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Article

# Comparative Medico-Legal Frameworks for Psilocybin Regulation: A March 2026 Update

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## Abstract

In the past year, the medical regulation of psilocybin-assisted therapy has expanded across additional international jurisdictions, requiring an update to the original medico-legal synthesis. Newly established or clarified regulatory pathways in New Zealand, Germany, Switzerland, the Czech Republic, and at the United States federal level reflect continued evolution in therapeutic governance. Within the United States, Utah and New Mexico have now joined Oregon and Colorado in establishing lawful medical access pathways. These developments build upon earlier reforms in Alberta, Canada and Australia, where structured psychiatric prescribing frameworks were implemented. This update consolidates recent statutory amendments and regulatory decisions to provide a current comparative overview of jurisdictions permitting lawful medical use of psilocybin. By distinguishing comprehensive medical regulation from restricted or exceptional access schemes, this revised analysis maintains clarity within an increasingly dynamic global regulatory landscape.

**Keywords:** psilocybin-assisted therapy; drug policy and regulation; medico-legal analysis; mental health law; psychedelic medicine

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## Key Points: Global access pathways for psilocybin-assisted therapy

### *Structured medical access frameworks*

Jurisdictions that have implemented formalised regulatory pathways integrating psilocybin into supervised clinical practice include:

- United States (state-level)
  - Oregon
  - Colorado
  - Utah
  - New Mexico
- Canada (provincial-level)
  - Alberta
- Australia (federal-level)
- Czech Republic

### *Limited or compassionate access pathways*

Jurisdictions permitting psilocybin use only under exceptional, case-by-case mechanisms include:

- Canada (federal-level)
- United States (federal-level)
- Denmark

- Switzerland
  - Germany
  - New Zealand
- Key distinction*
- Structured medical frameworks – enable regulated therapeutic use within defined clinical systems.
  - Limited access pathways – restrict use to exceptional circumstances, typically requiring individual approvals where no satisfactory treatments exist.

## Background

The global regulation of psilocybin-assisted therapy remains heterogeneous and rapidly evolving. The original manuscript did not include Switzerland and Utah in the United States, which are now incorporated as new sections reflecting regulatory developments. Since publication of the original manuscript, additional jurisdictions, New Zealand, Germany, the Czech Republic, and New Mexico in the United States, have introduced or formalised pathways permitting medical use of psilocybin (Brnzei, 2026). These developments expand the cohort of regions adopting structured therapeutic governance.

This article provides an update to the author's previous editorial (Brnzei, 2025), incorporating significant regulatory developments across multiple jurisdictions since its publication. In light of the rapid pace of reform, a more detailed comparative medico-legal analysis is necessary to maintain accuracy and conceptual clarity.

Unlike existing literature, which often provides high-level summaries, this analysis systematically identifies and references the specific statutory and regulatory provisions governing psilocybin use in each jurisdiction, allowing for a more precise medico-legal interpretation of lawful access pathways.

As previously identified, Oregon and Colorado in the United States, Alberta in Canada, and Australia established comprehensive medical frameworks integrating psilocybin into regulated health systems (Brnzei, 2025). Federal regimes in the United States, Canada and Denmark have historically limited access to special access programs, terminal illness provisions, or tightly controlled licensing systems rather than routine psychiatric prescribing.

Given the pace of reform, an updated synthesis is necessary to ensure accurate medico-legal understanding of jurisdictions authorising lawful therapeutic psilocybin use.

## Scope of Analysis

This analysis is confined to jurisdictions that have established explicit legal pathways permitting the medical use of psilocybin within regulated clinical or therapeutic frameworks. It does not examine broader drug policy settings such as decriminalisation, non-enforcement practices, or jurisdictions where psilocybin may be available outside formal medical regulation (e.g., through retreat models or other quasi-legal, non-medical frameworks). By maintaining a strict focus on codified medical access pathways, this paper aims to preserve medico-legal clarity and avoid conflating fundamentally distinct regulatory approaches.

## New Developments

*State of Utah, United States*

In 2024, Utah enacted Senate Bill 266<sup>1</sup> (SB266), creating a three-year pilot program to allow the controlled therapeutic use of psilocybin within a tightly regulated medical framework (Utah State

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<sup>1</sup> Senate Bill 266, 65th Legislature (Utah, United States, 2024).

