

Mini Review

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The Impact of Associations on Accessibility of Medicinal *Cannabis* in Brazil Looking at Fasciculated Roots of Policy and Access to Products

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ABSTRACT

This mini-review analyzes the crucial role of associations in improving access to medical *Cannabis* in Brazil. It highlights the facilitating role of social control, which paves the way for access to medical *Cannabis* in the country by promoting public debates and generating evidence from real-life experiences. These associations exert a significant influence on the development of policies and patient access to *Cannabis*-derived products. Despite the lack of specific regulatory frameworks, they are emerging as essential entities in the healthcare landscape, particularly for patients in need of *Cannabis*-based treatments. In addition to facilitating access to medicine through advocacy and legal support, these organizations are also involved in the production and supply of medical *Cannabis*. This review addresses the current challenges facing the associations, such as strict prohibitionist policies, the need for quality standards, and limited research. It also discusses potential opportunities in the absence of a robust regulatory environment, with growth supported by a fasciculated root system.

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Introduction

The objective of this mini-review is to analyze the role and impact of civil associations in the healthcare sector of Brazil, particularly focusing on the provision and production of medical *Cannabis*. It aims to explore the opportunities, challenges, and limitations faced by these associations in integrating *Cannabis* into the Brazilian healthcare system amid regulatory uncertainties. The principle of associativism or cooperatives work, structured as a productive model, contributed to the consolidation of the productive capitalist system in Brazil, based on solidarity, cooperation and community participation, with a focus on the individual [1]. In the European context, cooperativism or associativism, also known as the solidarity economy, emerged historically with the first cooperatives at the end of the 18th century as a response to the social challenges of the industrial revolution.

In Latin America, this practice first appeared in Colombia in 1986 and is noteworthy, although it has a more political character,

influenced by the socio-economic reality of each region [2]. According to Rozeto the solidarity economy is understood as an alternative economic approach based on solidarity and work, providing social and cultural benefits that have a positive impact on society as a whole. Whether it is called the third sector, cooperativism, associativism, solidarity economy, social and solidarity economy, popular economy, informal economy or common good economy, this model occupies a significant space in social and working life, interacting with the spheres of the state and the market as “community organizations based on cooperation” [3]. Recently, the application of the collective group model has been observed in the medical *Cannabis* sector, especially among patients who use it. This community movement emerged as a response to state inaction and prohibitionist policies [4]. In this context, such organizations play a crucial role in providing support and care, information, training, and facilitating access for patients and their families to *Cannabis*-based medicines, a plant that remains prohibited in Brazil.

The phenomenon of civil associativism in Brazil is a recent development, emerging in the 2010's and promoting significant

changes both in legal practices - which have made self-cultivation possible as an exception - and in the regulation of importation, now supervised by the National Health Surveillance Agency (ANVISA) [4,5]. These initiatives brought a new perspective, a therapeutic bias focused on the well-being of the patient, and ensured access to medical *Cannabis*. In addition, they promoted public debate on medical *Cannabis* while generating evidence through the accumulation of experience and the creation of practice-based knowledge. This knowledge was also linked to certified expertise, strengthening its political relevance, and supporting the idea of experimental treatment for rare or difficult-to-control pathologies or for treatments considered unsatisfactory by the patient or family. In this way, they contributed to the production of knowledge and evidence.

The importance of associations in the Brazilian healthcare landscape is fundamental to understanding the vital role of the civil associative in providing a structure that ensures quality, safety and effectiveness. These associations are crucial in providing pharmaceutical assistance services, complementing public institutions, and filling significant gaps in medical care. They are active agents of change, essential for overcoming the costs associated with quality control and monitoring the production chain, from manufacturing to delivery of medicines to patients. Associations play a crucial role in the Brazilian public service as a gateway to affordable pharmaceutical treatments.

