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Expert recommendations for Germany's integration of psychedelic-assisted therapy

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Abstract

As clinical trials for psychedelics move into phase III in the USA, Europe must address its lag in integrating professional education around psychedelic-assisted therapy (PAT) and supporting psychedelic drug research. This paper evaluates the necessary frameworks for implementing PAT in Germany, emphasizing the nation's potential leadership role within the European Union. With Australia having already approved MDMA and psilocybin for mental health indications, the Ukrainian government exploring MDMA treatment for war-related PTSD, and initial clinical trials involving MDMA and LSD with patients in Switzerland which restarted the restricted medical use of these substances around 2014, the medical authorization of psychedelics in these countries establishes precedent showcasing both the promise and challenges of researching and implementing PAT in nations where the substances were formally scheduled as illicit substances. Key challenges include establishing rigorous standards for practitioner training, accessibility, and defining regulatory oversight. This paper focuses on the development of robust infrastructure in Germany, which will support the roll out of PAT, and details ethical considerations, training protocols, and governmental roles in the formulation of treatment frameworks. This approach aims not only to guide Germany in adopting PAT but also to influence broader European policy, ensuring that patients receive ethically sound and proficient care. The findings suggest pathways for Europe to reclaim its historical lead in psychiatric and therapeutic innovation.

Keywords Healthcare, Ketamine, MDMA, Psilocybin, Psychedelics, Psychedelic-assisted psychotherapy

Introduction

Psychedelic-assisted therapy (PAT) is a modality of mental health treatment that merges psychotherapeutic interventions with psychedelic states, often facilitated by substances such as lysergic acid diethylamide (LSD), psilocybin, and 3,4-Methylenedioxy-methamphetamine (MDMA). The latter two being in phase III trials. Whereas MDMA is considered an entactogen that enhances self-awareness and emotional connectivity, psilocybin is a naturally occurring psychedelic compound found in certain mushrooms. Recent research suggests that these and other psychedelics, all small molecules, most with benzene or phenyl rings, uniquely work by reopening a "critical period" in the brain, allowing for new learning within social contexts in a process involving changes in brain plasticity and oxytocin signaling [1]. Despite their classification as a Schedule I drugs under the Controlled Substances Act by the Drug Enforcement Agency (DEA) in the United States, their therapeutic potential has been increasingly recognized, with demands from the public to make them available for

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those with treatment resistant conditions. These among other developments resulted in MDMA being granted Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA) for the treatment of treatment-resistant PTSD (TR-PTSD) in phase II, (phase III studies were for 'moderate to severe' PTSD). Psilocybin (COMP360) and a deuterated psilocybin analogue (CYB003) were granted FDA Breakthrough Therapy designation for treatment resistant depression (TRD) [2–4].

Methodologically rigorous clinical research suggests that PAT may offer substantial long-term alleviation of symptoms in patients suffering from psychopathologies such as PTSD, TRD, major depressive disorder (MDD), end of life anxiety, obsessive–compulsive disorder (OCD), substance use disorders (SUD), psychotic conditions, and more [5, 6]. Notably, a single session of substance-assisted therapy has been reported to lead to significant symptom reduction, with some patients achieving remission that can persist for at least twelve months [7]. This enduring effect underscores the potential of psychedelic-assisted therapy in providing therapeutic outcomes that are significantly superior to antidepressant medications such as SSRIs, which often have poor efficacy rates and unwanted side-effects such as agitation, weight gain, sexual performance difficulties, gastrointestinal issues, and other symptoms [1, 8].

In February 2024, Lykos (formerly MAPS PBC) submitted a new drug application (NDA) to the FDA for MDMA (Midomafetamine) capsules in combination with psychotherapy for the treatment of PTSD [9]. Following the submission, a citizen petition was filed, raising concerns about the integrity of the clinical trials. This prompted the FDA to convene an advisory board meeting in June 2024 to review the claims. The petition raised several issues, including alleged bias in the trial design, inadequate sample diversity, insufficient double-blinding, underreporting of adverse events such as sexual misconduct, and confusion regarding the integration of psychotherapy within the study design [10]. Despite the principal view that MDMA trials are sound, and even the FDA's participation in the creation and oversight of the studies these concerns influenced the FDA's review process. Subsequently, in August 2024, the FDA issued a final decision rejecting the NDA under the Prescription Drug User Fee Act (PDUFA). It is important to note however that the FDA encouraged ongoing MDMA research and asked for another Phase III trial.

This decision led to additional actions, including the Journal of Psychopharmacology retracting three articles related to the MDMA clinical trials conducted by the MAPS research team and the initiation of an FDA investigation. Lykos has since filed for a reevaluation of their NDA. If approved, MDMA would become the first psychedelic-assisted therapy officially recognized in the United States.

As unexpected as the August 2024 rejection of the application by Lykos for approval of MDMA was for some, the hope based on the phase II studies, remains that either MDMA or psilocybin will within the next two to three years receive a positive evaluation from the FDA although the exact timing remains unknown. Unlike the MDMA trials, where the FDA was initially satisfied with the blinding process prior to the advisory board meeting, Compass' psilocybin trials were designed to minimize the unblinding caused by psychotropic effects, following the FDA's advice to their satisfaction until this day.

Lykos and Compass have been the two major companies driving development, and although Lykos has yet to submit a new phase III proposal, Compass continues with their phase III clinical trial. In general enthusiasm in the field for further research continues as there remains a need for novel treatments, and despite the uncertainty, the FDA seems generally favorable toward psychedelic medicine [10].

This paper outlines the current and required infrastructure for the successful integration of PAT, including rescheduling of psychedelic drugs beyond ketamine, accessibility, reimbursement strategies, accreditation of practitioners, ethical considerations and educational requirements. The role of the German government and affiliated agencies is pivotal in shaping this framework, ensuring that the setup not only complies with regulatory standards but also supports the ethical deployment of these therapies.

Moreover, with the European Medicines Agency (EMA) currently deliberating on the integration of psychedelics within the European framework, Germany has a unique opportunity to lead by example, showcasing a meticulous approach to the adoption of psychedelic-assisted therapies and must therefore also prepare to accommodate these innovative treatments [11]. This could serve as a model for other European nations, promoting a harmonized approach to these promising treatments across the continent.

The first half of this paper covers the regulatory environment in Germany, as it is impossible to understand the steps required to make PAT a reality without some in-depth understanding of the country's unique health care system. The second half of this paper covers the German provision of outpatient mental healthcare and how and where PAT would fit and critically, proposes a training scheme for the education of PAT facilitators.

Historical roots of psychedelics in Germany

Psychedelic research in Germany harkens back to the 1910s and 1920s when the atypical psychedelic MDMA

was first synthesized, and pioneering research was being conducted on the properties of mescaline. During this early period, Beringer and colleagues [12] saw in mescaline and similar substances, an opportunity to explore the phenomenology of psychopathology, creating what they described as 'model psychoses.' Although problematic in many ways, this stream of research opened up a new dimension of empathy and understanding into the experience of individuals with chronic psychosis [13]. In fact, the research carried out at the University of Heidelberg, culminating in Beringer's habilitation thesis "Der Meskalinrausch" from 1927, can be considered the first major work in the field of psychedelic psychopharmacology in the West [12]. Another noteworthy event in the history of psychedelic drugs in German-speaking Europe is Albert Hoffman's accidental discovery of the properties of lysergic acid diethylamide (LSD) on April 19, 1943, which accelerated interest in psychedelic compounds throughout the Western world [14]. In particular, this landmark event led to the widespread experimental use of psychedelics for a diverse range of psychiatric conditions across Europe and North America.

This period of research during the 1950s and 1960s, though short-lived, would later become known as the first wave of psychedelic research [14, 15]. During this brief moment in history, Betty Eisner, a German-educated American, first described the implementation of low-dose LSD in combination with psychotherapy, making a major contribution in the field which still today remains underrecognized [16]. Margot Cutner, a German psychoanalyst who was leading psychedelic research in England after fleeing from the Nazis, provided some of the first insights on the relevance of the role of the facilitator in psychedelic-assisted therapy (PAT) and the now well-known notion of 'set and setting' [16]. Following this, Hanscarl Leuner coined the term "psycholytic therapy" at the University of Göttingen underscoring the drug's therapeutic potential in a sub-threshold dose range [17]. Despite Leuner and colleagues' extensive research on LSD being among the most comprehensive bodies of work on the topic to date, it has been largely neglected until recently due to never being published in English [18].

