21 November 2018
EMA/664833/2018
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 12-15 November 2018

During its November 2018 meeting, the CHMP reviewed 7 recommendations for eligibility to PRIME: 7 were denied.

The individual outcomes adopted this month are listed below.

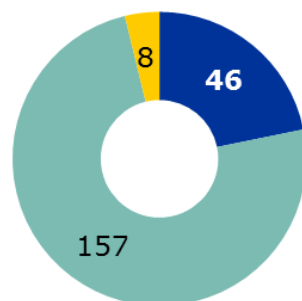## Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy	Dermatology	Treatment of Dystrophic Epidermolysis Bullosa	Nonclinical+ Clinical exploratory	SME
Advanced Therapy	Immunology-Rheumatology-Transplantation	Treatment of therapy-refractory acute graft-versus-host disease in patients following allogeneic haematopoietic stem cell transplantation	Nonclinical+ other	Other
Biological	Cardiovascular Diseases	Treatment of pulmonary hypertension	Nonclinical + Tolerability first in man	SME
Chemical	Psychiatry	Treatment of Post-Traumatic Stress Disorder	Nonclinical+ Clinical exploratory	SME
Chemical	Other	Treatment of Duchenne muscular dystrophy	Nonclinical+ Clinical exploratory	SME
Chemical	Immunology-Rheumatology-Transplantation	Treatment of moderate to severe alopecia areata patients with 50% or greater scalp hair loss (including alopecia totalis and alopecia universalis)	Nonclinical+ Clinical exploratory	Other
Chemical	Uro-nephrology	Treatment of primary hyperoxaluria	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 15 November 2018
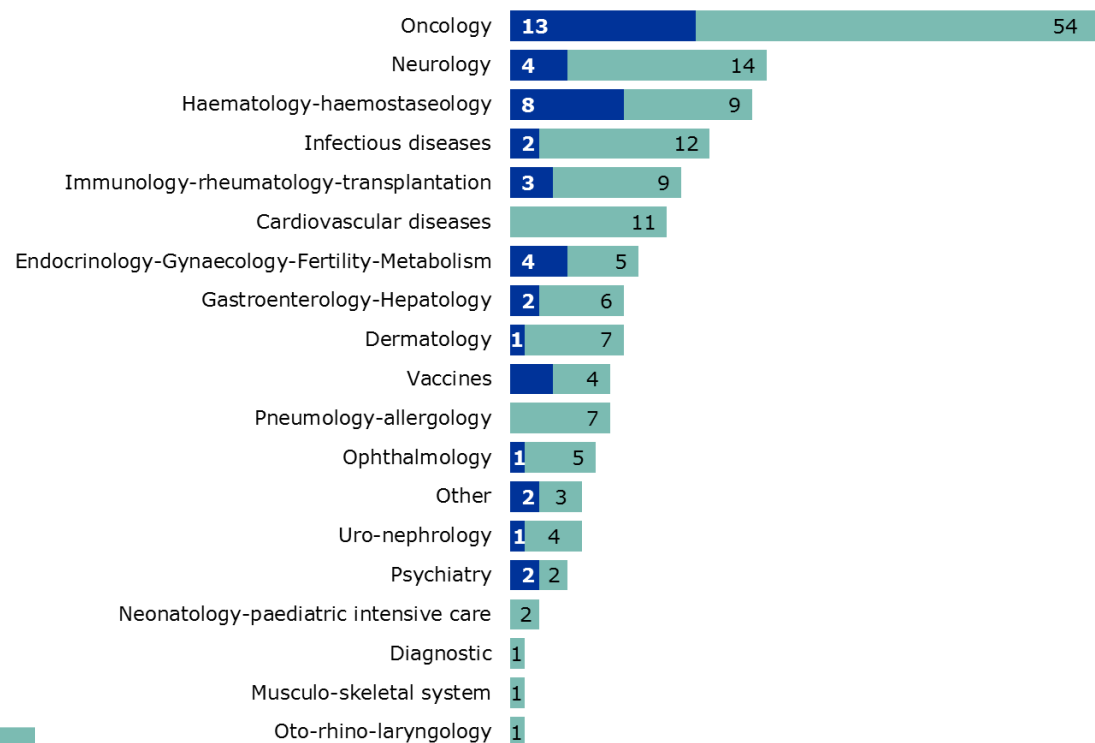

Donut chart:
- Granted: 46
- Denied: 157
- Out of scope*: 8

Legend: ■ Granted ■ Denied ■ Out of scope*

By therapeutic area

Therapeutic area	Granted	Denied
Oncology	13	54
Neurology	4	14
Haematology-haemostaseology	8	9
Infectious diseases	2	12
Immunology-rheumatology-transplantation	3	9
Cardiovascular diseases		11
Endocrinology-Gynaecology-Fertility-Metabolism	4	5
Gastroenterology-Hepatology	2	6
Dermatology	1	7
Vaccines		4
Pneumology-allergology		7
Ophthalmology	1	5
Other	2	3
Uro-nephrology	1	4
Psychiatry	2	2
Neonatology-paediatric intensive care		2
Diagnostic		1
Musculo-skeletal system		1
Oto-rhino-laryngology		1

By type of applicant

Type	Granted	Denied
SME	23	91
Other	23	63
Academic		3

Legend: ■ Granted ■ Denied

* 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.