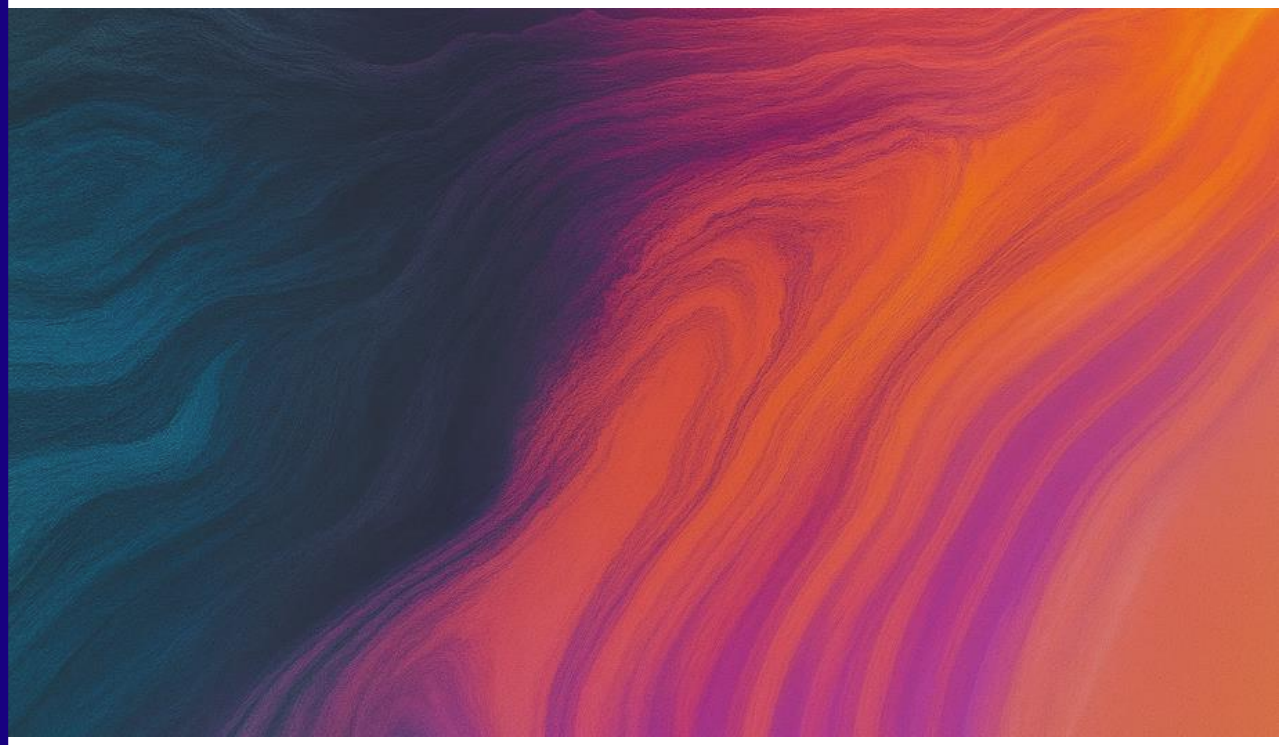
Psychedelics and Regulatory Decision-Making



Roundtable Report

8th May 2025, University of Birmingham

Introduction

In recent years, there has been an escalating resurgence of interest in, research on, and the use of psychedelics as part of treatment for a range of mental health conditions including depression, anxiety, obsessive-compulsive disorder, eating disorders, substance abuse, and post-traumatic stress disorder. The substances which have been the subject of this renewed focus include psilocybin, lysergic acid diethylamide (LSD), 3,4-methylenedioxymethamphetamine (MDMA or ecstasy), N,N-Dimethyltryptamine (DMT), ibogaine, and more. Clinical studies on these substances are showing some promising results. However, despite this promise, in many jurisdictions around the world, psychedelics are often 'Schedule 1' and/or 'Class A' substances under national drugs laws. This means that, according to the law, they are considered to have no therapeutic value and pose a high risk to public health. As such, they are subject to the highest level of restrictions under national regimes, generally meaning that their use, possession, and sale are illegal.

