03 March 2021
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Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 22-25 February 2021

During its February 2021 meeting, the CHMP reviewed 4 recommendations for eligibility to PRIME which were denied.

The individual outcomes adopted this month are listed below.

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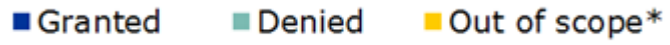
Eligibility denied

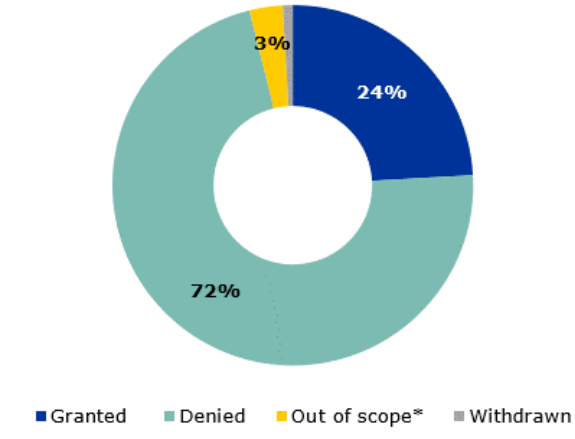
Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy Medicinal Product	Endocrinology-Gynaecology-Fertility-Metabolism	Stem cell therapy for ovarian insufficiency including Diminished Ovarian Reserve (DOR), Premature Ovarian Failure (POF), Primary Ovarian Insufficiency (POI) and Poor Ovarian Response (POR)	Nonclinical + Clinical exploratory	SME
Chemical Medicinal Product	Musculoskeletal disorders	Treatment of Fibrodysplasia Ossificans Progressiva	Nonclinical + Clinical exploratory	Other
Chemical Medicinal Product	Oncology	Treatment of adult patients with ROS1-positive, advanced non-small cell lung cancer (NSCLC), not previously treated with ROS1 inhibitors	Nonclinical + Clinical exploratory	Other
Immunological Medicinal Product	Oncology	Adjuvant treatment of stage IIB/IIC melanoma after surgical resection	Nonclinical + 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 25 February 2021

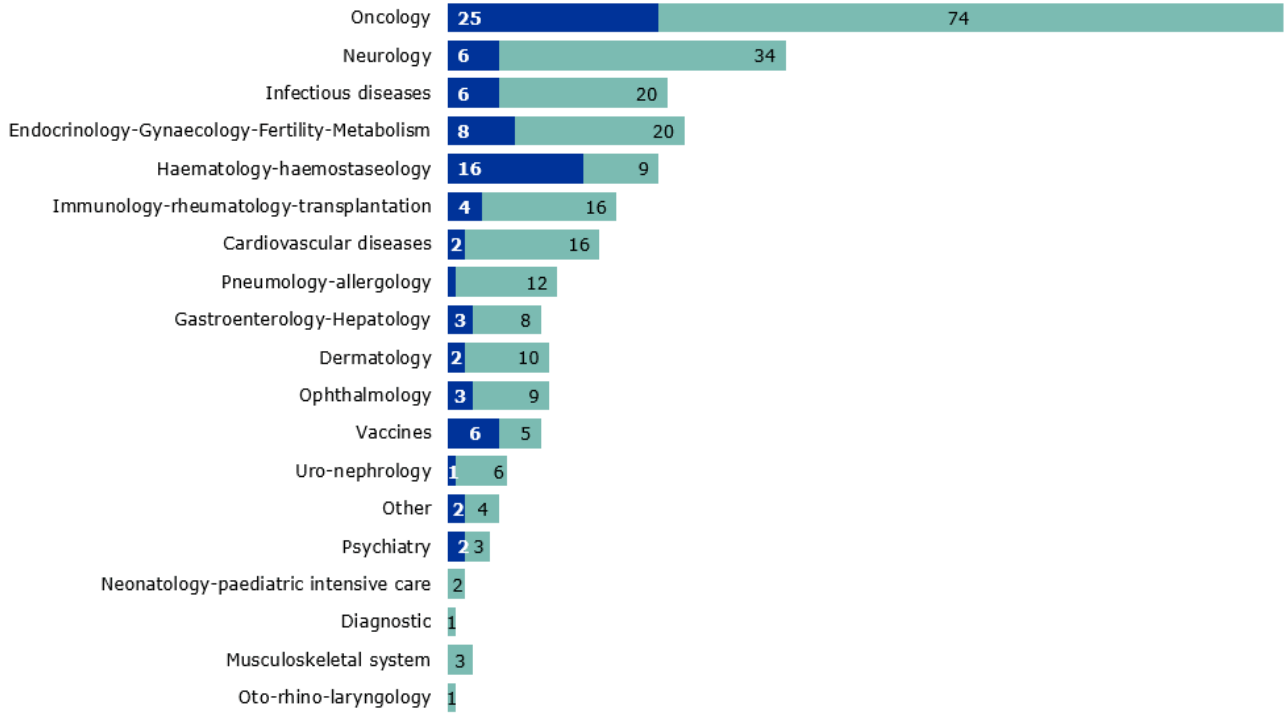


Overall number



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.