A surprising turn of events occurred when in 1961, the United States passed the seemingly politically motivated US Controlled Substances Act, which resulted in an immediate and indefinite suspension of psychedelic research throughout the U.S. Europe was quick to follow suit, and psychedelics became labeled as potentially dangerous and addictive with no accepted medical use [19]. Subsequently, despite early breakthroughs and extensive research, these restrictions ushered in a prohibition era that would last decades, hampering progress and limiting the exploration of psychedelic compounds throughout the Western world. Germany was no exception, and psychedelic treatments now being championed for their therapeutic potential were outlawed.

Economic burden of treating PTSD and depression in Germany

The economic and human costs of PTSD and depression in Germany highlight an urgent need for more effective interventions [20]. Trauma-related healthcare costs range from 524.5 million to 3.3 billion euros annually [21], while depression adds another 1 to 5.2 billion euros [22, 23]. Current pharmaceutical treatments, such as serotonin-reuptake inhibitors (SSRI), offer limited efficacy and fail to fully address the needs of individuals with PTSD, depression, or their comorbidities [24].

A recent study of German insurance claims highlighted both the direct and indirect costs of PTSD (ICD-10-GM F43.1) [20, 21]. PTSD patients typically suffer for about 6 years, with a 50–100% likelihood of comorbid conditions such as major depressive disorder (MDD), panic disorder, and substance use disorder (SUD). Per-patient costs were 43,000 EUR, three times higher than for those without PTSD, driven by increased healthcare utilization, impaired work capacity and reduced quality of life. PTSD also accounts for approximately 200,000 Disability-Adjusted Life Years (DALYs) annually in Germany, a metric that reflects both premature mortality and years lived with disability, quantifying the overall burden of disease [25].

Similarly, depression carries significant economic burdens with indirect costs from labor absenteeism, social benefits, and prevention measures estimated at 10 to 16 billion euros annually, surpassing direct healthcare costs [26, 27]. Depression accounts for approximately 470,000 DALYs in Germany [28], while globally, PTSD contributes an additional 3 million DALYs, underscoring its substantial public health impact.

In short, PTSD and depression remain conditions with a high unmet need. SSRIs, first introduced in 1988 (fluoxetine), are still the primary pharmaceutical treatment for many psychological disorders, despite their limited efficacy and adverse side effects, including symptom exacerbation and suicidal thoughts [29].

Regulatory landscape

The European Medicines Agency (EMA) grants marketing authorization for new medicines across the EU. The sponsor of the medication submits an application for approval to the EMA following phase III trials, and after EMA approval, marketing authorization is granted, which allows the medication to be sold in all European Union member states. Sponsors then must decide which

member states they wish to enter, as, even if the Sponsor has marketing authorization, each EU state has its own rules about how health insurers will be reimbursed for new medications. European member states furthermore have country specific processes and infrastructure around the provision of therapeutic services which are an essential part of PAT.

In Germany, the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) oversees both clinical trial approval (pre- and post-EMA approval) and the documentation as well as considerations related to safety, efficacy, and quality, and specific labeling requirements tailored to the German context (Fig. 1).

The German gatekeeper institutes to access for psychotherapy

More importantly, as soon as a sponsor decides to enter the German market with a newly EMA approved medication, the process for reimbursement is started [30]. This process is not a federal process in Germany, rather is managed by a committee established in 2004 called the "Federal Joint Committee" (Gemeinsames Bundesausschuss also known as the 'GBA') which negotiates costs to be reimbursed by federal insurers for new medications directly with pharma (Fig. 1). A legal reform in 2011 on the reimbursement of pharmaceuticals, the *Arzneimittelmarkt -Neuordnungsgesetz* (AMNOG) governs a process that includes representatives from insurers, healthcare professionals, and patients, who provide input into the GBA decision regarding the value of a new medication, independently from the government [31]. Psychedelic substances for example if they are to be introduced into Germany, will undergo re-evaluation based on the results of EU based clinical studies, a process that has already taken place with the atypical psychedelic substance esketamine [32].

In its deliberations, the GBA must consider assessments from the Institute for Quality and Efficiency in Health Care (IQWiG), a federal institute responsible for evaluating the quality, effectiveness, and efficiency of medical treatments, which is funded through contributions from German health insurers [33]. The IQWiG compares new therapies, such as psychedelics in combination with psychotherapy, with standard therapies such as cognitive-behavioral therapy (CBT), trauma-focused therapy, EMDR and pharmacotherapy involving

Fig. 1 Institutions involved in approval and access of pharmaceuticals in Germany

antidepressants such as SSRIs, or serotonin-norepinephrine reuptake inhibitors (SNRIs) [34–37].

the IQWiG may face challenges in evaluating a new therapy such as MDMA if there are insufficient comparisons with standard therapies in the published literature, in such cases the absence of direct head-to-head data can lead the IQWiG to conclude that a therapy's benefit cannot be adequately assessed, potentially overlooking its actual therapeutic value.

How European institutes influence German regulation—the UN and EMA

In the EU, the regulation of psychedelics follows a framework where Member States classify drugs and precursors based on the three UN Conventions of 1961, 1971, and 1988. This classification system is designed to control and supervise their legitimate scientific or medical use while reducing risks to public health by restricting use of harmful substances [38]. Psychedelics are subject to international control as per the 1971 United Nations Convention on Psychotropic Substances. This convention restricts the utilization of these substances solely to medical and scientific endeavors (articles 5 and 7). While acknowledging the potential therapeutic benefits of certain psychotropic substances, it also considers their inherent risk of abuse.

Moreover, the annex to the 1971 Psychotropic Substances convention categorizes substances into four schedules based on their potential for abuse and therapeutic utility and degree of control required. Schedule I, which includes psychedelics and their analogues, comprises substances deemed to present a high risk of abuse, posing a severe threat to public health with minimal or no therapeutic value.

Although the EMA plays a pivotal role in interpreting and implementing international conventions within the European Union (EU), unlike the UN, it, does not establish distinct schedules for psychedelics. Each member state has its own laws and regulations governing the scheduling classification, use, and distribution of psychedelics and bears the responsibility for enforcement of these laws.

The EMA provides guidance on establishing a positive risk–benefit balance of psychedelics and offers early involvement of regulators, qualification procedures, and scientific advice.

Intellectual property and patent protection for psychedelic compounds

In Germany, introducing a new medicine to the market involves navigating several challenging regulatory steps. Merck, the German pharmaceutical company credited with synthesizing MDMA in 1912, did not hold a patent on the compound, thus allowing MDMA to enter the public domain without proprietary restrictions. Therefore, unlike many pharmaceuticals, MDMA lacks patent protection, and does not have market exclusivity under regulatory frameworks in any jurisdiction.

Other psychedelic compounds, such as psilocybin also lack patent protection due to the fact that the compound is not novel. For example, Sandoz did not patent psilocybin as a compound, but instead patented methods of its extraction and its use to induce "therapeutic tranquilization". However, despite the inability to patent psilocybin itself, many patents related to psilocybin have been granted and continue to be filed. These patents cover areas such as formulations, methods of use, delivery methods and manufacturing processes. Analogues and novel polymorphs derived from or based on psilocybin could also be patentable, offering significant opportunities for intellectual property beyond the compound itself [39].

Regulatory considerations and access implications

In the US, the FDA employs a strategy of rescheduling illicit drugs demonstrated in clinical trials to have a therapeutic purpose, by typically rescheduling only the formulation utilized in clinical trials and leaving the pure substance scheduled, thereby limiting user access to only the approved pharmaceutical [40]. This methodology, as seen in the case of CBD (cannabidiol), aims to facilitate access to therapeutic formulations while exerting control over the raw substance. It is anticipated that the EMA may adopt a comparable scheduling approach to future psychedelics such as MDMA and psilocybin. In some cases, drugs may be authorized through alternative pathways, such as compassionate use or special access programs, particularly if they demonstrate significant therapeutic benefits and meet safety standards. Australia represents a unique case in this regard.

In an unprecedented move, the Australian Therapeutic Goods Administration (TGA) made the decision to down-schedule MDMA and psilocybin (from "no therapeutic use", Schedule 8 to "potential therapeutic benefits", Schedule 9) as of July 1st, 2023, permitting authorized psychiatrists to prescribe them for PTSD and treatment-resistant depression [41]. Access is regulated through an Authorized Prescriber scheme, which facilitates controlled access to MDMA and psilocybin by granting qualified psychiatrists in Australia the authority to prescribe only for specific indications and patient populations.

