



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 17-20 July 2017

During its July 2017 meeting, the CHMP reviewed 8 recommendations for eligibility to PRIME: 1 was granted and 7 were denied.

The individual outcomes adopted this month are listed below.

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Eligibility granted

Name*	Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Vocimagene amiretroreprevec	Advanced Therapy	Oncology	Treatment of high grade glioma	Nonclinical + Clinical exploratory	SME

* Name of the active substance, INN, common name, chemical name or company code.

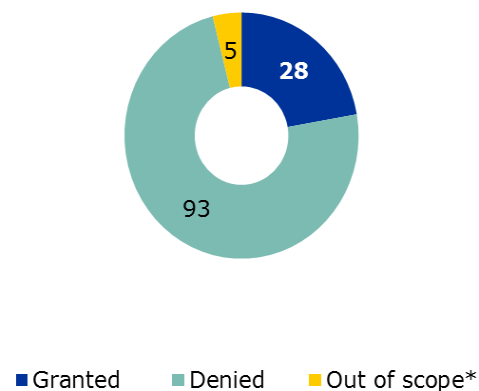
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other types of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Biological	Oncology	Treatment of metastatic melanoma C	Nonclinical + Clinical exploratory	Other
Chemical	Oncology	Treatment of cholangiocarcinoma	Nonclinical + Clinical exploratory	SME
Advanced Therapy	Neurology	Treatment of ischaemic stroke	Nonclinical + Clinical exploratory	SME
Chemical	Ophthalmology	Treatment of neurotrophic keratitis	Nonclinical + Clinical exploratory	SME
Chemical	Dermatology	Treatment of chronic hand eczema	Nonclinical + Clinical exploratory	Other
Advanced Therapy	Oto-rhino-laryngology	Treatment of genetic muscular disorder	Nonclinical + Clinical exploratory	Academic
Biological	Other	Treatment of light chain amyloidosis	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.

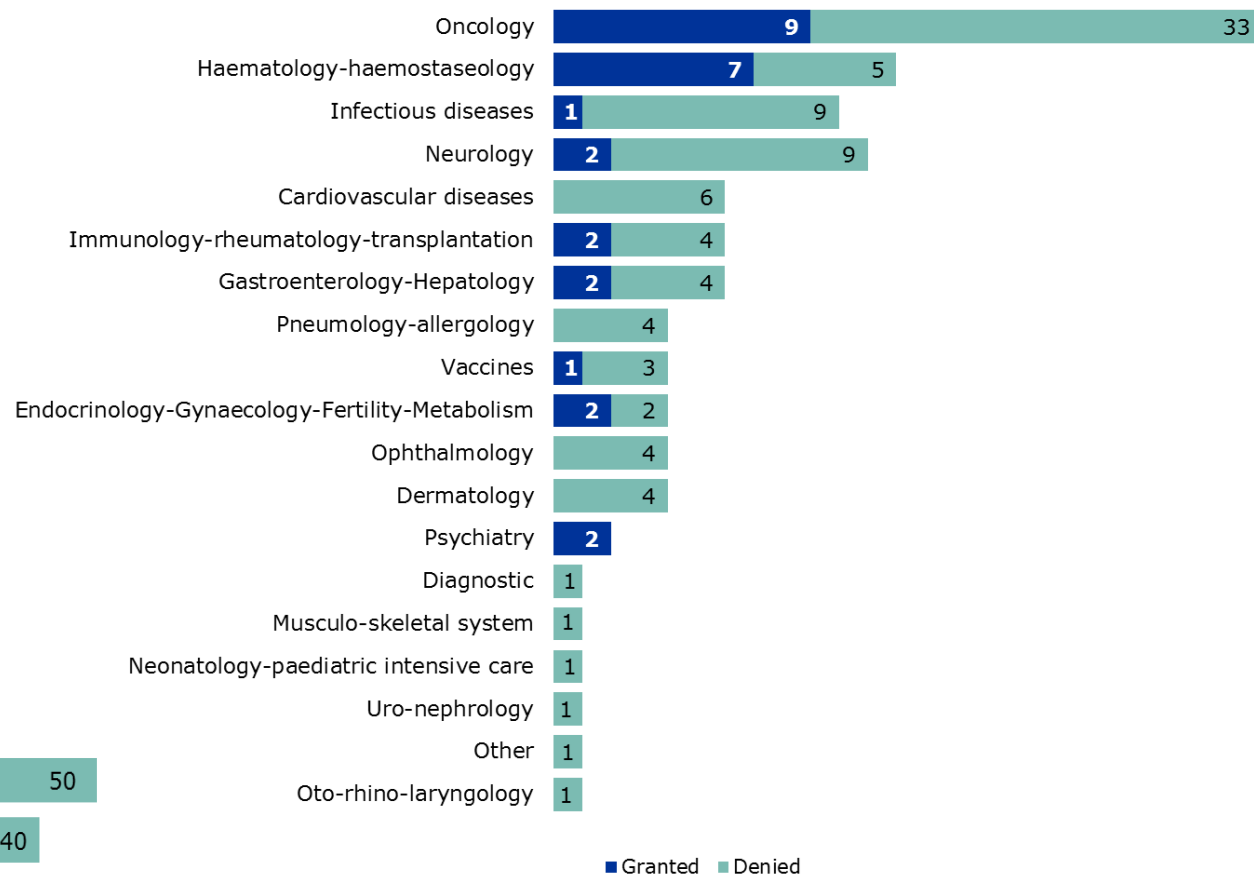
Cumulative overview of recommendations on PRIME eligibility requests adopted by 20 July 2017



By type of applicant



By therapeutic area



* One eligible product has subsequently been withdrawn from the scheme at the applicant's request
 Out of scope 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.