



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 April 2023
EMA/898162/2022
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 27-30 March 2023

During its March 2023 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
mRNA-4157 (V940)	Advanced Therapy Medicinal Product	Oncology	Treatment of melanoma	Nonclinical + Clinical exploratory	Other
VX-880	Advanced Therapy Medicinal Product	Endocrinology- Gynaecology- Fertility-Metabolism	Treatment of type 1 diabetes (T1D) mellitus with impaired hypoglycaemia awareness and severe hypoglycaemia	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

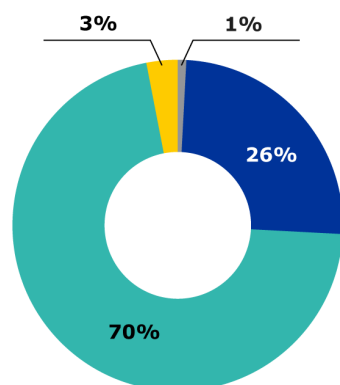
Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Infectious diseases	Treatment of chronic hepatitis B	Nonclinical + Clinical exploratory	Other

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 PRIME eligibility recommendations adopted by 30 March 2023

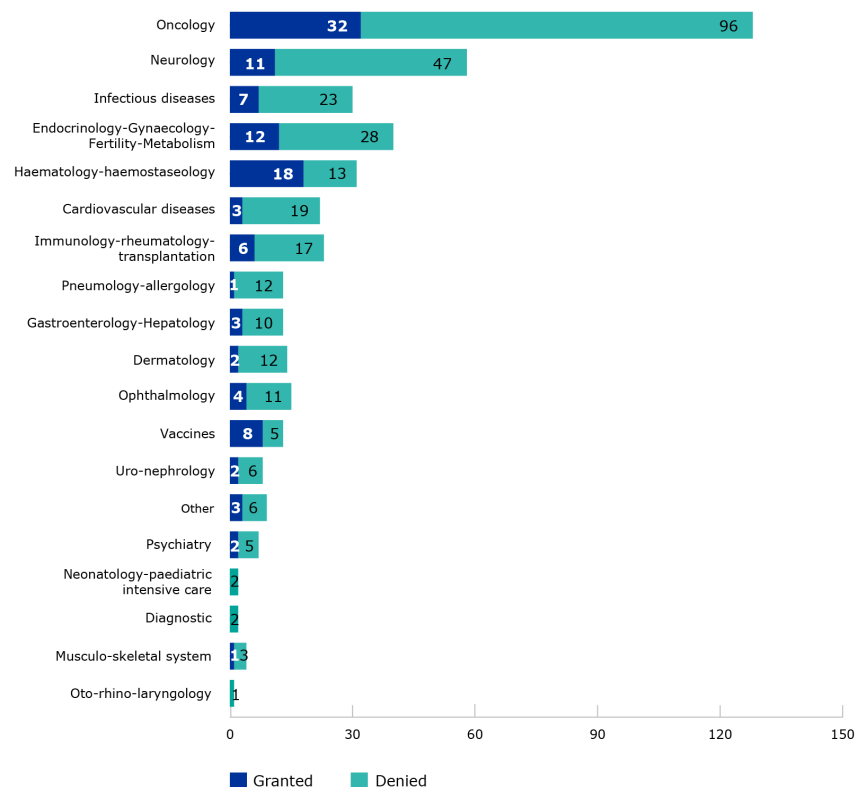
■ Granted ■ Denied ■ Out of scope* ■ Withdrawn

Overall number

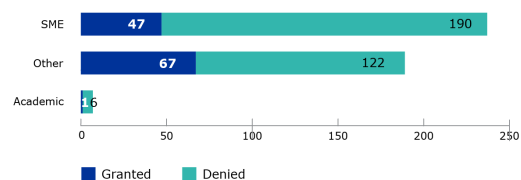


■ Granted ■ Denied ■ Out of scope* ■ Withdrawn

By therapeutic area



By Applicant Type



* 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.