NEW REGULATORY FRAMEWORK FOR MEDICINAL *CANNABIS*

EVERYTHING YOU NEED TO KNOW

The importation and commercialization of medications and industrialized products containing cannabidiol (CBD) and/or tetrahydrocannabidiol (THC) for medicinal use has been permitted since 2015 and has been growing annually in Brazil. In February 2025, ANVISA (Brazilian Health Regulatory Agency) undertook a revision of ANVISA RDC nº 327/2019, which set forth requirements for the importation, commercialization, medical prescription, and dispensing of Cannabis products, and which shall be replaced by ANVISA RDC nº 1.015/2026, effective as of 05/04/2026.

Additionally, definitive rules were approved for the local cultivation and manufacturing of such products for medicinal, pharmaceutical, or research purposes (ANVISA RDC nº 1.012/2026 and ANVISA RDC nº 1.013/2026).

On an experimental basis, ANVISA also established a regulatory sandbox for conducting controlled tests and generating evidence on experimental techniques and technologies involving products or services related to Cannabis sativa, specifically: (i) cultivation intended for medicinal purposes; (ii) production of herbal pharmaceutical inputs; and (iii) development, preparation, and supply of Cannabis-based preparations for medicinal use (ANVISA RDC nº 1.014/2026).

Registration and Commercialization of Cannabis Products (effective 05/04/2026)

Cannabis products remain a differentiated category but shall be subject to the rules for oversight, control, storage, importation, distribution, transportation, production, and dispensing applicable to medications and pharmaceutical inputs. ANVISA RDC nº 1.015/2026 shall fully replace ANVISA RDC nº 327/2019.

Important to know:
ANVISA has more than 50 registered Cannabis products. Medications based on Cannabis sativa remain subject to specific regulation.

Exclusions: cosmetics, smoking products, medical devices, and food products based on Cannabis sativa (including any of its derivatives).

Permitted routes of administration


Inhalation


oral


buccal


sublingual


dermatological

Prescription forms

Special Control Prescription

CBD with THC content less than or equal to 0.2%

Type "A" Prescription Notification
CBD with THC content above 0.2%

Target audience

Patients without a satisfactory therapeutic alternative with medications registered in the country and/or patients with serious debilitating diseases.

General rules

Cannabis products must be manufactured under practices that ensure their pharmaceutical quality and safety for human use and may NOT:

- ✖ contain pharmaceutical inputs of known toxic risk or toxic chemical substances in concentrations exceeding proven safe limits;
- ✖ contain isolated substances of synthetic or semi-synthetic origin (except those with an exclusively excipient function, proven for the formulation and of pharmaceutical use);
- ✖ be modified-release, nanotechnological, or PEGylated;
- ✖ be in the form of herbal drug of the Cannabis sativa species or its parts, even after stabilization and drying processes, or in its cut, crushed, or powdered form, even if made available in any pharmaceutical form;
- ✖ be the subject of free samples.

- ✓ The Sanitary Authorization (AS) for Cannabis products must be requested prior to their importation, manufacturing, or commercialization.

  The AS shall have a validity of 5 years (renewable once for an equal period).

  Products holding an AS issued prior to ANVISA RDC nº 1.015/2026 may be renewed.

- ✓ Cannabis products that have been authorized shall have a period of up to 1 year to be commercialized (from the date the AS is granted); otherwise, they shall be canceled by ANVISA.
- ✓ The company holding the AS is responsible for the quality and safety of Cannabis products distributed and commercialized within the national territory. The implementation of post-marketing monitoring actions is mandatory, including any recall and reporting of adverse events.
- ✓ Quality control may be outsourced. For finished product quality control analyses and stability studies, the company must be a laboratory accredited within the Brazilian Network of Analytical Health Laboratories (REBLAS) or a manufacturer holding a valid Good Manufacturing Practices Certificate (CBPF) for medications.
- ✓ Packaging must contain tamper-evident closure mechanisms, as well as identification and security features enabling traceability of the Cannabis product. Anti-counterfeiting mechanisms are optional.
- ✓ Changes to the product may require ANVISA's review (e.g., new commercial presentation, concentration, or flavor; change or addition of the manufacturing site; change to the label or informational leaflet).

Advertising

- Advertising of Cannabis products may only be directed to physicians, dental surgeons, and pharmacists.
- ✖ The disclosure of any information not approved by ANVISA in the informational leaflet and product labeling is prohibited.

