Wednesday 18 October
EMA/668873/2016
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 9-12 October 2017

During its October 2017 meeting, the CHMP reviewed 7 recommendations for eligibility to PRIME: 3 were granted and 4 were denied.
The individual outcomes adopted this month are listed below.

Additionally, the CHMP reviewed data on progress to proof of concept and confirmed eligibility for A4250 in the treatment of progressive familial intrahepatic cholestasis, which was initially granted eligibility to the scheme at early stages of development (proof of principle/proof of mechanism) on 13 October 2016.

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Eligibility granted

Name*	Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Entrectinib	Chemical	Oncology	Treatment of NTRK fusion-positive, locally advanced or metastatic solid tumours in adult and paediatric patients who have either progressed following prior therapies or who have no acceptable standard therapy	Nonclinical + Clinical exploratory	SME
Humanized antibody targeting B cell maturation antigen conjugated with maleimidocaproyl monomethyl auristatin F	Biological	Oncology	Treatment of relapsed and refractory multiple myeloma patients whose prior therapy included a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 antibody	Nonclinical + Clinical exploratory	Other
Human immunoglobulin G1 constant region - human ectodysplasin-A1 receptor-binding domain fusion protein	Biological	Dermatology	Treatment of X-linked hypohidrotic ectodermal dysplasia	Nonclinical + 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

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical	Pneumology-Allergology	Treatment of Idiopathic Pulmonary Fibrosis	Nonclinical + Clinical exploratory	Other
Advanced Therapy	Cardiovascular Diseases	Treatment of patients with acute myocardial infarction	Nonclinical + Clinical exploratory	SME
Biological	Neurology	Treatment of metachromatic leukodystrophy	Nonclinical + Clinical exploratory	Other
Chemical	Haematology - Hemostaseology	Treatment of Sickle Cell Disease	Nonclinical + Clinical exploratory	Other

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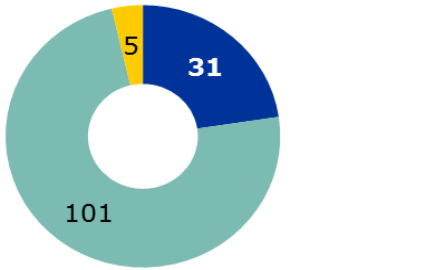
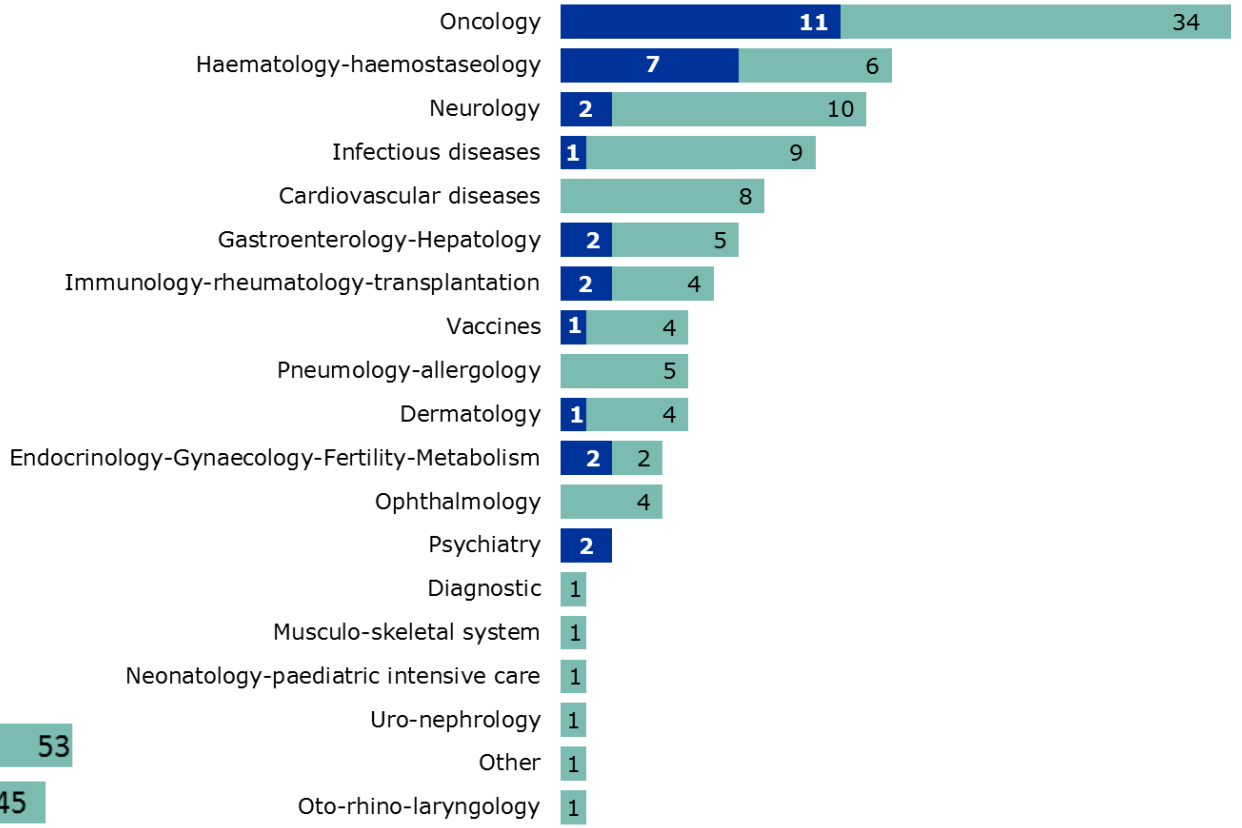
Cumulative overview of recommendations on PRIME eligibility requests adopted by 12 October 2017

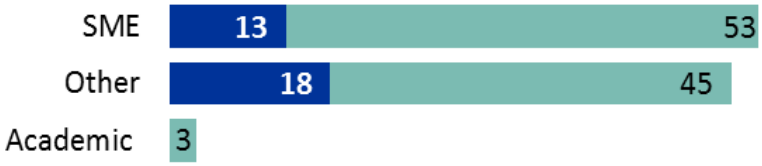


Granted Denied Out of scope*

By therapeutic area



By type of applicant



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.