Such a move does not seem likely by the EMA, particularly in the wake of the August 2024 MDMA rejection of the FDA, which seems to lean towards more conservative approaches in drug regulation and is anticipated to closely observe and potentially adopt strategies similar

to the FDA's approach. Regarding scheduling and access considerations, Australia's groundbreaking decision to down-schedule MDMA shifted the paradigm in psychiatry and drug regulation somewhat, setting a precedent for other countries to reconsider their approach to psychedelics in therapeutic contexts.

Evolving opinion of the EMA on psychedelics

The EMA aims to create a supportive regulatory framework to facilitate psychedelic medicine as a novel form of therapy and on March 16, 2023, acknowledged the potential of PAT for various mental health conditions. However, concerns were raised at that time regarding the challenges developers may encounter in meeting the rigorous scientific and regulatory standards required for marketing authorization of these products. Despite a plethora of clinical trials in the EU involving psilocybin, MDMA, and LSD, the trials were deemed insufficient to form a regulatory decision. Further, complex study designs were emphasized as essential for generating robust and comprehensive evidence [42].

Recognizing the therapeutic potential of psychedelic medicine and the relative regulatory gaps in this area however, the EMA more recently conducted a multi-stakeholder workshop on psychedelics – 'Towards an EU regulatory framework'. Marion Haberkamp, representing the BfArM and speaking on behalf of the EMA, covered the most recent EMA perspective on the European implementation, regulation, and scheduling of psychedelics at this public forum conducted in mid-April 2024 [43]. The EMA identified three main categories of challenges in approving psychedelics for use, namely scientific, legal, and implementation obstacles. Scientific challenges include maintaining double-blind conditions due to the subjective effects of psychedelics, determining optimal therapeutic doses, ensuring long-term efficacy, integrating psychotherapy into therapy, and managing potential adverse effects such as anxiety and addiction [43].

In terms of regulation, the key consideration, she noted, is establishing a positive risk–benefit balance. While clinical trials are yielding intriguing results, they also raise concerns, necessitating longer and larger studies for thorough evaluation. The integration of psychedelic administration with psychological support or psychotherapy is seen as an issue that will require careful consideration. Finally, the EMA emphasizes the importance of a mechanism-of-action-based assessment regarding the safety and potential for addiction. Before these issues are addressed, it is not likely that any recommendation for a change in scheduling will be considered by the EMA.

However, to close the identified data gaps, the EU recently awarded a €6.5 million grant for the PsyPal trial, a clinical study involving 19 partners from nine European countries. While Germany is not represented in the initial cohort of research supported through this initiative, the EU-centric data generated through this endeavor would advance EMA's decision-making.

Finally, there is a precedent for legal therapeutic access at least to MDMA-AT created in the EU through a recent report by the Dutch State Commission "MDMA- Beyond Ecstasy" [44]. Across the EU therefore, the work on developing capacity for deploying MDMA-AT for PTSD treatment through a national-scale naturalistic study is underway.

Germany-specific scheduling of psychedelics

In Germany, the scheduling of psychedelics and other controlled substances is regulated by the Narcotics Act (Betäubungsmittelgesetz, BtMG) and the Neue-psychoaktive-Stoffe Gesetz (NpSG). This legislation categorizes substances into various schedules based on criteria such as their potential for abuse, therapeutic value, and societal impact.

Psychedelic compounds typically fall within the scope of illegal substances as outlined in the Narcotics Act. Specifically, they are classified as "non-prescription narcotics" *(nichtverschreibungsfähige Betäubungsmittel*) and the possession, manufacture, distribution, and consumption without proper authorization are prohibited.

Accessibility to psychedelic therapy and barriers

With this in mind, there are currently very few legal avenues for patients to access not-approved psychedelics in Germany. According to the Narcotics Act in Germany, psychedelics including LSD, MDMA, mescaline and psilocybin are classified as "not marketable", meaning that they cannot be used for therapeutic purposes by law (BtMG, Anlage I, § 1 Abs. 1). Therapeutic supervision of psychedelic substance consumption for medications such as Psilocybin or DMT constitutes a legal gray area according to the German Narcotics Act, for example, in cases in which patients independently obtain and consume the substances while the consumption is only accompanied therapeutically afterwards as integration therapy [45].

However, this therapeutic intervention still entails criminal risks for both patient and therapist as consumption of the aforementioned substances is only allowed in scientific studies [46].

Access through clinical trials in the EU

With the surge of psychedelic therapy research in the US, and data collection being advanced in progressive European Union member states such as the Netherlands, Switzerland, and now Ukraine, other key players

such as Germany are starting to reconsider their policies, attitudes, and approach towards psychedelic interventions. As of April 2024, the EU database for clinical trials showed 29 studies for use of psychedelics in CNS conditions, including 19 for psilocybin, 7 for MDMA, and 3 with LSD [42].

As clinical research on psychedelic therapy gains momentum across the EU, ongoing studies have the potential to drive shifts in regulatory frameworks and public perceptions regarding PAT in Germany [47]. Notably, the "EPIsoDE" study [48] is a key initiative exploring the efficacy and safety of psilocybin in treating therapy-refractory depression in Berlin and Mannheim. This study was funded by the German government (Bundesministerium für Bildung und Forschung) initially with 2.6 million and later topped up to almost 5 million. If successful, this placebo-controlled bi-center study should be a major step towards the approval of psilocybin. Currently, according to the study process, psilocybin is in phase 3 of clinical trials for treatment-resistant depression [49]. The trial, which began in 2021, was completed in the first half of 2024. First results show a 17% response rate 6 weeks after dosing (25 mg). Full long-term follow-up results remain pending publication. Other psychedelics are under investigation for the same indication. It is also worth mentioning that other psychedelics are being investigated for TRD, including 5-MeO-DMT, which is currently the subject of an international phase IIb study conducted by Beckley Psytech, with multiple study sites across Europe including several sites in Germany.

Charité Universitätsmedizin Berlin was running a small (MAPS-sponsored) multi-center pivotal study examining MDMA-assisted psychotherapy for the treatment of severe PTSD (Charité—Universitätsmedizin Berlin, n.d.) Critically, patient accessibility to MDMA in compassionate use in Germany depends on the capacity of such trials to accommodate German patients (see diagram, Fig. 2). Recruitment of participants in Europe however has been suspended since 2021.

Compassionate use of non-approved substances—access to scheduled psychedelics after regulatory approval in other countries

In Germany, patients may potentially access FDA-approved substances that are not yet approved by the EMA through the compassionate use pathway. This process is regulated by the Compassionate use (Arzneimittel-Härtefall-Verordnung (AMHV) law in the Medicinal Products Act (Arzneimittelgesetz) (AMG §22, Paragraph 2, No. 6) which applies when patients suffer from a disease leading to severe disability or are life-threatening and cannot be satisfactorily treated otherwise. Additionally, there is a hardship program for patient groups (AMG §21, Paragraph 2, No. 3), under which medicinal products may be brought to market without approval or authorization. The medicinal product must be provided at no cost in these cases.

If a psychedelic is deemed necessary for a patient's treatment, mental healthcare providers theoretically could apply for compassionate use. According to the BfArM Compassionate Use flowchart, if there is an ongoing marketing authorization application or if there is an ICH-GCP Trial ongoing in a 3rd country in the intended indication (7), but not accessible clinical trial in Germany, then compassionate use may be possible (Fig. 2).

Compassionate use is not typically approved by the BfArM if there is patient access through a clinical trial in the country. however unclear how German regulatory agencies will navigate access to psychedelics within compassionate use programs (Supplementary Table 1).

Current therapy infrastructure—therapy vs pharmaceuticals for PTSD treatment

Current first line pharmaceutical treatments for PTSD and depression consist of primarily SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors) which purportedly alleviate symptoms by targeting serotonin reuptake in the brain [29]. Studies have shown that these primarily address affective symptoms such as depressed mood and psychic anxiety, with weaker or absent effects on other symptoms [29]. Recent studies have found the effects of SSRIs & SNRIs only modestly more effective than placebo [50–52]. These pharmaceuticals have subsequently been found to often require concurrent psychotherapy for optimal efficacy.

Despite their wide approval and use, it does not appear that they are more efficacious than psychotherapy alone, and thus far, they do not offer the same immediate effects or potential for prolonged relief as PAT [53, 54]. Recent publications on the mechanism of action of psychedelics demonstrate moreover that psychedelics bind with up to 1000×higher affinity to newly discovered secondary BDNF receptor binding sites than SSRIs, shedding light on the biochemical differences [1]. In spite of this, they have been widely prescribed as a standalone treatment for depression, Notably SSRIs were approved for the treatment of depression without the requirement for concurrent therapy [55].