Labels and packaging of Cannabis products must be written in Portuguese and must have features that inhibit dispensing and administration errors, unintended exchanges, or misuse.

Mandatory statements include: "Warning: This product is not a medication and its efficacy and safety have not been evaluated by ANVISA" and "May only be sold with prescription retention."

Cultivation for Medicinal and/or Pharmaceutical Purposes (effective 08/04/2026)

ANVISA RDC nº 1.013/2026 permits the cultivation, acquisition, research, importation, storage, distribution, and supply of Cannabis sativa for medicinal and/or pharmaceutical purposes with THC content less than or equal to 0.3%. Cultivation of the plant with total THC content exceeding 0.3% shall require prior approval from ANVISA, subject to compliance with additional requirements.

Supply and distribution is limited to:

Between establishments holding a Special Authorization (AE) from ANVISA for Cannabis cultivation activities (when dealing with plant material intended for cultivation); and/or

To the following establishments (when dealing with plant material not intended for cultivation):

- Manufacturers of pharmaceutical inputs or medications (for research purposes) holding an AE from ANVISA;
- Laboratories or research institutions holding an AE or a Simplified Special Authorization for Teaching and Research Institutions (AEP) from ANVISA.

An authorization modality for the importation and exportation of substances, plants, fungi, medications, and products subject to special control for Teaching and Research Institutions.

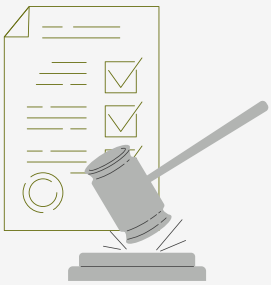
Approval of the AE shall depend on (among other things):

- ✓ Description of the areas and indication of the georeferenced geographic coordinates of the cultivation area;
- ✓ Documentation demonstrating the origin and means of access to the propagation material;
- ✓ Organizational chart describing the responsibilities and duties of each position involved in the cultivation stages;
- ✓ Estimate of the quantity to be cultivated per hectare and per square meter, consistent with the intended activity;
- ✓ Building design and compliance with worker safety requirements and built environment standards, as well as environmental sanitation requirements.

Prohibitions:

- ✗ Importation of seeds for the sole purpose of distribution is prohibited.
- ✗ Exportation of the Cannabis sativa plant species, including seeds, is prohibited (except for returning imported material to the country of origin).
- ✗ Importation and exportation of the Cannabis sativa plant species through accompanied or unaccompanied luggage, by Simplified Import Declaration (DSI), as well as through express and postal shipments, is prohibited.

The importation and exportation of Cannabis sativa and its seeds shall also be subject to the rules of the Ministry of Agriculture and Livestock (MAPA).

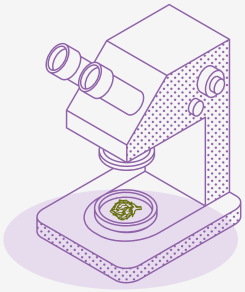


Key Obligations

- Documentation proving the genetic origin of the species and THC content less than or equal to 0.3%.
- Traceability procedures ensuring identification of the plant species at the cultivation site, allowing, at a minimum, identification by batch number of the cultivation stage, the start date of the respective stage, the variety, and the quantity of plants, from the acquisition of seeds and mother plants through to processing or final destination.
- Laboratory analyses for each batch of herbal drug obtained from cultivation.
- Submission of production estimates and Quarterly and Annual Reports on Psychoactive Substances and Other Substances Subject to Special Control (BSPO) to ANVISA.
- Transportation must be carried out by companies licensed for this activity involving medications, pharmaceutical inputs, or other products subject to special control.

Cultivation for Exclusive Research Purposes (effective 08/04/2026)

Pursuant to ANVISA RDC nº 1.012/2026, the AE granted by ANVISA encompasses planting, growing, harvesting, handling, transfer, donation, importation, exportation, storage, and processing of the plant species, through to product development, including research with co-products obtained, for any purpose exclusively related to research.



Cultivation intended exclusively for research purposes may only be carried out by:

- Public Scientific, Technological, and Innovation Institution (ICT);
- Higher education or technical education institution recognized by the Ministry of Education (MEC); or
- Manufacturers of pharmaceutical inputs or medications.

ANVISA RDC nº 1.012/2026 also encompasses research in *in vitro* formats or research in which there is no vegetative growth of the plant species.

ANVISA approval of each individual research project shall not be required; however, the institution must keep research projects documented and available for health inspection.

