



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Press office

## Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 25-28 February 2019

During its February 2019 meeting, the CHMP reviewed 7 recommendations for eligibility to PRIME: 1 was granted and 6 were denied. The individual outcomes adopted this month are listed below.

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**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands  
**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)  
**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

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## Eligibility granted

Name*	Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Recombinant adeno-associated viral vector serotype S3 containing codon-optimised expression cassette encoding human coagulation factor IX variant (FLT180a)	Advanced therapy	Haematology-haemostaseology	Treatment of haemophilia B	Nonclinical+ Clinical exploratory	SME

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

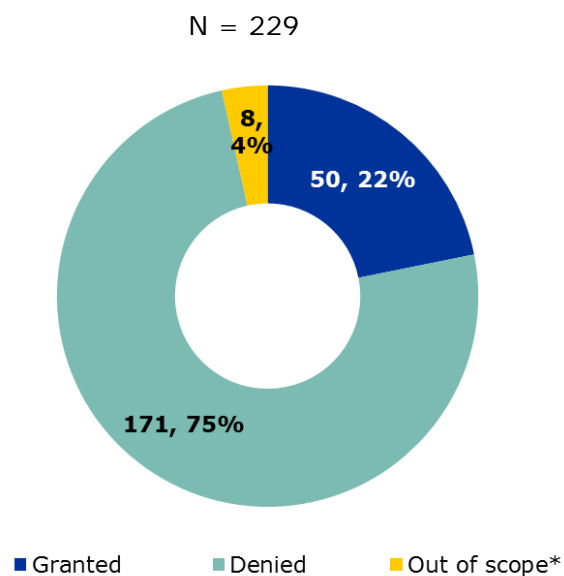
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other types of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

## Eligibility denied

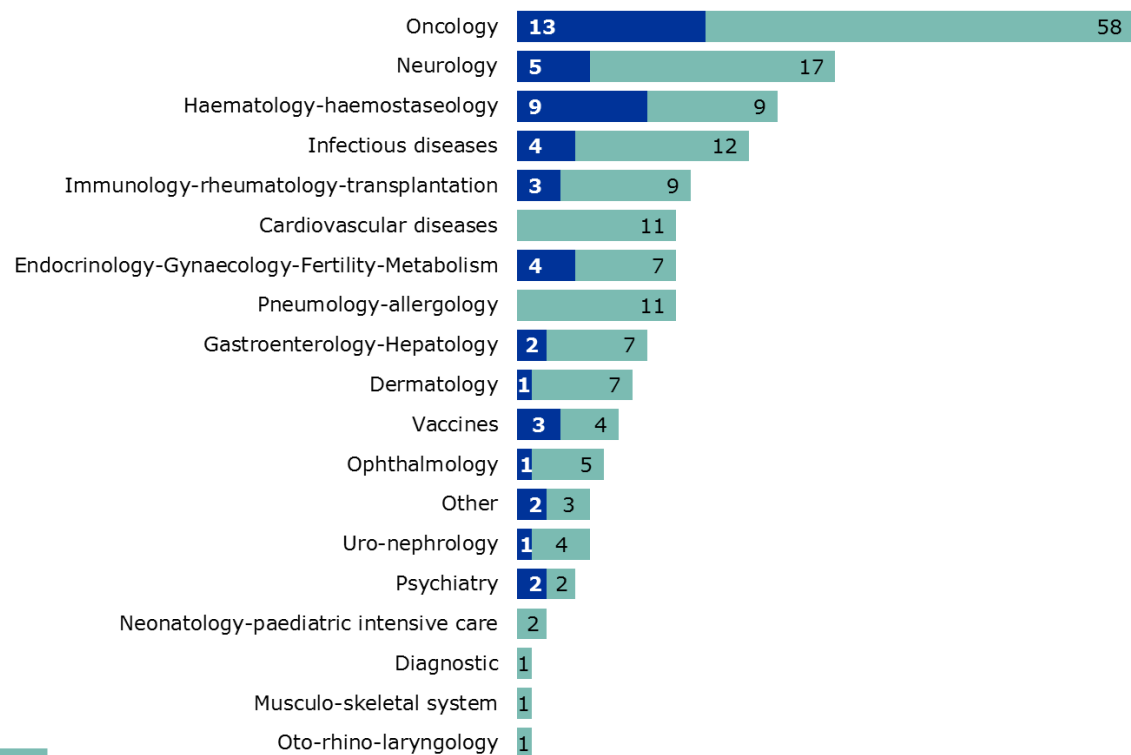
Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical	Endocrinology-Gynaecology-Fertility-Metabolism	Treatment of cancer cachexia	Nonclinical+ Clinical exploratory	SME
Chemical	Gastroenterology-Hepatology	Treatment to reduce hepatic injury in high-risk patients following a potentially hepatotoxic quantity of acetaminophen	Nonclinical+ Clinical exploratory	SME
Chemical	Oncology	Treatment of advanced and/or recurrent endometrial cancer	Nonclinical+ Clinical exploratory	SME
Chemical	Oncology	Treatment of Mantle Cell Lymphoma	Nonclinical+ Clinical exploratory	Other
Chemical	Oncology	Treatment of myelodysplastic syndrome	Nonclinical+ Clinical exploratory	SME
Chemical	Pneumology-Allergology	Treatment of acute exacerbations of Chronic Obstructive Pulmonary Disease	Nonclinical+ Clinical exploratory	SME

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## Cumulative overview of recommendations on PRIME eligibility requests adopted by 28 February 2019



### 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.