



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 June 2025  
EMA/200552/2025  
Press office

## Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 16-19 June 2025

During its June 2025 meeting, the CHMP reviewed 6 recommendations for eligibility to PRIME: 2 were granted and 4 were denied. The individual outcomes adopted this month are listed below.

---

**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

An agency of the European Union



## Eligibility granted

Name*	Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
ELA 026	Biological Medicinal Product	Immune system disorders	Treatment of secondary Hemophagocytic lymphohistiocytosis (sHLH)	Clinical exploratory	SME
Povetacicept	Biological Medicinal Product	Renal and urinary disorders	Treatment of Primary Membranous Nephropathy (pMN)	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.

## Eligibility denied

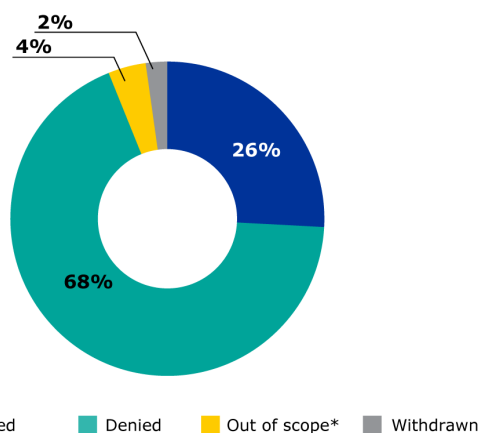
Product type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Biological Medicinal Product	Oncology	Treatment of Multiple Myeloma	Non-clinical + clinical exploratory	Other
Biological Medicinal Product	Vaccines	Prevention of tuberculosis disease	Non-clinical + clinical exploratory	Other
Advanced Therapy Medicinal Product	Oncology	Treatment of adult patients with relapsed or refractory large B-cell lymphoma or follicular lymphoma grade 3B after 1 line of chemoimmunotherapy	Non-clinical + clinical exploratory	Other
Chemical Medicinal Product	Metabolism and nutrition disorders	Treatment of Hyperuricemia and tophi in adult patients with gout who are refractory to conventional therapy	Non-clinical + clinical exploratory	Other

SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other type of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

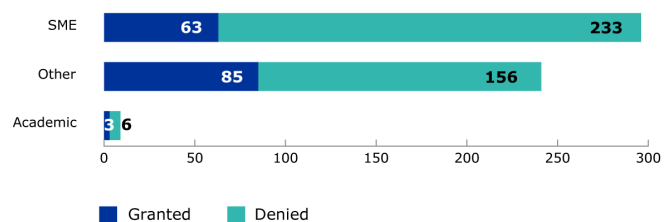
## Cumulative overview of PRIME eligibility recommendations adopted by 19 June 2025

■ Granted ■ Denied ■ Out of scope\* ■ Withdrawn

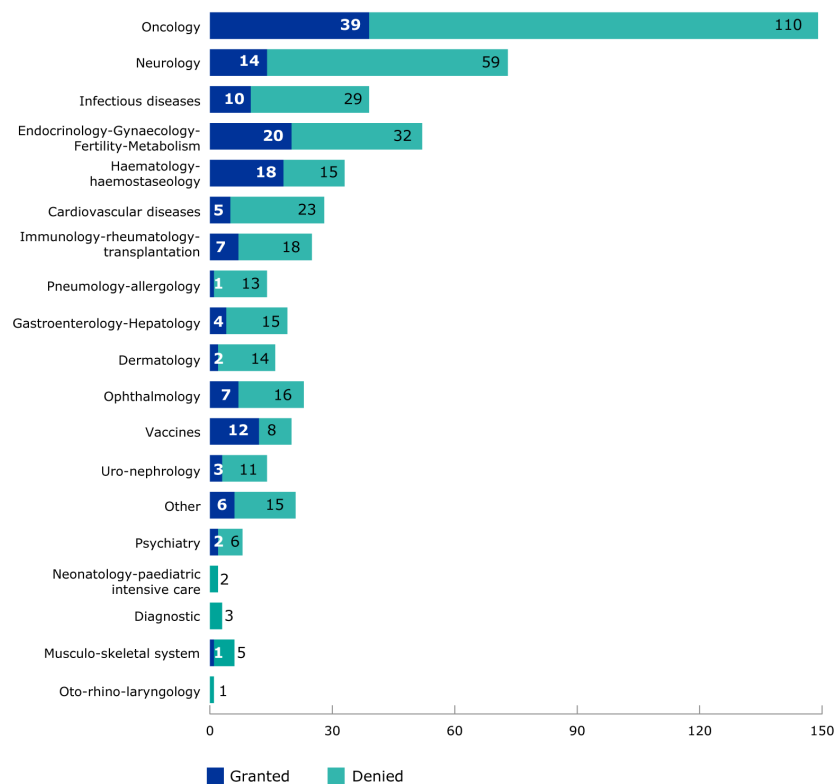
### Overall number



### By Applicant Type



### By therapeutic area



\* 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.