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ORIGINAL ARTICLE

Sanitary regulation of *Cannabis*-derived products authorized for importation in Brazil: Characteristics and regulatory trajectory

Regulação sanitária de produtos derivados de Cannabis autorizados para importação no Brasil: características e trajetória normativa

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ABSTRACT The regulation of *Cannabis*-derived products for medicinal purposes in Brazil is currently a topic of great importance, but faces challenges related to importation, safety, and efficacy of these products. The aim of this study was to analyze the regulatory framework of *Cannabis*-derived products authorized for importation in Brazil. This is a descriptive study, based on the analysis of lists published by Anvisa, between 2015 and 2024, concerning *Cannabis*-derived products authorized for importation. The products included in the most recent 2023 list were also analyzed against the parameters established by current regulations. The analysis revealed a continuous increase in the number of products, with 577 additional items since 2015. It was observed that 69.2% of the products did not specify CBD and THC concentrations, and 13.2% presented inaccurate information on labels. Of the 542 products analyzed, 347 originated from the United States, and 17 (5%) had irregularities reported by the Food and Drug Administration (FDA). The current regulatory gap regarding *Cannabis*-derived products authorized for importation allows their entry into the country without ensuring sanitary compliance. The urgent implementation of adequate regulation is required, defining legal and technical aspects to guarantee safe and high-quality products for the population.

KEYWORDS *Cannabis*. Cannabidiol. Legislation, drug. Brazilian Health Surveillance Agency.

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RESUMO *A regulação de produtos derivados de Cannabis para fins medicinais no Brasil é tema de grande importância na atualidade, mas enfrenta desafios relacionados à importação, segurança e eficácia dos produtos. O objetivo do estudo foi analisar o panorama regulatório dos produtos derivados de Cannabis autorizados para importação no Brasil. Trata-se de estudo descritivo, baseado na análise das listas publicadas pela Anvisa, entre 2015 e 2024, sobre produtos derivados de Cannabis autorizados para importação. Analisaram-se, também, os produtos contidos na última lista de 2023, frente aos parâmetros estabelecidos pelas normativas vigentes. A análise das listas revelou aumento contínuo no número de produtos, com 577 itens a mais desde 2015. Observou-se que 69,2% dos produtos não especificavam a concentração de CBD e THC, e 13,2% apresentaram informações indevidas nos rótulos. Dos 542 produtos analisados, 347 eram dos Estados Unidos da América, e 17 (5%) apresentaram irregularidades registradas pelo Food and Drug Administration. A atual lacuna regulatória relacionada aos produtos derivados de Cannabis autorizados à importação permite sua entrada no País sem garantia de adequação sanitária. É urgente a implementação de regulação adequada para esses produtos, definindo aspectos legais e técnicos, visando à garantia de produtos seguros e de qualidade para a população.*

PALAVRAS-CHAVE *Cannabis. Canabidiol. Legislação de medicamentos. Agência Nacional de Vigilância Sanitária.*

Introduction

Cannabis sativa is a plant that has been used for medicinal purposes for centuries, but only recently has it been studied with greater scientific rigor to substantiate its possible medical indications[1]. The plant contains more than 400 constituents, including phytocannabinoids. The best known and most studied of these are tetrahydrocannabinol (THC) and cannabidiol (CBD)[2].

Currently, only one *Cannabis*-derived product classified as a medicine is available in Brazil. Worldwide, there are also few such products[3]. Products with some evidentiary support that delineate the medical use of *Cannabis* include those for treating drug refractory epilepsies, multiple sclerosis, nausea related to oncologic treatments, stimulating appetite, and providing analgesia, as adjuvants in neuropathic pain[4-6].

Meanwhile, the National Health Surveillance Agency (ANVISA) has placed products that are not medicines within a new regulatory category: *Cannabis*-derived products. Beginning in 2014, Brazil started to regulate the use of these products with a resolution from the Federal Council of Medicine (FCM) addressing the compassionate use of cannabidiol to treat epilepsy in children and adolescents refractory to conventional therapies[7]. Since then, the topic has evolved, and new regulations have emerged to address access to *Cannabis*-derived medicinal products in Brazil.

Currently in force, two instruments, Collegiate Board Resolution (RDC) No. 327, of December 9, 2019, and RDC No. 660, of March 30, 2022, stand out. The former authorizes the manufacture, importation, and marketing of *Cannabis*-derived products in Brazil. These products can be sold in retail pharmacies with a medical prescription and an informed consent form (ICF) signed by the customer. It further stipulates that products whose active ingredients consist exclusively of phytopharmaceuticals from *Cannabis sativa* must contain predominantly cannabidiol (CBD) and no more than 0.2% tetrahydrocannabinol (THC); formulations with THC content above 0.2% are restricted to palliative care settings[8].

