



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 April 2021
EMA/25119/2021
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 19-22 April 2021

During its April 2021 meeting, the CHMP reviewed 5 recommendations for eligibility to PRIME: 1 was granted and 4 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
CTX001	Advanced Therapy Medicinal Product	Haematology - Hemostaseology	Treatment of transfusion-dependent β -thalassemia	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

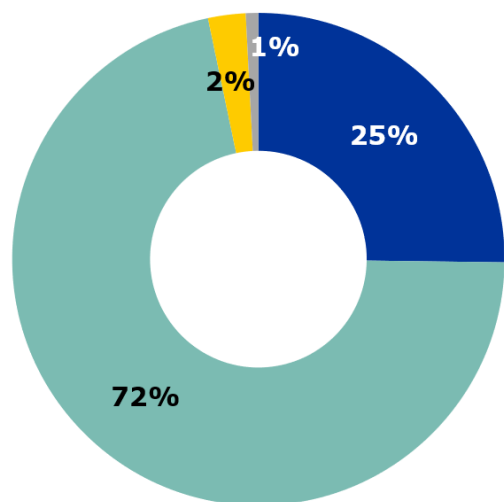
Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Psychiatry	Treatment of cognitive impairment in adult patients with schizophrenia (CIAS)	Nonclinical + Clinical exploratory	Other
Chemical Medicinal Product	Gastroenterology-Hepatology	Treatment of Primary Biliary Cholangitis	Nonclinical + Clinical exploratory	Other
Chemical Medicinal Product	Oncology	Treatment of Glioblastoma	Nonclinical + Clinical exploratory	SME
Chemical Medicinal Product	Endocrinology-Gynaecology-Fertility-Metabolism	Delay of preterm delivery in women with spontaneous preterm labour	Nonclinical + Clinical exploratory	SME

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Cumulative overview of PRIME eligibility recommendations adopted by 22 April 2021

■ Granted ■ Denied ■ Out of scope* ■ Withdrawn

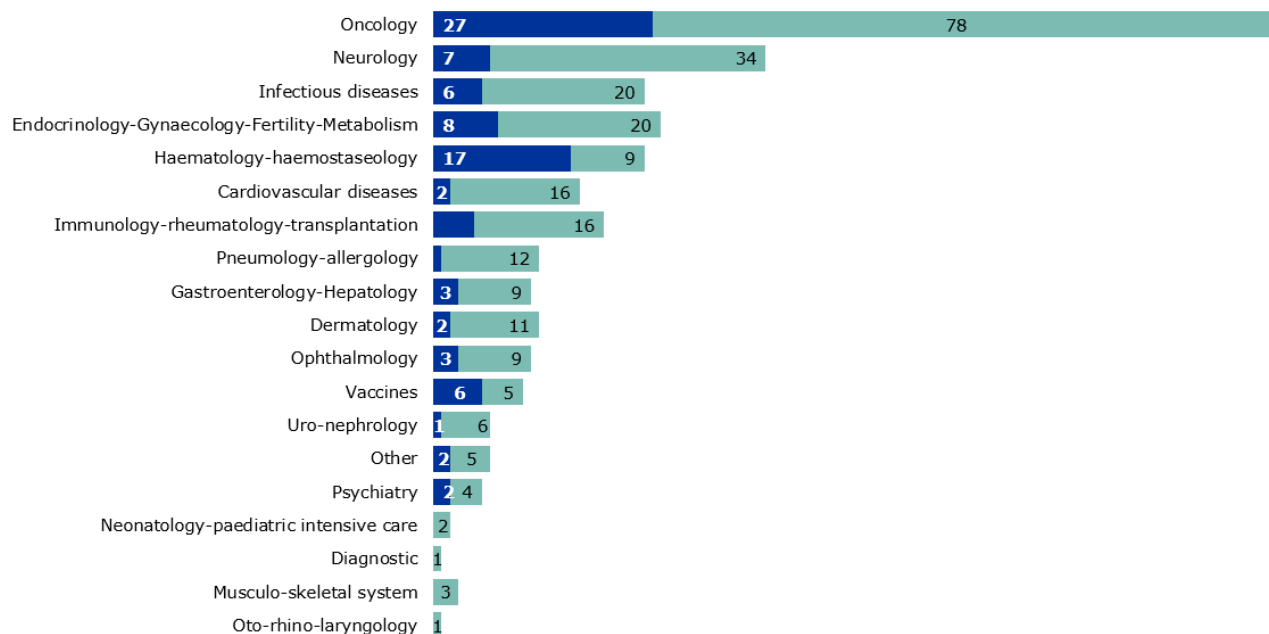
Overall number



By Applicant Type



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.