NEW REGULATION ON CANNABIS-BASED PRODUCTS

The ANVISA Collegiate Board of Directors Resolution No. 327/2019, published on December 11th, 2019 sets forth the procedures for granting marketing authorizations, as well as the requirements for the manufacturing, sale, prescription, dispensing, monitoring and inspection of Cannabis Products for medicinal purposes.

Time Limits

This Resolution must be reviewed within three (3) years after its publication and enters into force in March 2020.

Cannabis cultivation – even for the purposes of extraction as a pharmaceutical ingredient – remains an unregulated issue in Brazil.

Highlights

Definition of Cannabis Products

The manufactured product intended for medical purposes containing *Cannabis sativa* exclusively as active plant derivatives or phytopharmaceuticals and subject to a marketing authorization by ANVISA.

Marketing authorization of Cannabis Products

- Valid for a period of five (5) years that is not subject to extension, starting from the date of publication of the marketing authorization in the Official Gazette of the Brazilian Federal Government (DOU). Cannabis Products that do not comply with drug regulatory standards within the mentioned timeframe will have their marketing authorization cancelled.
- Before or upon its expiration, the marketing authorization holder must apply for a drug marketing authorization, subject to a new filing procedure.
- Cannabis Products will be authorized for oral or nasal use only.
- If the THC concentration levels are up to 0.2%, the medical prescription of a product must be allowed only for use by terminally ill patients or those who have exhausted treatment alternatives.
- Isolated substances of synthetic or semi-synthetic origin, except those with excipient functions, or substances which are potentially toxic at the dosages used are not allowed in the chemical composition.

Company Minimum Capability

I. A Federal Operating Permit (*Autorização de Funcionamento*) ("AFE") that includes manufacture or importation activities with medicines;

II. A Special Operating Permit (*Autorização Especial*) ("AE");

III. A Good Manufacturing Practices Certificate (*Certificado de Boas Práticas de Fabricação*) ("CBPF");

IV. Compliance with Good Distribution and Storage Practices ("BPD");

V. A technical and scientific rationale that justifies the formulation of the medical Cannabis Product and route of administration;

VI. Technical documentation evidencing the quality of the product;

VII. Operational capability for carrying out quality control analysis in Brazil; and

VIII. Capacity to receive and handle reports of adverse effects and technical complaints about the product.

Only those manufacturers that have a medical CBPF certificate issued by ANVISA or importing companies that comply with medical BPD may request the marketing authorization and manufacture the cannabis products.

Further regulations that remain in full force and effect

- ANVISA Collegiate Board of Directors Resolution No. 17/2015 – Provides for rules on the direct importation of CBD and THC products by individuals given that it is for personal use only and if prescribed by a medical doctor for therapeutic purposes.
- CFM Resolution No. 2,113/2014 - Authorizes the therapeutic use of CBD in the fields of neurology, neurosurgery and psychiatry, mainly for epilepsy treatment in children and adolescents.
- Ordinance No. 344/1998 - Regulates the use of CBD and THC in medicines, at a maximum concentration of 30 mg per milliliter for each of these components.

	Do's	Don'ts
Labeling, packaging and advertisement	■ Cannabis Products must be labeled with the name of the plant or plant derivative along with the name of the company responsible for the product. ■ When a company applies for more than one Cannabis Product with similar qualitative chemical compositions, varying only in THC and CBD concentrations, the concentration of these cannabinoids should be part of the product name. ■ The batch number, date of manufacture (month/year) and expiry date (month/year) must be printed on the product's packaging in a way that is easily understandable, legible and with indelible ink, using letters of the largest possible size for easy reading and identification. ■ The packaging of Cannabis Products must contain identification and security mechanisms that enable the product to be traced from manufacture or import to the time of dispensing, as provided for in specific standards.	■ Cannabis Products cannot be marked with trade or brand names. ■ The advertising of any Cannabis Product is expressly prohibited. ■ Free samples are not allowed.
Importation and Manufacturing Possibility of outsourcing quality control tests.	■ The company must import the pharmaceutical inputs in the form of vegetable derivatives, phytopharmaceuticals, in bulk, or manufactured products. ■ If the Cannabis Product or the raw materials from which it originates, are manufactured in more than one location, documentation must be provided for each product or raw material relating to its respective location.	■ Importation of the cannabis plant or parts thereof is not allowed.
Sale	■ The dispensing of medicinal Cannabis Products must be restricted to non-compounding pharmacies or drugstores, upon presentation of a prescription by a legally qualified medical professional.	■ The marketing of the Cannabis Product is only authorized after the publication of the marketing authorization in the DOU. ■ Cannabis products are not allowed to be marketed in the form of a vegetable-based drug of the cannabis plant or its parts, even after the stabilization and drying processes, or in its crushed or pulverized form, even if available in any pharmaceutical form.

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