



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 October 2021
EMA/324213/2021
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 11-14 October 2021

During its October 2021 meeting, the CHMP reviewed 6 recommendations for eligibility to PRIME: 1 was granted and 5 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
Pabinafusp alfa (JR-141)	Biological Medicinal Product	Endocrinology- Gynaecology-Fertility- Metabolism	Treatment of Mucopolysaccharidosis type II (MPS II)	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.

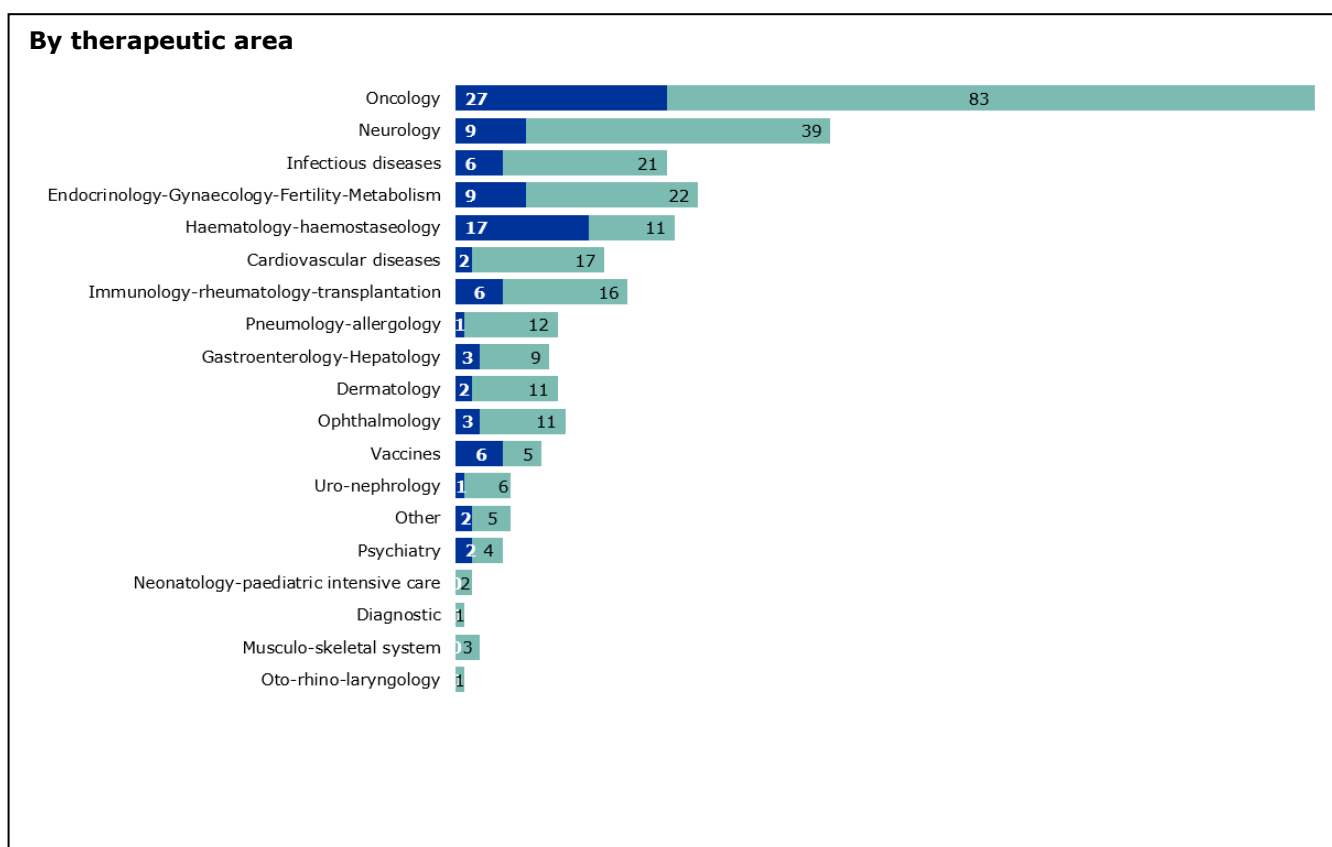
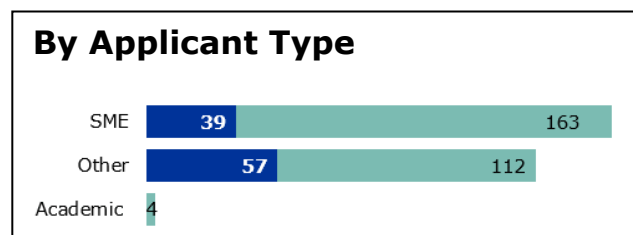
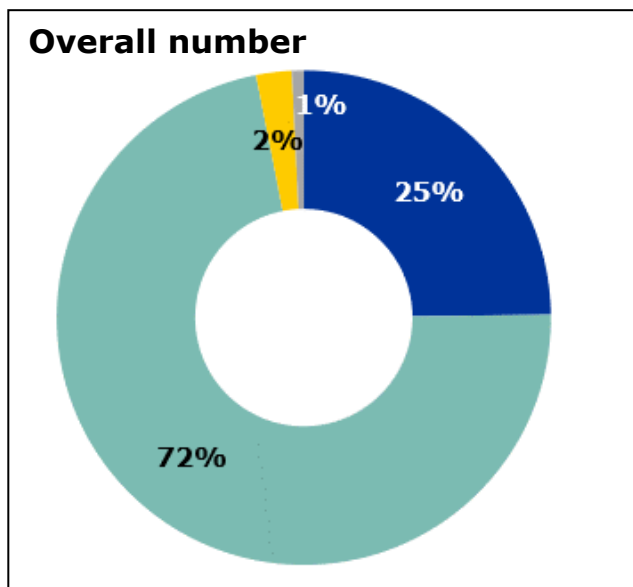
Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Endocrinology-Gynaecology-Fertility-Metabolism	Treatment of Niemann-Pick disease, Type C (NPC)	Nonclinical + Clinical exploratory	SME
Biological Medicinal Product	Neurology	Treatment of Alzheimer's disease	Nonclinical + Clinical exploratory	Other
Chemical Medicinal Product	Endocrinology-Gynaecology-Fertility-Metabolism	Type 1 diabetes	Nonclinical + Clinical exploratory	Other
Advanced Therapy Medicinal Product	Ophthalmology	Leber's Hereditary Optic Neuropathy (LHON) associated with ND4 G11778A mutation	Nonclinical + Clinical exploratory	Other
Chemical Medicinal Product	Haematology - Hemostaseology	Treatment of polycythaemia vera	Nonclinical + Clinical exploratory	SME

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Cumulative overview of PRIME eligibility recommendations adopted by 14 October 2021

■ 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.