The historical approval processes for SSRIs, coupled with the changing understanding of the role of therapy in anxiety disorder treatment, is informing the ongoing debate about to what extent any regulation of therapy has in the post-approval phase for psychedelics. Several psychedelic drug development initiatives currently entail administering the investigational drug, followed by psychotherapy either during the acute effects or in

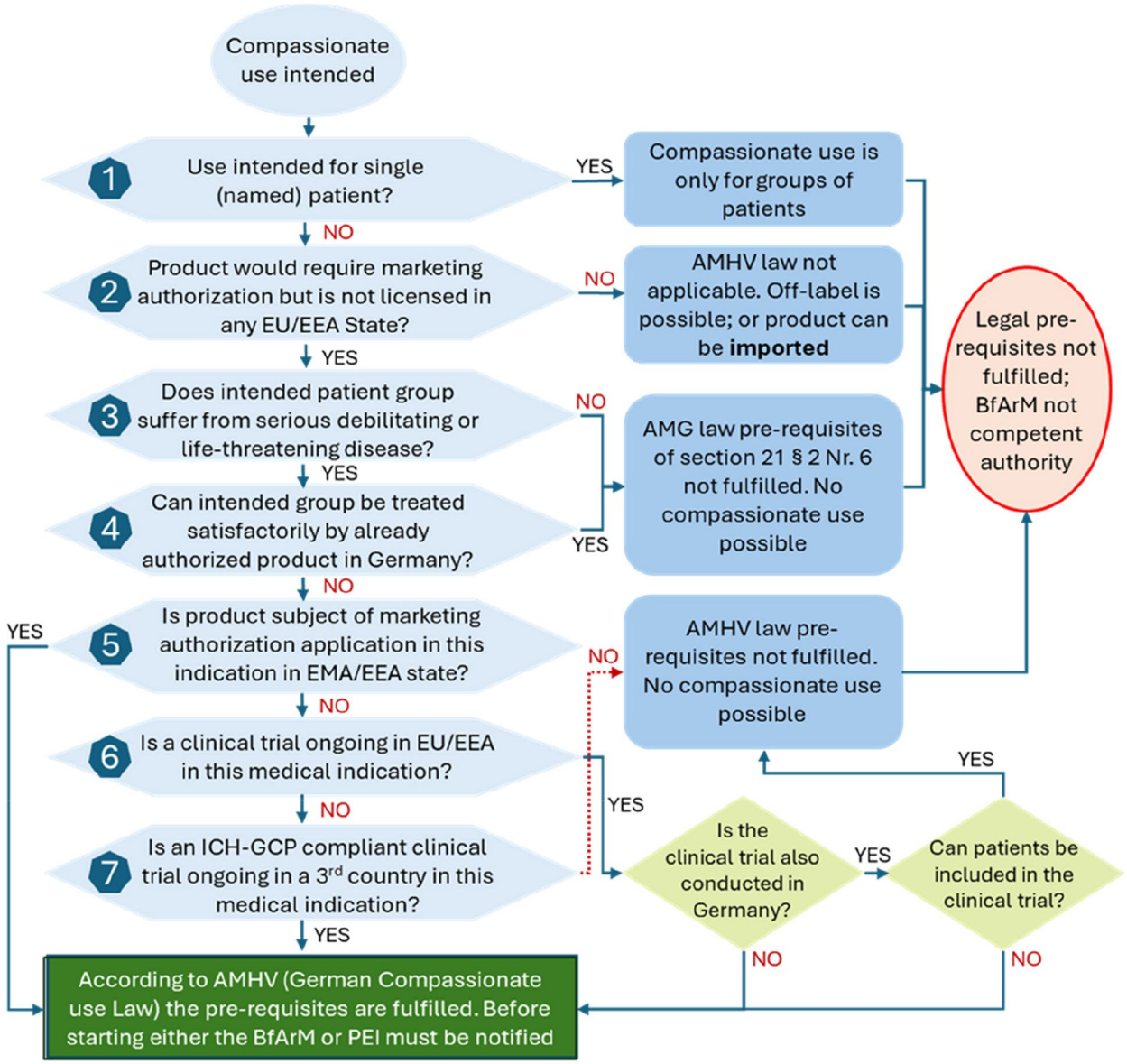


Fig. 2 Is psychedelic compassionate use possible? German flow-chart for compassionate use programs

subsequent sessions, complicating the evaluation of drug effectiveness and presenting a challenge for product labeling in the future [56], p. 9), the contribution of the psychotherapy component to any efficacy observed with psychedelic treatment had as of June 2023, not been characterized. Although the FDA has called for it, researchers are against conducting trials that omit psychotherapy as they consider this unethical.

Regulators therefore grapple with the ongoing question if such characterization is required as the regulatory authorities involved in marketing authorization and reimbursement (BfARM, EMA and GBA) do not govern psychotherapy. Should the label for psychedelic substances require administration only in the context of psychotherapy, other regulatory agencies would be required to define the necessary parameters of that therapy.

The German experience with PTSD

There is data on the Germany-specific expenses associated with PTSD which assessed both the direct and indirect expenses as well as its occurrence rate within Germany over a five-year period from 2010 to 2017 using national insurance claims [20]. This study is useful as the data also points to the efficacy of interventions

implemented by the insurers and the extent to which these interventions in the long run reduced the severity of PTSD.

Relevant to the debate on the centrality of the therapy component of PAT, the finding that 94% of individuals with PTSD utilized PTSD-specific outpatient services in the year after the index diagnosis implies that therapy constitutes an essential aspect of managing PTSD [20]. International guidelines furthermore highly recommend psychotherapy as the treatment option of choice for PTSD, with empirical evidence supporting its effectiveness [57].

Beyond MDMA, other psychedelics, such as psilocybin, have shown promise in the treatment of PTSD. Early phase trials and case studies suggest that psilocybin, when combined with psychotherapeutic support, may significantly reduce PTSD symptoms [58]. This expanding evidence base indicates that the therapeutic potential of psychedelics for PTSD extends beyond MDMA, underscoring the need for further research into psilocybin and other substances as adjuncts to psychotherapy.

The problem of outpatient psychotherapy in Germany

Outpatient psychotherapy has become an essential part of therapy for mental health disorders; and in a study of 22,000 insurance claims from six German insurers, its implementation has been demonstrated to result in significant reductions in work disability days, hospitalization days, and inpatient costs from the first year before the therapy to the first year following therapy suggesting that cost savings are achieved by reducing the need for more intensive and costly forms of healthcare utilization, such as hospitalization [57]. However, there are issues in Germany with access to therapy services which will also affect the availability of PAT if and when it is approved.

In Germany, access to mental health care, including psychotherapy, is facilitated through a combination of employment-independent public and private health insurance systems and includes office-based psychotherapists, psychiatrists, psychiatric hospitals, and outpatient clinics, as well as rehabilitation centers and community mental health care facilities [59]. In addition, approximately 1.9 million patients per year receive outpatient psychotherapeutic care [60].

However, despite the availability of mental health services, which are free of charge, disparities in access and treatment duration persist. Importantly, in contrast to the USA, Canada, and some other EU states, access to mental health care in Germany is largely free of extra charges for most individuals [61]. However, while access to mental health care may be theoretically unencumbered, bottlenecks in care do persist. Therefore, the evolving landscape of PAT will prompt considerations about German-specific accessibility and reimbursement frameworks.

The Federal Joint Committee (GBA) serves as the central decision-making entity governing the provision and reimbursement of psychotherapeutic services within Germany's statutory health system, which covers approximately 74 million individuals [59]. As the apex body of joint self-government, comprising physicians, psychotherapists, dentists, hospitals, and health insurance funds, the GBA plays a crucial role in defining the parameters for outpatient therapy. Through its *Guidelines for Psychotherapy*, the GBA ensures that all patients receive qualified and adequate care in outpatient settings, however, the scope of psychotherapy, while wide, remains constrained by the specific diagnoses outlined in the International Classification of Diseases (ICD-10 GM, [62]).

Therefore, questions remain regarding the GBAs potential role in determining the reimbursement framework for PAT. The shortcomings of the entire system of outpatient therapy are notably encapsulated in three key areas: current provision, planning for future demand, and the educational training system for psychotherapists.

