



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

02 March 2022
EMA/67989/2022
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 21-24 February 2022

During its February 2022 meeting, the CHMP reviewed 3 recommendations for eligibility to PRIME: 3 were denied.

The individual outcomes adopted this month are listed below.

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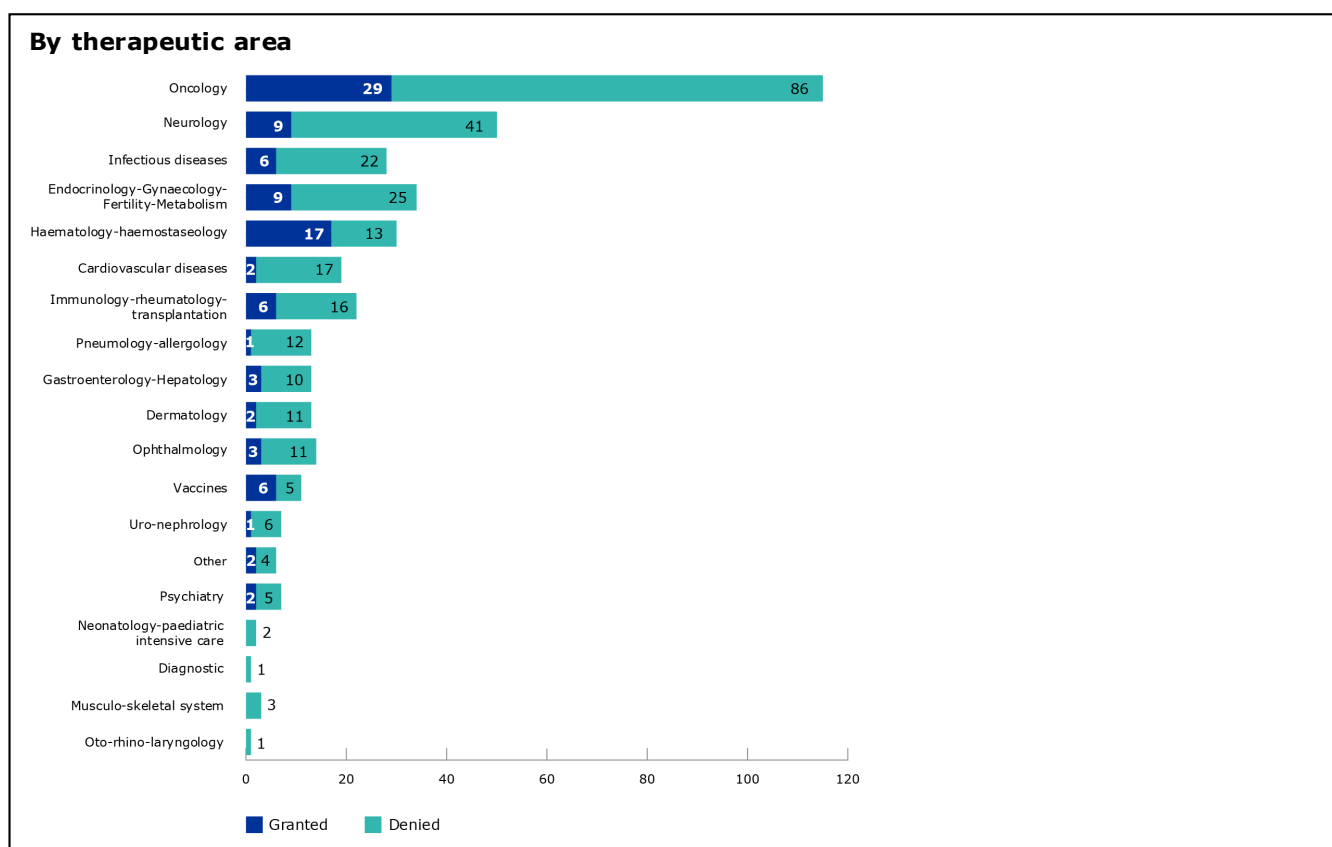
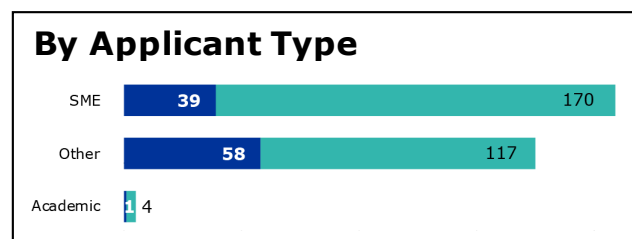
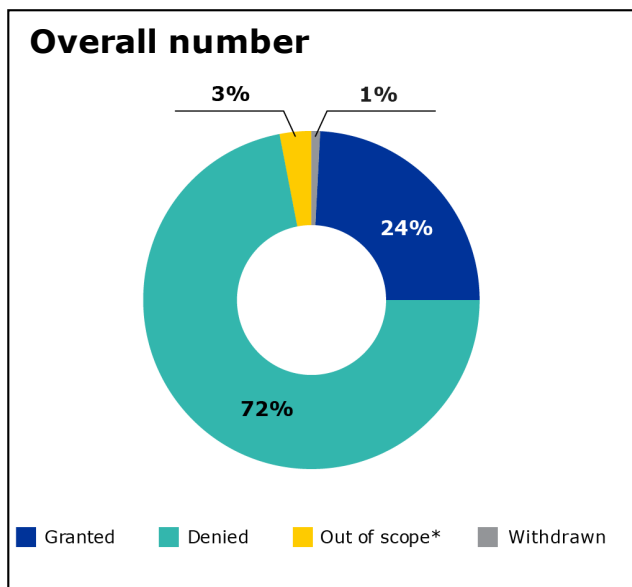
Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Oncology	Treatment of patients with advanced solid tumors that have an NTRK gene fusion who have progressed following treatment with 1 or 2 prior TRK tyrosine kinase inhibitors (TKIs) (with or without prior chemotherapy) and have no satisfactory alternative treatments	Nonclinical + Clinical exploratory	Other
Chemical Medicinal Product	Neurology	Treatment of non-traumatic subarachnoid haemorrhage	Nonclinical + Clinical exploratory	SME
Chemical Medicinal Product	Haematology – Hemostaseology	Control of erythrocytosis either as a monotherapy or in combination with cytoreductive therapies in polycythaemia vera patients	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 PRIME eligibility recommendations adopted by 24 February 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■ Granted ■ Denied ■ Out of scope* ■ Withdrawn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.