

Current legislation on medical cannabis. History, movements, trends and counter-tendencies, in the Brazilian territory

Legislação atual sobre cannabis medicinal. Histórico, movimentos, tendências e contratendências no território brasileiro

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ABSTRACT

BACKGROUND AND OBJECTIVES: *Cannabis sativa* is a plant that has been used by humankind for many years and is in the media spotlight due to its pharmacological features, being considered the great therapeutic option of the century. With the advent of the Drug Law (*Lei de Drogas* - Law No. 11,343/2006) there was a starting point for the situation of cannabis in Brazil. Thus, the objective of this narrative review was to discuss information about legal issues regarding cannabis in the Brazilian territory.

CONTENTS: The Collegiate Directorate Resolution (*Resolução da Diretoria Colegiada* - RDC) No. 327 of December 2019, published by Brazilian Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária* - ANVISA), provides on the procedures for granting health authorization for manufacturing and importation, as well as establishes requirements for marketing, prescription, storage, monitoring and surveillance of cannabis products for medicinal purposes to human use. The Bill of Law (*Projeto de Lei* - PL) No. 399/2015, proposed to amend article 2 of Law No. 11,343, of August 23, 2006, to enable planting and marketing of drugs containing extracts, substrates or parts of the cannabis plant.

CONCLUSION: Cannabis cultivation in Brazil would make a great contribution not only to the pharmaceutical industry, but also to the agricultural industry, generating jobs and reducing

raw material costs for drugs. However, the slow pace of Brazilian politics would be an obstacle. There is a need for more consolidated and specific legislation to regulate cannabis.

Keywords: Cannabis, History, Law enforcement, Law of supply and demand, Medical marijuana.

RESUMO

JUSTIFICATIVA E OBJETIVOS: A *Cannabis sativa* é uma planta utilizada pela humanidade há muitos anos e está em evidência nas mídias devido ao seu caráter farmacológico, sendo considerada a grande opção terapêutica do século. Com o advento da Lei de Drogas (Lei nº 11.343/2006) houve um ponto de partida para a situação da cannabis no Brasil. Dessa forma, o objetivo desta revisão narrativa foi discorrer sobre informações acerca de questões legais quanto à cannabis no território brasileiro.

CONTEÚDO: A Resolução da Diretoria Colegiada (RDC) nº 327, de dezembro de 2019, publicada pela Agência Nacional de Vigilância Sanitária (ANVISA), dispõe sobre os procedimentos para a concessão da autorização sanitária para a fabricação e a importação, bem como estabelece requisitos para a comercialização, prescrição, dispensação, monitoramento e a fiscalização de produtos de cannabis para fins medicinais de uso humano. O Projeto de Lei (PL) nº 399/2015, propôs alterar o artigo 2º da Lei nº 11.343, de 23 de agosto de 2006, para viabilizar o plantio e a comercialização de fármacos que contenham extratos, substratos ou partes da planta cannabis.

CONCLUSÃO: O cultivo da cannabis no Brasil traria uma grande contribuição não só para a indústria farmacêutica, como também para a indústria agrícola, na geração de empregos e na redução dos custos da matéria-prima de fármacos. No entanto, a morosidade da política brasileira seria um empecilho. Há necessidade de uma legislação mais consolidada e específica para regulamentação da cannabis.

Descritores: Aplicação da lei, Cannabis, História, Lei da oferta e da procura, Maconha medicinal.

INTRODUCTION

Cannabis sativa is a plant that has been used by humankind for many years and is in the media spotlight due to its pharmacological features¹.

Around the year 1549, it is believed that cannabis appeared in Brazil brought by African slaves, having a rapid dissemination among this population and the indigenous population.

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HIGHLIGHTS

- *Cannabis sativa* is a plant that has been used by mankind for many years and is in the media spotlight due to its pharmacological character.
- With the advent of the Drug Law (*Lei de Drogas* - Law No. 11.343/2006) there was a starting point for the situation of cannabis in Brazil.
- A new resolution from the Brazilian Federal Council of Medicine (*Conselho Federal de Medicina* - CFM 2.324, dated October 11, 2022), has further restricted the prescription of cannabidiol (CBD) for therapeutic purposes.

