

## Profile of judicialized cannabis: Analyzing technical notes

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The study aimed to analyze the profile of requests for medicinal cannabis-based products within the Technical Notes (TNs) of the e-NatJus platform. Conducted as a descriptive documentary research, it utilized secondary data from the platform, covering TNs published from 2018 to August 31, 2023. Among the 672 identified TNs, a substantial number, 83 % (n=558), presented unfavorable opinions. The applicants, predominantly male (53.12 %), spanned various age groups from newborns to the elderly. Geographically, requests were distributed across 23 states in Brazil, with Rio Grande do Sul being the most representative (19.6 %). Diagnostic confirmation relied on medical reports, and prevalent diagnoses included “unspecified speech or language development disorder” (CID F80.9) and “epilepsy” (CID G40), accounting for 19.34 % and 18.6 % of TNs, respectively. The findings offer a comprehensive view of the judicialization of health concerning medicinal cannabis in Brazil. In light of divergent results for similar therapeutic goals, the study emphasizes the necessity for clinical guidelines and robust scientific research to ascertain the effectiveness and safety of cannabis-based medications. Clear guidelines are crucial to ensure the effective and safe use of medicinal cannabis in the judicial context.

**Keywords:** Health judicialization. Medicinal Cannabis. Brazil. Pharmacovigilance. Medical diagnostics.

### INTRODUCTION

The judicialization of health has been a growing phenomenon in Brazil. It is a resource used for citizens to have the right to medical treatments, medication, and procedures, often not available in an effective or timely manner through the Public Health System (*Sistema Único de Saúde - SUS*) (Marinho, 2020). In this context, the most frequently sought resources include high-cost treatments, specific medications, surgical procedures and, more recently, cannabis products (medicinal cannabis) for the treatment of various medical conditions (Faria, 2021). However, this judicial option has generated a significant annual increase in demands for financial resources that

are very limited in the health budgets of municipalities, states, and the federal government (Freitas, Fonseca, Queluz, 2020).

The number of new cases presented in the courts in relation to the healthcare system, both public and private, increased by 19 % between 2021 and 2022. During 2022, more than 460,000 cases were initiated, indicating an increase in healthcare-related litigation in Brazil. Notably, the area of supplementary health was the most impacted, with a growth of 1.56 % between 2020 and 2021, which rose to 19.86 % in 2022. Meanwhile, cases related to the SUS experienced a slight decrease, going from 19.14 % between 2020 and 2021 to 18.26 % in 2022 (Machado, 2023).

In 2016, aiming to establish effective communication between the legal system and the healthcare system, the National Council of Justice (*Conselho Nacional de Justiça - CNJ*) took an important action. Through Resolution No. 238, dated September 6 2016, in partnership with the renowned Sírio Libanês Hospital (SLH) and the Ministry of Health (MH), the CNJ launched the Legal

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Action Notification System (e-NatJus) (Tribunal de Justiça do Estado do Ceará, 2020). This innovative platform is available on the CNJ electronic portal, representing an important step in the search for more efficient and integrated management of issues related to the judicialization of healthcare in Brazil (Almeida *et al.*, 2022)

The e-NatJus system was created to monitor and consolidate information about the judicialization of health in Brazil. It was implemented as a tool to provide a comprehensive view of lawsuits across the country, providing data for analysis and informed decision-making (Ministério da Saúde, 2009).

One of the primary functions of the e-NatJus system is to facilitate the preparation of TNs that address health issues. Through this platform, health professionals, legal professionals, and experts can collaborate more effectively in the analysis of cases of health judicialization. TNs are fundamental documents that support judicial decisions related to access to medical treatments, medications, and health procedures. They are prepared based on evidence-based health criteria and legal criteria, considering applicable legislation. The e-NatJus system speeds up this process, promoting more fluid and transparent communication between the professionals involved, with the potential to improve the quality of judicial decisions related to healthcare in Brazil (Ferreira, 2016).