The stakeholders involved are active agents of change, essential for overcoming the costs associated with quality control and monitoring of the production chain, which includes everything from production to delivery of medicines to the patient. Associations play a crucial role in the Brazilian public service as a gateway to affordable pharmaceutical treatments. However, there are significant challenges, particularly in the healthcare sector. Issues such as ensuring clinical efficacy and quality of medicines are paramount. When considering herbal medicines such as *Cannabis*, it is crucial to address the pharmacological and quality implications that can affect patients' health. Issues such as quality variation, lack of standardization, drug interactions, and specific pharmacological issues need to be rigorously managed.

Pharmaceutical care that addresses the social determinants of health is essential. In addition, it's critical that patients understand the importance of a multidisciplinary approach to the management of their conditions. This requires the involvement of various stakeholders in the health sector, including government agencies, research institutions and health professionals [6]. In Barbosa's as mentioned earlier, the author emphasizes that these patients and caregivers often acquire knowledge by sharing experiences with each other. They learn about self-cultivation, methods of oil production, how to adjust and monitor doses, and the effects of homemade medicines, as well as understanding treatment with pharmaceutical drugs based on medical *Cannabis*. Today, there are about 80 medical *Cannabis* associations in Brazil, located in different states of the country [7]. Their operation is directly linked to court orders and legal authorizations, without the support of regulatory bodies due to the lack of regulation. These associations provide *Cannabis*-based medicines as well as health services; many have physicians who prescribe medicinal *Cannabis*, while others have professionals from different health fields who provide integrative and complementary services. According to the II Yearbook of Medicinal *Cannabis* in Brazil about 430.000 patients are treated with *Cannabis* derivatives, of which 219.000 import medicines, 97.000 have access to medicines

in community pharmacies, and about 114.000 patients are treated through civil associations. This shows the importance of this sector for access to treatment in the country [7]. Understanding this new role of associations, both in the production and supply of medicines and in the provision of health care through services such as pharmaceutical assistance, is fundamental to the process of discussion aimed at building critical thinking and forming regulations that consider this new model of health care that is developing in our country.

Which are the Limitations and Barriers

In general, the idea of involving the civil association as an active player in the health care of patients using medical *Cannabis*, both in the provision of health care and in the production of medicines, and the success of this new model as an ally of pharmaceutical care in the Brazilian public service, face limitations and obstacles. The root of these difficulties is primarily related to prohibitionism, which initially had a religious-moral character, followed by a scientific perspective focused on the notion of addiction, and culminating in the legal characterization of the criminal offense [8]. This is the first limiting factor that, as in a game of cards, leads to the appearance of other limitations and barriers, often related to prohibitionism, influences that can be seen even after legalization in different countries in Latin America [9]. In addition to the challenges posed by prohibitionism, there is a significant lack of research or limitations in several areas related to medical *Cannabis*. These areas range from seed cultivation and traceability, good agricultural practices, harvesting and post-harvest procedures, to the production of the medicine itself for tropical conditions in Latin America, primarily Brazil. An additional obstacle is the lack of rigorous quality control based on good practices. Relevant aspects in the pharmaceutical and agronomic universe, such as dosage, standardization of extracts and variability of phenotypic and genotypic characteristics (morphological, genetic and chemical), as well as ensuring organic cultivation, directly affect the quality of treatment and the confidence of prescribers in the associations. These are critical factors in ensuring the quality and efficacy of medical *Cannabis* products to ensure that patients receive consistent, safe, and effective treatment.

Furthermore, there is a gap in the availability of trained human resources to meet the demand, whether in the areas of cultivation, drug production, or Active Pharmaceutical Ingredients of *Cannabis* (APIs). This shortage also extends to pharmaceutical care and healthcare, where it is imperative to have properly trained professionals to assist and monitor patients using medical *Cannabis*. Such training can be achieved through targeted studies and training for the various professionals involved. It is clear that the barriers stemming from prohibitionism have implications beyond legal issues, permeating technical aspects, research and human resources training, which increases the complexity of the challenges to be overcome for the effective implementation of a healthcare model based on medical *Cannabis* in the context of the Brazilian public service.

