



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 December 2020
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Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 07-10 December 2020

During its December 2020 meeting, the CHMP reviewed 3 recommendations for eligibility to PRIME: 1 was granted and 2 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
ECT-001-CB	Advanced Therapy Medicinal Product	Oncology	Urgent allogeneic haematopoietic stem cell transplantations	Nonclinical + 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.

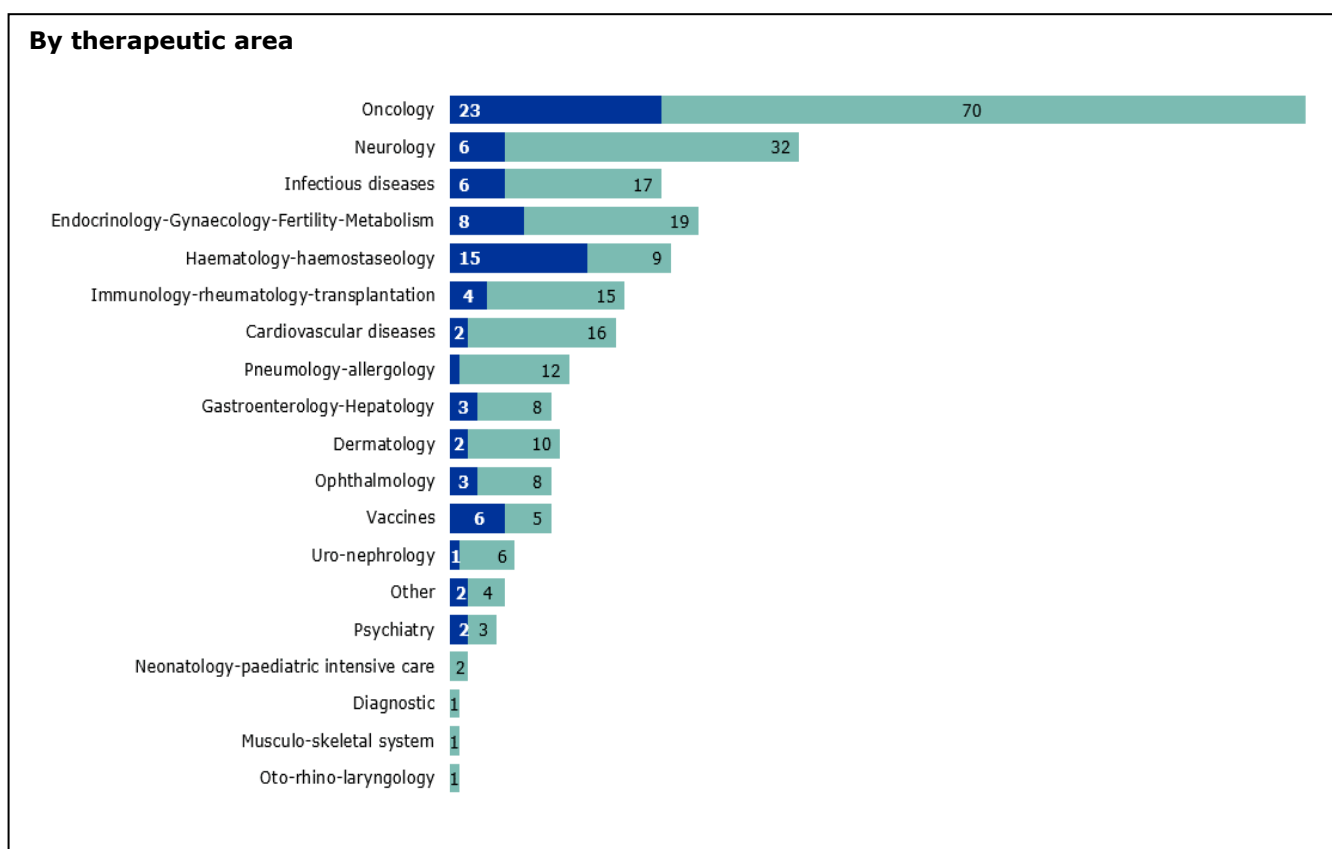
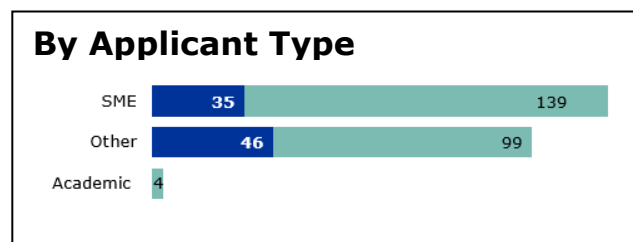
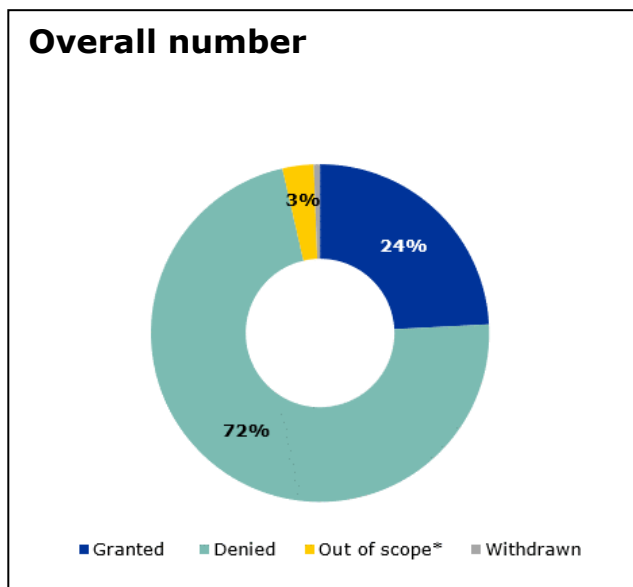
Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Endocrinology-Gynaecology-Fertility-Metabolism	Treatment of Hypoparathyroidism	Nonclinical + Clinical exploratory	SME
<i>Biological Medicinal Product</i>	<i>Oncology</i>	<i>Treatment of genetically defined cancers (histology-independent)</i>	<i>Nonclinical + Clinical exploratory (early entry)</i>	<i>SME</i>

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Cumulative overview of PRIME eligibility recommendations adopted by 10 December 2020

■ Granted ■ Denied ■ Out of scope*



* 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.