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Due to its popularization, it came to be considered as a drug used for some diseases by French and British doctors^{1,3}. In Brazil cannabis gained strength in the 1930s, in parallel with the repression of its use³. Until the 1980s, the National Institute on Drug Abuse (NIDA) only intended to show deleterious effects of cannabis, blocking any study that showed its beneficial effects^{1,4}. In the 1990s, cannabis was highlighted due to the discovery of the endocannabinoid system, with its receptors and neurotransmitters, which led to a comprehension of pain modulation, analgesia, sleep cycles, and other processes⁵.

Until 1920, marijuana cultivation was driven by its use in the paper and textile industries, and it was smoked by black people, some bohemians in Europe, and immigrants. In the United States the plant was used by less privileged classes. At the same time, cannabis was used in the pharmaceutical industry and in the automobile industry, with the development of a marijuana-based fuel by Ford company⁵.

During the 1929 crisis in the United States, with the advent of Prohibition, crimes increased and, according to rumors, the reason was the influence of the plant. Such rumors were spread around the world by American diplomats in their actions in the League of Nations and the United Nations (UN)⁵.

In 1830, Brazil passed the first law prohibiting the use and sale of marijuana. The penalty for those who used the plant was more severe than for those who trafficked it, because, at that time, the traffickers were from the white middle class and the users were slaves. As of 1960, several studies were conducted in England, Canada and the United States and all recommended a change in the laws against cannabis. At the time, little was done; however, today, some countries have already legalized its use, including recreational use⁵. Nowadays, with the advent of medical cannabis, the great therapeutic option of the century has emerged, being used in the treatment against nausea in patients undergoing chemotherapy, in people with HIV to increase appetite, to relieve the symptoms of multiple sclerosis, against anxiety, for pain relief, and against drug addiction⁵.

LEGISLATION

With the advent of the Drug Law (*Lei de Drogas* - Law No. 11.343/2006) there was a starting point for the situation of cannabis in Brazil⁶. In article 2, sole paragraph of the referred law, it is foreseen that the Brazilian Federal Government may authorize the planting, cultivation, and harvesting of plants such as marijuana exclusively for medicinal or scientific purposes, in a predetermined location and time period, subject to inspection, which has never occurred since the law came into effect^{6,7}.

Illegal use of cannabis is considered a crime and, according to article 28 of Law 11.343/2006, it is foreseen that whoever acquires, saves, keeps in storage, transports or brings with them, for personal consumption, drugs without authorization or in disagreement with legal or regulatory provisions, will be subject to the following penalties: I - Warning about the effects of drugs; II - Community service; III - Educational measure of attendance to a program or educational course^{5,7}.

The trial of Extraordinary Appeal No. 635.659 at the Brazilian Supreme Court, which began in 2015 and discussed the unconsti-

tutionality of the Drug Law's article 28, which defines personal consumption of drugs as a crime, was supposed to be resumed between June and November 2019. However, this did not happen and only three ministers voted⁵.

In 2011, through the Argument of Noncompliance with Fundamental Precept No. 187, the Brazilian Supreme Court, by majority decision of its Plenary, recognized the constitutionality and legitimacy of the Marijuana March (*Marcha da Maconha*) movement, guaranteeing the free exercise of the right to expression and gathering, which contributed to a debate in society. The rule became the right to respond criminal charges in freedom^{6,8}. The reporting minister Gilmar Mendes voted for the unconstitutionality of article 28. Justice Edson Fachin voted in favor of decriminalizing the possession of marijuana for personal use. Justice Luís Roberto Barroso suggested, in his vote, that the possession of up to 25 grams of marijuana should be a parameter for personal use. The trial will be resumed with the vote of minister Alexandre de Moraes, but there is still no date to restart it⁵. In 2015, the Brazilian Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária* - ANVISA), through the Collegiate Directorate Resolution (*Resolução da Diretoria Colegiada* - RDC) No. 3, updated the list of special control substances, provided in Ordinance SVS/MS No. 344/98, including cannabidiol (CBD), just as the RDC No. 17, which defined the procedures and criteria for importation of CBD-based products by individuals for medical treatment upon prescription by a qualified professional^{6,10,11}.

In 2016, there was an update on the SVS/MS Ordinance No. 344/98, in which ANVISA allowed the registration of cannabis-derived drugs in the concentration of 30 mg/mL of CBD and 30 mg/mL of tetrahydrocannabinol^{6,12}. In the year 2017, ANVISA included *Cannabis sativa* as a medicinal plant in the Brazilian common nomenclature through RDC No. 156¹³.

