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CANNABIDIOL AND MEDICAL CANNABIS IN BRAZIL: WHAT PHYSICIANS NEED TO KNOW

CANABIDIOL E CANNABIS MEDICINAL NO BRASIL: O QUE OS MÉDICOS PRECISAM SABER

CANNABIDIOL Y CANNABIS MEDICINAL EN BRASIL: LO QUE LOS MÉDICOS DEBEN SABER

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ABSTRACT

Objective: To review the pharmacological, clinical, and regulatory principles governing the medical use of cannabinoids in Brazil, with emphasis on pharmaceutical-grade products currently authorized for sale in Brazilian pharmacies. Methods: This narrative review synthesized literature published between 2015 and 2025 through searches in PubMed, Scopus, and SciELO, and incorporated Brazilian regulatory documents from the National Health Regulatory Agency (ANVISA). Results: CBD demonstrates robust efficacy for a narrow range of refractory childhood epilepsies and shows promising, though still limited, therapeutic potential in chronic pain, anxiety, and sleep disturbances. In Brazil, recent regulatory advances have enabled the commercialization of oral formulations with varying CBD and THC profiles, expanding therapeutic options while also demanding careful attention to pharmaceutical quality, dosing, safety monitoring, and drug–drug interactions. Divergence between Brazilian and U.S. regulatory models reinforces the need for clinicians to understand the specific legal and prescribing requirements unique to the Brazilian context. Conclusion: Medical cannabinoid use in Brazil is rapidly evolving. Effective and responsible prescribing requires detailed knowledge of cannabinoid pharmacology, clinical indications, adverse-effect profiles, and regulatory obligations. Continued investment in high-quality clinical trials and real-world evidence is essential to define long-term safety, therapeutic value, and cost-effectiveness across diverse patient populations.

Keywords: Cannabis. Cannabidiol. Medical Marijuana. Therapeutic Use. Government Regulation.

RESUMO

Objetivo: Revisar os princípios farmacológicos, clínicos e regulatórios que regem o uso medicinal de canabinoides no Brasil, com ênfase em produtos de grau farmacêutico atualmente autorizados para comercialização em farmácias brasileiras. Métodos: Esta revisão narrativa sintetizou a literatura publicada entre 2015 e 2025 por meio de buscas nas

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bases PubMed, Scopus e SciELO, incorporando documentos regulatórios brasileiros da Agência Nacional de Vigilância Sanitária (ANVISA). Resultados: O CBD demonstra eficácia robusta para um grupo restrito de epilepsias infantis refratárias e apresenta potencial terapêutico promissor, embora ainda limitado, no tratamento de dor crônica, ansiedade e distúrbios do sono. No Brasil, avanços regulatórios recentes permitiram a comercialização de formulações orais com perfis variados de CBD e THC, ampliando as opções terapêuticas e exigindo, simultaneamente, atenção rigorosa à qualidade farmacêutica, à posologia, ao monitoramento de segurança e às interações medicamentosas. As divergências entre os modelos regulatórios brasileiro e norte-americano reforçam a necessidade de que os médicos compreendam os requisitos legais e de prescrição específicos do contexto brasileiro. Conclusão: O uso medicinal de canabinoides no Brasil está em rápida evolução. Uma prescrição eficaz e responsável requer conhecimento detalhado da farmacologia dos canabinoides, das indicações clínicas, dos perfis de efeitos adversos e das obrigações regulatórias. O investimento contínuo em ensaios clínicos de alta qualidade e em evidências de vida real é essencial para definir a segurança a longo prazo, o valor terapêutico e o custo-efetividade em diversas populações de pacientes.

Palavras-chave: Cannabis. Canabidiol. Maconha Medicinal. Uso Terapêutico. Regulamentação Governamental.

