



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

28 March 2018  
EMA/50576/2018  
Press office

## Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 19-22 March 2018

During its March 2018 meeting, the CHMP reviewed 3 recommendations for eligibility to PRIME: 1 was granted and 2 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
Lumasiran	Chemical	Uro-nephrology	Treatment of Primary Hyperoxaluria Type 1	Nonclinical + Clinical exploratory	Other

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

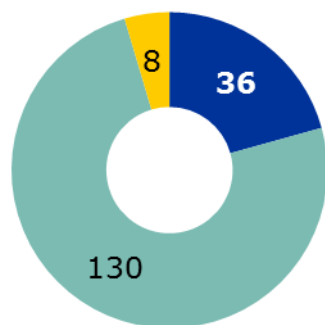
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other types of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

## Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical	Oncology	Treatment and prevention of skin toxicity caused by targeted anti-cancer drugs, especially EGFR inhibitors	Nonclinical + Literature	SME
Chemical	Infectious Diseases	Prevention of cardiac surgery infection	Nonclinical + Clinical exploratory	SME

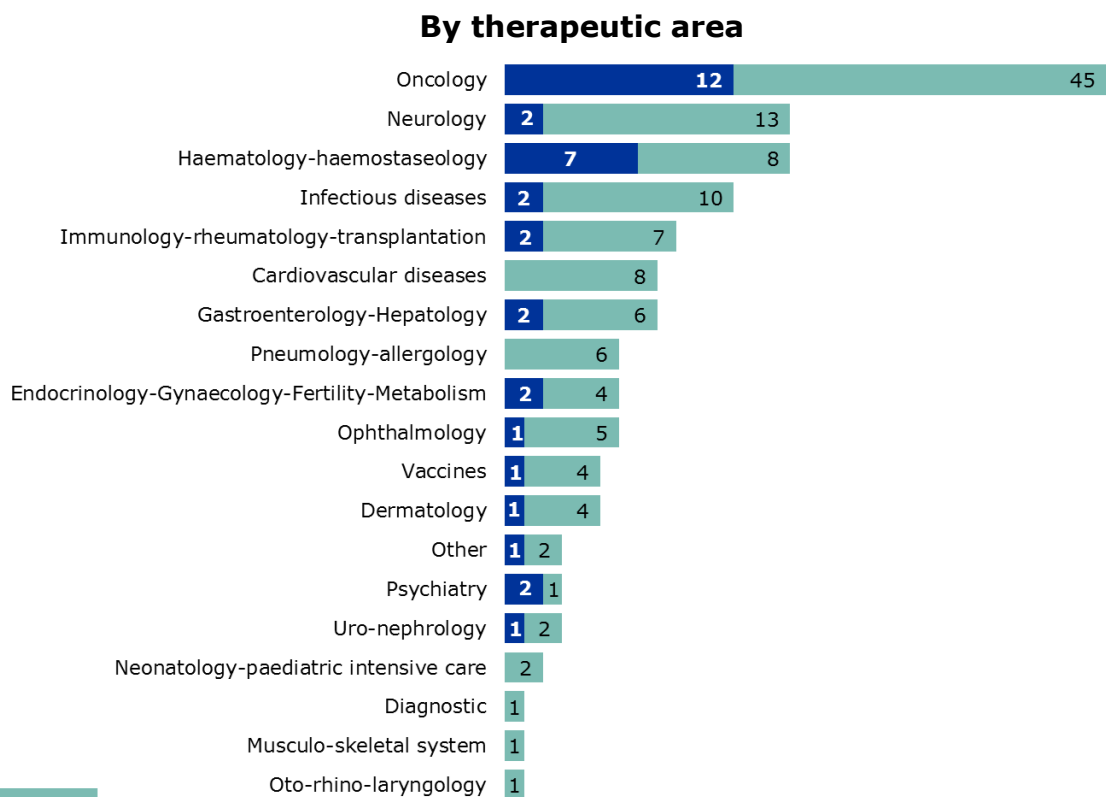
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other type of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

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



■ Granted ■ Denied ■ Out of scope\*

### By type of applicant



■ 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.