



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

Wednesday 20 September  
EMA/668862/2016  
Press office

## Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 11-14 September 2017

During its September 2017 meeting, the CHMP reviewed 4 recommendations for eligibility to PRIME: 4 were denied.

The individual outcomes adopted this month are listed below.

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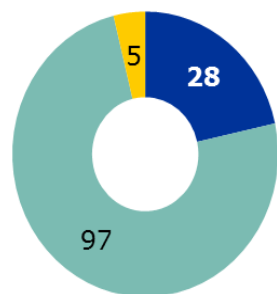


## Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical	Gastroenterology-Hepatology	Treatment of eosinophilic oesophagitis	Clinical exploratory	Other
Biological	Cardiovascular Diseases	Increase in fistula survival and use for haemodialysis	Nonclinical + Clinical exploratory + Clinical confirmatory	SME
Chemical	Vaccines	Prevention against Influenza	Nonclinical + Clinical exploratory	SME
Biological	Oncology	Treatment of stage IV oesophageal carcinoma	Nonclinical + 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 adopted by 14 September 2017

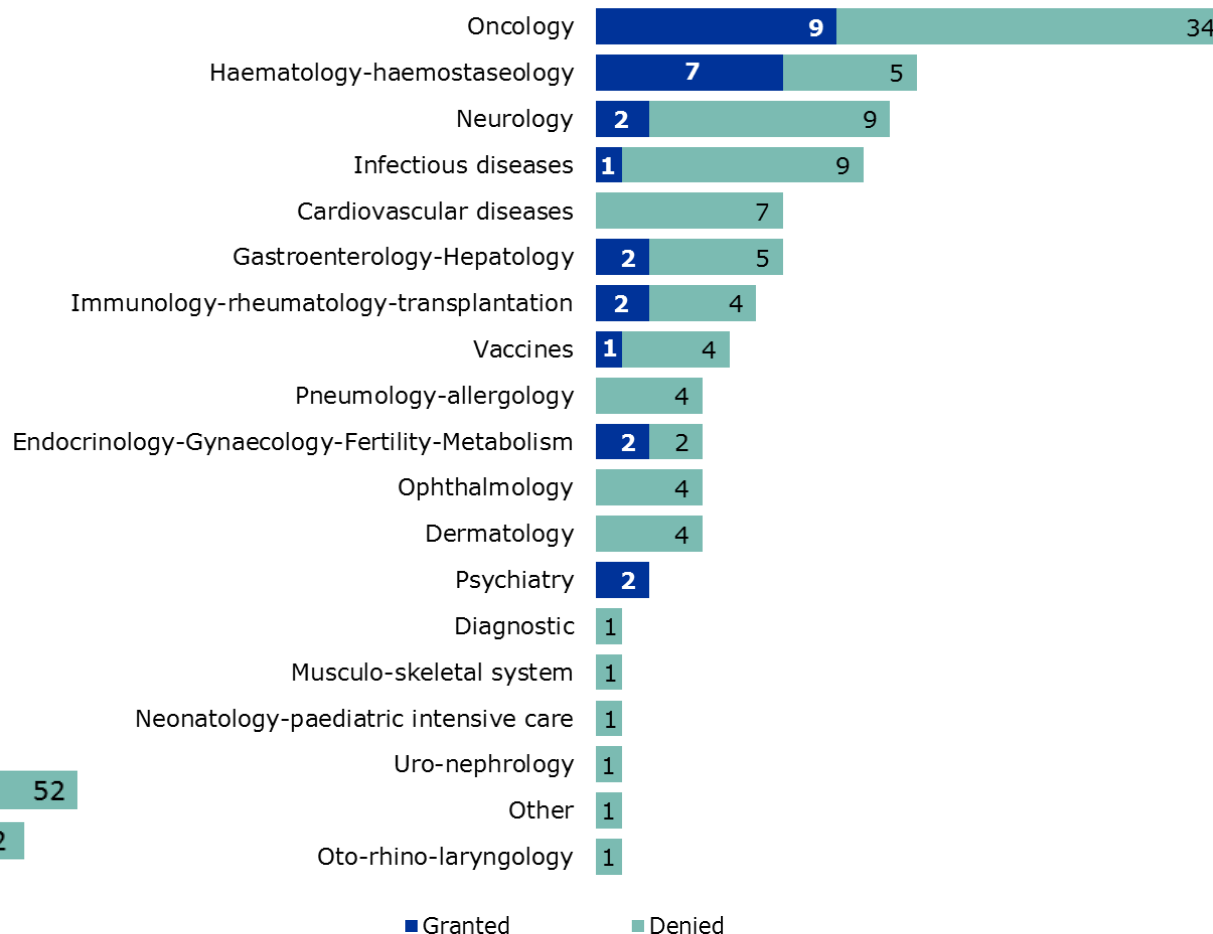


■ Granted ■ Denied ■ Out of scope\*

### By type of applicant



### By therapeutic area



■ Granted ■ Denied

\* One eligible product has subsequently been withdrawn from the scheme at the applicant's request  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