Health economic analyses have revealed a significant disparity in resource allocation in Germany, with a disproportionate emphasis on inpatient treatment and outpatient drug prescriptions [59]. This is not only inefficient, but it also does a disservice to the increasing demand for outpatient psychotherapy. According to the German Psychotherapy Society (Deutsche Psychotherapeuten Verein), in 2021 inpatient psychiatric treatment came to about 8 billion Euro/year while outpatient psychotherapy costs totaled about 2.7 billion per year. The German mental healthcare system has room to allocate additional resources to outpatient therapy services, including eventually PAT as cost saving treatment modalities, as studies show that every euro invested into psychotherapy pays off threefold for society as a whole within a year [63].

Bottlenecks in access to insured psychotherapy

In theory, every German has the ability to access insurer covered psychotherapy (Supplementary Table 2) In reality, accessing psychotherapy services remains a formidable challenge for Germans, as the system is structured in a way that limits access to therapists covered by public health insurance.

The GBA (Fig. 1) is the entity responsible for estimating the number of psychotherapists a patient will likely need to see in their lifetime, a calculation that drives the overall numbers of psychotherapists necessary in the country as a whole [64]. Legally it is the "Kassenärztliche Vereinigung (KV)" (Association of Doctors who

treat the publicly insured), tasked with ensuring the actual supply of health services, with the caveat that the supply must remain "in budget". Both institutions in the end conspire in different ways to result in a restriction to access of insurance covered psychotherapy services. This is because the KV also functions as a lobby group advocating for doctors' interests while ensuring health service provision is sufficient, appropriate, and economical by updating regional coverage plans based on local supply and demand evaluations. More importantly, the KV also directly determines the numbers of psychotherapy practitioners in a given region by setting the number of available licenses or "Kassensitze".

The scarcity of such psychotherapy licenses creates a bottleneck, forcing many patients to either pay out-of-pocket for private care or navigate complex bureaucratic processes to secure reimbursement for therapy. This is compounded by a lack of information and represents a major barrier to accessibility which is particularly relevant in the context of PAT, where timely access is essential for effective treatment.

The COVID-19 pandemic has furthermore intensified the strain on mental health services, leading to an elevated demand for psychotherapy in a system already overburdened prior to the pandemic, with prolonged waiting periods of three to nine months for outpatient psychotherapy, according to a 2019 analysis by the German Psychotherapists Association (BtPK) of 300,000 insured patients [65]. Despite an increased demand for therapy, faced with the futility of finding rapid longer term psychotherapy services, only half of the patients-initiated treatment after consultation, with over 80% opting for short-term therapy of up to 24 h [65].

The GBA for its part, denies accountability for adjusting license limits, asserting that such decisions lie within the purview of regional KVs. However, this assertion belies the GBA's own authority to increase licenses at the federal level, a power wielded in 2019 when around 800 licenses were added nationwide, still only a third of what were estimated to be required [66].

Systemic inertia however prevails. Doubts arise regarding the rationale of restricting therapists from moving out of rural areas, as historical patterns suggest it is anxiety about income security among medical therapists that have influenced license restrictions. The stagnation is symptomatic of a larger issue: a lack of genuine interest among stakeholders, including KVs and public health insurers, in expanding capacity to meet the pressing needs of patients.

Politicians harbor concerns regarding the proliferation of therapy services, apprehending that an increase in the availability of licenses may lead to a surge in demand driven in this case by increased supply, consequently resulting in heightened financial burden on public health insurance companies. Addressing these structural deficiencies and fears will be required to foster an environment conducive to the effective integration of PAT.

Insurance coverage and reimbursement for psychedelic-assisted therapy sessions

Another hurdle for therapists who provide PAT is the lack of a Germany specific billing code which reflects the real costs of PAT, as this influences the reimbursement process. Since its introduction treating patients with Spravato can be reimbursed. Ketamine-assisted psychotherapy on the other hand is not, as it still needs to be used as an "off-label-use" intervention, billing codes listed in a table called the Gebührenordnung für Ärzte (GOÄ) are insufficient to adequately code for PAT. Limitations on the number of therapy hours that can be billed per week present a significant barrier for therapists aiming to provide PAT responsively To illustrate, ketamine-assisted psychotherapy involves preparation sessions, one or up to five substance-assisted sessions followed by integration sessions taking approximately 20–26 therapy hours, costing between 1000—5400€ (https://ketaminpro.de/kosten/). German private health insurance providers decide on a case-by-case basis whether there is a medical necessity and the number of sessions, whether and which proportion of the costs can be covered [67]. If, for example, ambulant PAT can be shown to prevent a long inpatient stay the insurer may be inclined to cover some or all the costs.

Training programs and ethical framework

Emerging research continues to underscore the therapeutic potential of PAT, leading to a notable shift in acceptance among healthcare professionals. While specific numerical data from past years are pending, the trend indicates a substantial increase in practitioners recognizing the potential of these treatments [68–70].

In Europe, advocacy groups such as PAREA have been instrumental in promoting the recognition of psychedelics as legitimate medicines. Their efforts have advanced to the European Parliament, where a collaboration among the largest associations has resulted in the formation of an action group (MEP Action Group For The Medical Use Of Psychedelics) aimed at the medicalization of these substances.

The training required to master the facilitation of psychedelic-assisted therapies is still in its infancy and remains difficult to quantify due to several factors. Economic and time constraints pose significant challenges to delivering comprehensive training, and there is substantial variability in both practitioners' expertise and the interpersonal complexities inherent to mental health

disorders. Given these constraints, it is unrealistic to expect training programs to cover all possible scenarios. Instead, they should aim to provide a strong foundational knowledge that can be expanded through field experience, continuous education, and supervision, allowing practitioners to adapt and grow as they encounter diverse clinical situations.

Ketamine—therapy in the context of Germany's first approved psychedelic

Ketamine, an NMDA receptor antagonist that also upregulates brain-derived neurotrophic factor (BDNF), has demonstrated efficacy in reducing symptoms across various mental health conditions. While its most extensively studied use is in treatment-resistant depression (TRD) [71], ketamine has also shown promise in substance use disorder (SUD) [72] and anxiety disorders [73]. Furthermore, ketamine provides rapid and effective relief of symptoms in post-traumatic stress disorder (PTSD) that are refractory to selective serotonin reuptake inhibitors (SSRIs), with benefits extending to comorbid conditions such as chronic pain [74].

Esketamine, the S-enantiomer of ketamine, has been widely approved for the treatment of major depression and TRD. Administered as a nasal spray (Spravato®), in combination with an SSRI, esketamine produces rapid reductions in depressive symptoms and suicidal ideation, with continued improvement over the course of a month, outperforming traditional antidepressant therapies [75].

In comparison, psilocybin shows antidepressant effects within 24 h, with sustained benefits lasting up to 12 months [76]. Some studies have suggested that psilocybin may be as effective, if not superior, to escitalopram in treating depression, with long-term effects lasting up to six months compared to the SSRI group [77].

Although ketamine's antidepressant effects are rapid, its direct influence on brain plasticity, as observed in experimental studies, is short-lived, typically lasting between 30 min to an hour, with clinical benefits extending up to a week [1, 7]. In contrast, serotonergic psychedelics such as psilocybin and LSD exhibit longer-lasting neuroplasticity and therapeutic effects, with improvements sustained for weeks or even months. This differential may be explained by the higher affinity of psilocybin and other psychedelics for specific receptor sites related to BDNF modulation [1].

While the exact mechanisms underlying the antidepressant effects of psilocybin and other serotonergic psychedelics remain to be fully elucidated, these substances consistently demonstrate more durable therapeutic benefits, likely due to their phenomenological effects and the incorporation of psychotherapeutic guidance [78]. In contrast, ketamine is often studied within a "pharmacological paradigm," where the subjective experience and psychotherapeutic context are minimized, which may limit its long-term efficacy.

Ketamine, introduced as an anesthetic in 1969, is the only legal medicine with psychedelic properties currently available for clinical use in Germany. However, access to ketamine therapy is largely restricted to specialized clinics capable of administering it intravenously. The off-label use of ketamine in the treatment of mental health conditions, particularly TRD, anxiety disorders, and PTSD, has shown promise, but its widespread clinical use is hindered by practical barriers. Intramuscular administration, a more feasible alternative, has yet to be widely adopted by ketamine-assisted psychotherapy (KAP) providers in Germany. Furthermore, the absence of ketamine lozenges or other oral formulations, which are not compounded by German pharmacies, has further limited patient accessibility.

The therapeutic effects of ketamine are largely independent of the route of administration, with outcomes being more influenced by the preparation, psychotherapeutic guidance, and follow-up care provided after the ketamine-assisted sessions [78]. Unfortunately, many clinics that focus solely on the pharmacological aspects of ketamine administration often co-administer benzodiazepines to suppress the conscious experience. This approach not only diminishes the therapeutic processing of the experience but may also interfere with ketamine's action as an NMDA receptor antagonist.

