



Regulatory and Development Landscape in the EU

What is the current regulatory status of psychedelic medicines in the EU? What are the current therapeutics in the development pipeline, and what are the possible timelines for their approval? Through this segment, we'll unravel the complexities, shed light on the challenges and opportunities, and provide a clear picture of the EU's evolving psychedelic landscape.

Session 1

THE REGULATORY LANDSCAPE AND PATHWAYS TO ACCESS IN THE EU

Tadeusz Hawrot

Session 2

THE PSYCHEDELIC DRUG DEVELOPMENT PIPELINE

Josh Hardman

Development and Implementation of Psychedelics in the EU

What does the path from laboratory to patient look like for psychedelic medicines in the EU? How can developers navigate the complex process, from EMA authorisation to HTA and pricing evaluations? What are the key challenges in designing effective trials within the EU's diverse regulatory environment, and what strategies can be employed to overcome them? This segment explores the multifaceted development and implementation process, uncovers critical insights, and provides a comprehensive roadmap, guiding you through the intricacies of bringing psychedelic medicines to those who need them most.

Session 3

TOWARDS MARKETING APPROVAL OF PSYCHEDELICS - DESIGNING TRIALS AND ENGAGING WITH REGULATORS

Panelists: Amir Inamdar, Pavel Balabanov, PsyPan, Tom McDonald, Vanina Popova

Moderator: Paul Bezodis

Session 4

INTRODUCTION TO HEALTH TECHNOLOGY ASSESSMENT AND COST-EFFECTIVENESS

Martin Gisby

Session 5

CAPTURING THE VALUE FOR PATIENTS, PAYERS, AND PUBLIC - THE COST-EFFECTIVENESS OF PSYCHEDELIC TREATMENTS

Panelists: Anne Katrin Schlag, Elliot Marseille, Sherry Rais

Moderator: Martin Gisby

Pre-Approval Access

How can patients get legal access to psychedelic therapies before they're officially approved? How can experiences from pre-approval access programs shape best practices and guidelines for safe and effective use? In this segment, we'll learn from early access and compassionate use programs in Switzerland, Canada, and Australia and hear from therapists and patients about the dilemmas they face.

Session 6

CATCH 22: THE INACCESSIBILITY OF PSYCHEDELIC TREATMENTS IN THE CONTEXT OF THE WIDE AVAILABILITY OF PSYCHEDELICS IN THE WILD

Alex Lethen, Renske Blom

Session 7

PRE-APPROVAL ACCESS - GLOBAL APPROACHES TO OFFERING PSYCHEDELIC THERAPIES FOR SPECIFIC PATIENTS GROUP: LESSONS LEARNED FROM AUSTRALIA, SWITZERLAND AND CANADA

Panelists: Benjamin Lightburn, Brigit Toebe, Helena Aicher, Paul Liknaitzky

Moderator: Metten Sommers

Session 8

LESSONS LEARNED FROM KETAMINE

Session 9

OPEN SPACE SESSIONS