Legislature, 2024). Rather than broadly legalising or decriminalising the substance, the law authorises limited access for patients with treatment-resistant mental health conditions under structured clinical oversight, analogous to Australia's Authorised Prescriber (AP) scheme. Only designated healthcare systems that operate at least 15 licensed hospitals in the state or are closely affiliated with an institution of higher education are permitted to operate the psilocybin-assisted therapy program. This ensures administration occurs within established hospital settings. The legislation reflects a cautious, research-centred approach focused on safety, data collection, and therapeutic evaluation rather than commercial access or decriminalisation.

#### *State of New Mexico, United States*

In 2025, New Mexico became the fourth state in the United States to create a legal pathway for medical psilocybin access when Governor Michelle Lujan Grisham signed the New Mexico Senate Bill 219<sup>2</sup> (SB219) (New Mexico Legislature, 2025b). SB219 enacted statute<sup>3</sup> to permit the therapeutic use of psilocybin within a controlled framework to treat approved medical conditions (New Mexico Legislature, 2025a). Unlike Oregon and Colorado, where medical legalisation occurred through voter initiatives (Brinzei, 2025), New Mexico established a psilocybin access framework through legislative action. The *Medical Psilocybin Act* (New Mexico, United States), which passed with strong bipartisan support, directs the New Mexico Department of Health to develop and oversee a regulated program allowing approved healthcare providers to administer psilocybin in licensed settings. The program permits access for qualifying patients, including minors if deemed medically appropriate by a licensed provider, who are diagnosed with specified conditions such as Treatment-Resistant Depression, Post-Traumatic Stress Disorder (PTSD), Substance Use Disorders (SUDs), and end-of-life distress. The Department retains authority to expand the list of qualifying conditions, positioning the law as a structured, medicalised model focused on therapeutic oversight rather than decriminalisation.

#### *Czech Republic*

In the Czech Republic, Parliament adopted a reform that enables therapeutic psilocybin to be prescribed and used for certain mental disorders starting 01 January 2026 (European Union, 2026). The change amends key health and drug-control laws, in particular section 79a of the *Pharmaceuticals Act*<sup>4</sup>, to create a lawful route for prescribing, dispensing, and administering individually prepared medicinal products containing psilocybin (Czech Republic, 2026). The relevant statute provision is set out below:

For therapeutic purposes, an individually prepared medicinal product containing psilocybin for therapeutic use may be prescribed, dispensed and used in accordance with the Act on Addictive Substances in accordance with the implementing legal regulation. A medicinal product containing psilocybin for therapeutic use may only be prescribed on a request form with a blue stripe, which contains the name, surname and date of birth of the patient for whom it is intended. The dispensing of a medicinal product containing psilocybin for therapeutic use may only be carried out by a doctor with specialised qualifications, who administers it to the patient and who is responsible for ensuring that its prescription and administration comply with the conditions under the regulation issued pursuant to paragraph 3.

Implementation is designed to occur through an accompanying Government Regulation that sets out strict clinical conditions, including defined psychiatric indications, dose and monthly quantity limits, mandatory post-administration medical supervision, and tight professional

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<sup>2</sup> Senate Bill 219, 57th Legislature (New Mexico, United States, 2025).

<sup>3</sup> Medical Psilocybin Act (New Mexico, United States)

<sup>4</sup> Act No. 378/2007 Coll. (Czech Republic) s 79a(2).

restrictions (eg. prescribing limited to qualified psychiatry and psychotherapy specialists). The explanatory memorandum frames the reform as a targeted response to worsening population mental health, aiming to translate clinical research into controlled practice while maintaining rigorous safeguards against misuse and diversion (European Union, 2026).

### *New Zealand*

In New Zealand, psilocybin is classified as a Class A<sup>5</sup> controlled drug, reflecting its status as a substance with a high risk of harm. Despite this classification, statutory provisions permit medical access under tightly controlled circumstances, psilocybin may be prescribed with approval from the Director-General of Health<sup>6</sup> (Ministry of Health, 2024).

On 19 June 2025, the first approval for medical psilocybin use was granted to a psychiatrist, marking a significant development in New Zealand's therapeutic landscape (Ministry of Health, 2025). This was followed by the publication of regulatory guidance by Medsafe on 24 July 2025, outlining the framework for psilocybin access (Medsafe, 2025). The scheme operates as a special access pathway, allowing psilocybin-assisted therapy use outside of clinical trials in community treatment settings under strict regulatory oversight. This model reflects a cautious, case-by-case approach, enabling therapeutic access while maintaining stringent controls on prescribing and administration.