Among the medications frequently subject to judicialization in Brazil, those that are high cost or difficult to access through the SUS stand out. In addition to traditional treatments such as oncological and immunosuppressive therapies, in recent years medicinal cannabis has emerged as an important issue of judicialization in health (Araújo *et al.*, 2021). Patients seeking medical cannabis often turn to the court system to obtain authorization for its therapeutic use, facing significant regulatory and bureaucratic challenges. This practice reflects the growing demand for therapeutic alternatives, especially in the treatment of conditions such as refractory epilepsy, chronic pain, spasticity

in neurological diseases, and others (Mazurkiewicz-Beldzińska, Zawadzkaa, 2022). The judicialization of these medications, including medicinal cannabis, highlights the need for a broader debate on access to medicinal treatments and the regulation of these resources in the context of Brazilian public health.

In this sense, the study aims to analyze the profile and the TNs for requesting medicinal cannabis available on the e-NATJus electronic portal for public consultation.

## MATERIAL AND METHODS

This is a descriptive documentary research, in which secondary data available on the e-NatJus platform (<https://www.cnj.jus.br/e-natjus/pesquisaPublica.php>) was used. The objective was to evaluate all TNs published on this platform, covering the period from its implementation in 2018 until August 31, 2023. The search and selection of TNs were carried out during the month of August 2023, with inclusion criteria focused exclusively on TNs that dealt with the request for medications based on medicinal cannabis.

The selection of e-NatJus as the data source was based on its relevance as the official platform of the CNJ for the publication of TNs related to judicial demands regarding the request for medicinal cannabis-based medications. The choice of this database allowed access to a wide range of documentary information on cannabis medication requests, covering a large period.

On e-NatJus, filters were selected that best met the TN search strategy, covering the type of technology such as “Medication”, the existence of registration with the National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária* - ANVISA), the active ingredient requested, “Tetrahydrocannabinol+cannabidiol”, and the existence of scientific evidence. The variables of interest in this study, extracted from the TNs, are described in Table I, which provides a comprehensive view of the variables of interest used, as well as the categories established for subsequent analysis.

**TABLE I** - Study variables

Established categories	Variables
Patient characteristics	Gender; Age; State; Diagnosis; Method used by the plaintiff in the TN* to describe the confirmation of the reported medical diagnosis.
Treatment characteristics	Specification of the medication and dosage; Indication complies with the approval record with ANVISA*; Status of this registration.
Scientific Basis	Scientific evidence Most recent bibliographic references used in the preparation of the TN*.
Conclusion	Opinion; Justification; Institution responsible for the TN*

\*TN (Technical Note); ANVISA (National Health Surveillance Agency).

The variables were categorized according to the information contained in the TN, such as “YES”, “NO” or “Not Informed”.

The evaluation of the scientific evidence that supported the requests, as well as the identification of urgency in the TNs, was also conducted, with these variables being equally dichotomized as “YES” or “NO”. The variable “conclusion” was binarized as “favorable opinion” or “not favorable”.

The collected data were analyzed and distributed in frequency for categorical variables, and measures of central tendency were used for continuous variables. Excel® software version 2003 was used to build the database.

## RESULTS

After applying the search filters, namely “type of technology”, “registration with ANVISA”, “active ingredient”, and “existence of scientific evidence”, a total of 674 TNs were identified.

Subsequently, a thorough analysis was carried out with the purpose of excluding those that did not comply with the inclusion criteria established for this study. Consequently, two TNs were excluded: one for being outside the stipulated analysis period and the other for being requests unrelated to medications, including demands related to medical procedures (n=1). Therefore, the present study analyzed a total of 672 TNs that met the defined inclusion criteria.

The mean age of individuals who submitted legal requests to obtain medicinal cannabis was calculated at 21.8 years, covering an age range that ranged from 0 to 89 years. About half of these applicants were male (N=357, 53.12 %).

Among the 280 municipalities that used the platform to seek support on issues related to judicialization, Salvador stood out as the municipality with the highest number of requests (N=54, 8.0 %), followed by Porto Alegre (n=37, 5.5 %).

