



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

7 May 2026  
EMA/93274/2026  
Press office

## Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 20-23 April 2026

During its April 2026 meeting, the CHMP reviewed 10 recommendations for eligibility to PRIME: 4 were granted and 6 were 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
<i>Zertomibgene cazparovec</i>	<i>Advanced Therapy Medicinal Product</i>	<i>Cardiac disorders</i>	<i>Treatment of hypertrophic cardiomyopathy due to mutations in the MYBPC3 gene encoding cardiac myosin-binding protein C</i>	<i>Non-clinical + clinical exploratory</i>	<i>SME</i>
<i>Adeno-associated virus vector serotype 9 containing the PKP2 gene (TN-401)</i>	<i>Advanced Therapy Medicinal Product</i>	<i>Cardiac disorders</i>	<i>Treatment of arrhythmogenic right ventricular cardiomyopathy due to plakophilin-2 gene mutations</i>	<i>Non-clinical + clinical exploratory</i>	<i>SME</i>
Adeno-associated virus serotype 2.7m8 containing the ChRown transgene	Advanced Therapy Medicinal Product	Eye disorders	Treatment of Retinitis Pigmentosa	Non-clinical + clinical exploratory	Other
Efimosfermin alfa	Biological Medicinal Product	Hepatobiliary disorders	Treatment of metabolic dysfunction-associated steatohepatitis (MASH)	Non-clinical + 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.

*Product(s) in italic have been granted eligibility to the scheme at early stages of development (proof of principle/proof of mechanism).*

## Eligibility denied

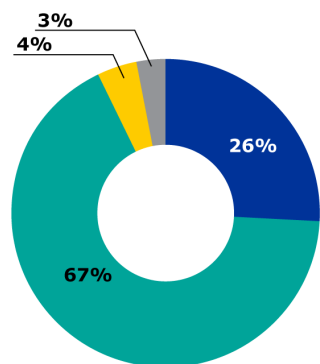
Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy Medicinal Product	Congenital, familial and genetic disorders	Treatment of ornithine transcarbamylase deficiency	Non-clinical + clinical exploratory	SME
Advanced Therapy Medicinal Product	Musculoskeletal and connective tissue disorders	Treatment of difficult to treat rheumatoid arthritis	Non-clinical + clinical exploratory	SME
Advanced Therapy Medicinal Product	Eye disorders	Treatment of neovascular age-related macular degeneration	Non-clinical + clinical exploratory	Other
Biological Medicinal Product	Blood and lymphatic system disorders	Treatment of Acute Myeloid Leukaemia	Non-clinical + clinical exploratory	Other
Chemical Medicinal Product	Oncology	Treatment of patients with SSTR2-positive unresectable or metastatic neuroendocrine tumors (NETs)	Non-clinical + clinical exploratory	SME
Chemical Medicinal Product	Nervous system disorders	Treatment of Acute Ischemic Stroke	Non-clinical + clinical exploratory	Other

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## Cumulative overview of PRIME eligibility recommendations adopted by 23 April 2026

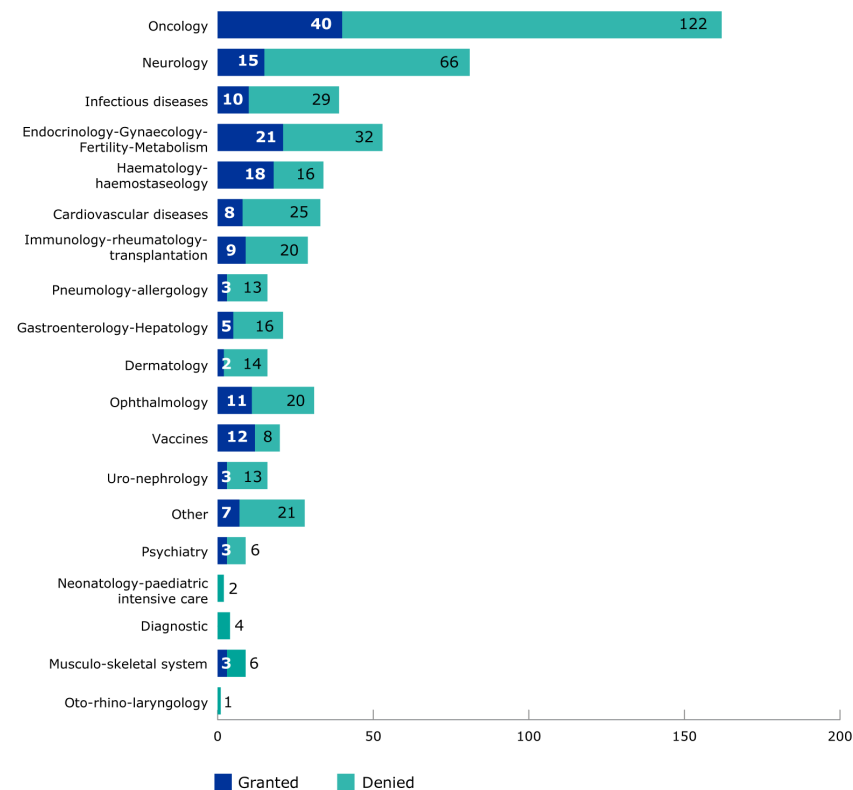
■ Granted
 ■ Denied
 ■ Out of scope\*
 ■ Withdrawn

### Overall number

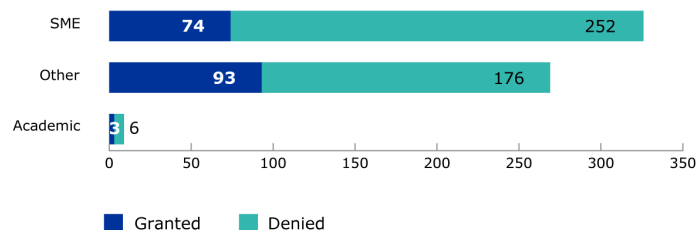


■ Granted
 ■ Denied
 ■ Out of scope\*
 ■ Withdrawn

### 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.