But, in light of recent research, this is beginning to change. Australia rescheduled both psilocybin and MDMA in early 2023, New Zealand has approved a psychiatrist to prescribe, supply, and administer psilocybin, and several states in the United States and provinces in Canada have implemented various (and varying) decriminalisation strategies. Meanwhile, in the UK in July 2025, the Home Office recently announced plan to pilot treating psychedelics as if they were on Schedule 2 for research conducted within university or hospital settings. However, despite these changes, routes to regulatory approval for psychedelics remain fraught with challenges, something demonstrated in 2024 by the high-profile rejection by the US Food and Drug Administration (FDA) of an application by Lykos Therapeutics for an MDMA-assisted therapy for PTSD. In its rejection, the FDA raised concerns about trial methods, possible bias, and long-term safety, highlighting the complexities with integrating novel (and indeed contested) treatments into regulatory frameworks built around more conventional models of evidence and risk assessment.

On 8th May 2025, we hosted a roundtable with a range of stakeholders to critically explore the current and potential future legal and regulatory landscapes on the therapeutic use of psychedelics. Funded by the Institute of Advanced Studies, and hosted at the University of Birmingham, the event was held as part of the Psychedelics and Regulatory Decision-making project. In attendance were academics from a range of disciplines (including psychopharmacology and law/regulation), lived experience experts, neuroscientists, clinical trial experts, and representatives from drugs science and policy organisations. The workshop sought views on questions such as:

What are the current legal/regulatory barriers to conducting research on psychedelics for therapeutic purposes?

What are the current legal/regulatory barriers to the authorisation and use of psychedelics for therapeutic purposes in clinical settings?

Are there lessons which could be learned from other jurisdictions/the authorisation and rescheduling of other substances?

What are some of the barriers to rolling out psychedelic therapy/psychedelics assisted therapy in national health systems, such as the NHS?

What could law- and policymakers can learn from retreats or traditional uses when enacting legal, regulatory, and policy changes?

What does an ideal future regulatory landscape look like for psychedelics?

Themes from the Day

Research

The first step towards the medicalisation of psychedelics is research which adequately demonstrates clinical efficacy and safety. However, as shown by the FDA's rejection of Lykos' MDMA application, conducting this research requires overcoming numerous socio-legal barriers. During the roundtable several of these barriers were discussed, including obtaining a UK Home Office licence for conducting research on Schedule 1 substances (a process described as lengthy, opaque, and inconsistent), high costs, difficulties identifying appropriate research sites, and challenges ensuring sufficiently representative participant samples. A number of live questions as they relate to conducting clinical trials were also identified, including appropriate approaches to participant 'blinding' and how best to measure the effectiveness of psychedelics as a stand-alone intervention where therapy is an integral part of treatment.

Despite an increase in research and clinical trials of psychedelics for a range of mental health conditions, participants at the roundtables advised that there remain significant gaps in clinical knowledge. These range from lack of understanding of potential biological interactions/physiological effects (e.g., interactions between certain drugs and cardiac receptors) to understanding efficacy in complex cases (such as for those with multiple mental health conditions) to gaps in sampling data (e.g., limited research on women). There also remain challenges with adequately taking account of qualitative evidence regarding patient experience within traditional clinical trial paradigms.

Authorisation and Use

Participants at the roundtable further discussed how psychedelic substances are currently classified, and what kinds of authorisation pathways exist – or could be constructed – for their safe and effective deployment within health services. Participants highlighted that current authorisation frameworks are designed for discrete pharmaceutical agents; by contrast, psychedelic therapy is a multifaceted intervention works best where the patient is able to prepare and get into an appropriate mind set, be conducted in a safe and comfortable setting, and have continued ongoing therapeutic support.

