



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

28 February 2018  
EMA/777146/2017  
Press office

## Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 19-22 February 2018

During its February 2018 meeting, the CHMP reviewed 6 recommendations for eligibility to PRIME: 1 was granted and 5 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
<i>Adenovirus associated viral vector serotype 8 containing the human CNGB3 gene (AAV2/8-hCARp.hCNGB3)</i>	<i>Advanced therapy</i>	<i>Ophthalmology</i>	<i>Treatment of achromatopsia associated with defects in CNGB3</i>	<i>Nonclinical + Tolerability first in man</i>	<i>SME</i>

\* 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.

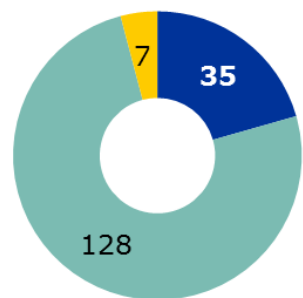
*Product(s) in italic have been granted eligibility to the scheme at early stages of development (proof of principle/proof of mechanism).*

## Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Biological	Haematology - Hemostaseology	Treatment of Hematopoietic stem cell transplant-associated thrombotic microangiopathy	Nonclinical + Clinical exploratory	SME
Biological	Uro-nephrology	Treatment of Immunoglobulin A nephropathy	Nonclinical + Clinical exploratory	SME
Chemical	Psychiatry	Treatment of patients with chronic schizophrenia who are experiencing inadequate benefit on their current antipsychotic therapy.	Nonclinical + Clinical exploratory	SME
Chemical	Endocrinology-Gynaecology-Fertility-Metabolism	Treatment of Allan-Herndon-Dudley-Syndrome	Nonclinical + Clinical exploratory	SME
Chemical	Pneumology-Allergology	Treatment of F508del cystic fibrosis	Nonclinical + Clinical exploratory	SME

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## Cumulative overview of recommendations on PRIME eligibility requests adopted by 22 February 2018



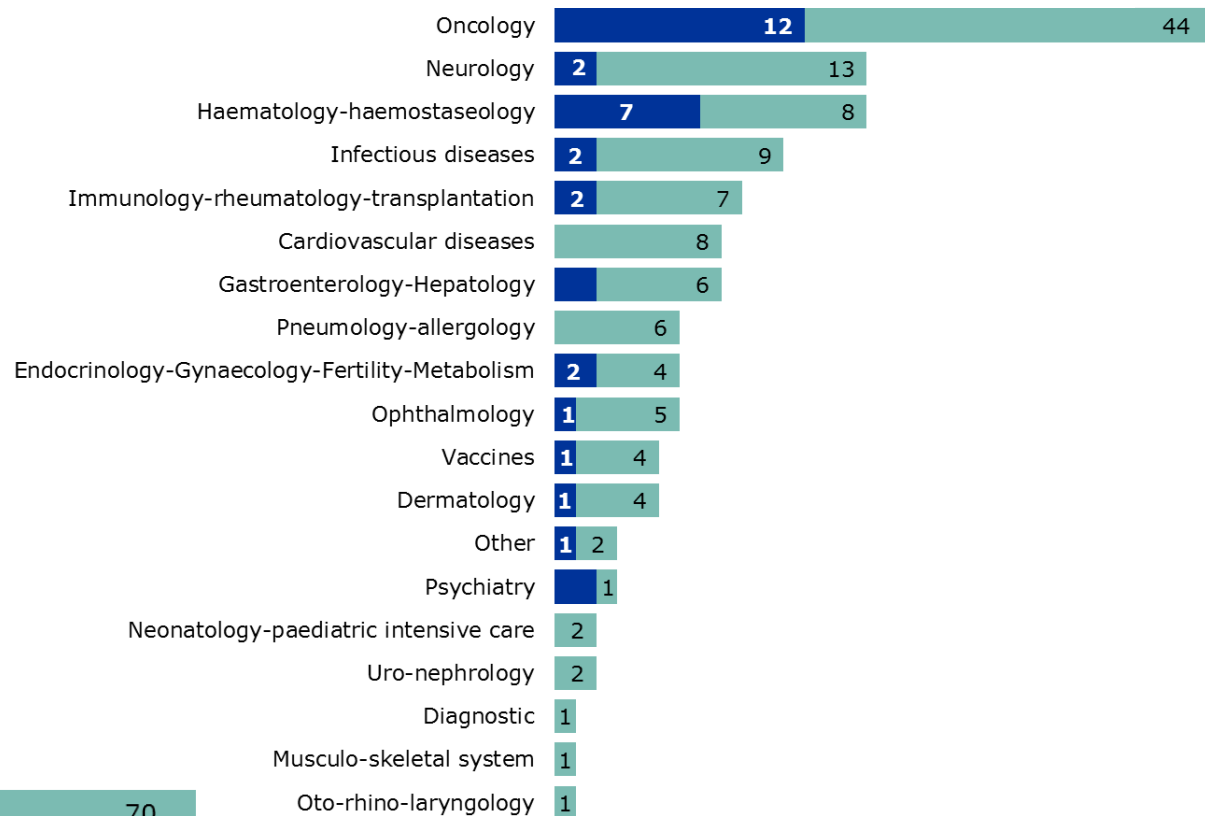
■ Granted ■ Denied ■ Out of scope\*

### By type of applicant



■ Granted ■ Denied

### 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.