



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 26-29 January 2026

During its January 2026 meeting, the CHMP reviewed 6 recommendations for eligibility to PRIME: 1 was granted and 5 were denied. The individual outcomes adopted this month are listed below.

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Eligibility granted

| Name* | Product type | Therapeutic area | Therapeutic indication | Type of data supporting request | Type of applicant |
|---|------------------------------------|-------------------------|--|-------------------------------------|-------------------|
| Autologous T-cells transduced with lentiviral vector expressing a chimeric antigen receptor directed against CD19 | Advanced Therapy Medicinal Product | Immune system disorders | Treatment of Systemic Lupus Erythematosus (SLE) either with or without renal involvement (Lupus Nephritis, LN) | Non-clinical + 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.

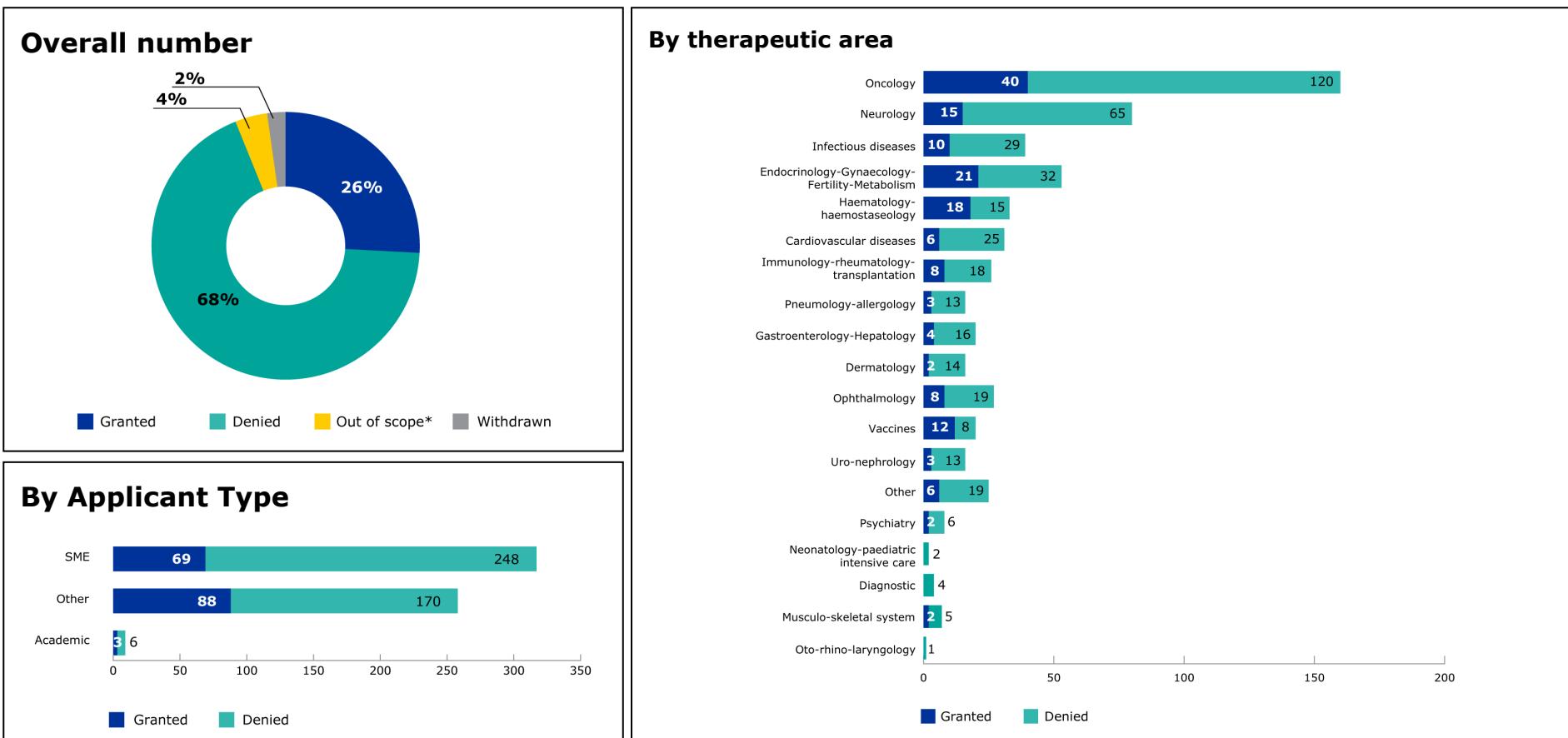
Eligibility denied

| Product type | Therapeutic area | Therapeutic indication | Type of data supporting request | Type of applicant |
|------------------------------------|--|---|-------------------------------------|-------------------|
| Advanced Therapy Medicinal Product | Congenital, familial and genetic disorders | Treatment of inherited retinal dystrophies due to dysfunction in the ABCA4 gene | Non-clinical + clinical exploratory | SME |
| Advanced Therapy Medicinal Product | Cardiac disorders | Treatment of advanced heart failure | Non-clinical + clinical exploratory | SME |
| Advanced Therapy Medicinal Product | Oncology | Treatment of mantle cell lymphoma | Non-clinical + clinical exploratory | Other |
| Chemical Medicinal Product | Congenital, familial and genetic disorders | Treatment of spinal and bulbar muscular atrophy | Non-clinical + clinical exploratory | Other |
| Chemical Medicinal Product | Nervous system disorders | Treatment of acute ischaemic stroke | Non-clinical + clinical exploratory | Other |

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Cumulative overview of PRIME eligibility recommendations adopted by 29 January 2026

■ Granted ■ Denied ■ Out of scope* ■ Withdrawn



* 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.