RESUMEN

Objetivo: Revisar los principios farmacológicos, clínicos y regulatorios que rigen el uso médico de los cannabinoides en Brasil, con énfasis en los productos de grado farmacéutico actualmente autorizados para su venta en farmacias brasileñas. Métodos: Esta revisión narrativa sintetizó la literatura publicada entre 2015 y 2025 mediante búsquedas en PubMed, Scopus y SciELO, e incorporó documentos regulatorios brasileños de la Agencia Nacional de Vigilancia Sanitaria (ANVISA). Resultados: El CBD demuestra una eficacia sólida para un rango limitado de epilepsias infantiles refractarias y muestra un potencial terapéutico prometedor, aunque todavía limitado, en el dolor crónico, la ansiedad y los trastornos del sueño. En Brasil, los recientes avances regulatorios han permitido la comercialización de formulaciones orales con diversos perfiles de CBD y THC, ampliando las opciones terapéuticas y exigiendo, al mismo tiempo, una atención cuidadosa a la calidad farmacéutica, la dosificación, la vigilancia de la seguridad y las interacciones medicamentosas. La divergencia entre los modelos regulatorios de Brasil y Estados Unidos refuerza la necesidad de que los clínicos comprendan los requisitos legales y de prescripción específicos del contexto brasileño. Conclusión: El uso médico de cannabinoides en Brasil está evolucionando rápidamente. Una prescripción eficaz y responsable requiere un conocimiento detallado de la farmacología de los cannabinoides, las indicaciones clínicas, los perfiles de efectos adversos y las obligaciones regulatorias. La inversión continua en ensayos clínicos de alta calidad y en evidencia del mundo real es esencial para determinar la seguridad a largo plazo, el valor terapéutico y la relación costo-efectividad en diversas poblaciones de pacientes.

Palabras clave: Cannabis. Cannabidiol. Marihuana Medicinal. Uso Terapéutico. Regulación Gubernamental.

1 INTRODUCTION

Cannabinoid-based therapy (CBT) has drawn increasing attention in clinical practice because of its therapeutic potential across several neurological, psychiatric, and oncologic conditions (1, 2). *Cannabis* broadly refers to products derived from plants of the Cannabis genus, whereas *cannabinoids* denote the active compounds found within these plants, in addition to their synthetic analogues (3). Cannabis naturally contains multiple cannabinoids, including Δ9-tetrahydrocannabinol (Δ9-THC, hereafter THC) - the primary psychoactive constituent responsible for the characteristic "high" - and cannabidiol (CBD), a non-intoxicating compound with distinct pharmacologic and clinical effects (4,5). Although THC and CBD share the same botanical origin, their pharmacological profiles diverge substantially (5). THC is associated with euphoria, altered perception, and appetite stimulation, whereas CBD - largely devoid of psychoactive activity - has been linked to anxiolytic, anticonvulsant, anti-inflammatory, and antipsychotic properties (3,6).

Over recent decades, basic and clinical research has substantially broadened our understanding of the mechanisms of action, safety profile, and therapeutic applicability of cannabinoids. Randomized clinical trials have shown the efficacy of CBD for refractory epilepsies such as Dravet syndrome and Lennox–Gastaut syndrome (7,8), while observational studies have pointed toward potential benefits for chronic pain, anxiety, and spasticity (9,10).

In Brazil, the regulatory framework for cannabis-based products has evolved substantially since 2015, culminating in RDC No. 327/2019, which established criteria for manufacturing and commercialization, and RDC No. 660/2022, which standardized importation procedures (11,12). These regulations expanded access to oral formulations dispensed in pharmacies under specific prescription requirements. In this context, evidence-informed prescribing has become essential to ensure safe and appropriate clinical use.

2 METHODOLOGY OF THE REVIEW

This work was designed as a narrative review. The literature search was conducted in PubMed, Scopus, and SciELO, combining DeCS/MeSH descriptors with free-text terms because of the heterogeneous indexing of articles addressing sanitary regulation and the medical use of cannabinoids. The following keywords were employed: "Cannabis," "Medical Marijuana," "Therapeutic Use," and "Government Regulation," in addition to broad combinations such as "cannabis AND medical marijuana" and "cannabis AND government

regulation," which were used to pick up relevant studies that were not indexed under specific descriptors.