The geographic distribution of TNs revealed a comprehensive representation of requests for medicinal cannabis-based products in 23 states in Brazil. The South region ranked first with 312 (46.4 %) TNs, followed by the Northeast with 201 (30 %), Southeast with 115 (17.1 %), Central-West with 29 (4.3 %), and North with 15 (2.2 %), showing a national distribution of these demands. The most representative state was Rio Grande do Sul, with 132 TNs (19.6 %). These data highlight the extent of the judicialization of healthcare related to medical cannabis in different regions of the country, emphasizing the importance of considering regional disparities when addressing this issue (Table II).

**TABLE II** - Sociodemographic characteristics of applicants for medicinal cannabis products described in the Technical Notes, e-NATJus, 2023, N= 672

Variable	n	%
Age	21.8 ± 4.38 *	-
Gender		
Female	314	46.7
Male	357	53.12
Total	672	100
State of Origin		
Rio Grande do Sul	132	19.6
Bahia	119	17.7
Paraná	96	14.2
Santa Catarina	84	12.5
Minas Gerais	53	7.88
Amapá	1	0.14
Roraima	1	0.14
Rondônia	2	0.29
**Others	184	27.38
Total	672	100

\*Standard Deviation

\*\*States: Acre, Alagoas, Distrito Federal, Espírito Santo, Maranhão, Mato Grosso, Mato Grosso do Sul, Pará, Paraíba, Pernambuco, Rio de Janeiro, Rio Grande do Norte, Sergipe, and São Paulo.

Regarding the diagnoses of patients mentioned in the TNs who requested medications based on medicinal cannabis, the most prevalent included “unspecified speech or language development disorder” (CID F80.9) and “epilepsy” (CID G40), corresponding to 19.34 % and 18.6 % of the TNs, respectively.

Regarding the methods adopted by plaintiffs in the TNs to confirm the most common medical diagnosis, it was noted that the medical report was universally used, being present in all TNs (100 %), as shown in Table III.

**TABLE III** - Characteristics of the treatment of applicants for medicinal cannabis products described in the Technical Notes, e-NatJus, 2023, N=672

Variable	n	%
Medical diagnosis		
F80.9 (Unspecified speech or language development disorder)	130	19.0
G40 (Epilepsy)	125	18.6
F84.0 (Childhood Autism)	85	12.6
M79.7 (Fibromyalgia)	56	8.3
R52.1 (Chronic intractable pain)	37	5.5
Others**	242	36
Total	672	100
Method presented in the technical note to describe confirmation of medical diagnosis.		
Medical report	672	100
Others	0	0
Total	672	100

Others\*\*:E10, E75.4, F41.2, F00, F00.1, F00.2, F03, F20, F20.1, F20.3, F23.2, F32, F32.1, F33, F33.3, F41.0, F41.1, F41.2, F42, F71, F72, F80.0, F80.8, F83, F84, F84.1, F84.3, F84.4, F84.5, F90.0, F90.9, F99, G11, G11.3, G11.8, G20, G21, G23.1, G24, G30, G30.0, G30.8, G35, G40.0, G40.1, G40.2, G40.3, 40.4, G40.5, G40.8, G40.9, G41.8, G43, G47, G50.0, G56.4, G63.2, G71.3, G80, G80.8, G80.9, G82.1, G85.1, G93.4, H35.0, I63, M19, M23.2, M35.7, M47.9, M50.1, M51.1, M54.5, M75.1, M89.0, N80, Q85.1, Q99.2, R46.3, R52, R52.2, S14.3, Z73

Among the 672 TNs analyzed, only 230 of them (34.2 %) detailed the requested medication, providing information about the commercial name, manufacturing laboratory, and financial value. The remaining TNs (65.6 %) only mentioned the active ingredient, which was “Tetrahydrocannabinol + cannabidiol”.

