

1 July 2020 EMA/254662/2020 Press office

## Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 22-25 June 2020

During its June 2020 meeting, the CHMP reviewed 2 recommendations for eligibility to PRIME: 2 were denied. In addition, 1 request was received but not started by EMA as it was deemed outside the scope of the scheme.

The individual outcomes adopted this month are listed below.

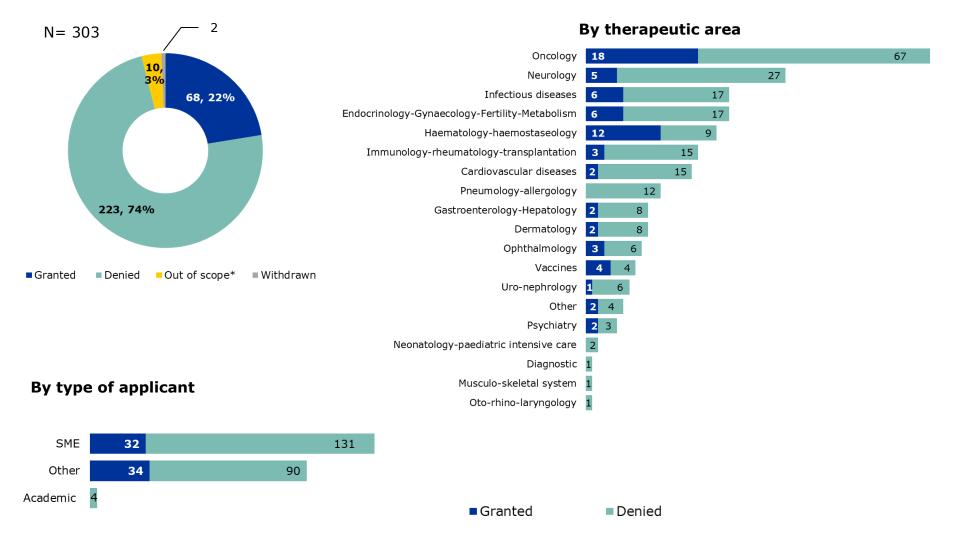


## **Eligibility denied**

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Radiopharmaceutical	Oncology	Treatment of relapse/refractory multiple myeloma in patients having received four prior treatment regimens or more	Nonclinical+ Clinical exploratory	SME
Biological	Immunology- Rheumatology- Transplantation	Treatment of systemic sclerosis	Nonclinical+ Clinical exploratory	SME

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 recommendations on PRIME eligibility requests adopted by 25 June 2020



<sup>\*</sup> 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.