This adversity directly affects the patient, who is forced to purchase products of often questionable quality. This applies both to the domestic market, including extracts produced by patient associations in Brazil, and to imported medicinal *Cannabis* products for personal use, as established by RDC 660/2022 (Resolution of the Collegiate Board) [10]. Between 2015 and 2020, there has been an increase of approximately 1800% in imports by individuals and/or associations [11]. This fact represents one of the main challenges, as such products are not subject to any

control program in Brazil. The lack of a solid and comprehensive regulatory framework exacerbates this situation, creating an environment of uncertainty regarding the quality and efficacy standards of medical *Cannabis* products available to patients. It is imperative that regulatory advances ensure the quality and safety of *Cannabis*-based medicines, thereby safeguarding the well-being of patients.

In addition, without the assurance of medicines that meet good practice requirements, there is a shortage, coupled with high costs, of *Cannabis*-based products available in community pharmacies in Brazil. The public health system has shown a cautious and incipient approach to the free distribution of these products. In most cases, when the public health system makes such medicines available, it is through legal actions in which patients seek to obtain a permit to grow and extract medicinal *Cannabis* medicinal oils [11]. This dynamic subjects patients to a stressful and bureaucratic routine. In addition, there is a shortage of medical professionals who prescribe medical *Cannabis*-about 2% of physicians in Brazil, out of a current universe of 502,475 physicians [8,12]. These factors, combined with the previously mentioned challenges, such as the history of prohibitionism, the lack of research and development, and the absence of a regulatory framework focused on the civil association, where good practices are the main focus, rather than a complex framework designed for the industrial sector, constitute a complex and challenging scenario for the effective integration of medical *Cannabis* into the Brazilian health system.

Exploring Opportunities Amidst Regulatory Uncertainty Integrating Medicinal *Cannabis* into the Brazilian Healthcare Landscape

In the current scenario of a lack of a solid regulatory framework for medicinal *Cannabis* in Brazil, there are numerous opportunities that can be leveraged to promote the responsible and beneficial use of this plant. Among the most important opportunities are:

Growing Social Demand and General Awareness

Society has shown an increasing interest in the possibilities of treatment with *Cannabis* therapy. This increase in demand, coupled with greater awareness of the potential medicinal benefits of the plant, creates a conducive environment for the development of policies and initiatives that favor the integration of *Cannabis* into integrative medicine. Specialized clinics and counseling services could be developed. These could provide personalized care, advice and support to patients seeking *Cannabis*-based treatments.

Research and Development Potential

Cannabis encompasses a wide range of compounds that may have therapeutic and nutraceutical applications beyond medicinalization. The potential for research and development of new *Cannabis*-based drugs and treatments is enormous, and exploration of this area can lead to significant advances in medicine as well as the development of new business models. By capitalizing on the research potential, companies focused on the development of innovative *Cannabis* -based medicines and therapies can be established. This may include partnerships with universities and research institutions to develop new compounds and treatments.

Potential for Education and Awareness

There is a need to educate both health care professionals and the general public about the uses and benefits of medical *Cannabis*. Education and awareness programs can help dispel myths and stigmas associated with the plant and promote a more accurate and evidence-based understanding. Entrepreneurs can create

online platforms dedicated to medical *Cannabis* education and awareness. These platforms could offer courses, webinars, and educational materials for healthcare professionals, patients, and the general public.

Advocacy and Political Influence

Active participation of advocacy groups and political influence are critical to raising awareness among lawmakers about the importance of developing a regulatory framework for *Cannabis*. Through coordinated efforts, it is possible to foster a constructive dialogue that considers the interests and needs of patients and society at large. Specialized *Cannabis* advocacy and policy advisory agencies could be developed. These agencies would work with governments, legislators and regulators to help create a favorable regulatory framework and advocate for the interests of patients and the *Cannabis* industry.