We included articles published between 2015 and 2025, written in English, Portuguese, or Spanish, as well as regulatory documents issued by the Brazilian Health Regulatory Agency (Agência Nacional de Vigilância Sanitária, ANVISA). Given their central role in shaping the Brazilian regulatory landscape - distinct from the more fragmented U.S. federal–state framework - Collegiate Board Resolutions (Resoluções da Diretoria Colegiada, RDCs) No. 327/2019 and No. 660/2022 were retrieved directly from ANVISA's official website.

The selection process focused on the relevance of each document to the objectives of the review, encompassing pharmacologic, clinical, and observational studies, along with regulatory analyses that could shed light on the current framework governing the medical use of cannabinoids in Brazil.

3 LITERATURE REVIEW

3.1 ENDOCANNABINOID SYSTEM

The endocannabinoid system is a signaling network composed of cannabinoid receptors - primarily cannabinoid receptor types 1 and 2 (CB1 and CB2) - their endogenous ligands (endocannabinoids), and the enzymes responsible for their synthesis and degradation (13). This system regulates key physiological functions such as pain modulation, mood regulation, appetite, memory, and immune activity (13).

CB1 is a G protein–coupled receptor (GPCR) - a large family of cell-surface receptors that transmit intracellular signals after binding an activating molecule. CB1 is highly expressed in the central nervous system, especially in the prefrontal cortex, hippocampus, and amygdala, which are regions involved in cognition, emotion, and reward processing (14). Through these pathways, CB1 mediates many of the psychoactive effects of THC. Although expressed at lower levels outside the brain, peripheral CB1 receptors - present in tissues such as the heart and vasculature - may influence vasodilation and myocardial contractility when activated by cannabinoids (15). CB2, also a GPCR, is predominantly found in peripheral tissues a its activation is associated with anti-inflammatory and broader immunomodulatory effects and plays little to no role in the psychoactive effects attributed to cannabis. (4)

3.2 PHARMACOLOGY AND MECHANISMS OF ACTION

The endocannabinoid system can be modulated by exogenous cannabinoids, which include phytocannabinoids, synthetic cannabinoids, and cannabis-derived products (4).

THC, a psychoactive phytocannabinoid naturally present in the *Cannabis* genus, acts as a partial agonist of the cannabinoid receptors CB1 and CB2 and modulates the release of key neurotransmitters such as dopamine, γ-aminobutyric acid (GABA), and glutamate. This activity underlies its psychoactive effects, including euphoria, perceptual changes, and appetite stimulation, and contributes, in susceptible individuals, to anxiety, psychotic-like symptoms, and tachycardia (14,15). The predominance of CB1 receptors in brain regions involved in cognition, mood regulation, and reward processing helps explain the variable neurobehavioral responses observed with THC exposure. Δ8-tetrahydrocannabinol, a structural analogue of THC, produces similar effects but with lower potency (4).

Unlike THC, cannabidiol does not act as a direct CB1 agonist. Its effects appear to involve modulation of multiple receptor systems, including serotonergic and transient receptor potential pathways, which may contribute to its anxiolytic and anti-inflammatory properties (2,5).

3.3 BRAZILIAN REGULATORY FRAMEWORK

Brazilian regulation has evolved substantially since 2015, when the exceptional importation of cannabis-derived products for medical purposes was first authorized. A major milestone occurred with the publication of RDC No. 327/2019, which established criteria for the manufacturing, commercialization, quality control, and post-marketing surveillance of cannabis products within the national territory. Subsequently, RDC No. 660/2022 revised and streamlined the rules governing individual (person-specific) importation, thereby expanding access and formalizing administrative procedures (11,12).

Under the current regulatory model, products containing ≤0.2% THC or those formulated with isolated CBD are classified as B-prescription medications (blue prescription form). Formulations containing THC concentrations above 0.2% require an A-prescription (yellow form), reflecting stricter controls associated with substances that carry higher psychoactive potential. (11). This tiered framework guides medical prescribing, defines dispensing requirements, and underpins pharmacovigilance activities across the country. (11)

3.4 ROUTES OF ADMINISTRATION

In Brazil, cannabis-derived products commercialized in pharmacies under RDC 327 are oral, mainly solutions such as drops and syrups, in accordance with RDC No. 327/2019 and subsequent regulatory updates (11,16). Inhaled, topical, or other alternative routes described in the international literature are not permitted for commercialization in Brazilian pharmacies. (16,17).