### *Switzerland*

Switzerland has established a leading, though limited case-by-case medical framework for psilocybin-assisted therapy, permitting its use in carefully controlled clinical contexts since 2014 (Madero et al., 2026). Although psilocybin remains classified as a prohibited substance under Swiss narcotics law, the Federal Office of Public Health may grant individual exemptions<sup>7</sup> to authorised psychiatrists and physicians for therapeutic use in patients with severe psychiatric conditions (Justement GmbH, 2023).

This exemption-based model enables case-by-case access under strict regulatory oversight, with treatment typically restricted to patients who have not responded to conventional therapies. Notably, there has been a significant increase in the number of approved exemptions since 2021, reflecting growing clinical interest and demand. Switzerland's approach represents a well-established special access framework, balancing restrictive drug control with limited, medically supervised therapeutic use.

### *Germany*

In Germany, in 2025, the Federal Institute for Drugs and Medical Devices authorised a Compassionate Use Program (CUP) for psilocybin, marking a significant development in clinical access (Zentralinstitut für Seelische Gesundheit, 2025). This program permits the use of psilocybin in patients with treatment-resistant depression under strictly controlled conditions. This framework is grounded in the *Medicinal Products Act*, which permits the provision of unapproved medicinal products for patients with serious or life-threatening conditions lacking satisfactory authorised treatment options (Federal Office of Justice, 2024). The relevant statutory provision<sup>8</sup> is set out below:

are made available free of charge under the conditions specified in Article 83 of Regulation (EC) No. 726/2004 for administration to patients with a seriously debilitating disease or whose disease is life-threatening and who cannot be treated satisfactorily with an authorised medicinal product; this applies equally to medicinal products that do not fall under the

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<sup>5</sup> Misuse of Drugs Act 1975 (New Zealand) sch 1.

<sup>6</sup> Misuse of Drug Regulations 1977 (New Zealand) s 29.

<sup>7</sup> Federal Act of 3 October 1951 on Narcotics and Psychotropic Substances (Switzerland) [Narcotics Act, NarcA] art 8(5).

<sup>8</sup> Arzneimittelgesetz (Germany) [Medicinal Products Act] s 21(2)(3).

categories stipulated in Article 3 (1) or (2) of Council Regulation (EC) No. 726/2004; procedures are specified in an ordinance pursuant to section 80.

This provision should be read in conjunction with the following clause<sup>9</sup>:

the competent higher federal authority and the persons involved in the placing on the market in cases of compassionate use pursuant to section 21 (2) no. 3 in conjunction with Article 83 of Regulation (EC) No. 726/2004

The CUP operates as an expanded access mechanism, allowing individual patients to receive psilocybin in justified exceptional cases where no satisfactory authorised treatments are available and participation in clinical trials is not feasible. Access is restricted to specialised clinical settings, with treatment delivered under intensive medical supervision and accompanied by psychotherapy. This framework does not constitute formal medical approval but represents a highly controlled, case-by-case access pathway, reflecting Germany's cautious and research-oriented approach to psilocybin-assisted therapy.

## Conclusion

The regulation of psilocybin-assisted therapy remains highly heterogeneous, reflecting differing policy approaches to balancing therapeutic innovation with patient safety. A clear distinction has emerged between jurisdictions that have implemented structured medical frameworks and those that permit access only through limited or compassionate use mechanisms.

This differentiation is essential for medico-legal clarity. Structured frameworks enable regulated clinical use within defined healthcare systems, whereas limited access pathways restrict use to exceptional circumstances, typically requiring individual approvals and heightened oversight. Conflating these models risks misrepresenting the scope of lawful therapeutic access and complicating regulatory interpretation.

As the evidence base continues to develop, there is a discernible shift toward more formalised models of care. Maintaining clear conceptual distinctions between regulatory approaches will be critical to supporting coherent policy development and the safe integration of psilocybin into clinical practice.

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<sup>9</sup> Ibid s 80(3c).

enabling deeper exploration and analysis of the regulatory frameworks governing psilocybin in these jurisdictions, particularly in the context of medical use.

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