RDC No. 660/2022, in turn, sets forth the criteria and procedures for the importation of *Cannabis*-derived products by individuals, upon medical prescription, establishing a streamlined authorization process for such imports. Since then, applications submitted by patients have prompted ANVISA to periodically issue administrative acts containing lists that specify *Cannabis*-containing products authorized for import[9].

The medical *Cannabis* market has grown over the years in Brazil and worldwide. Brazil recorded a turnover of approximately BRL 850 million in 2024, with projections of substantial expansion in the coming years[10]. This context is dominated primarily by foreign companies, which currently channel their products to the country through individual authorizations that permit the entry of imported products into Brazil.

The regulation of *Cannabis*-derived products constitutes yet another challenge among the many ANVISA has faced since its inception. As in Brazil, *Cannabis* regulation has generated regulatory controversies in several countries[11,12]. The existing gaps in the national context raise concerns regarding the efficacy and safety of these products and the health of the population[3]. Accordingly, the objective of this study was to analyze the current regulatory landscape of *Cannabis*-derived products authorized for importation in Brazil.

Materials and methods

This was a cross-sectional, descriptive study that analyzed the lists of *Cannabis*-derived products authorized for importation by ANVISA, published between May 2015 and April 2024. These represent, respectively, the first and the last lists issued within the study period.

All data sources were publicly available and included resolutions, technical notes, and the websites of manufacturers and of the regulatory agencies in the products' countries of origin. The lists of *Cannabis*-derived products were obtained from ANVISA's website; those that could not be obtained directly were requested from the Agency via the Transparency Portal[13]. To analyze growth in the number of products, we compared versions of the lists published between 2015 and 2024. Technical Note No. 57/2023 was used for product-level analyses, as it was the list in force at the start of data collection.

Additional information was obtained from the websites of the manufacturers and regulatory agencies in the countries of origin. The variables analyzed included trade name, manufacturer, country of origin, and product composition (types and concentrations of cannabinoids). Other variables related to aspects contained in RDC No. 327/2019 and RDC No. 660/2022 were also sought on the companies' own websites, such as: dosage form, route of administration, availability of information on product classification and composition, availability of labeling information, existence of a certificate of analysis, existence of a report of stability tests/studies conducted by the manufacturer, and existence of technical documentation on product quality.

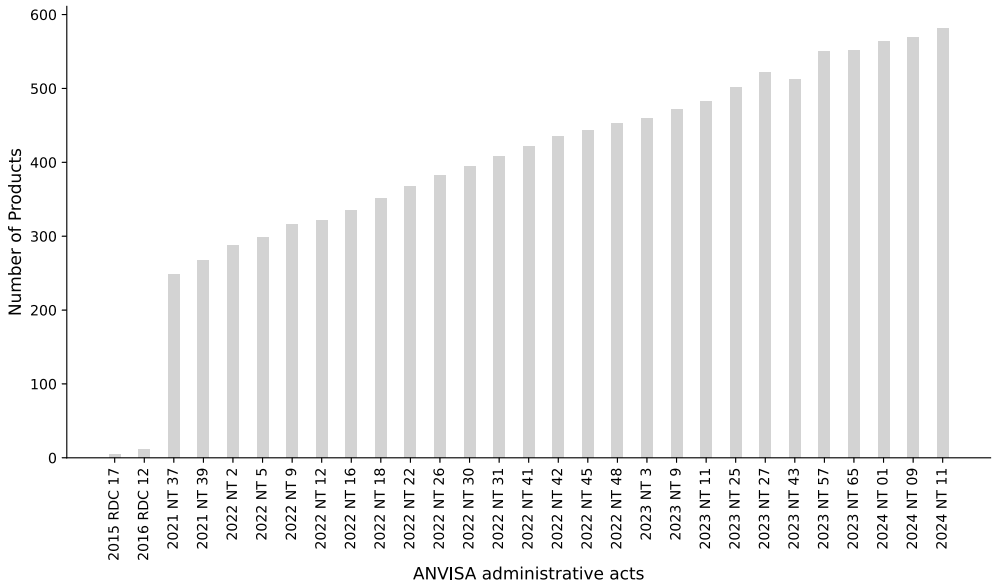
Analyses combined qualitative and quantitative approaches and were organized into three groups: (i) comparison of the lists published between 2015 and 2024—at this stage, analyses were descriptive and comparative across list versions, noting changes in the number of products over time and assessing both the quantitative and qualitative dimensions of these differences, including the number of new unique products in each list relative to the others; (ii) assessment of compliance with current legislation—at this stage, the requirements set forth in RDC No. 327/2019 and RDC No. 660/2022 were considered. Although the former specifically addresses products authorized for manufacture and marketing in Brazil, rather than imports, the analysis sought to illustrate the extent to which imported products do or do not conform to the established parameters. This analysis was deemed relevant to identify potential differences between the two product categories (imported and those authorized for manufacture and marketing) available for use in the country, given that the intended purpose of use is the same regardless of category; and (iii) analysis of the regulatory status of products in their countries of origin—at this stage, irregularities in imported products were investigated by querying the websites of the respective regulatory agencies.