This approach differs from markets such as North America, where inhaled products and high-potency formulations are widely available (17). The Brazilian model prioritizes regulated, pharmaceutical-grade oral products to ensure standardization, traceability, and patient safety (11,12).

Finally, distinctions between regulated and unregulated markets are critical. Products obtained outside licensed pharmacies may present substantial variability in cannabinoid concentration, composition, and purity, posing potential health risks (4, 18). In Brazil, centralized regulatory oversight aims to minimize exposure to unstandardized or adulterated products (11) (Table 1 and Table 2).

3.5 CLINICAL INDICATIONS

Unlike the U.S. regulatory model, in which specific cannabinoid formulations carry formal FDA-approved indications, the Brazilian framework (ANVISA RDC No. 327/2019) authorizes the prescription of cannabis-based products without predefined labeled indications (11,12,16).

Therapeutic decisions therefore rely primarily on physician judgment supported by available scientific evidence. Among clinical indications, the strongest evidence supports purified cannabidiol (CBD) as adjunctive therapy for treatment-resistant pediatric epilepsies, including Dravet syndrome, Lennox–Gastaut syndrome, and tuberous sclerosis complex (7,8). For chemotherapy-induced nausea and vomiting (CINV), cannabinoids may be considered only in refractory cases despite optimized antiemetic regimens, with overall weak to moderate evidence (9). Dronabinol is approved in the U.S. for HIV/AIDS-related anorexia, although clinical benefit appears modest (19).

For most other conditions—including chronic noncancer pain, multiple sclerosis–related spasticity, cancer pain, insomnia, dementia, and psychiatric disorders—evidence remains limited or insufficient to recommend first-line use. Professional societies consistently

advise caution, particularly given the neuropsychiatric and cardiovascular risks associated with THC exposure (11, 19, 20).

Before prescribing, clinicians should screen for high-risk scenarios such as unstable cardiovascular disease, personal or family history of psychotic disorders, pregnancy, and potential drug–drug interactions. (20-22). Cannabidiol is a known inhibitor of CYP3A4 and CYP2C19, requiring careful monitoring in patients receiving medications with narrow therapeutic windows, including warfarin, tacrolimus, and clobazam. (21)

3.6 SAFETY AND ADVERSE EFFECTS

Cannabidiol (CBD) is generally well tolerated, with adverse events typically mild to moderate, including somnolence, diarrhea, fatigue, and reduced appetite (3,22). Elevated transaminases have been reported, particularly in patients receiving concomitant antiseizure medications such as clobazam, reflecting pharmacokinetic interactions mediated by CYP2C19 inhibition (21,22). Dose adjustment and hepatic monitoring may be required.

In contrast, tetrahydrocannabinol (THC) is more frequently associated with dose-dependent neuropsychiatric effects, including anxiety, paranoia, and psychosis, as well as cardiovascular effects such as tachycardia and arrhythmias (19,20). Chronic or heavy use has been linked to cannabinoid hyperemesis syndrome, tolerance, and cannabis use disorder (3).

Certain clinical conditions confer higher risk of adverse outcomes, including pregnancy, unstable cardiovascular disease, and personal or family history of psychotic disorders (1,19). Careful patient selection is therefore essential before initiating cannabinoid therapy (Table 1 and Table 2).

Risk mitigation strategies include preferential use of formulations with lower THC content, gradual dose titration, avoidance of concomitant central nervous system depressants, and use of regulated products to ensure standardized composition and quality (18).

4 CONCLUSION

Medical use of cannabinoids in Brazil is expanding rapidly within a regulatory framework that remains more structured and restrictive than that of North America. CBD has demonstrated clear efficacy for a limited set of refractory pediatric epilepsies, while THC- and CBD-containing formulations may offer therapeutic benefit in selected conditions when

conventional therapies fail. However, evidence for most non–FDA-approved indications remains insufficient, and meaningful clinical benefit is often modest compared with established treatments.

