



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

23 May 2022  
EMA/67993/2022  
Press office

## Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 16-19 May 2022

During its May 2022 meeting, the CHMP reviewed 3 recommendations for eligibility to PRIME: 2 were granted and 1 was 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
DNL310	Biological Medicinal Product	Endocrinology- Gynaecology-Fertility- Metabolism	Treatment of mucopolysaccharidosis type II	Nonclinical + Clinical exploratory	Other
VX-147	Chemical Medicinal Product	Uro-nephrology	Treatment of proteinuric apolipoprotein L1 (APOL1)-mediated chronic kidney disease in patients who have 2 APOL1 genetic mutations (G1/G1, G1/G2, or G2/G2)	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.

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

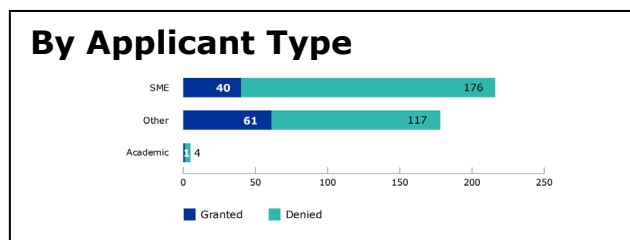
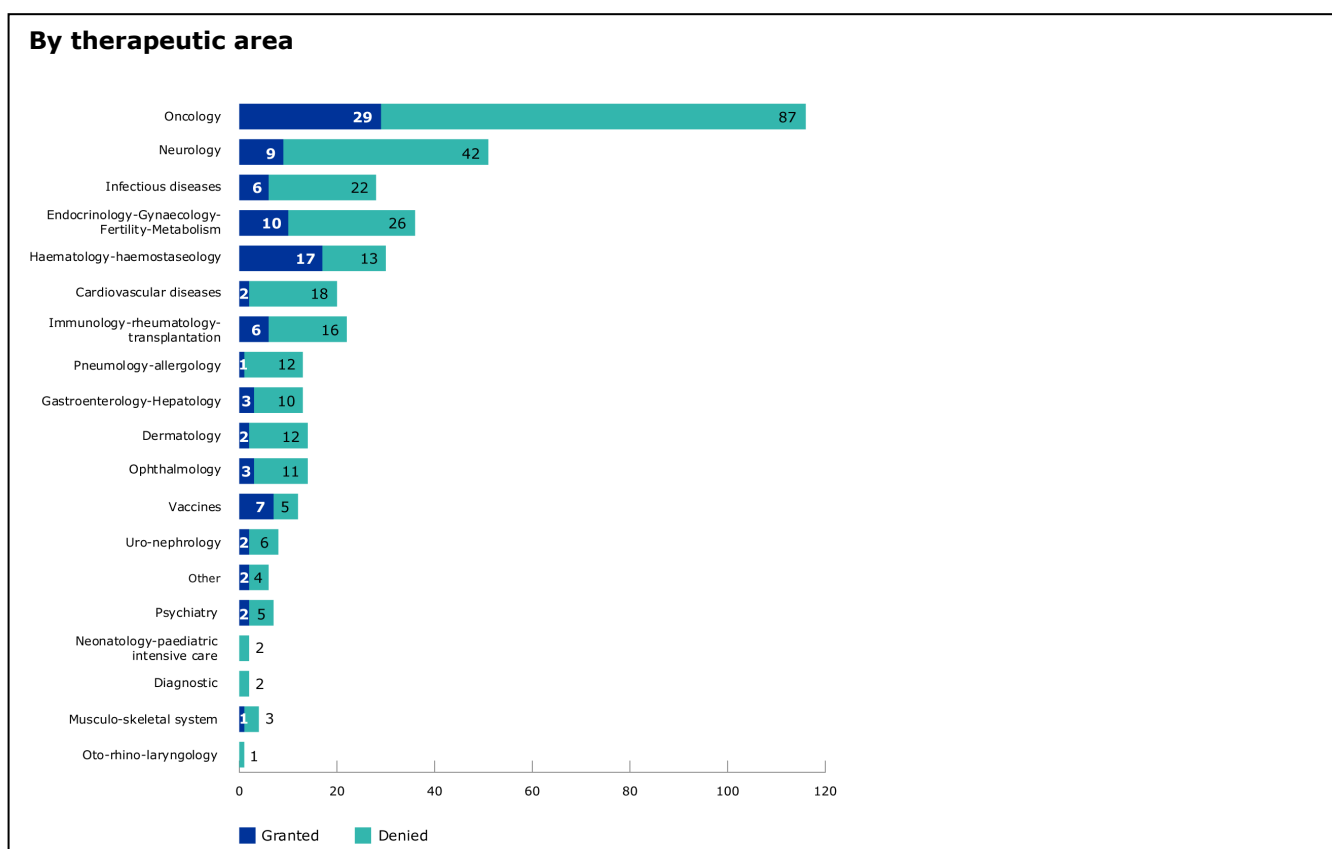
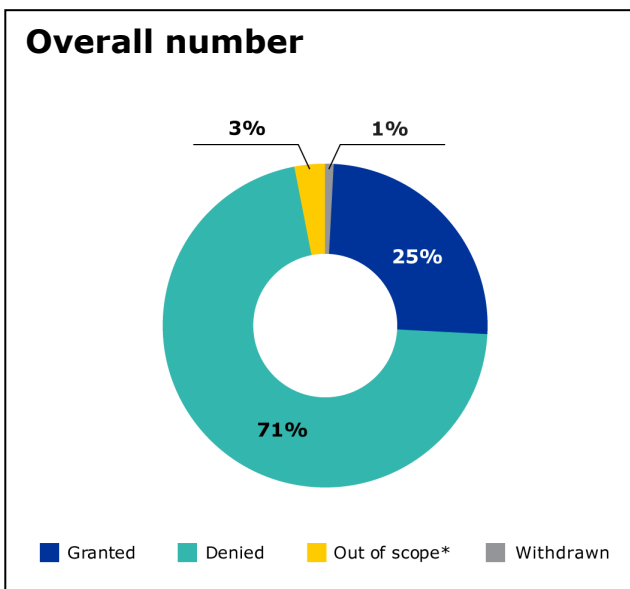
## Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Biological Medicinal Product	Cardiovascular Diseases	Treatment of acute Coronary Syndromes	Nonclinical + Clinical exploratory	SME

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## Cumulative overview of PRIME eligibility recommendations adopted by 19 May 2022

■ Granted ■ Denied ■ Out of scope\* ■ Withdrawn



\* 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.