



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 September 2023
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Press office

Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 11-14 September 2023

During its September 2023 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.

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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Eligibility granted

Name*	Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Iopofosine I-131	Radiopharmaceutical Medicinal Product	Oncology	Treatment of patients with Waldenstrom's macroglobulinemia (WM) who received at least two prior lines of therapy	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.

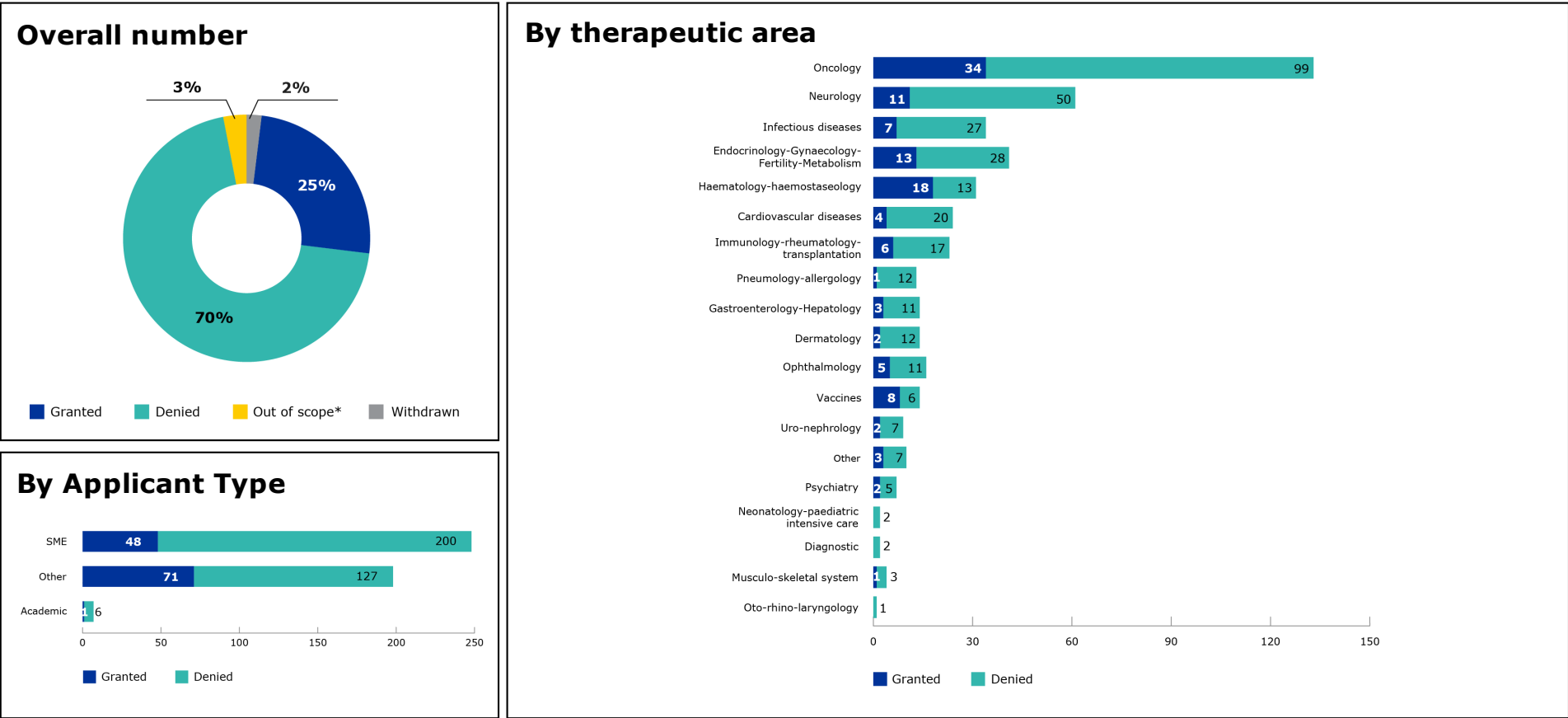
Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy Medicinal Product	Gastroenterology-Hepatology	Treatment of Acute-on-chronic liver failure (ACLF)	Nonclinical + Clinical exploratory	SME
Advanced Therapy Medicinal Product	Oncology	Treatment of adult patients with relapsed or refractory multiple myeloma who have received four or more classes of prior therapies	Nonclinical + Clinical exploratory	Other
Biological Medicinal Product	Infectious Diseases	Treatment of sepsis and septic shock	Nonclinical + Tolerability first in man	SME
Chemical Medicinal Product	Infectious Diseases	Treatment of infections due to <i>Acinetobacter baumannii-calcoaceticus</i> complex (ABC)	Nonclinical + Clinical exploratory	Other
Chemical Medicinal Product	Neurology	Treatment of Amyotrophic Lateral Sclerosis	Nonclinical + Clinical exploratory	SME

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Cumulative overview of PRIME eligibility recommendations adopted by 14 September 2023

■ 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.