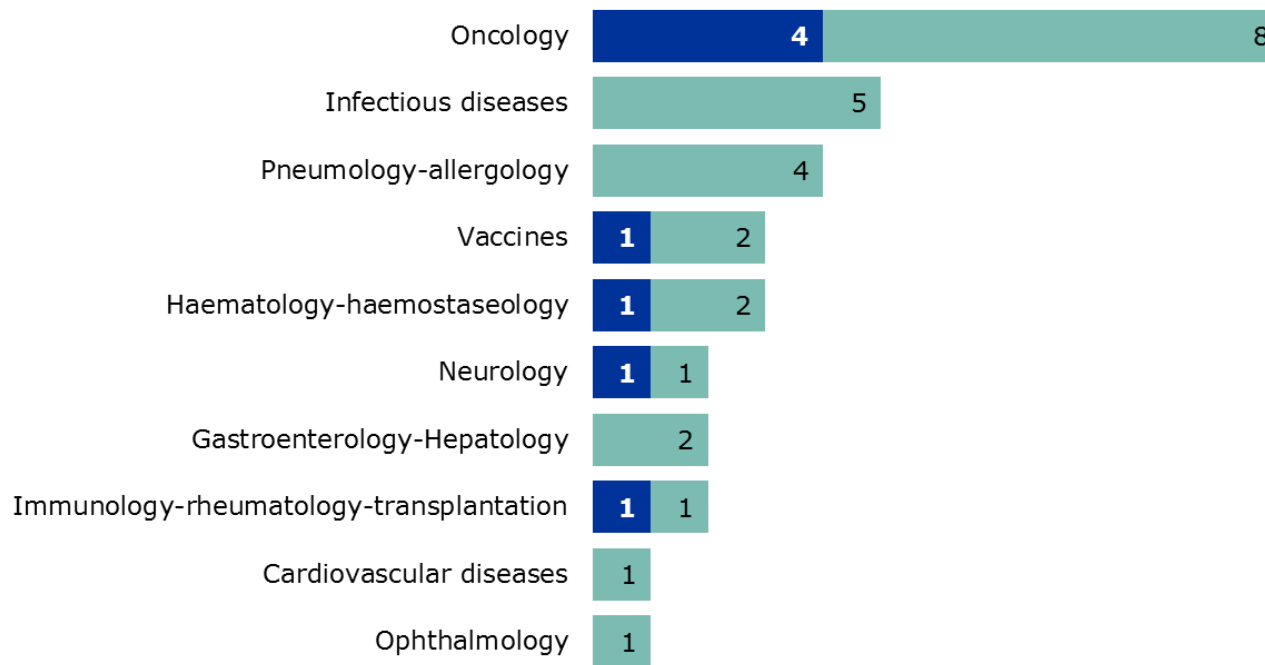
■ Granted ■ Denied ■ Out of scope\*

### By type of applicant



■ Granted ■ Denied

### 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.