However, some felt that clinical trial design (and its attendant paradigms and terminology) remains framed around satisfying overly narrow regulatory requirements and standards, rather than optimising the intervention/therapy at hand. This raised questions about whether existing pathways for medicines authorisation are suitable or adequate for psychedelic therapies.

Participants at the roundtable also identified practical challenges which require resolution prior to the more widespread adoption of psychedelics as therapeutics. These include, for example, what constitutes informed consent in psychedelic therapy, how best to integrate different substances within healthcare pathways, and establishing processes for long-term follow-up.

Implementation in Practice

Issues around the delivery of psychedelics as treatment and long-term follow up were prominent and participants spoke about the barriers of implementing psychedelic-assisted therapies in practice. Participants debated the suitability of clinical versus retreat-based settings, noting that sterile environments might hinder therapeutic outcomes due to the importance of context in psychedelic experiences. Concerns were raised particularly about patient safety, professional liability, and the financial burden of current therapeutic models, which include intensive training and dual-therapist protocols. These issues were highlighted as particularly acute in contexts where healthcare is provided as a national service which rely on public funding and have to resolve competing demands on finite resources.

A recurring theme in the discussions concerned the necessity of long-term integration and support beyond the psychedelic session itself, which many saw as essential for sustained psychological transformation. However, participants recognised that this ambition may clash with the realities of overstretched healthcare systems. The discussion invoked the social model of disability to argue for a broader therapeutic aim: addressing systemic and contextual factors that contribute to suffering. Access emerged as a critical concern, with participants warning that psychedelic therapies could become the preserve of private clinics, mirroring the trajectory of cannabis-based treatments in the UK. This raises urgent questions about equity, affordability, and the risk of excluding those most in need.

Changes to Regulation and Policy

Given the number of shifts in law and regulation in across different jurisdictions, participants unsurprisingly discussed these, including the current systems in Australia, Portugal, Canada, and Switzerland. However, they noted that any robust comparison to the UK context required a deeper socio-legal analysis given divergences between legal, regulatory, and policy approaches across jurisdictions: to drugs generally, political attitudes toward decriminalisation, historical contexts, and selected exemptions. Participants cautiously suggested that lessons could also be learned from other spheres such as the cannabis-based products for medicinal use in the UK. Again, however, the need for sensitivity to context was emphasised.

As such, participants emphasised that any change to existing regulations (e.g., rescheduling or decriminalising specific substances/activities) requires nuance. They were concerned that overly restrictive regulation could drive people toward unregulated or underground markets, while too permissive a regime might invite backlash. Participants raised particular concerns about psychedelics following the same route as cannabis products, where media narratives have driven a perception of cannabis as being a 'party' drug, despite it being now more easily accessible for certain health conditions. Participants also briefly highlighted that any reform would need to consider the shifting commercial landscape for psychedelics. Namely, when interest in psychedelics for the treatment of mental health conditions began to rise the landscape was typified by collaborative, open approaches to data sharing. However, participants at the roundtable felt this was changing, with commercial organisations increasingly seeking proprietary protections (such as patents). They emphasised that this could have negative implications for access, equity, and innovation, particularly if enforcement leads to an "anti-commons" effect, stifling smaller organisations or non-profit initiatives.

Emerging Questions and Next Steps

Despite the increase in interest in, and research on and about, psychedelics for therapeutic purposes, the roundtable discussions highlighted persisting and under-researched gaps in knowledge, particularly when it comes to wider legal, regulatory, and policy issues. These include:

- How can clinical research on psychedelics overcome socio-legal and methodological barriers to establish robust evidence of safety and efficacy?
- Are current regulatory and authorisation frameworks fit for purpose when it comes to complex, context-dependent psychedelic therapies?
- What infrastructure and professional standards are needed to safely and equitably implement psychedelic-assisted therapies in practice?
- What forms of knowledge and expertise should count in shaping the future of psychedelics/psychedelic assisted therapy?

Acknowledgments

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PSYCHLES
PSYCHEDELICS: LAW, ETHICS, & SOCIETY

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