Development of Quality Standards

The implementation of rigorous quality standards is essential to ensure the safety and efficacy of *Cannabis* products. This includes good agricultural and manufacturing practices, as well as guarantees of purity and potency of compounds. With the development of quality standards, there is a need for specialized *Cannabis* quality control and product certification laboratories. These laboratories could provide analysis and certification services to ensure that products meet stringent safety and efficacy standards.

Strategies for Income Generation, Environmental Protection and Biodiversity

Cannabis can be integrated into sustainable development strategies. The cultivation of the plant can generate income for farming communities, and sustainable cultivation practices can contribute to environmental conservation. In addition, maintaining the biodiversity of *Cannabis* varieties is essential for future research and development of new products. Entrepreneurs can invest in agribusinesses that focus on sustainable *Cannabis* cultivation and implement practices that promote environmental conservation and biodiversity [13]. In addition, ecotourism can be explored by offering guided tours of sustainable farms and educational initiatives on the importance of environmental conservation in the *Cannabis* industry. The civil association could be inserted into different business model landscapes, thus becoming viable and diversifying. Given the opportunities and business models presented above, a pertinent question arises: is oil production the only avenue of action, or can associations play a more diversified role in a scenario that includes health services, guidance to patients on their *Cannabis* rights, and even cooperatives of patients engaged in self-cultivation? Indeed, associations can expand their activities beyond oil production. In summary, they have the potential to play a multifaceted and valuable role in the medical *Cannabis* ecosystem, contributing to the enrichment of health services, advocacy for patients' rights, and the promotion of quality and sustainability practices.

The discussion surrounding *Cannabis* as a herbal plant is complex and multifaceted, involving a variety of stakeholders, including healthcare professionals, legislators, patients, and society at large. An effective way to address this complexity is through an analogy with plant physiology, where the *Cannabis* plant can be viewed as an organic system operating within a specific regulatory and social environment. First, the leaves of the *Cannabis* plant can be viewed as essential elements in carrying out photosynthesis, a vital process that, in the analogy, represents meeting the needs of patients. The leaves absorb sunlight to produce energy, just as

public health policies must capture the needs of the population to provide effective solutions. In this context, photosynthesis symbolizes the ability of public health policies to meet the needs of those in need of *Cannabis*-based treatments and to stimulate social control that transforms regulatory resources into direct therapeutic benefits. On the other hand, the root of the plant in its fulcrum form would ideally be represented by the role of health oversight and government, serving as the main source of support and nourishment for the system. The reality, however, is more complex. Instead of a single central root, a fasciculated root system is observed in which various entities, including patient advocacy groups, non-governmental organizations, and research institutions, act as roots, absorbing nutrients from various sources and contributing in various ways to the support and development of the plant. This fasciculated root system is emblematic of how *Cannabis* is integrated into the health care system: multiple, diverse, and highly interconnected, with each part contributing significantly, but without a single dominant entity that centralizes authority and control.

This complexity is further accentuated when considering the regulatory and societal barriers facing medical *Cannabis*. As a plant in the ecosystem of phytomedicine production, *Cannabis* faces significant barriers similar to the ecological challenges faced by a plant in its natural environment. These include cultural resistance and stigmas associated with its use, strict government regulations that limit its research and clinical application, and the need for constant monitoring to ensure the safety, efficacy, and potency of derived products. Therefore, the question of whether *Cannabis* is a herbal plant is not merely rhetorical, but rather a critical question that challenges our regulatory and clinical paradigms. Answering this question requires continuous and adaptive evaluation of scientific evidence, patient experience, and public health policy to ensure that the integration of *Cannabis* into the therapeutic armamentarium is done responsibly and evidence-based. In addressing these issues, we must be as adaptive and resilient as the plant itself, seeking solutions that respect both the potential and the limitations of this phytomedicine within its ecosystem called Brazil.

Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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