Results

Evolution of the lists of products authorized for importation

The analysis of the lists of products authorized for importation issued by ANVISA administrative acts revealed a continuous increase in the number of items from the first publication in 2015 to the most recent list analyzed in January 2024. Initially, the 2015 and 2016 lists were published as RDCs; beginning in 2017, they started to be released as technical notes. Over the nine-year period, 29 administrative acts were identified. The last list analyzed, available in Technical Note No. 11/2024, comprised 582 products authorized for importation, reflecting an increase of 577 items since the first list in 2015 (*graph 1*).

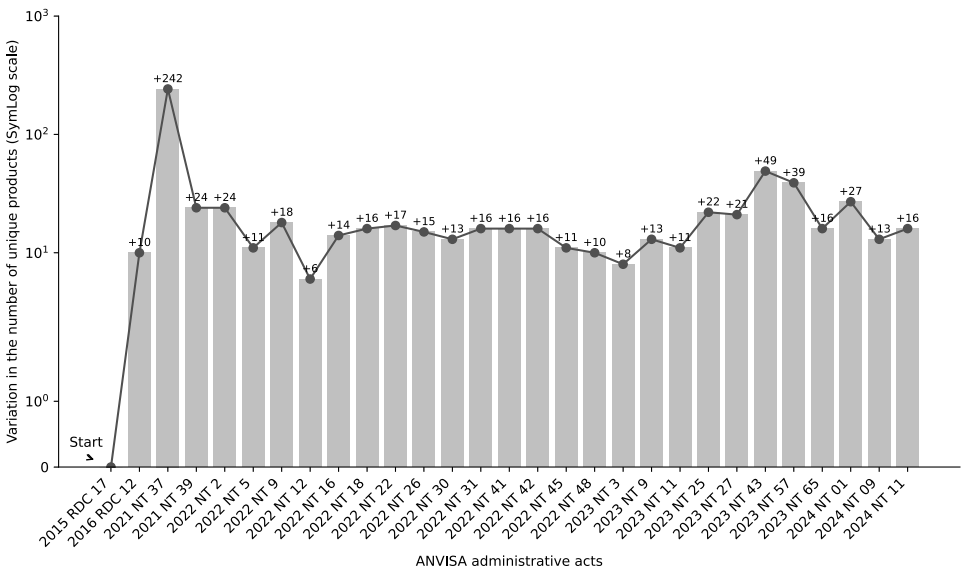
Graph 1. Evolution of the number of *Cannabis*-derived products in administrative acts issued by ANVISA between 2015 and 2024. Brazil, 2025



Source: Prepared by the authors (2025).

With respect to the unique products in each list, the analysis of the 29 lists identified 690 unique products, as shown in *graph 2*.

Graph 2. Evolution of the number of unique *Cannabis*-derived products per administrative act issued by ANVISA. Brazil, 2025



Source: Prepared by the authors (2025).

Characteristics of products authorized for importation

Of the 542 products with import authorization listed in the document analyzed (Technical Note No. 57/2023), different pharmaceutical dosage forms (FDFs) were observed. However, the dosage form could not be identified for a large share of products (32.6%) due to a lack of the available information. Among those for which the dosage form could be identified, the most frequent are shown in *table 1*. Less frequent forms were grouped under the category 'Other', comprising creams, capsules, elixirs, solutions, gels, and sprays. Some products were presented in non-pharmaceutical forms, including flower and oil.

Table 1. Pharmaceutical dosage forms and routes of administration of *Cannabis*-derived products authorized for importation. Brazil, 2025

Pharmaceutical Dosage Forms	**N**	**%**
Oils/tinctures/extracts	331	90.43
Other	21	5.47
Non-pharmaceutical forms	14	4.10
Total	**366**	**100**
Route of Administration		
Oral	329	90.8
Topical	17	4.7
Sublingual	8	2.2
Inhalation	6	1.7
Nasal	1	0.3
Rectal	1	0.3
Total	**362**	**100**

Source: Prepared by the authors based on the manufacturers' websites (2025).

