



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

19 October 2023  
EMA/898139/2022  
Press office

## Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 9-12 October 2023

During its October 2023 meeting, the CHMP reviewed 7 recommendations for eligibility to PRIME: 4 were granted and 3 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
Messenger RNA encoding Cas9, Single guide RNA targeting the human KLKB1 gene	Advanced Therapy Medicinal Product	Cardiovascular diseases	Treatment of hereditary angioedema	Non-clinical + Clinical exploratory	Other
4D-150	Advanced Therapy Medicinal Product	Ophthalmology	Treatment of neovascular (wet) age-related macular degeneration (wet AMD)	Non-clinical + Clinical exploratory	SME
ANX007	Biological Medicinal Product	Ophthalmology	Treatment of Geographic Atrophy (GA) secondary to age-related macular degeneration (AMD)	Non-clinical + Clinical exploratory	SME
Anti-(insulin receptor) human monoclonal antibody	Biological Medicinal Product	Endocrinology - Gynaecology - Fertility - Metabolism	Treatment of hyperinsulinaemic hypoglycaemia due to congenital hyperinsulinism	Non-clinical + 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.

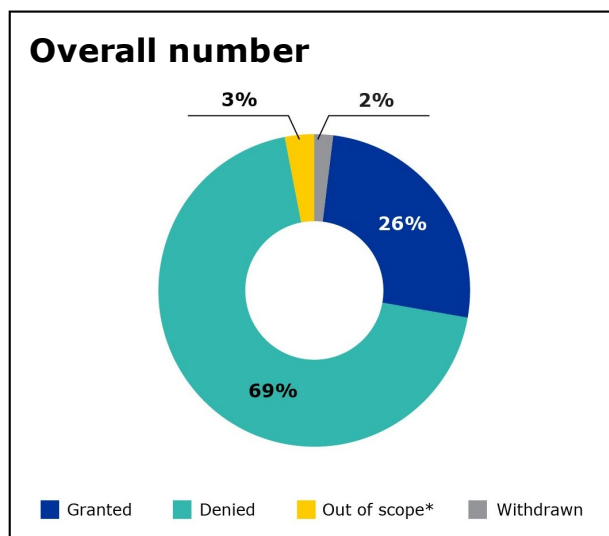
## Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Dermatology	Treatment of Hidradenitis Suppurativa	Non-clinical + Clinical exploratory	SME
Biological Medicinal Product	Diagnostic	Diagnosis of breast cancer	Non-clinical + Clinical exploratory	SME
Biological Medicinal Product	Gastroenterology- Hepatology	Treatment of ulcerative colitis	Non-clinical + Clinical exploratory	SME

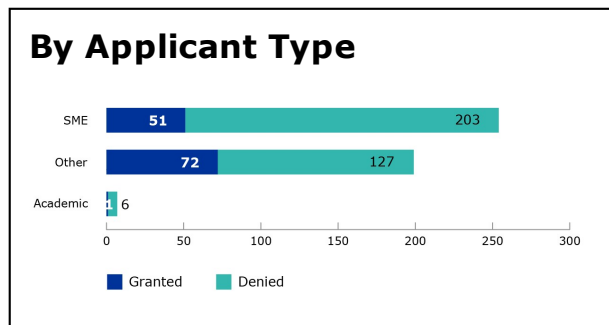
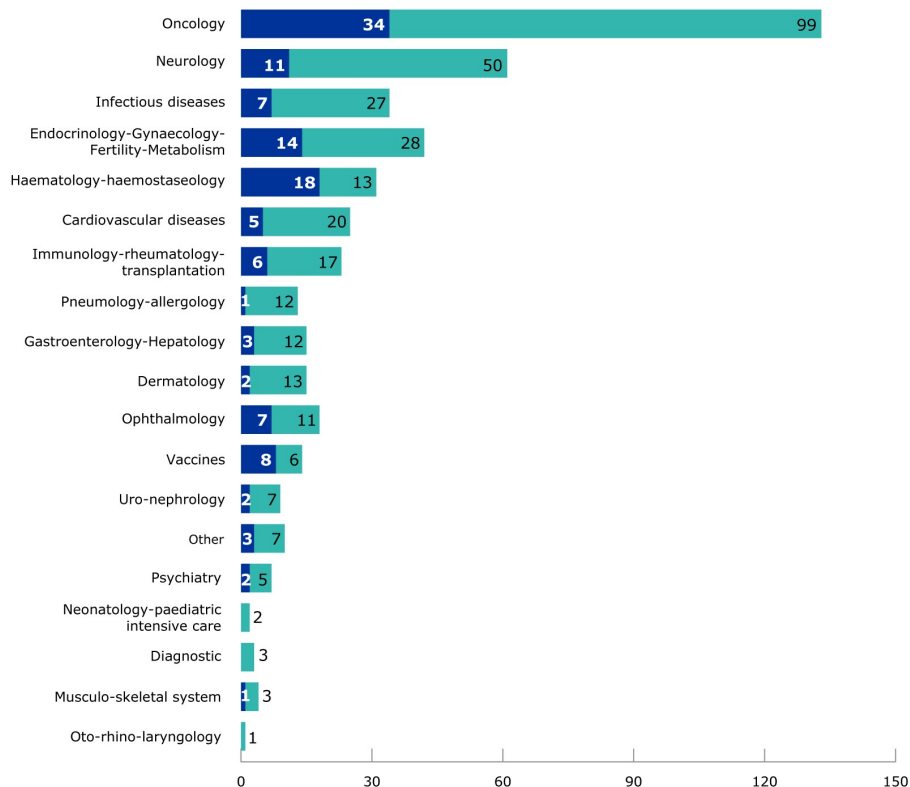
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## Cumulative overview of PRIME eligibility recommendations adopted by 12 October 2023

■ Granted ■ Denied ■ Out of scope\* ■ Withdrawn



### 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.