RDC No. 327 of December 2019, published by ANVISA, provides on the procedures for granting health authorization for manufacturing and importation, and establishes requirements for the marketing, prescription, storage, monitoring and surveillance of cannabis products for human use for medicinal purposes¹⁴. As highlights of RDC No. 327/2019, it can be considered that cannabis products containing exclusively *Cannabis sativa* derivatives or phytochemicals as active ingredients must have predominantly CBD and no more than 0.2% tetrahydrocannabinol (THC). However, cannabis products may contain THC above 0.2%, provided they are intended for palliative care exclusively for patients with no therapeutic alternatives and in irreversible or terminal clinical situations¹⁴.

Cannabis products can be prescribed when other therapeutic options available in the Brazilian market have been exhausted. The requirements for prescribing cannabis products should not include matters of cost, convenience or operational needs. Cannabis products may be prescribed when the prescribing physician is the attending physician directly responsible for the patient. The indication and mode of use for cannabis products are responsibility of the attending physician^{7,15}. The physician must inform the patient or their legal representative about the risks, adverse effects, and efficacy of the drug.

The patient or, if not possible, his legal representative, must sign the Free and Informed Consent Term (FICT), which must be supplemented with specific data of the cannabis product. FICT must be used according to the model established in Annex III of Resolution No. 327/2019 or other established by the respective Class Councils and must be signed in two copies, one retained by the patient or his legal representative and the other filed by the attending physician¹⁴.

The registration of drugs based on *Cannabis spp.* and its derivatives and phytochemicals must follow the current legislation and Anvisa is the agency that will grant the Health Authorization for the manufacture and importation of products from the plant, and this authorization will have an unextendable term of five years, counting from the date of publication of the authorization in the Official Brazilian Federal Gazette (*Diário Oficial da União* - DOU). The company responsible for the product for which the Health Authorization was granted may, within the period of validity of the authorization, request regularization of the product by means of drug registration, following the specific legislation in force. Until the expiration of its Health Authorization, the company that intends to manufacture, import, and commercialize cannabis products in Brazil must apply for regularization through drug registration^{14,21}.

Cannabis products may not show trade names, must be designated by the name of plant derivative or phytopharmaceutical accompanied by responsible company name, and must be used only orally or nasally¹⁴.

There is a ban on any advertising of cannabis products, including the distribution of “free samples”, and the prescription of cannabis products must be restricted to medical professionals legally qualified by the Brazilian Federal Council of Medicine (*Conselho Federal de Medicina*)¹⁴.

Commercialization of cannabis products is only authorized after publication of the Health Authorization concession. After the concession expiration, the product cannot be manufactured and imported for commercialization in Brazil¹⁴.

For the purposes of manufacturing and commercializing cannabis products in Brazil, the company must import pharmaceutical ingredients in the forms of plant derivative, phytopharmaceutical, in bulk, or industrialized product. Importation of the *Cannabis spp.* plant or parts thereof is not allowed¹⁴.

Only manufacturing companies that have the Good Manufacturing Practices Certificate (*Certificado de Boas Práticas de Fabricação* - CBPF) for drugs, issued by ANVISA, or importing companies that comply with the Good Distribution and Storage Practices (*Boas Práticas de Distribuição e Armazenamento* - BPDA) for drugs can apply for the Health Authorization and manufacture cannabis products¹⁴.

Another important point of RDC No. 327/2019 is its transience, as this resolution should be revised within three years of its publication, which occurred in December 2019, according to the sole paragraph of article 77¹⁴.

Bill of Law (*Projeto de Lei* - PL) No. 399/2015, which proposes to alter article 2 of Law No. 11.343 of August 23, 2006, to allow the planting and marketing of drugs that contain extracts, substrates, or parts of the *Cannabis sativa* plant in their formulation, was approved by the special commission of the Brazilian House of Representatives

(*Câmara dos Deputados*) on June 8, 2021, it should then go to the Federal Senate, where it would be discussed and voted on. However, a group of representatives filed an appeal, postponing the entire process, and the bill will have to be voted in plenary¹⁶.