Current treatment protocols that rely on pharmacological intervention alone, without the integration of psychotherapeutic support, overlook a critical component of psychedelic-assisted therapy. Studies consistently demonstrate that the combination of ketamine or serotonergic psychedelics with psychotherapeutic guidance significantly enhances and prolongs their therapeutic effects.

In Germany, private clinics increasingly offer ketamine for major depressive disorder, trauma-related conditions, and acute suicidality. Some argue that the dissociative effects of Ketamine are not to be considered psychedelic and remain skeptical of their potential. Ketamine-Assisted Psychotherapy (KAP), which combines ketamine´s psychoactive and pharmaceutical effects with therapeutic guidance, is gaining traction due to its potential for longer-lasting benefits, though it remains underemphasized. While Esketamine, marketed as Spravato, is reimbursed by insurance, its high cost and lack of psychotherapeutic integration are points of contention. Expanding access to KAP through proper education and training and emphasizing its therapeutic value are essential for maximizing ketamine's potential in mental health care. Unlike ketamine, classic psychedelics such as psilocybin

have shown a superior safety and efficacy profile, with fewer concerns regarding addiction potential. To fully realize the therapeutic potential of psychedelics, including ketamine, there is a growing need to shift away from a purely pharmacological approach toward one that integrates evidence-based psychotherapeutic interventions, a model already established with other psychedelics.

Existing framework for PAT practitioners training and certification

There exists a significant mismatch between the availability of psychotherapists trained in PAT methods and the demand from patients. Despite the lengthy training required for psychotherapists to obtain licensure, specialized training for PAT is still nascent, and in Germany, there is currently no established integration of psychedelic treatment approaches in the curriculum for psychotherapist training [79]. Previous attempts to establish a recognized curriculum for this specialized therapy have not yet been accredited by official regulatory bodies.

Those programs that do exist range from informal semi-therapeutic training to elite, expensive and time-extensive courses that encompass basic neuroscience, supervision by experts, and experiential learning with both pharmacological and non-pharmacological interventions. Nonetheless, none of these programs have achieved certification by German medical or psychotherapeutic boards. These courses might provide an advantage when applying to be part of clinical trials using psychedelics, however they do not provide official certification to use these substances in therapy.

Swiss model for PAT training

The Swiss model offers an instructive case study. Since its inception around 2014, this approach has allowed psychiatrists to apply for special permission to use psychedelics in therapy [80, 81].

Training in PAT, based on the training program of the Swiss Medical Association for Psycholytic Therapy (SÄPT) comprises the acquisition of theoretical content based on scientific research outcomes, frameworks and settings, psychotherapeutic content of the sessions, hands-on training in group and individual exercises, supervision, dealing with emergency situations and psychedelic self-experience in order to develop an understanding of the client while taking the treatment [82]. Alarmingly, this critical course work is not mandatory.

However, despite these inroads, PAT is far from standard integration into curricula of psychiatric or psychotherapeutic training and while this has enabled access to MDMA, psilocybin, and LSD for the Swiss population, it presents numerous challenges: the application process must be repeated for each session, and psychiatrists often struggle to justify the extensive time required for these sessions within a billing system that limits the weekly therapy hours. Critically, the regulatory agency lacks mechanisms to assess the qualifications on PAT of the psychiatrists applying to administer these sessions. This model, although functional in a smaller country, raises concerns about its scalability and the potential for errors as the popularity of these treatments increase.

US framework and experience with provider guidelines and training

As the country closest to marketing authorization, the USA has a head start in the consideration of requirements for training of PAT practitioners and their accreditation. [83]. For the last two years diverse voices from academia and industry have attempted to create a licensing Board which would have the political gravity, financial backing, and academic credibility to establish an accepted national board and a testing procedure which could be implemented for the entire country. Some of the authors have first-hand experience in these attempts and from experience can attest to the difficulty of the task.

Two major issues that have made the creation of such a board so difficult is the issue of grandfathering an older generation of mental health professionals with limited training in cultural competency, and how to handle the political hot potato of how to integrate knowledge from traditional, and underground facilitators, often from Indigenous people groups in the Americas, who are coming from healing traditions outside of the Western medical system.

US & Canadian training models for psychedelic practitioners

Despite these difficulties, experience with PAT in the MAPS clinical studies and the training provided to therapists participating in the trials have deepened the knowledge of how to work successfully with these substances, and MAPS practitioners have contributed to a framework which takes some of the most critical issues into account [84].

The proposed framework from Rochester and colleagues [85] outlines a dual-tier approach to practitioner credentialing, comprising a primary facilitator and prescriber who holds a license or appropriate credentials in a mental health profession, and a secondary facilitator who possesses at least a bachelor's level degree or equivalent. In this structure, the secondary facilitator operates under the supervision of the primary facilitator [85]. While this model aligns with current best practices, it remains subject to evolution, as ongoing research may explore alternative facilitation methodologies.

The development of the Rochester model was a three-stage process. In stage one, an expert committee outlined

and drafted the essential issues. In the second and third stages, the committee reached out consecutively to a broad range of scholars, researchers, practitioners, and therapists across Canada, all united by a shared interest in psychedelic medicine. They were united by the recognition that working with the non-ordinary states of consciousness mediated by psychedelics and entheogens can carry some risks and requires specialized training.

The educational portion includes foundational learning about the therapeutic, spiritual, and ritual uses of psychedelics cross-culturally and throughout human history. Trainees would learn about current and evolving research on psychedelics and the ethics of working with people experiencing a non-ordinary state of consciousness (NOSC). This would also include training in harm reduction, trauma, and addiction, as well as behavioral pharmacology, including psychotropic drugs, therapeutic indications, and the societal impact of substances. All trainees would be required to engage in multicultural study and training, including theoretical frameworks and practical aspects of working with those from marginalized and racialized communities. Finally, it requires training for individuals to practice as skilled facilitators and integration counselors for psychedelic treatment sessions, which includes both didactics and supervised practice, as well as personal supervised experiences in the form of fieldwork.

Facilitators require a minimum of 100 h of supervised PAT experience, inclusive of three completed cases encompassing diverse individuals undergoing NOSC, alongside 48 h of direct client interaction and should refrain from practicing beyond their established areas of expertise. The Rochester training model is being implemented in the interdisciplinary approach for psychedelic practitioners at the University of Ottawa, where learners can receive a MA degree in Psychedelic and Consciousness Studies [86].

This model specifically notes that elders in Indigenous entheogen traditions or ordained clergy of recognized, licensed entheogen religions have internal credentialing and do not need additional credentials for the entheogens they are apprenticed in, emphasizing the importance of respecting and preserving these traditions amidst the establishment of regulatory criteria and standards.

Core competencies and prerequisites—PAT training US Model

The Rochester model sets out a list of core and pre-requisite competencies required for the safe and effective facilitation of psychedelic sessions safely and effectively (Table 1). Both primary and secondary facilitators are expected to provide evidence of such training, be members of accountability groups, as well as engage in continuing education as appropriate.

Notably, for the MAPS sponsored German localized clinical trials for MDMA in PTSD trainers with experiences in PAT were brought in from the USA, as per MAPS protocol, these trainers all had been required to have at least one session where they took MDMA in the

Table 1 Rochester model—core competencies to be achieved post training

Core Competencies	Content Descriptions
Therapeutic Alliance, Ethical Care, Confidentiality	Prior evidence of competency in establishing therapeutic rapport, upholding ethical principles, and maintaining client confidentiality
Cultural Sensitivity, Diversity, Bias Awareness	Proficiency in cultural sensitivity, awareness of biases, and respect for diversity among clients
Psychedelic Research, Treatment, Integration	Comprehensive training in psychedelic research, treatment modalities, integration practices, both Western and traditional approaches
Indigenous Knowledge Appreciation	Critical awareness and appreciation of traditional Indigenous knowledge regarding sacred plants and healing practices
History of NOSC Participation	Participation in NOSC sessions such as Holotropic Breathwork, understanding their historical significance in exploring human potential
Spiritual and Religious Issues	Understanding of pertinent spiritual and religious concepts, and awareness of psychospiritual phenomena emerging during and after sessions
Differentiation of Spiritual Emergence, Emergency	Ability to differentiate between spiritual emergence, emergency, cultural distress, and mental illness, and provide appropriate support
Legal Issues, Harm Reduction	Familiarity with legal aspects of entheogens and psychedelics, along with harm reduction strategies
Biological, Pharmacological Basics	Understanding of the biological and pharmacological effects of entheogens and psychedelics on the brain and body
Consciousness Studies, Philosophy, Phenomenology	Knowledge of consciousness studies, philosophy of mind, and phenomenology, relevant to psychedelic experiences
Supervised Personal Experience	Completion of supervised personal experiences with entheogens or psychedelics in licensed/sanctioned settings

same conditions the patients would have experienced MDMA, or had some other suitable supervised experience of a non-ordinary state of consciousness [84]. This is a recommendation in the Rochester framework, in line with best practices in the field, and may become a consideration in any eventual accreditation process [87].

