



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 May 2021
EMA/25123/2021
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 17-20 May 2021

During its May 2021 meeting, the CHMP reviewed 2 recommendations for eligibility to PRIME: 1 was granted and 1 was 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
<i>CTI-1601</i>	<i>Biological Medicinal Product</i>	<i>Neurology</i>	<i>Treatment of Friedreich's Ataxia</i>	<i>Nonclinical + Tolerability first in man</i>	<i>SME</i>

* 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).

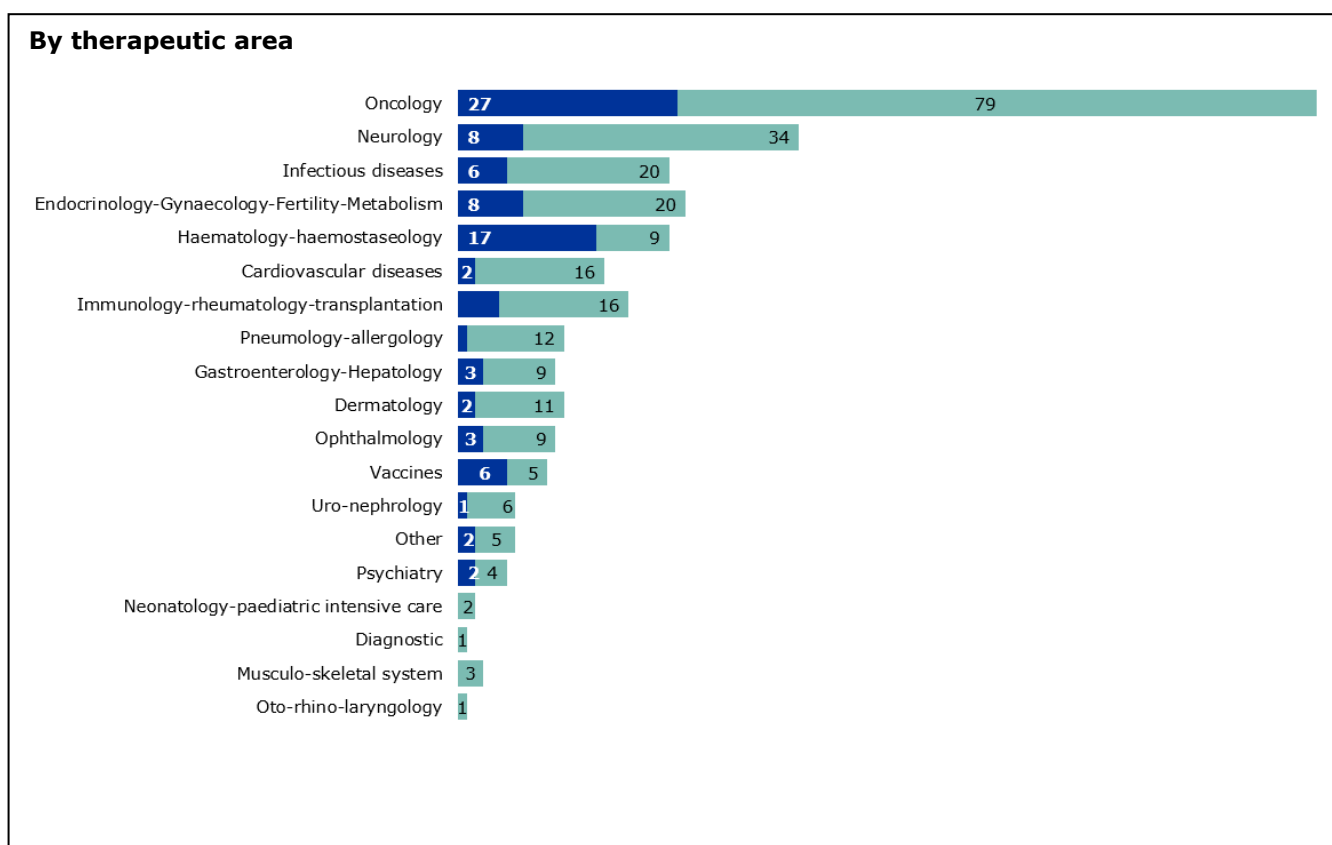
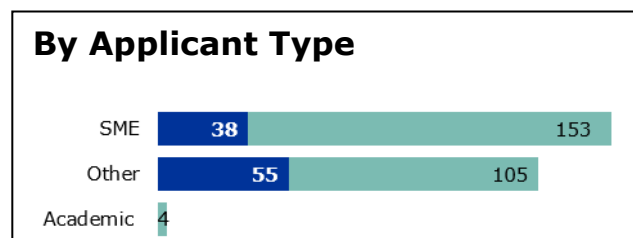
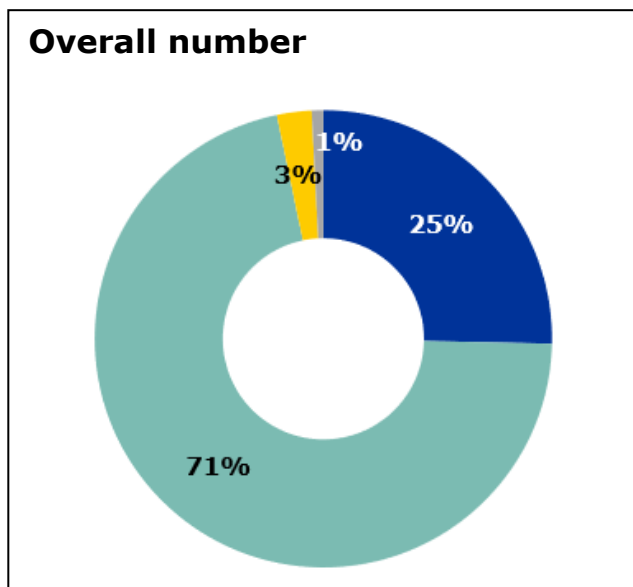
Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy Medicinal Product	Oncology	Treatment of BCG unresponsive non-muscle invasive bladder cancer	Nonclinical + Clinical exploratory	Other

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Cumulative overview of PRIME eligibility recommendations adopted by 20 May 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■ Granted ■ Denied ■ Out of scope* ■ Withdrawn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.