As approved by the Special Commission of the House of Representatives (*Comissão Especial da Câmara dos Deputados*), delivery, storage, distribution, prescription, and commercialization to individuals remains prohibited, and cultivation of the plant will be done exclusively by duly authorized legal entities and must observe minimum safety conditions^{6,16}.

The Bill of Law text provides that cannabis-based drugs may be produced and commercialized in any pharmaceutical form and without restriction on prescription. According to the Bill of Law, there is no need to exhaust all therapeutic measures before prescribing cannabis-based drugs^{16,17}.

The Brazilian Public Health System (*Sistema Único de Saúde*) pharmacies will be able to cultivate cannabis and manufacture cannabis-based products, which may improve patient access to these drugs^{6,16}.

Cannabis cultivation should be done indoors, in greenhouses. Industrial hemp plants, on the other hand, can be grown in open spaces, but these must be designed so that no outsiders can enter them^{6,16}.

Products made from industrial hemp will be authorized for production and marketing in the cosmetics industry, personal care industry, food industry, and non-medical veterinary industry¹⁶.

Institutions linked to research, which are previously authorized by public authorities, can cultivate, plant, harvest, process, manipulate, transfer, transport, store, import and export seeds¹⁶.

Non-profit patient organizations established for this purpose will be able to process and cultivate cannabis, as well as manufacture and supply products for their members. They will also be offered a line of credit in official banks¹⁶.

In 2014, the Brazilian Federal Council of Medicine, through Resolution No. 2113, approved the use of cannabinal for the treatment of epilepsies refractory to conventional treatments in adolescents and children, providing obligations for both legal guardians and prescribing physicians^{6,9}. A new resolution from the Brazilian Federal Council of Medicine (CFM 2,324, October 11, 2022), has further restricted CBD prescription for therapeutic purposes¹⁹.

The previous resolution, published in 2014 (CFM 2113/14), suffered much criticism from the medical community¹⁹. Due to the eight-year lapse living with an extremely restricted and outdated resolution, there was a great expectation on the part of doctors, patients, and legal community that the new regulation would expand the list of possible CBD prescriptions¹⁹.

However, the recent resolution limited CBD prescription to treatment of epilepsies in children and adolescents refractory to conventional therapies in cases of Dravet syndrome, Lennox-Gastaut syndrome, and tuberous sclerosis complex¹⁹. Therefore, the authorization for CBD use became even more precarious, keeping out adults, the elderly, and several treatments that could benefit from its use¹⁹.

The new resolution ignored recent studies that have demonstrated the benefits of CBD in the treatment of many pathologies,

