



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

28 February 2024  
EMA/71120/2024  
Press office

## Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 19-22 February 2024

During its February 2024 meeting, the CHMP reviewed 3 recommendations for eligibility to PRIME: 1 was granted and 2 were 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
AUP1602-C	Advanced Therapy Medicinal Product	Endocrine disorders	Treatment of non-healing Diabetic Foot Ulcer	Non-clinical + Clinical exploratory	SME

\* 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.

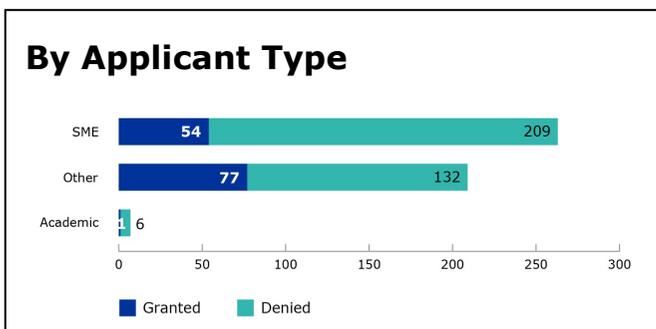
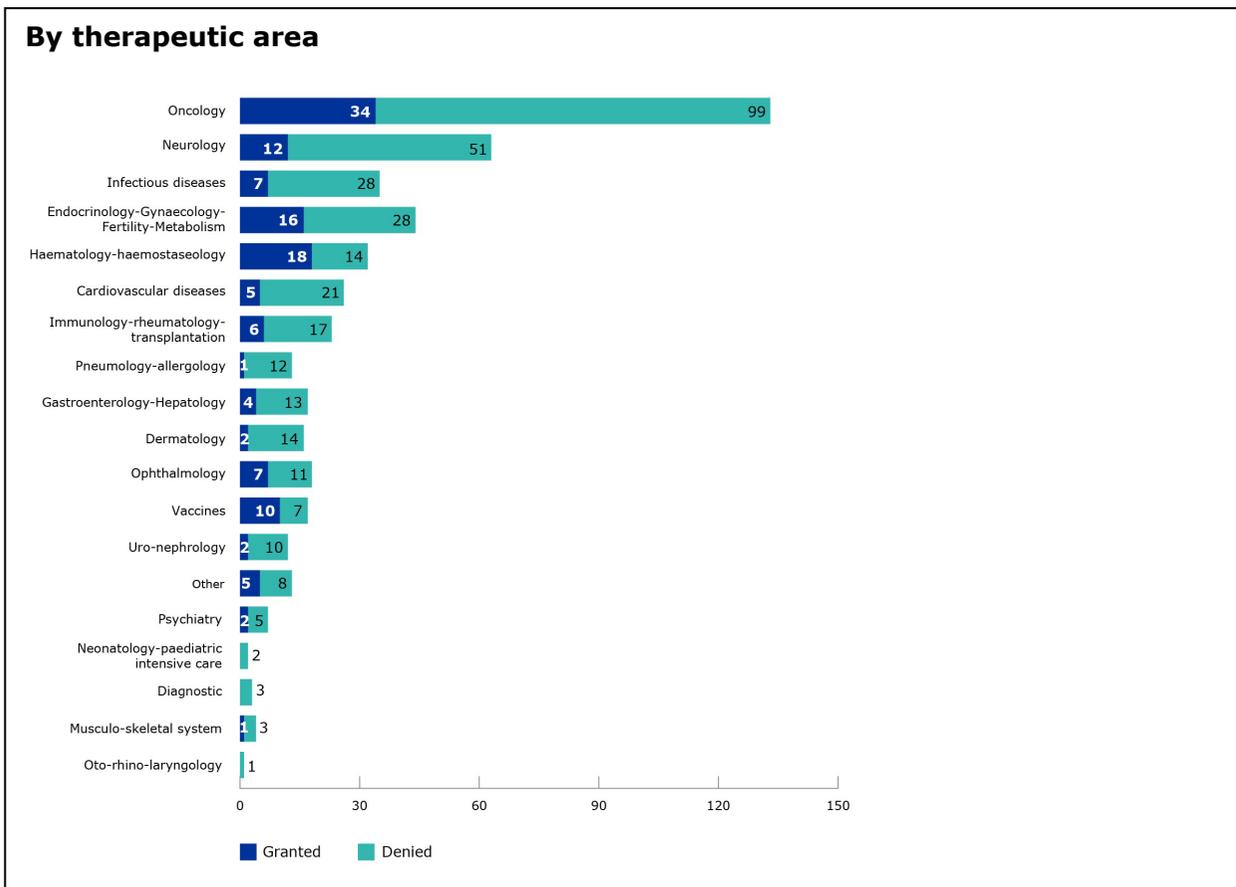
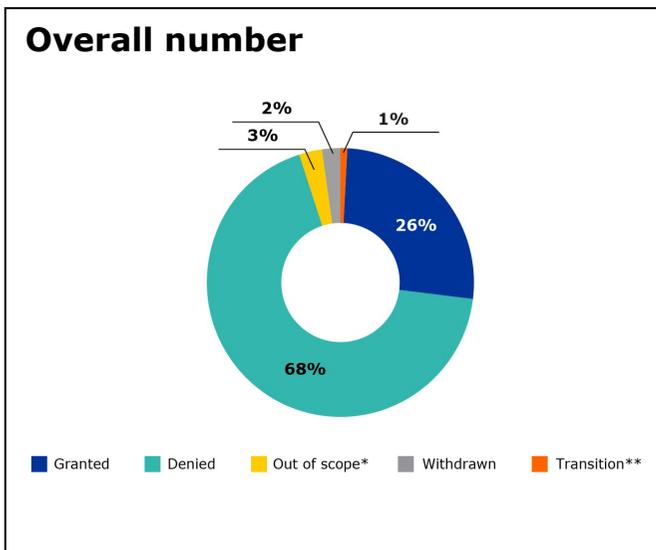
## Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical Medicinal Product	Gastrointestinal disorders	Treatment of pain related to oral mucositis	Non-clinical + Clinical exploratory	SME
Biological Medicinal Product	Infectious Diseases	Treatment of septic shock	Non-clinical + Clinical exploratory	SME

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## Cumulative overview of PRIME eligibility recommendations adopted by 22 February 2024

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 ■ Withdrawn   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



\* 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.