



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 25-28 June 2018

During its June 2018 meeting, the CHMP reviewed 4 recommendations for eligibility to PRIME: 3 were granted and 1 was 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
Deoxycytidine / deoxythymidine	Chemical	Endocrinology-Gynaecology-Fertility-Metabolism	Treatment of Thymidine Kinase 2 Deficiency	Nonclinical + Clinical exploratory	SME
<i>Mycobacterium tuberculosis (MTBVAC)</i>	<i>Immunological</i>	<i>Vaccines</i>	<i>Active immunization against tuberculosis disease in newborns, adolescents and adults</i>	<i>Nonclinical + Tolerability first in man</i>	<i>SME</i>
Setmelanotide	Chemical	Endocrinology-Gynaecology-Fertility-Metabolism	Treatment of obesity and the control of hunger associated with deficiency disorders of the MC4R receptor pathway	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.

Product(s) in italic have been granted eligibility to the scheme at early stages of development (proof of principle/proof of mechanism).

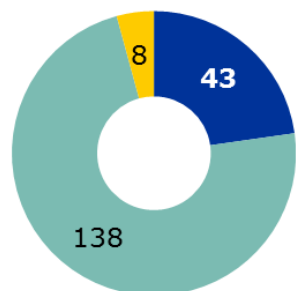
Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Biological	Oncology	Treatment of adult patients with HER2-positive breast cancer	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.

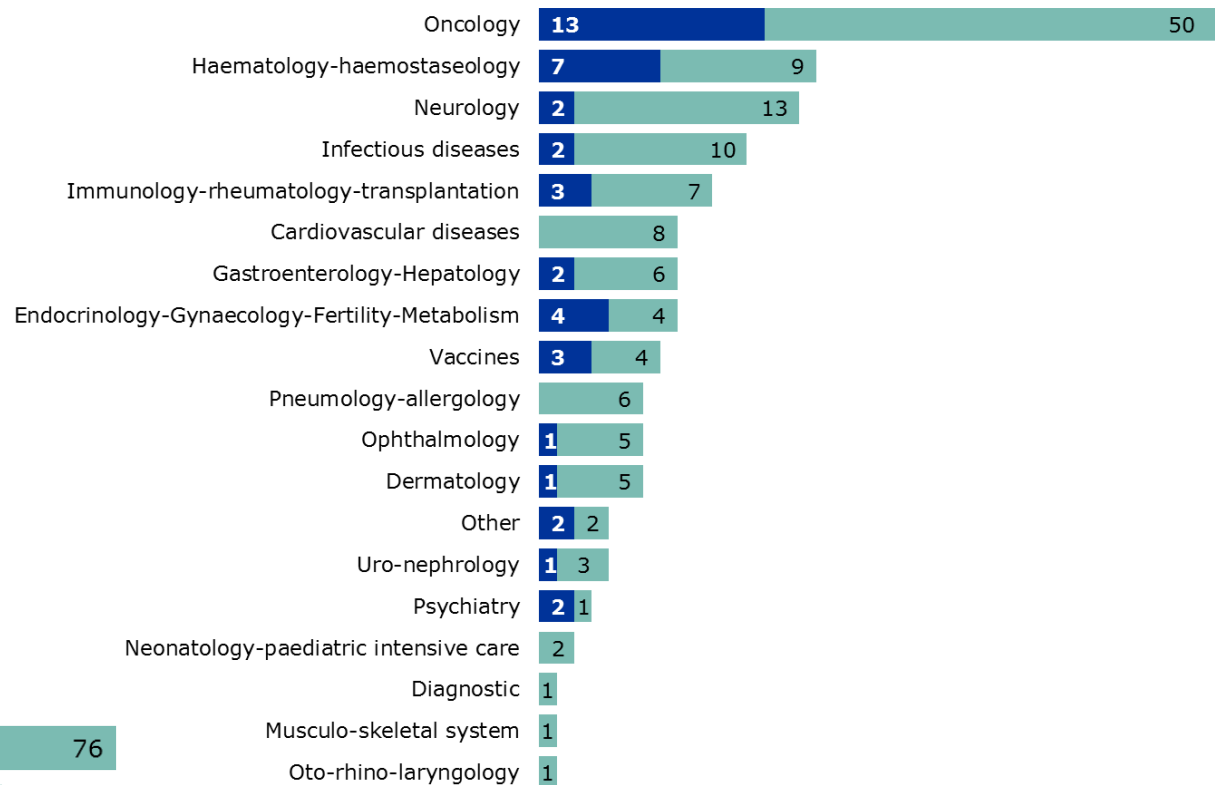
Cumulative overview of recommendations on PRIME eligibility requests adopted by 28 June 2018

Corr*



■ 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.

*Figures corrected on page 4.