



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Press office

## Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 23-26 February 2026

During its February 2026 meeting, the CHMP reviewed 5 recommendations for eligibility to PRIME: 3 were granted and 2 were denied. The individual outcomes adopted this month are listed below.

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**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands  
**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)  
**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

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## Eligibility granted

Name*	Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Allogeneic peripheral blood mononuclear cells treated with mitomycin C	Advanced Therapy Medicinal Product	Immune system disorders	Individualized immunosuppression in living donor kidney transplantation	Non-clinical + clinical exploratory	SME
Bretisilocin	Chemical Medicinal Product	Psychiatric disorders	Treatment of Major Depressive Disorder	Non-clinical + clinical exploratory	Other
<i>SPL84</i>	<i>Chemical Medicinal Product</i>	<i>Respiratory, thoracic and mediastinal disorders</i>	<i>Treatment of cystic fibrosis for patients carrying the 3849 mutation</i>	<i>Non-clinical + clinical exploratory</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).*

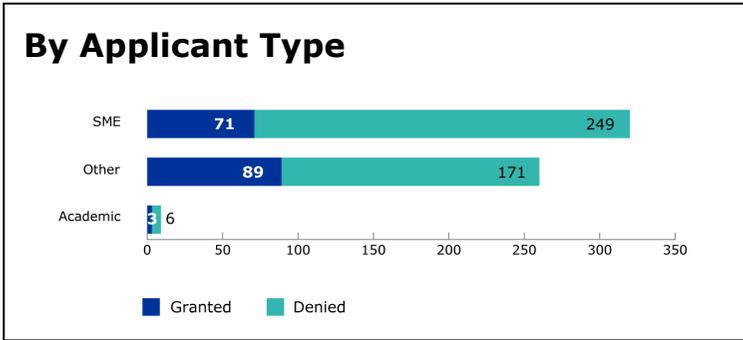
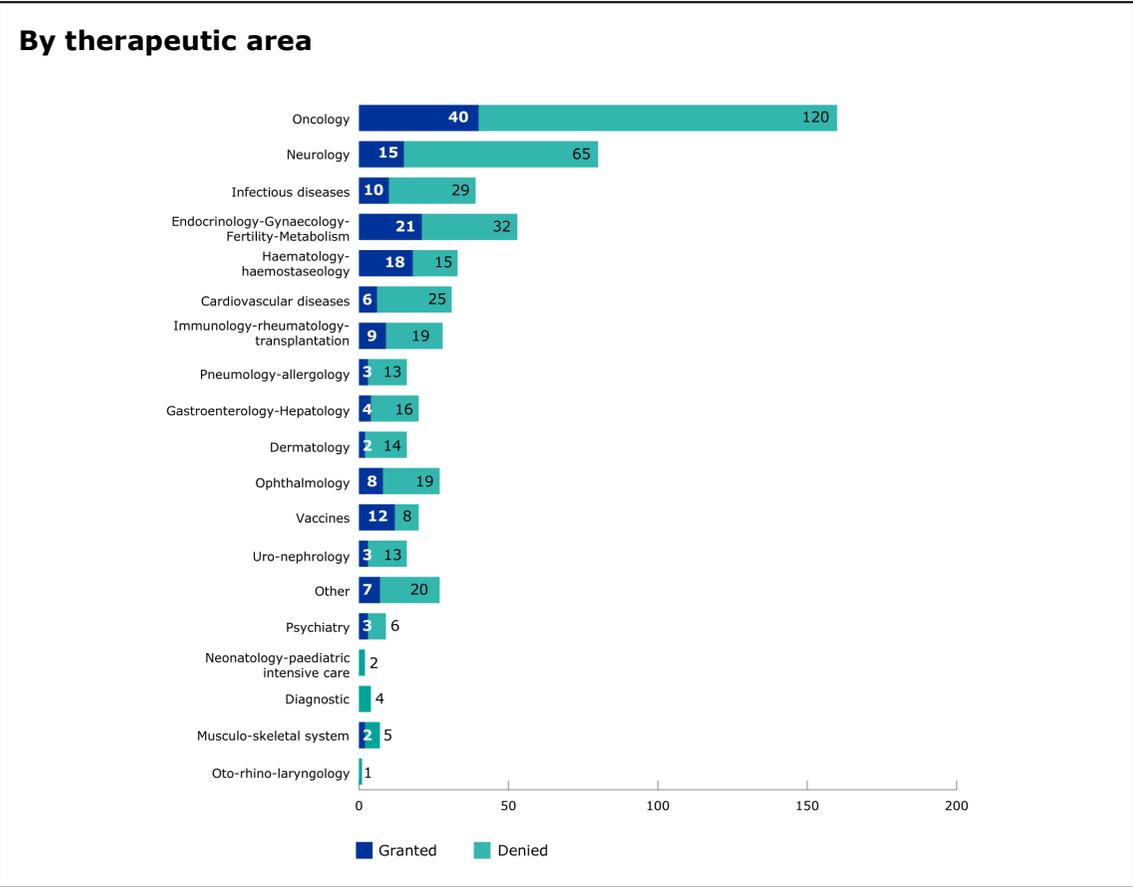
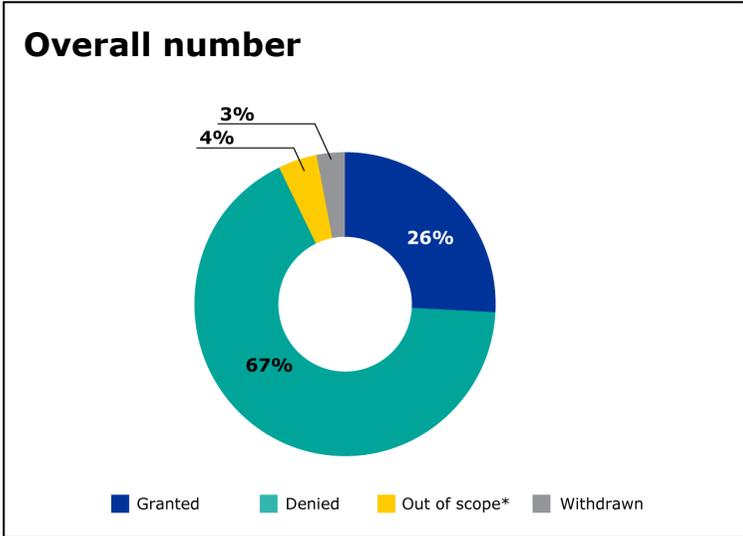
## Eligibility denied

Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy Medicinal Product	Nervous system disorders	Treatment of Duchenne muscular dystrophy	Non-clinical + clinical exploratory	Other
Biological Medicinal Product	Immune system disorders	Treatment of Pulmonary Sarcoidosis	Non-clinical + clinical exploratory	SME

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# Cumulative overview of PRIME eligibility recommendations adopted by 26 February 2026

■ 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.