26 April 2017
EMA/668824/2016
Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 18-21 April 2017

During its April 2017 meeting, the CHMP reviewed 5 recommendations for eligibility to PRIME: 1 was granted and 4 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
Adeno-associated viral vector serotype 5 containing human factor IX gene (AMT-060)	Advanced therapy	Haematology - Hemostaseology	Treatment of severe haemophilia B	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
Chemical	Oncology	Treatment of patients with advanced or metastatic ALK-positive non-small cell lung cancer	Nonclinical + Clinical exploratory	Other
Advanced therapy	Oncology	Treatment of metastatic melanoma	Nonclinical + Clinical exploratory	SME
Advanced therapy	Cardiovascular Diseases	Treatment of chronic cardiac ischemia	Nonclinical + Clinical exploratory	Academic
Chemical	Neurology	Treatment of Rett syndrome	Nonclinical + Tolerability first in man	SME

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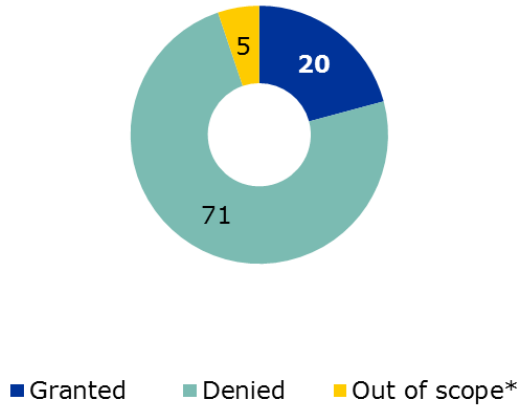
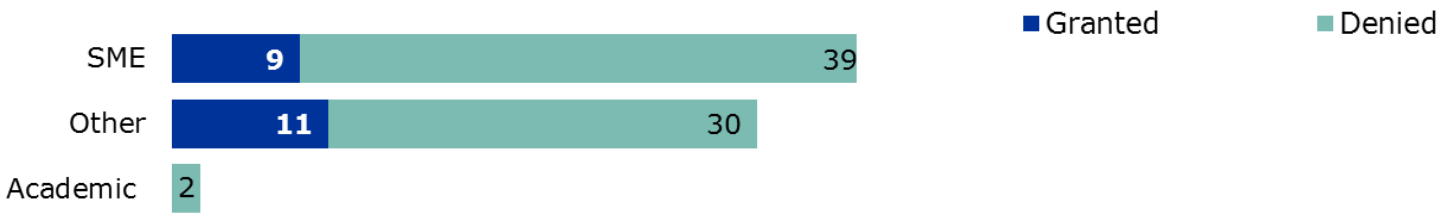
Cumulative overview of recommendations on PRIME eligibility requests adopted by 23 March 2017



By therapeutic area

By type of applicant



* One eligible product has subsequently been withdrawn from the scheme at the applicant's request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