26 April 2022
EMA/67991/2022
Press office

# Recommendations on eligibility to PRIME scheme

## Adopted at the CHMP meeting of 19-22 April 2022

During its April 2022 meeting, the CHMP reviewed 5 recommendations for eligibility to PRIME: 2 were granted and 3 were denied. In addition, 1 request was received but not started by EMA as it was deemed outside the scope of the scheme.
The individual outcomes adopted this month are listed below.

## Eligibility granted

| Name* | Substance type | Therapeutic area | Therapeutic indication | Type of data supporting request | Type of applicant |
|---|---|---|---|---|---|
| *BCX9250* | *Chemical Medicinal Product* | *Other, please specify: Musculoskeletal and connective tissue disorders* | *Treatment of fibrodysplasia ossificans progressiva* | *Nonclinical + Tolerability first in man* | *SME* |
| GBS6 (Group B Streptococcus 6-Valent Polysaccharide Conjugate Vaccine) | Immunological Medicinal Product | Vaccines | Prevention of Group B streptococcal invasive disease due to the vaccine serotypes in infants by active immunization of pregnant women | 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.

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

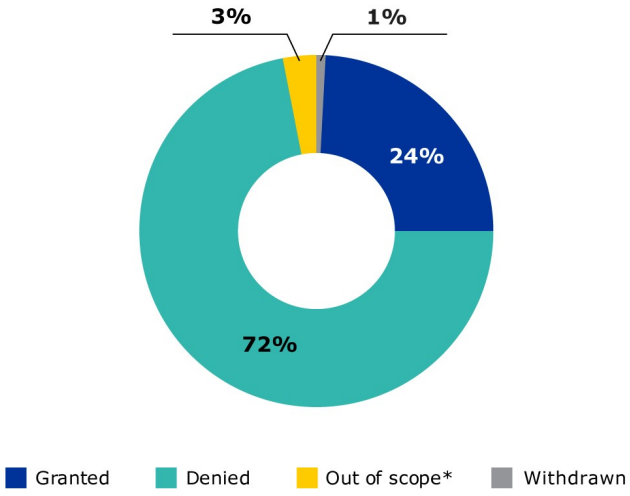
## Eligibility denied

| Substance type | Therapeutic area | Therapeutic indication | Type of data supporting request | Type of applicant |
|---|---|---|---|---|
| Chemical Medicinal Product | Endocrinology-Gynaecology-Fertility-Metabolism | Treatment of congenital hyperinsulinism | Nonclinical + Tolerability first in man | SME |
| Chemical Medicinal Product | Dermatology | Treatment of recessive dystrophic epidermolysis bullosa | Nonclinical + Clinical exploratory | SME |
| Radiopharmaceutical Medicinal Product | Diagnostic | Diagnosis of indeterminate renal masses previously identified on CT or MRI as clear cell Renal Cell Carcinoma (ccRCC) or non-ccRCC. | Nonclinical + Clinical exploratory | SME |

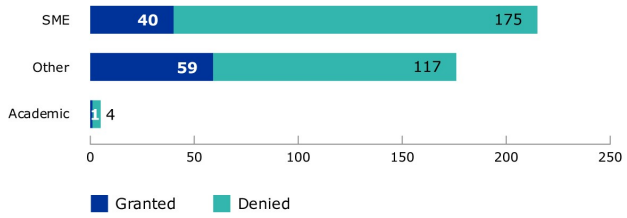
SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other type of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

# Cumulative overview of PRIME eligibility recommendations adopted by 22 April 2022

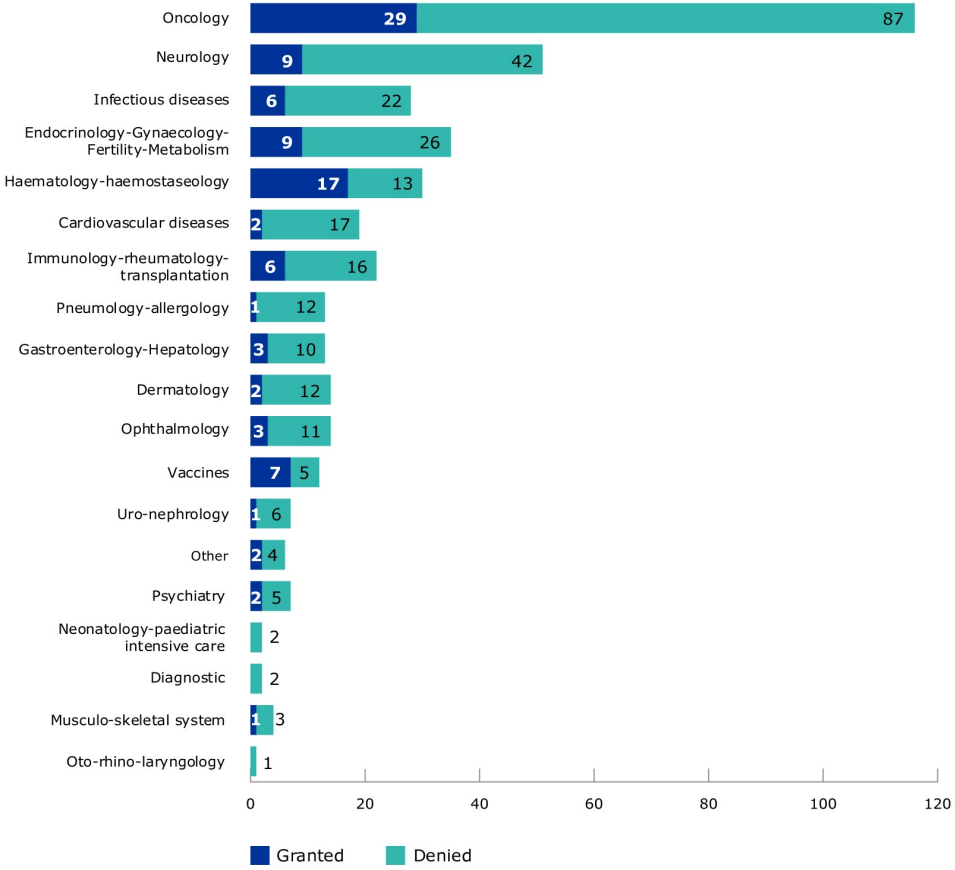

## Overall number




## By Applicant Type




## By therapeutic area




* 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.