Likewise, the majority of TNs examined did not contain information about the prescribed dosage (59.5 %). Only a small number of TNs (0.44 %) reported that the patient was undergoing cancer treatment, and all TNs stated that the requested medication(s) were registered with ANVISA, with the vast majority (97.8 %) indicating that this registration is active. Furthermore, all TNs (100 %) indicated that the requested medication was not available within the SUS.

Among the specified medication brands, the most frequently mentioned was MEVATYL, with a share of 1.3 %. This brand, despite not being of national origin, has a significant presence in the Brazilian market, demonstrating the acceptance and demand for quality products among patients. In second place was TERRAMED FULL SPECTRUM 3000/30 mL, with a 1.1 % share, indicating a diversification of options available to consumers. Notably, Cannabidiol Prati-Donaduzzi 20 mg/mL also stood out, with a share of 0.59 %. This product is the result of a collaboration between the renowned Faculty of Medicine of the University of São Paulo (USP) and Prati-Donaduzzi, one of the main drug manufacturers in Brazil (Prati-Donaduzzi, 2018). The entry into the market of a national cannabidiol-based product is a significant milestone, reflecting the commitment of Brazilian institutions to meet the therapeutic needs of patients. These data suggest an increase in the acceptance and availability of cannabidiol-based medications in the country, highlighting the importance of continuous research and adequate regulations to ensure safe and effective access to these products (Table IV).

**TABLE IV** - Characteristics of treatment and proposed technology of applicants for medicinal cannabis products described in the Technical Notes, e-NatJus, 2023, N=672

Variable	n	%
Description of the active ingredient of the requested medication		
Specified	230	34.2
Not specified (Tetrahydrocannabinol+cannabidiol)	441	65.6
Total	672	100
Dosage		
Specified	272	40.5
Not informed	400	59.5
Total	672	100
Is the medication available in the Public Health System (SUS)?		
Yes	0	0
No	672	100
Total	672	100

Regarding the conclusions of the TNs, the majority of them presented non-favorable opinions (n=558, 83 %), with justifications often related to the lack of robust studies to support the requests.

Regarding temporal distribution, the year 2023 stood out, leading in the number of conclusions (n=439, 65.3 %). In contrast, the years 2022 and 2021 presented 191 (28.4 %) and 40 (5.9 %) conclusions, respectively. Interestingly, even when there were references to recent studies, the conclusions are often based on studies from 2021 for TNs published in 2023 and 2021, and on studies from 2019 for TNs completed in 2022.

It was also observed that a small portion of the conclusions (2.2 %) included the criterion “risk to life or serious damage to organs” as part of their justification.

## DISCUSSION

The judicialization of health in Brazil is a complex phenomenon that manifests itself in several ways, including the search for access to medicinal cannabis-based products. The data presented in this study provide a comprehensive view of this scenario, highlighting the diversity of patients seeking this form of treatment.

A notable aspect lies in the wide age range of applicants, which ranges from newborns to the elderly. This scenario reflects the diversity of medical needs and the growing realization that medicinal cannabis can offer benefits at different stages of life. This encompasses patients of all ages, from those facing challenges such as refractory epilepsy in childhood to older individuals seeking treatments for neurodegenerative diseases (Castillo-Arellano *et al.*, 2023).

Furthermore, the geographic scope of the requests, which encompasses patients from 23 different states, signals the spread of the debate about the therapeutic use of medicinal cannabis throughout the national territory. This highlights that the judicialization of health related to medicinal cannabis is not restricted to a specific location in Brazil, but emerges as a concern on a national scale. Such geographic spread of the phenomenon reflects the need for a holistic and coordinated approach at the national level to deal with the clinical, legal, and ethical implications of medicinal cannabis, aiming to ensure

adequate access and patient safety in all regions of the country (Dutra, Oliveira, Santos, 2021).

With regard to medical diagnoses, it is interesting to note that speech or language development disorders and epilepsy are the most prevalent. This suggests that patients with serious neurological conditions see medicinal cannabis as a treatment option (Souza, Silva, Oliveira, 2020). However, it is essential to highlight the need for solid scientific evidence that supports the use of medicinal cannabis for these conditions, as well as for other pathologies that can be treated with this compound.