11. Agência Nacional de Vigilância Sanitária (Brasil). Resolução nº 03, de 26 de janeiro de 2015. Dispõe sobre a atualização do Anexo I, Listas de Substâncias Entorpecentes, Psicotrópicas, Precursoras e Outras sob Controle Especial, da Portaria SVS/MS nº 344, de 12 de maio de 1998. Diário Oficial da União 26 de Jan 2015; Seção 1.
12. Agência Nacional de Vigilância Sanitária (Brasil). Portaria nº 344, de 12 de maio de 1998. Aprova o regulamento técnico sobre substâncias e medicamentos sujeitos a controle especial. Diário Oficial da União 12 de mai 1998; Seção 1.
13. Agência Nacional de Vigilância Sanitária (Brasil). Resolução nº 156, de 11 de agosto de 2006. Dispõe sobre o registro, rotulagem e reprocessamento de produtos médicos. Diário Oficial da União 11 de ago 2006; Seção 1.
14. Agência Nacional de Vigilância Sanitária (Brasil). Resolução nº 327, de 09 de dezembro de 2019. Procedimentos para a concessão da Autorização Sanitária para a fabricação e a importação, bem como estabelece requisitos para a comercialização, prescrição, a dispensação, o monitoramento e a fiscalização de produtos de Cannabis para fins medicinais, e dá outras providências. Diário Oficial da União 11 de dez 2019; Seção 1.
15. Fugii SY. Acesso aos tratamentos à base de cannabis sativa: procedimento judicial [Internet]. Rev Consultor Jurídico. 2021Nov [citado em 26 de maio de 2022].
16. Congresso Nacional (Brasil). Projeto de Lei nº 399, de 23 de fevereiro de 2015. Altera o artigo 2º da Lei 11.343, de 23 de agosto de 2006, para viabilizar a comercialização de medicamentos que contenham extratos, substratos ou partes da planta Cannabis sativa em sua formulação. Coordenação de Comissões Permanentes – DECOM- P_7696. Proposta sujeita à apreciação do Plenário.
17. Tavares G. Marco regulatório da Cannabis pode atrair investimentos [Internet]. Rev consultor jurídico. 2022 Jan [citado em 28 de maio de 2022].
18. Grecco M. Cannabis: 6 tendências globais para o uso medicinal e industrial [Internet]. 2020 Jun [citado em 14 de maio de 2022]. Disponível em: <https://nam12.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.istoedinheiro.com.br%2F&data=05%7C01%7C%7C%94b-49bb99124e48f9c008da41ba211a%7C84df9e7fe9f640afb435aaaaaaaaaa%7C1%7C0%7C637894564921450063%7CUnknown%7CTWFpbGZsb3d8eyJWljoImC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IjEhaWwiLCJXVCi6Mn0%3D%7C3000%7C%7C%7C&sd=FMMDY5yAbGZb-Ji3aYop4rjDw90X5vSz9JWKLfzCkF4%3D&reserved=0>
19. Oliveira LF. Nova resolução do Conselho Federal de Medicina restringe o uso da Cannabis medicinal no Brasil. Citado em 20 out 2022. Disponível em: <https://www.migalhas.com.br/depeso/375654/resolucao-do-cfm-restringe-uso-da-cannabis-medicinal-no-brasil>.
20. Brasil. O que é o sistema endocanabinoide? HempMeds Brasil, 2017. Disponível em: <https://hempmeds.com.br/o-que-e-o-sistema-endocanabinoide>. Acesso em: 30 de maio de 2022.
21. Mori L. Como o uso de maconha medicinal tem crescido no Brasil. BBC News Brasil, 2018. Disponível em: <https://www.bbc.com/portuguese/geral-44283537>. Acesso em: 01 jun. 2022.
22. Barros A, Peres M. Proibição da maconha e suas raízes históricas escravocatas [Internet]. Rev Periferia. Jul-dez 2011; v.3, nº 2. Disponível em: <https://doi.org/10.12957/periferia.2011.3953>.
23. Holloway, Thomas. Polícia no Rio de Janeiro. Repressão e Resistência numa cidade do século XIX. Rio de Janeiro: Fundação Getúlio Vargas, 1997.
24. Jesus A; Fernandes L; Elias P; Souza A. Legalização da maconha para fins medicinais. Rev Curso de Direito da Universidade Braz Cubas V1 N1: Maio de 2017.
25. CEBRID, Centro Brasileiro de Informações sobre Drogas Psicotrópicas. O que é maconha. Disponível em http://www2.unifesp.br/dpsicobio/cebrid/quest_drogas/macanha.htm Acesso em: 01 jun. 2022.
26. Bizzoto A, Brito A. Nova Lei de Drogas, Rio de Janeiro: Lumen, 2007.
27. Moraes A. Direito constitucional. 25ª ed. São Paulo: Atlas, 2010.
28. Epifânio F. Cannabis sativa e a regulamentação pela ANVISA: um estudo sob a ótica jurídica, Mossoró, 2019.
29. Agência Nacional de Vigilância Sanitária (Brasil). Resolução nº 66, de 18 de março de 2016. Dispõe sobre a atualização do Anexo I (Listas de Substâncias Entorpecentes, Psicotrópicas, Precursoras e Outras sob Controle Especial) da Portaria SVS/MS nº 344, de 12 de maio de 1998. Diário Oficial da União 18 de mar 2016; Seção 1.
30. Brasil. Congresso. Câmara dos Deputados. Decreto no 54.216, de 27 de agosto de 1964. Promulga a Convenção Única sobre Entorpecentes. Brasília, DF, 01 set. 1964. Disponível em: <https://www2.camara.leg.br/legin/fed/decret/1960-1969/decreto-54216-27-agosto-1964-394342-publicacaooriginal-1-pe.html>. Acesso em: 01 jun 2022.
31. Câmara de Regulação do Mercado de Medicamentos Conselho de Ministros (Brasil). Resolução nº 3, de 4 de maio de 2009. Proíbe a aplicação de preço máximo ao consumidor - PMC a medicamentos de uso restrito a hospitais. Diário Oficial da União 4 de maio 2009.