



SURVEY ON MEDICINAL USE OF PSYCHEDELICS

prepared by Jevgenija Vienazindyte (Law Firm of Jevgenija Vienazindyte) and Dovydas Gudziunas (Ellex Valiunas) (Lithuania) in collaboration with partners: Houthoff (The Netherlands), Uría Menéndez Abogados (Spain), Stevens & Bolton (UK), De Gaulle Fleury (France), Hengeler Mueller (Germany), Bech-Bruun (Denmark), Portolano (Italy), Morais Leitão, Galvão Teles, Soares da Silva & Associados (Portugal)

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According to WHO, in 2019, “1 in every 8 people, or 970 million people around the world were living with a mental disorder, with anxiety and depressive disorders the most common”. Despite general obstacles that personal health sector faces while developing a new treatment for any health disorder, there has not been a major treatment breakthrough since the ‘blockbuster’ psychiatric medicines in the 1990s. So, treatment of mental disorders really needs bigger attention. Currently there are at least 2 clinical trials, recognized as a breakthrough therapy by the FDA, with MDMA and psilocybin for treating PTSD and depression, respectively. Number of clinical and research centers are implementing clinical trials with psychedelics in Europe (Imperial College, Henri-Mondor University Hospital and researcher at the Brain Institute [ICM] in Paris, Zurich University, to name a few).

The **aim** of this **Survey** was to collect **generic responses** on two questions related to the **use** of **psychedelic** substances for **medicinal** purposes (see below in Q1 and Q2) in different countries.

This Survey could be indicative and useful for **businesses, clinicians, researchers, regulators** and **patients**.

Note responses are **not exhaustive** and shall not be used as legal advise. Please seek for a professional legal consultation for your specific situation.

Q1:

Is medicinal use of psychedelics (e.g. LSD, MDMA, psilocybin, DMT, ibogaine etc.) (or any other controlled like Schedule I substance drug) somehow specifically regulated?

Q2:

Is administration of psychedelics allowed for medicinal purposes, for instance in assisted psychotherapies, as a treatment protocol of depression, PTSD, OCD?

For instance:

State of Oregon (USA) has legalized psilocybin for medical use under Oregon's 2020 Measure 109—or the “Oregon Psilocybin Services Act”

In Oregon, a person may obtain a license to manufacture psilocybin products, operate a psilocybin service center, facilitate psilocybin services, and test psilocybin products. The actual legal services available to a client of a psilocybin service center include a “preparation session,” “administration sessions,” and an “integration session.”

For more information see:

<https://foxrothschild.neotalogic.com/a/statepsychedelicslaws>

Country	Q1	Q2	Contacts for further legal consultation
<p>Denmark</p>	<p>Yes. Danish Act no. 1334 of 9 December 2019 on Euphoriant Substances together with Executive Order no. 2446 of 12 December 2021 on Euphoriant Substances. Euphoriant substances that are subject to control in Denmark are listed in the Schedule to the Order on Euphoriant Substances and substances can be included in the lists via amending executive orders.</p> <p>The “A List” in the Order includes substances that must not be found in Denmark. The “B, D and E Lists” include substances that can only be used for medical and scientific purposes. The C List includes substances which are subject to control in their unprepared form but are not generally regulated by the legislation when contained in pharmaceutical preparations.</p>	<p>Medicinal products must be authorised by the Danish Medicines Agency or the European Commission before they can be marketed in Denmark. A medicinal product can only be authorised and made available to the public if scientific studies have provided sufficient evidence of the medicine’s quality, efficacy and safety.</p> <p>If the euphoriant substance has not been authorised as a medicinal product, in some form, it may be accessible for use in clinical trials, cf. the Lists mentioned above - some euphoriant substances are strictly forbidden. By way of example, at current, psilocybin is used in clinical trials in Denmark (https://www.clinicaltrialsregister.eu/ctr-search/search?query=denmark+comp360).</p>	<p>Martin Dræbye Gantzhorn <MDG@bechbruun.com> Julie Christiansen, <JUCH@bechbruun.com> Gundula Maria Kjær <GMK@bechbruun.com></p>

Country	Q1	Q2	Contacts for further legal consultation
France	<p>Yes. Decree of 22nd February 1990 classifies psilocybin as an illegal drug. Article L. 3421-1 of the French Public Health Code forbids the use of illegal drugs.</p>	<p>No.</p> <p>French law does allow the use of certain drugs for medical use but it is restricted. For instance cannabis is under an experimental process. This derogatory regime does not cover psilocybin.</p> <p>However, the Sainte-Anne hospital in Paris will soon test psilocybin for the treatment of depression. This study, scheduled for 2023, will include 80 patients.</p> <p>Meanwhile, Luc Mallet, a psychiatrist at the Henri-Mondor University Hospital and researcher at the Brain Institute (ICM) in Paris, and his colleagues launched the AdelyLSD project in early December 2021. Raising 1.2 million euros to measure, among others, the effects of LSD on the treatment of alcoholism. The results of this study are expected for 2024.</p>	<p>Cécile Théard-Jallu <ctheardjallu@dgfla.com></p>

Country	Q1	Q2	Contacts for further legal consultation
Germany	No	<p>LSD, MDMA etc. are - with the exception of Ibogaine - listed in Annex I of the German Narcotics Act (Betäubungsmittelgesetz).</p> <p>As such, their use can only be permitted by the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte) for scientific or other purposes of public interest and only in exceptional cases.</p> <p>While the German Federal Administrative Court (Bundesverwaltungsgericht) has in one case recognized that the medicinal use of an Annex I substance can constitute such a public interest, the circumstances of that case were very specific (and did not concern psychedelics). In general, the use of these substances for medicinal purposes therefore remains legally excluded.</p> <p>However, of the substances mentioned above, Ibogaine poses an exception as it is not listed in Annex I of the German Narcotics Act. As a matter of fact, Ibogaine is not specifically regulated at all under German law. Since Ibogaine is a substance with potent pharmacological (and psychoactive) effects, it falls under the German Medicinal Products Act.</p> <p>In order to legally administer the substance as a medicinal product it would be necessary to obtain a marketing authorisation. At this point, no marketing authorisation for a medicinal product containing Ibogaine as an active ingredient has been issued.</p>	<p>Dirk Uwer <dirk.uwer@henger.com></p>

