November, 2023

MEDICINAL USE OF CANNABIS AND PSYCHEDELICS: REGULATORY ASPECTS

The growing number of scientific studies on the therapeutic properties of Cannabis Sativa and psychedelics point to the need for relevant updates in Brazilian regulation. Our Life Sciences and Healthcare experts provide the most up-to-date panorama on the subject, as well as prospects for the near future.

Cannabis Sativa

The import and sale of medicines and industrialized cannabis-based products for medicinal use is permitted and has been growing annually in Brazil. However, the planting, cultivation and consumption of flowers, oils or the plant itself still encounters regulatory limitations, resulting in judicial and legislative disputes.

These products predominantly have:

Type B prescription	Type A prescription	Type A prescription
CBD and no more than 0.2% THC	> 0.2% THC, when intended for palliative care	Medicines containing up to 30mg/ml of THC and CBD

Brazilian National Sanitary Agency (ANVISA)

Since 2015, Anvisa has allowed individuals to import industrialized products containing cannabidiol (CBD) and/or tetrahydrocannabidiol (THC) for their own use and for therapeutic purposes, with a medical prescription. In 2019, a second regulation was published dealing with the requirements for importing, marketing, prescribing and dispensing these products on the Brazilian market (ANVISA RDC No. 327/2019).

Limitations include: use in cosmetics, smoking, health products or food, as well as veterinary or recreational use. Manipulation of the substance is also prohibited, but some compounding pharmacies have been obtaining judicial authorization to handle derivatives of the plant.

Important to know:

1. Anvisa Technical Note no. 35/2023 from the Coordination of Controlled Products, published on July 2023, prohibits the importation of Cannabis plants or flowers in natura, however is being discussed in court.

2. The deadline for reviewing ANVISA RDC No. 327/2019 ran out at the end of 2022. The expectation is that a new text will be placed on public consultation by Anvisa in the coming months.

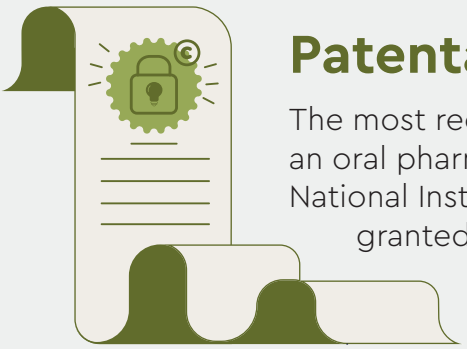
3. A regulatory proposal for definition of criteria and requirements involving the cultivation of cannabis for medicinal and scientific use was rejected by the Board in 2019 (Anvisa Public Consultation No. 655/2019).

Incorporation into the SUS

The Brazilian National Commission for the Incorporation of Technologies into the Public Health System (CONITEC), responsible for the incorporation, exclusion or alteration of health technologies within the Public Health System (SUS), as well as the constitution or alteration of clinical protocols and therapeutic guidelines, is discussing the inclusion of cannabis-based medicines and products for treatment in the public health system. To date, there have been two requests for the inclusion of concentrated cannabidiol, one for the treatment of refractory epilepsy and the other for multiple sclerosis, both have been denied.

In the opposite direction, more than 10 Brazilian states already have laws determining the distribution of these products by the SUS.

In 2020, the Federal Regional Court (TRF-1) accepted a request from the Federal Public Prosecutor's Office (MPF) at first instance asking the Federal Government to include THC and CBD-based medicines in the list of drugs distributed by SUS, provided that they are registered by Anvisa and that the alternatives currently available on SUS are not effective for the patient. However, the decision has been suspended and is pending.



Patentability

The most recent and relevant case of a patent protection application involves an oral pharmaceutical composition containing cannabinoids. In 2021, the National Institute of Intellectual Property (INPI), on appeal, annulled a patent granted on the grounds that the product in question did not present inventive step, which is one of the essential requirements for granting patents in Brazil.

Judicial Activity

STF
Supreme Federal Court

The STF is currently judging the decriminalization of the use of Cannabis Sativa for personal use (RE nº 635659, with general repercussion – Theme 506), having already formed a majority in favor of defining criteria to differentiate users from dealers. This understanding is positive for the expansion of the medicinal use of the plant.

STJ
Superior Court of Justice

Considering the lack of federal regulation on planting for medicinal use of cannabis, the judicial system currently has around 3,000 legal actions on the subject, made by patients or family members and associations. Through Special Appeal No. 2.024.250, the processing of all these cases has been suspended pending judgment by the First Section of the STJ.

Legislative Activity

At the federal legislative level, Bill No. 399/2015 is the most advanced proposal and proposes legalizing the cultivation of the plant for medicinal and industrial use. In addition, pharmacies within the SUS would be authorized to cultivate and process cannabis plants for medicinal purposes, as long as the safety requirements for cultivation, storage, transportation and prescription are fulfilled.

The text was approved by the House of Representatives, but is awaiting deliberation of an appeal against the Special Committee's conclusive assessment at the Board of Directors to be forwarded to the Senate.

Psychedelics

Scientific studies with psychedelics have shown promising results in the treatment of psychiatric illnesses such as refractory depression and panic disorder. Some countries are making progress in regulating the issue, while Brazil does not have specific rules or guidelines yet.

International Experience

The U.S. Food and Drug Administration (FDA), the agency responsible for regulating medicines, has non-binding guidelines for conducting clinical trials with psychedelic drugs. This document contains considerations on the configuration of clinical trials with substances such as psilocybin, LSD and MDMA, in view of the increase in the number of studies and companies interested in using these substances for the treatment of diseases such as refractory depression, panic disorder and other psychiatric illnesses. The FDA is currently analyzing the application for a drug containing MDMA.

In Oceania, the Therapeutic Goods Administration (TGA), the Australian regulatory agency, approved in July 2023, the direct prescription by doctors of psychedelic substances (psilocybin and MDMA) for patients with refractory depression or post-traumatic stress disorder (PTSD). It is the first country to recognize psychedelics as drugs with therapeutic effects.

Psychedelics in Brazil

In 2020, Anvisa approved ketamine hydrochloride, which acts the central nervous system for the clinical treatment of patients with depression resistant to common medications, by including it in list B1 (psychotropic substances) of the Technical Regulation on Substances Subject to Special Control (Ordinance/SVS No. 344/1998).

In the same decision, ketamine was reclassified from list C1 to B1. Both have been used off-label (i.e. when a drug is used for an indication other than that approved by a regulatory agency) in the treatment of resistant depression.

Other psychedelic substances that have already been used or are being studied for pharmacological use, such as LSD, Psilocybin, DMT and MDMA are still proscribed substances, i.e. they are still prohibited by Ordinance/SVS No. 344/1998 (List F2).

In practice, this classification makes it difficult to handle and carry out tests, requiring a series of special authorizations for this purpose.

Clinical trials with MDMA are already being conducted in Brazil for the treatment of post-traumatic stress disorder.

GET IN TOUCH

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