



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

31 July 2024  
EMA/332388/2024  
Press office

## Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 22-25 July 2024

During its July 2024 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*	Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
GD2-CART01	Oncology	Neoplasms benign, malignant and unspecified	Treatment of High Risk Relapsed/Refractory Neuroblastoma	Non-clinical + clinical exploratory	Academia

\* 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

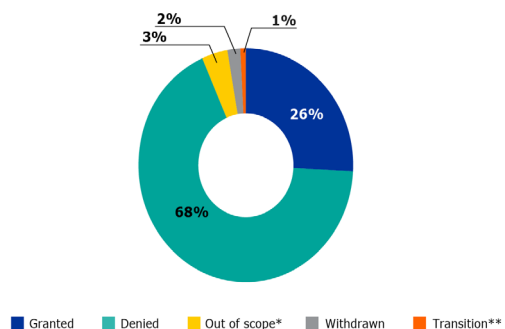
Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Biological Medicinal Product	Congenital, familial and genetic disorders	Treatment of mucopolysaccharidosis type IIIA (Sanfilippo A syndrome)	Non-clinical + clinical exploratory	SME

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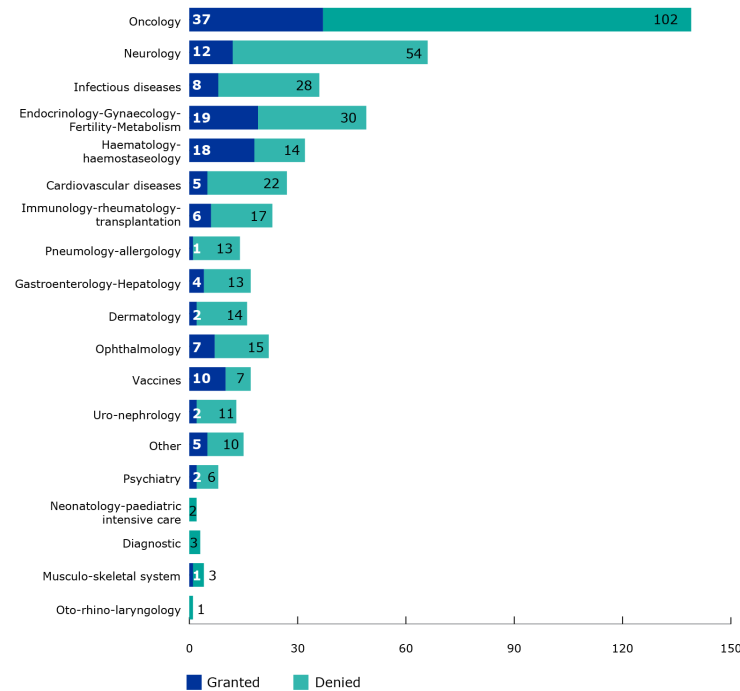
## Cumulative overview of PRIME eligibility recommendations adopted by 25 July 2024

■ Granted   
 ■ Denied   
 ■ Out of scope\*   
 ■ Withdrawn   
 ■ Transition\*\*

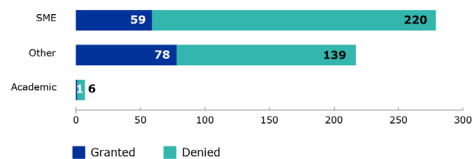
### Overall number



### By therapeutic area



### By Applicant Type



\* 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.

\*\* Application for transition from Early Entry to Full PRIME eligibility.