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<p>Italy</p>	<p>Only Scientific use of psychedelics is regulated (see next column)</p>	<p>General rule - Presidential Decree of October 9, 1990, No. 309 regulates the use of psychotropic substances (including LSD, MDMA, DMT...), which is generally prohibited. However, under Section 49, the Ministry of Health can issue authorizations to use certain quantities of psychotropic substances for purposes of: (i) scientific research, (ii) investigations required by the judicial authority. To get the authorization it is crucial to: predetermine the quantities of substances required and identify the person responsible for possession and scientific use. Additionally, the persons authorized to use the substances are obliged to record the following information in a special register endorsed by the local health authority: (a) the references of the authorization granted, (b) the quantity of substances in arrival and in stock, and (c) a description of the research.</p>	<p>Maria Balestriero <mbalestriero@portolano.it> Claudio Todisco <ctodisco@portolano.it></p>

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Lithuania	No.	<p>General rule - controlled substances under Schedule I (the strictest) can be used only if they are a part of a medicine registered in the national or European central registry of medicines.</p> <p>However, the use of psychedelics could be allowed under the officially carried clinical trial with approved protocol by national institutions.</p>	<p>Jevgenija Vienažindytė <jevgenija@vienazindyte.lt></p> <p>Dovydas Gudziunas <Dovydas.gudziunas@ellex.legal></p>

Country	Q1	Q2	Contacts for further legal consultation
The Netherlands	<p>Yes, Article 5 of the Dutch Opium Act provides for specific exemptions for medicinal use of psychedelics listed in Schedule I (hard drugs) and Schedule II (soft drugs) to that act. The conditions for the exemptions are laid down in the Dutch Opium Act Decree. The exemption for pharmacists and dispensing physicians applies to the designated substances included in the annexes to the Dutch Opium Act Decree. These designated substances include certain Schedule I substances (not including lysergide, such as LSD and MDMA) and all Schedule II substances excluding hashish. Designated institutes such as licensed hospitals (listed in Article 16 of the Dutch Opium Act Decree) have a full exemption for the medicinal use of all Schedule I and II substances. In other cases, an individual exemption for a specific prescription of Schedule I or II substances can be applied for.</p>	<p>Psychedelics may be prescribed and by the healthcare professionals and designated institutes mentioned in the answer to Q1, provided that the conditions of the Opium Act Decree are complied with.</p>	<p>Greetje van Heezik <g.van.heezik@houthoff.com></p>

Country	Q1	Q2	Contacts for further legal consultation
Portugal	<p>No.</p> <p>Psychedelics are listed in Schedule IIA of Portuguese Narcotics Act (Decree-Law no. 15/93, of 22nd January, 1993, as amended), which generically regulates the cultivation, production, manufacture, use, trade, distribution, import, export, transit, transport, possession and use of controlled substances (and others therein listed). Only medicinal use of cannabis is allowed under specific legislation.</p>	<p>No.</p> <p>As explained, the use of this substances is generically prohibited, although controlled substances may be used as a part of an approved medicine. However, according to information made available by media, Fundação Champalimaud is part of an international multisite clinical trial investigating the efficacy and safety therapeutic use of psilocybin in 200 patients with treatment-resistant depression.</p>	<p>Alessandro Azevedo <aazevedo@mlgts.pt></p>

Country	Q1	Q2	Contacts for further legal consultation
Spain	<p>The use, manufacture, import, export, trade, distribution and possession, as well as the inclusion in any preparation of the substances included in Schedule I of the 1971 Convention, are prohibited. However, exceptionally, competent authorities may authorise the use of certain quantities for medical or scientific research purposes only.</p> <p>[ex Spanish Royal Decree 2829/1977, of 6 October 1977, and Order of the Ministry of Health of 14 January 1981]</p>	<p>The administration of these substances would be allowed, by way of exception, in the context of duly authorised medical or scientific research.</p> <p>In any case, a medical research would also be subject, as a general rule, to the regulations on clinical trials (including Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use; and Spanish Royal Decree 1090/2015, regulating clinical trials with medicinal products, the Ethics Committees for Research with medicinal products and the Spanish Clinical Trials Register).</p>	<p>Alejandro Abad Chamorro <alejandro.abad@uria.com></p>

Country	Q1	Q2	Contacts for further legal consultation
UK	No.	<p>Generally, possession and supply of psychedelics is prohibited even for medicinal purposes.</p> <p>Just about all psychedelics such as ecstasy (MDMA), LSD and magic mushrooms are classed as the most harmful drugs under UK law - Class A under the Misuse of Drugs Act 1971 (MODA).</p> <p>Supplemental to MODA is the Misuse of Drugs Regulations 2001 which contain some exceptions to production of drugs depending on the medicinal value of the drug. Most psychedelics are classed under Schedule 1 and deemed to have no medicinal value.</p> <p>It is still possible for companies to manufacture and research Schedule 1 drugs if they obtain a license from the Home Office.</p> <p>Currently, the trials are carried out by Imperial College (having a special Center for Psychedelic Research) and by a private company - Clerkenwell Health with its focus on trials for assisting therapies with psilocybin</p>	Gustaf Duhs <Gustaf.Duhs@stevens-bolton.com>