The lack of specification of the requested medications in a significant portion of the TNs is an important concern. This can make it difficult to accurately analyze legal requests related to medical cannabis, creating ambiguities and potentially interfering with informed decision-making. To ensure the safety and effectiveness of treatment, it is essential that requests are detailed, including information about the specific medication, dosage, and other relevant characteristics (Sampaio, 2021).

It is interesting to note that, despite references to recent studies, conclusions are often based on older studies. This highlights the need to constantly update the evidence used in judicial decisions as new research and data emerge (Dutra, Oliveira, Santos, 2021).

It was also noted that in some minority cases of favorable opinions, the justification for authorizing the requested treatment includes the mention of “risk to life or serious damage to organs”, even when the reviewer points out the “lack of robust evidence and clinical studies”. This situation raises a fundamental question related to the basis of the TNs: the decision is based mainly on available scientific evidence or on the detailed description of health conditions considered serious enough to justify an “exception”, benefiting some to the detriment of many (Dutra, Oliveira, Santos, 2021).

In summary, the judicialization of health related to medicinal cannabis in Brazil is a multifaceted phenomenon that reflects the search for alternative treatments and the guarantee of access to potentially effective therapies. It is evident that the process of acquiring the medication in Brazil, in addition to being deeply unequal, is difficult when compared to the countries from which it is imported. This reveals the

need to expand and encourage discussions focused on the pharmaceutical industry and self-cultivation (Villas Bôas, Rezende, 2020).

In the current context, characterized by the substantial increase in lawsuits related to the supply of medications, treatments, and inputs derived from cannabis sativa, the study in question plays a prominent role. This work represents a milestone in the area, being unique in its approach to the TNs linked to these products. It is worth mentioning that the research was based exclusively on public domain information available on the e-NatJus platform, without access to restricted documents, such as medical records and medical reports, reserved solely for magistrates.

In relation to discussion of the legality of cannabis-based medicines in the healthcare systems, it is important to highlight the need for clarity and to create consistent regulation to ensure safe and effective access to these treatments. The lack of specific guidelines can lead to divergent interpretations of the law, contributing to healthcare judicialization. A cohesive national approach is essential to address these challenges and ensure that patients have fair access to needed treatments. According to Souza, Silva, Oliveira (2020), harmonizing healthcare policies and legislation is crucial to mitigate these issues.

Additionally, it is essential to note that the analysis focused on medications that are not part of the public healthcare network protocols. In this sense, the results obtained cannot be extrapolated to all medications, as each situation demands an individualized approach. In view of the context of increasing litigation, in which judicial decisions, understandably oriented towards the preservation of health and life, are not necessarily linked to compliance with legal norms related to public budgets, it becomes even more crucial for the State to promote the development of public policies and actions that facilitate access to cannabis sativa derivatives through alternatives that do not overload the already congested judicial system across the country.

This study provides a comprehensive view of the judicialization of health in the context of medicinal cannabis in Brazil. Given the divergent results for the same therapeutic objectives, this study highlights the need for clinical guidelines and robust scientific research

on the effectiveness and safety of cannabis-based medications and clear guidelines to ensure the effective and safe use of medicinal cannabis. The high incidence of unfavorable opinions highlights the importance of reviewing and improving the criteria for authorization of cannabis-based medications.

During the analysis, a significant gap in descriptive information about the requested treatments was noted. This absence not only hinders the technical assessment, but also makes it difficult to create a detailed patient profile. In this sense, analysis of the TNs, as well as the reference sources used in the conclusions, can shed light on a viable path for patients to gain access to these treatments. This involves understanding the priority information needed and the ability to challenge decisions based on outdated knowledge.

This study presents some inherent limitations, especially due to its reliance on a national database that may not capture all judicial processes related to medicinal cannabis in Brazil. This lack of coverage may result in an incomplete or biased view of health judicialization in this specific context. Therefore caution is necessary in interpreting the results and to avoid generalizing conclusions.

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