

27 July 2022 EMA/67996/2022 Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 18-21 July 2022

During its July 2022 meeting, the CHMP reviewed 4 recommendations for eligibility to PRIME: 1 was granted and 3 were denied. In addition, 1 request was received but not started by EMA as it was deemed outside the scope of the scheme.

The individual outcomes adopted this month are listed below.



Eligibility granted

Name*	Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Glenzocimab	Biological Medicinal	Haematology –	Treatment of acute ischemic stroke	Nonclinical + Clinical	SME
(ACT017)	Product	Hemostaseology		exploratory	

^{*} 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.

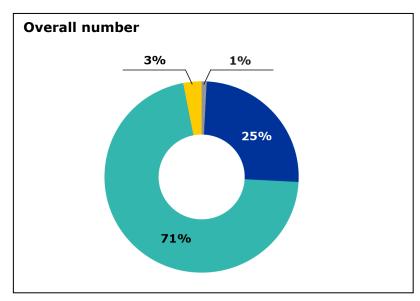
Eligibility denied

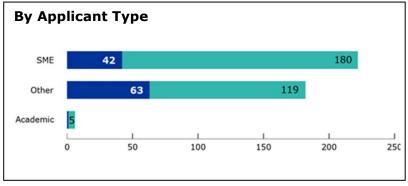
Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Neurology	Treatment of non-traumatic subarachnoid haemorrhage	Nonclinical + Clinical exploratory	SME
Chemical Medicinal Product	Oncology	Treatment of malignant glioma	Nonclinical + Clinical exploratory	SME
Chemical Medicinal Product	Oncology	First-line treatment of adult patients with metastatic or unresectable recurrent head and neck squamous cell carcinoma in combination with PD-1 inhibitors	Nonclinical + Tolerability first in man	SME

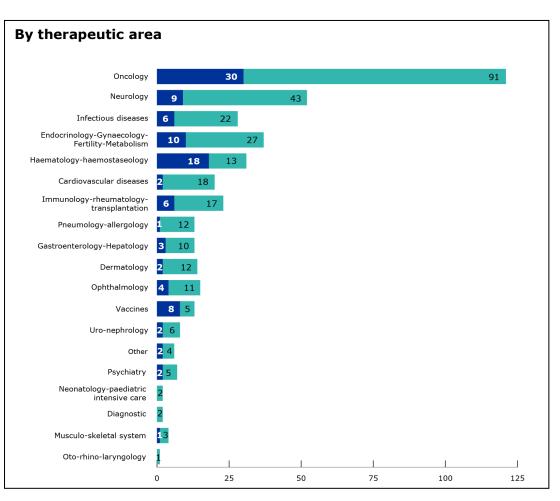
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Cumulative overview of PRIME eligibility recommendations adopted by 21 July 2022









^{*} 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.