Self-experience is a standard component of psychotherapy training, serving purposes that extend beyond merely enhancing empathy or deepening understanding of the patient's experience. It also provides therapists with an opportunity for personal psychological maintenance. This aspect of self-care is particularly critical for therapists working with non-ordinary states of consciousness, whether induced pharmacologically or through non-pharmacological means. Such practices not only prepare therapists to better navigate the therapeutic process but also help safeguard their mental health, ensuring they remain effective and resilient when engaging with patients' trauma and' vulnerable psychological states.

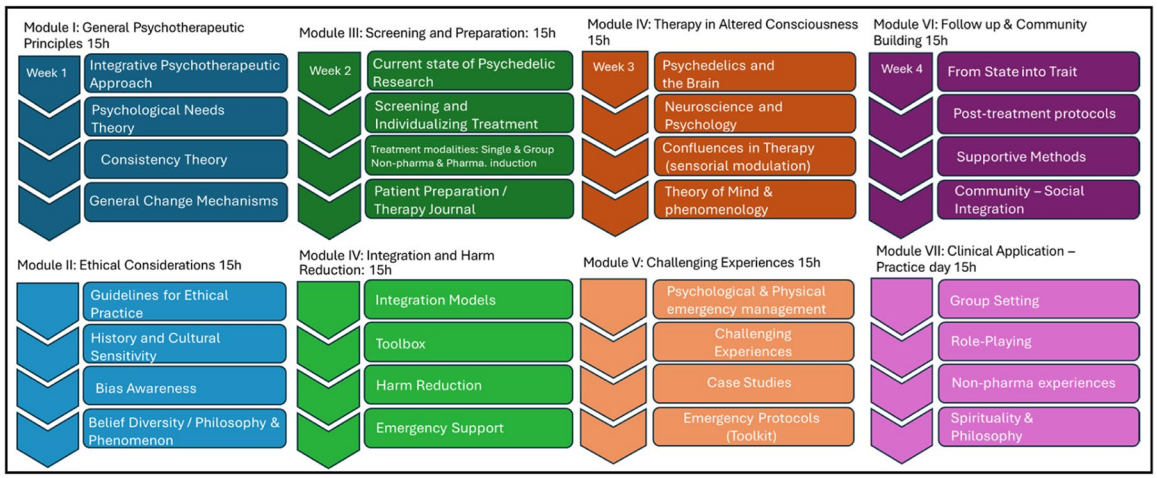
Psychedelic therapy practitioners accreditation—modeled on the German certificate for emergency medicine

The presence of two individuals during PAT sessions has become typical practice, and it is recommended that a similar approach in the German context be adopted [84, 85]. Having two individuals present provides oversight and accountability, particularly as the psychedelic takes effect and the patient enters a vulnerable state. One of these individuals should be a licensed practitioner and medical personnel, such as a psychiatrist or psychologist with psychotherapy experience, preferably with experience in treatment resistant cases and/or PTSD. Special emphasis is placed on physical safety and emotional support during the consumption of psychedelics [49].

To implement this, we propose a novel PAT training program (Table 2) adapted to the German condition, called Bildung und Nutzung von Traumähnlichenzuständen (BuNT) which loosely translates as Training and Kaleidoscope Dream-like States, akin to those in emergency medicine, with certification administered by local physicians' chambers (Ärztekammer) or external bodies.

Drawing parallels with Germany's "Zusatzbezeichnung Notfallmedizin" (Emergency Medicine) certification, which provides training for doctors from many specializations, this training program provides a flexible but solid core curriculum for PAT. To qualify for emergency medicine certification, physicians must have at least two years of clinical experience and six months experience in the emergency room or intensive care unit. The certification process includes an intensive 80-h course. Upon completion candidates need to gather a total of 50 cases of supervised practical experience in emergency scenarios followed by an oral examination by 2 experts (Supplementary Table 3). Certification is then granted by the German Landesärztekammer (State Chamber of Physicians). The success of this training model in preparing a wide array of physicians with different specializations to handle acute medical emergencies suggests its potential applicability to psychedelic therapy for therapists trained in different schools of psychotherapy.

Table 2 BuNT: Bildung und Nutzung von Traumähnlichen-zuständen (Kalidescope Dream-like States)—a new comprehensive 100 h PAT training model for German practitioners



This model contains all of the content also present in the Rochester Model adapted to a German context and is to be given in primarily in German with certified instructors [88]

The BuNT model involving a medical doctor paired with a nurse practitioner or psychotherapist mirrors the interdisciplinary approach employed in emergency medicine involving paramedics and medical doctors. This method creates robust safety nets, benefiting both practitioners and patients by ensuring a comprehensive care environment where responsibilities and expertise are shared. Such interdisciplinary collaboration is essential for maintaining high standards of patient safety and therapeutic effectiveness.

In the context of training PAT practitioners, Competency-Based Education (CBE) emerges as the most appropriate educational framework. Although other private trainings in Germany utilize the Outcome-Based Education (OBE) framework, we believe that Competency-Based Education (CBE) offers distinct advantages for training practitioners in PAT.

CBE emphasizes the attainment of specific competencies that are crucial for ensuring the safe and effective administration of PAT. This approach aligns seamlessly with the Rochester model, which outlines a comprehensive set of core competencies necessary for practitioners. CBE's flexibility allows trainees to progress at their own pace, ensuring mastery of each competency through adequate assessment and practical application. This method is particularly effective in accommodating the diverse educational backgrounds of practitioners, from those with traditional psychotherapeutic training to individuals rooted in Indigenous healing practices. By focusing on demonstrable skills and knowledge, CBE ensures that all practitioners meet consistent, high standards of care, crucial for the sensitive nature of work with psychedelics. This structured yet adaptable approach supports ongoing professional development and integration of new research findings, essential for the evolving field of psychedelic-assisted therapy.

In 2018, the Bundesärztekammer (Federal Chamber of Physicians) reformed the (Model) Specialty Training Regulations [89] to incorporate a competency-based education framework. This reform aligns with our proposed training model, which also adopts competency-based education principles. As such, our model is particularly suited to serve as a guideline for developing the necessary competencies for a German certified specialty training in PAT. By leveraging the established framework of the Bundesärztekammer, our approach ensures that the training is robust, standardized, and tailored to meet the specific requirements of PAT, thereby fostering a high level of professional readiness and efficacy among practitioners.

Training in transition

Ketamine, traditionally dubbed a dissociative anesthetic known for its ability to induce psychedelic states, is currently approved as an anesthetic and for managing acute pain. It is widely utilized in emergency medicine due to its favorable safety profile. Additionally, a growing body of research supports its therapeutic potential for mental health disorders, leading to its "off-label" use in several German clinics.

Given that ketamine is accessible off-label for treating mental health conditions, a rising number of clinics and hospitals offer it for severe cases, with approaches ranging from basic pharmacological intervention without therapeutic guidance to comprehensive psychedelic-assisted psychotherapy including all modalities and follow-ups. It is concerning that some ketamine applications occur without standardized PAT training, posing risks and reducing its therapeutic effects when not accompanied by appropriate therapeutic support. Conversely, this situation also presents an opportunity for therapists to gain experience in psychedelic-assisted therapy under supervision as MDMA therapy becomes more widely available, bridging the gap during this transitional period.

Another viable method for acquiring the necessary supervision hours to qualify in PAT could involve enrolling as a therapist in research studies that utilize psychedelic substances to treat mental health disorders. With the increasing acceptance of the potential of psychedelics as medicine among German psychiatrists, a number of studies are currently underway or in the planning stages.

Similar to conventional psychotherapy, and particularly with the emerging approach of combining psychedelic compounds with therapeutic interventions for the treatment of severe and treatment-resistant mental health conditions, it is recommended that practitioners continually update their knowledge in the rapidly advancing field of psychedelic-assisted psychotherapy. Furthermore, it is advisable to seek expert consultation and supervision following the completion of any certification program, especially regarding complex cases and any special issues that may arise, to ensure adherence to best practices and the latest scientific developments.