The institution shall present a control plan covering all conditions of the cultivation site with the objective of ensuring, at a minimum:

a. effective control of the activities carried out at the site;
b. implementation of continuous surveillance mechanisms throughout the entire perimeter;
c. access restricted exclusively to authorized personnel;
d. the existence of effective controls for mitigating the risk of diversion of the plant species, including a contingency plan in the event of incidents; and
e. containment and prevention of dissemination of Cannabis into the environment.

Security measures

- Seeds and plant species, whether dried or fresh, must be stored in a locked area exclusively designated for this purpose, under the responsibility of the Technical Officer or the lead researcher responsible for cultivation.
- The cultivation site and its adjacent areas must be protected by a physical barrier so as to prevent access by unauthorized persons.
- The perimeter and locations containing Cannabis must have an uninterrupted video surveillance system and a security alarm.
- Access control and identification must be implemented for the entry and exit of each person accessing areas containing Cannabis, with a log of personnel entry and exit, including date and time.
- An updated registry must be maintained of all authorized employees and service personnel who have access to the surveillance and video monitoring system, as well as to the cultivation areas.

Worth Monitoring

- **Regulatory Sandbox:** ANVISA shall publish a public call notice for legal entities that have been duly incorporated in Brazil for a minimum of 2 years. An Experimental Regulatory Adequacy Protocol shall be agreed upon between ANVISA and each participant, which must include: (i) the scope and limits of the authorized activities; (ii) the express and substantiated indication of the applicable health regulations — whether applicable in full, made more flexible, or temporarily waived; (iii) monitoring, evaluation, and supervision parameters set by ANVISA; (iv) the scenarios for adaptation, suspension, or termination of the Experimental Project; (v) the plan for discontinuation of activities and reintegration into the ordinary regulatory framework; (vi) minimum quality control requirements; (vii) traceability mechanisms; and (viii) obligations related to data generation and sharing.
- Definition of requirements for the cultivation, importation, and management of plant species by the Ministry of Agriculture and Livestock (MAPA).
- Regulation of the use of trade names for Cannabis products by ANVISA.
- Regulation of the compounding of magistral preparations containing CBD by pharmacies by ANVISA.
- Publication of technical guidance by ANVISA on control plans and monitoring of cultivation activities.
- Developments arising from the National Plan for the Regulation of Medicinal Cannabis (PNRC-Med), presented by the Federal Government in the Incident of Assumption of Jurisdiction nº 16 before the STJ (Superior Court of Justice), for the regulation of the cultivation and production of medicinal Cannabis.
- **Bill nº 399/15:** Seeks to regulate the cultivation, production, and access to medicinal Cannabis and industrial hemp, reflecting the mobilization of different sectors of society and the need for legislative harmonization with judicial and regulatory decisions.

- **Incorporation into the SUS (Unified Health System):** The National Commission for the Incorporation of Health Technologies into the Unified Health System (CONITEC), responsible for the incorporation, exclusion, or modification of health technologies within the SUS, as well as for the establishment or modification of clinical protocols and therapeutic guidelines, is discussing the inclusion of Cannabis-based medications and products for treatment within the public health network. To date, 2 incorporation requests for the inclusion of concentrated cannabidiol — one for the treatment of refractory epilepsy and another for multiple sclerosis — have been denied.

Conversely, more than 10 Brazilian states already have laws mandating the distribution of these products through the SUS. In 2020, the Federal Regional Court of the 1st Region granted a request by the Federal Prosecution Service at first instance, seeking to compel the Federal Government to include THC- and CBD-based medications on the list of drugs distributed by the SUS, provided they are registered with ANVISA and that the alternatives currently offered by the SUS are not effective for the patient. However, the decision is currently stayed, pending the adjudication of an appeal.

Psychedelics: In addition to medicinal Cannabis, scientific studies with other psychedelic substances have shown promising results for psychiatric treatments and palliative care — such as psilocybin (the active compound in magic mushrooms), DMT (contained in ayahuasca and authorized for religious use), MDMA (an amphetamine derivative), and LSD (lysergic acid).
However, some of these substances remain prohibited under Ordinance nº 344/1998 and the National Drug Policy Plan (PLANAD), which makes it difficult to obtain special authorizations for conducting studies in Brazil. On the other hand, since 2020, ANVISA has permitted the off-label use of esketamine hydrochloride and ketamine (when a medication is used for an indication other than that approved by a regulatory agency).

GET IN TOUCH

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