Safe and effective prescribing requires clinicians to integrate pharmacologic knowledge, familiarity with available Brazilian formulations, and awareness of potential drug–drug interactions and population-specific risks. Differences in safety profiles between CBD and THC - particularly the neuropsychiatric and cardiovascular risks associated with high-THC products - underscore the importance of individualized risk assessment and careful patient selection. Screening for comorbidities, adherence to harm-reduction principles, and ongoing monitoring are essential components of responsible cannabinoid therapy.

Despite significant regulatory advances, major gaps persist, including uncertainties regarding long-term safety, optimal dosing strategies, cost-effectiveness, and outcomes in vulnerable populations. As access increases and therapeutic use becomes more common, high-quality clinical trials, real-world evidence, and post-marketing surveillance will be critical to clarify the role of cannabinoids within Brazilian medical practice. Ultimately, the clinical success of cannabinoid-based therapies will depend on evidence-informed prescribing and continued collaboration among clinicians, researchers, and regulatory agencies.

Ethical considerations: narrative review based on publicly available sources; no ethics approval required.

Conflict of Interest: The authors declare that they have no conflicts of interest related to this manuscript.

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APPENDIX

Table 1

Cannabis-Based Products Requiring B-Prescription (Blue Form) in Brazil

Manufacturer	Formulations / Concentrations	THC	Prescription Type	Main Indications	Suggested Dosing
Prati-Donaduzzi	CBD 20, 50, 200 mg/mL (isolated)	≤0.2%	B (blue)	Anxiety, insomnia, refractory epilepsy	25–50 mg/day or 5–10 mg/kg/day
Ease Labs	CBD 100 mg/mL (isolated)	≤0.2%	B	Neuropathic pain, moderate anxiety	25–50 mg/day up to 300–600 mg/day
Farmanguinhos	CBD 200 mg/mL (isolated)	≤0.2%	B	Refractory epilepsies	Start 5 mg/kg/day up to 20–25 mg/kg/day
VerdeMed	CBD 23.75 and 50 mg/mL (isolated)	≤0.2%	B	Epilepsy, pain, anxiety	5–10 mg/kg/day or 25–50 mg/day
Belcher	CBD 150 mg/mL (isolated)	≤0.2%	B	High-dose use with low volume	5 mg/kg/day; e.g., 600 mg/day = 4 mL
Aura Pharma	CBD 50 mg/mL (isolated)	≤0.2%	B	Chronic pain, anxiety, insomnia	25 mg/day up to 5–10 mg/kg/day
NuNature	CBD 17.18 and 34.36 mg/mL (isolated)	≤0.2%	B	Pediatrics; cautious titration	5–10 mg/kg/day
Active	CBD 20 mg/mL (isolated)	≤0.2%	B	Anxiety, insomnia	200 mg/day = 10 mL
Eurofarma	CBD 20, 50, 100, 200 mg/mL (isolated)	≤0.2%	B	Dose flexibility	Example: 800 mg/day = 40 mL (20 mg/mL) or 4 mL (200 mg/mL)
Promediol	CBD 200 mg/mL (isolated); full-spectrum extract	≤0.2%	B	Refractory epilepsy; chronic pain	5–10 mg/kg/day

Note: Products authorized for commercialization in Brazilian pharmacies can be accessed through the official ANVISA website.

Table 2

Cannabis-Based Products Requiring A-Prescription (Yellow Form) in Brazil

Manufacturer	Formulations / Concentrations	THC	Prescription Type	Main Indications	Suggested Dosing
GreenCare	CBD + THC 79.14 and 160.32 mg/mL	>0.2%	A (yellow)	Cancer pain, spasticity	THC 0.1–0.2 mg/kg/day + CBD
Mantecorp	CBD + THC 79.14 and 160.32 mg/mL	>0.2%	A	Severe or palliative cases	THC 0.1–0.2 mg/kg/day
Promediol	CBD 200 mg/mL (isolated); full-spectrum extract	/ >0.2%	A	Refractory epilepsy; chronic pain	5–10 mg/kg/day

Note: Products authorized for commercialization in Brazilian pharmacies can be accessed through the official ANVISA website.