Cultural barriers to therapeutic alliance—when not to attempt PAT

One of the significant causes of PTSD is in individuals fleeing from war or persecution from places outside of Europe [90–92]. Refugees from the Middle East, Africa and Asia who have settled in Europe may have experienced trauma from persecution in their home countries but once they have settled in Europe, many have also been demonstrated to be further traumatized by microaggressions based on their national origin or racialization in their new home [91–95]. This racialization also has been found to cause a higher prevalence of PTSD in the

2nd generation German-citizen children of immigrants and/or BIPOC Germans (who may *also* have White German parents), which is compounded by the inability to describe and quantify the degree of the problem. Invisibility of one's pain potentiates trauma, and this can be seen in the decades-long refusal to acknowledge that racialization (discrimination based on shade of skin and presumed heritage) contributes to differences in life and health outcomes in Germany [91, 93, 96]. Mental health practitioners should expect to encounter such patients in their career, considering that 19.3 million people living in Germany have immigrant backgrounds, and this number does not include the German citizen children of BIPOC persons. Furthermore, native German citizens who have grown up in Germany but who are not racialized as White may also experience racial trauma through being otherized [93, 95, 97].

Racial trauma and how to treat it has not been traditionally a part of the curriculum for European schools of therapy and only recently has a comprehensive treatment in the literature [98, 99]. Mental health practitioners should understand and take note if they have the training required to be able to treat individuals who may have experienced trauma resulting from their skin colour, ethnic or national origins [96, 98]. For this among other reasons, certification of facilitators who are competent in the treatment of racial trauma is imperative.

Establishing a therapeutic alliance with patients of different cultural backgrounds and belief systems might be challenging and difficult to navigate for those who do not have experience in culturally informed therapy. Becoming aware of the epistemology and limitations of transcultural therapy attempts should be part of any training, especially when entering vulnerable states of consciousness.

Licensed practitioners who do not have competence surrounding racial trauma should not attempt PAT alone; One of the two facilitators must have expertise in treating racial trauma. This may be a new concept for many classically trained psychologists in Europe, however knowledge gained in the course of MAPS clinical trials has provided evidence for the importance of experience in this area [100]. Licensed mental health practitioners must complete training in addressing racial trauma before attempting PAT for patients with this indication, as was done with the independent evaluators in the MAPS Phase 3 trials [84].

Our model designed for Germany includes a module to provide initial training in this area and includes additional cultural competency and racial trauma modules which in the future should be a component of all psychotherapy training curricula, as is currently in the USA and Canada.

High unmet needs for trauma therapy drives rapid regulatory changes in Ukraine

When the full-scale war broke out in February of 2022 Ukraine's policy around psychedelics was among the most restrictive in the world. No use, not even for research, was allowed. Today accelerated regulatory changes are being made with the prospect of allowing use in clinical trials as soon as 2024/2025.

The drivers for these changes are a projected need for psychological support for a staggering 15 million Ukrainians, with 3–4 million Ukrainians requiring extended psychiatric care [101, 102]. These projections are in line with large population studies showing that wars cause larger proportions of the population to experience clinical symptoms of depression (up to 88.0%) and anxiety (up to 80.0%) [103].

In this light the regulators in Ukraine are realizing the need for regulatory change that would allow at least some form of access to PAT as a highly efficacious form of PTSD treatment. It is likely that the first area of focus will be PTSD in the armed forces population. A large-scale pilot study that would assess the effects of MDMA-AT in group therapy format is being drafted *(Olga Chernoloz personal communication*).

Ukraine is looking to align its policy with the EU counterparts. The matter of psychological recovery and rehabilitation carries broad-reaching socioeconomic impact beyond borders because the extent of the traumatized reaches across Europe. For Germany success in the Ukrainian context could have impacts on practice as 1.13 million Ukrainians fled to Germany because of the war, and many will require treatment for trauma.

The trauma of others

Asylum seekers and refugees experience sharply higher rates of PTSD (between 20%-59%) in Germany, creating a greater need for services in this specific high-need demographic [90, 92]. However, current German legislation mandates that insurance coverage for psychotherapy for refugees is only accessible after residing in the country for at least 18 months—except for refugees from Ukraine. However, this coverage may still not provide access to necessary psychotherapy services, as even Ukrainians must possess fluent German language skills because interpreter costs are not covered [104]. Furthermore, Germany has taken two additional steps in preventing psychotherapy services for non-Germans.

Germany amended the criteria for serious conditions which protect a patient from deportation in 2016, specifically removing PTSD from this list despite the high rates among this population. The assertion that PTSD does not pose a significant threat to life and well-being is inherently flawed. Specifically, the act of returning

individuals to a country where they have previously felt or still perceive their safety as compromised can trigger suicidal tendencies. It is essential to acknowledge that for humanitarian reasons a PTSD diagnosis alone should be justifiable grounds to block deportation of traumatized refugees.

Secondly, in 2019, the "Ordered Return Act" (Geordnete-Rückkehr"-Gesetz) was created which downgraded the professional role of psychotherapists in regards to assessing whether a refugee may be deported due to a serious mental illness. The act established that only psychiatrists, but not psychotherapists, may prevent deportation under the new law, a blow to the centrality of psychotherapists in diagnosing serious mental illness. This stipulation, compounded by the relatively fewer number of psychiatrists available, further reduces access to essential mental health services needed to prevent deportation.

This pattern of legislative changes and restrictions on access to mental health care raises significant concerns about the prioritization of mental health services for non-German people in Germany [104].

Conclusion and recommendations

The United States has slowly begun reversing the legislation created to uphold the War on Drugs by encouraging research into the safety and efficacy of drugs such as psilocybin, LSD, DMT, MDMA, ketamine, and others, for the treatment of diverse conditions including but not limited to depression, anxiety, PTSD, and substance use disorders.

With the several psychedelic compounds being granted breakthrough therapy designation, many reaching phase III trials with promising results, and the rescheduling of psychedelics by Australia, the EMA is on the pathway to loosen 50 year old restrictions on psychedelic use and Germany must find pathways to accommodate the research and use of psychedelics, which includes ensuring the Ministry of Health (Bundesministerium für Gesundheit, BfArM and the accrediting bodies ÄK) is ready to grant breakthrough status to provide therapy and study psychedelics in the same way the FDA has done.

In addition to regulatory infrastructure, Germany must also provide educational resources to researchers to promote safety and good research practices. A "Weiterbildungsordnung" (Specialty Training Regulation) by the German Bundesärztekammer should also be established to ensure a nationwide standard of training quality and offer official certification to practice in this modality. Moreover, funding must be made available to train practitioners to provide PAT, for racialized populations and those suffering from mental health conditions with high unmet needs.

The implementation of PAT in Germany requires a multifaceted approach encompassing ethical guidelines, training programs, cultural competency, and regulatory oversight. Collaboration between governmental agencies, regulatory authorities, and healthcare professionals is essential for successful implementation. By addressing these considerations, Germany can ensure that patients receive ethical and skilled treatment in psychedelic therapy settings.

Supplementary Information

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Supplementary Material 1.

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Authors' contributions
SP and SF wrote the main portions of the text and prepared Figs. 1 and 2. JL wrote the sections on history and contributed to sections specific to MDMA and SSRIs, SB wrote and contributed to sections on German specific institutions in regulatory and psychology matters, OC contributed to sections on Ukraine and treatment of war refugees, MW reviewed paper and wrote sections on SSRI and training for PAT in the USA. SF and SP collaborated on supplemental material, MW contributed the content for Table 1 and SP for Table 2. All authors reviewed and corrected the manuscript.

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Data availability
The data supporting the findings of this study, specifically the newly created BUNT Bildung und Nutzung von Traumähnliche-zustände (Kalidescope Dream-like States) - A new comprehensive 100 hour PAT training model for German practitioners training program, are available upon request. The outline of the BUNT training program is published within the paper, while the detailed modules are currently in the process of being copyrighted. Interested researchers can obtain the modules by contacting the corresponding author. The original Flowchart from the BfaRM is publicly available the version in the paper is adapted:
https://www.bfarm.de/SharedDocs/Downloads/EN/Drugs/licensing/clinicalTrials/compUse/AMHV-Flow-chart.pdf?__blob=publicationFile
All other data generated or analyzed during this study are included in this published article.

Declarations

Competing interests
Author Sonya Faber is employed by Angelini Pharma and is a partner in the company Bioville GmbH. The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest. The other authors declare no conflicts of interest.
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