



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 May 2018
EMA/116717/2018
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 23-26 April 2018

During its April 2018 meeting, the CHMP reviewed 3 recommendations for eligibility to PRIME: 3 were denied. The individual outcomes adopted this month are listed below.

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5550

Send a question via our website www.ema.europa.eu/contact

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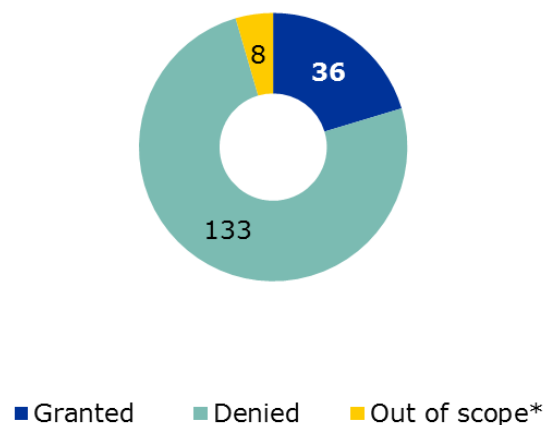


Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Chemical	Oncology	Reduction of the duration, incidence and severity of severe oral mucositis induced by radiation therapy, with or without systemic therapy	Nonclinical+ Clinical confirmatory	SME
Chemical	Oncology	Prevention and treatment of Gorlin syndrome	Nonclinical+ Clinical exploratory	Other
Chemical	Haematology - Hemostaseology	Treatment of Warm Antibody Autoimmune Haemolytic Anaemia who failed at least one prior treatment regimen	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.

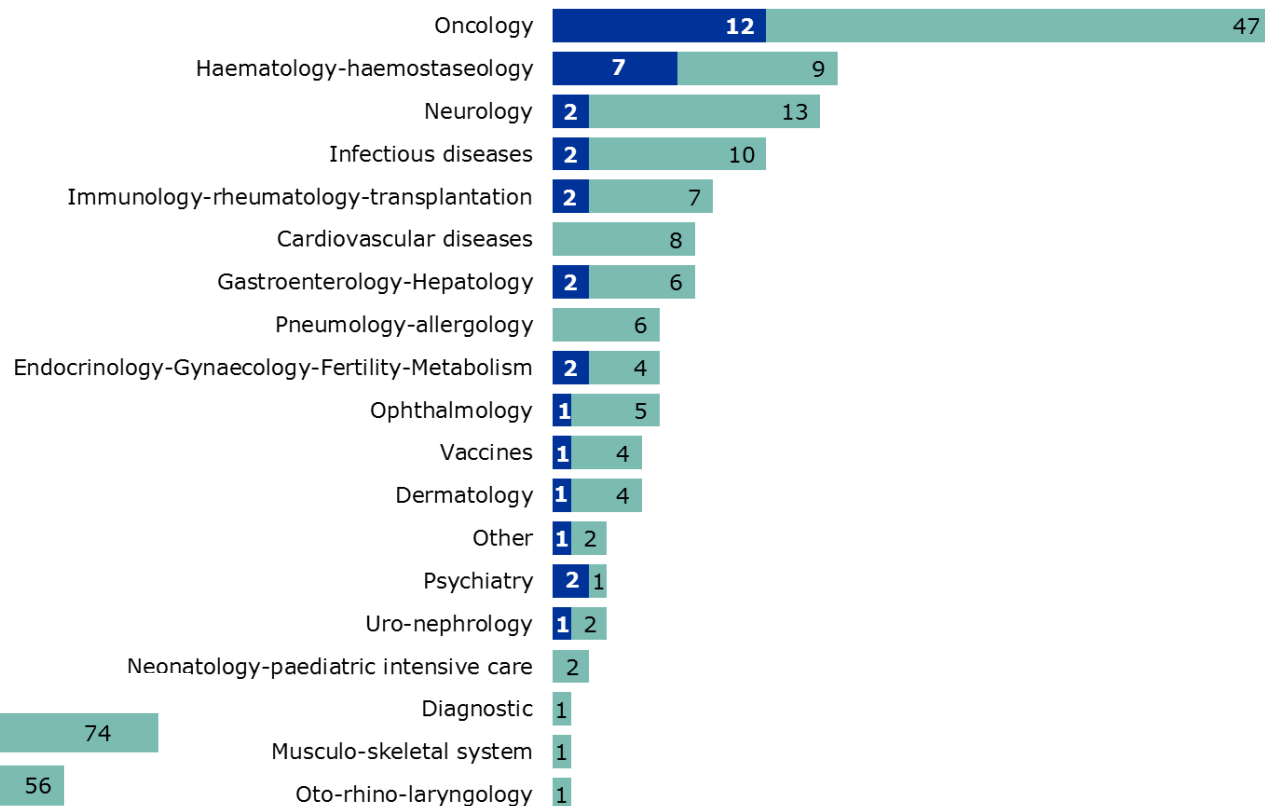
Cumulative overview of recommendations on PRIME eligibility requests adopted by 26 April 2018



By type of applicant



By therapeutic area



■ 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.