



MINISTERIO
DE SANIDAD



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Multi-stakeholder workshop on psychedelics – Towards an EU regulatory framework 16-17 April 2024 Hybrid meeting / EMA, Amsterdam

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SPRAVATO® reimbursed since 1/11/2022

Current reimbursed indication: Treatment-resistant depression

Challenges faced in Health technology assessment after approval

POPULATION

- Identification of target population out of the clinical trial
- Patients with comorbidity
- Therapy along with esketamine

INTERVENTION

- Administration
 - Supervised
 - Emergency wards
 - Hospitalization

COMPARATOR

- Definition of failure (no response) to previous therapies
- What about other therapies: Electroconvulsive, Intracranial Magnetic stimulation, psychologic therapy

OUTCOMES

- Definition of clinical significance: Delta for superiority
- Follow-up: testing for relapses
- Uncertainty long-term course of the disease

Thank you!

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