Regarding the route of administration (ROA), information was available for 362 products (*table 1*). Among these, the most frequently described ROAs were oral (90.8%), topical (4.7%), and inhalation (1.7%). On the manufacturers' websites, ROA information was not available for 49.7% of products.

Another parameter analyzed—described as mandatory by RDC No. 327/2019—was the labeling of THC and CBD concentrations. It was observed that 375 products (69.2%) did not specify the concentrations of the two phytocannabinoids, and only 167 (30.8%) reported THC and CBD concentrations on their labels.

Beyond the mere presence of this information, we verified whether CBD concentration predominated over THC, a parameter established by RDC No. 327/2019. Among the 167 products that reported both cannabinoid concentrations, CBD was predominant in 157 cases (92.3%). Ten products had THC concentrations ≥ CBD. Of these, six had equal concentrations of CBD and THC, four had substantially higher concentrations of THC—two of them with four times more THC than CBD—and one had 15 times more THC than CBD, according to the manufacturer's website.

Based on the analysis of each product's label and/or packaging, non-permitted elements

were identified in 63 products (11.5%), pursuant to Art. 32 of RDC No. 327/2019 (*table 2*). Notable among these were elements liable to inducing improper consumption, such as flavor claims, graphic figures, and even advertising.

Table 2. Presence of non-permitted elements on the label or packaging of *Cannabis*-derived products authorized for importation. Brazil, 2025

Element observed	N	%
Flavor claim	42	66.7
Image	8	12.7
Advertising	7	11.1
Symbols	3	4.8
Image and flavor claim	1	1.6
Intended use statement	1	1.6
Claimed to be a dietary supplement	1	1.6
Total	**63**	**100**

Source: Prepared by authors based on the manufacturers' websites (2025).

With respect to the presence of a certificate of analysis, for 489 products (90.0%) the document could not be found, whereas for 53 (10.0%) a certificate of analysis was located on the manufacturer's website. Querying the same sources did not reveal any cases in which product stability study reports could be found.

Regulatory status of products in their countries of origin

Regarding the final analysis, among the 542 products listed in the technical note, 347 (64.0%) originated from the United States of America (USA), 26 (4.8%) from Canada, 20 (3.7%) from the Netherlands, 18 (3.3%) from Switzerland, and 17 (3.1%) from Colombia. The remaining 115 products came from 30 other countries.

When consulting the websites of the regulatory agencies of these countries, no information on the regulatory status of the respective products was found, with the exception of the USA.

Regarding manufacturers based in the USA, the 347 products came from 280 companies. The consultation also revealed FDA Warning Letters issued for 17 products included in the list of products currently authorized for importation in Brazil, which represents about 5.0% of the U.S.-origin products. In two cases, the warnings were prompted by the products being marketed as dietary supplements; in nine cases, they were being marketed as drugs. Other cases involved marketing as veterinary drugs or the presence of an additive deemed unsafe. Notably, in two instances, the Warning Letters were already in place at the time ANVISA granted the import authorization.

Discussion

The evolution of the authorization lists for the importation of *Cannabis*-derived products shows an increase in the number of products over the years. This indicates growing diversity in the products demanded by the population,

given that authorizations are issued on the basis of individual requests.

Each approved request for a new product results in a new entry in the next list ANVISA publishes. Despite the differences seen with each publication—additions and, at times, removals—ANVISA does not elucidate the criteria for inclusion or exclusion. Insertions appear to be based solely on individual requests; however, no justification is provided for product removals. Even for additions, the appraisal of these inclusions seems limited, insofar as specific criteria related to quality and, consequently, product safety are not evaluated.

RDC No. 327/2019 establishes that *Cannabis*-based products may be presented in various pharmaceutical dosage forms, which would traditionally allow performance of physicochemical, chemical, and pharmacopeial quality-control tests, and even biopharmaceutical studies. Nevertheless, several products on the list were found to lack a defined dosage form, complicating the predictability of effects and potentially leading to more severe adverse events[8,14-16].

RDC No. 327/2019 specifies only the oral and nasal routes as authorized for administering *Cannabis*-derived products. Nevertheless, ointments and creams were observed on the list, as well as products indicating the rectal route, which can lead to irregular absorption and, consequently, undesirable effects[5,8,17]. The RDC further emphasizes that route selection should be guided by health professionals, according to patient needs and good manufacturing practices. However, under current conditions, the latter parameter cannot be verified, since ANVISA does not conduct sanitary inspections or certify good manufacturing practices for companies whose products are authorized for importation, leaving patients susceptible to risks that cannot be anticipated.

The marketing of products without disclosure of THC and CBD concentrations may constitute misleading advertising and irregular sales[8,18]. Moreover, this situation undermines the product's (already fragile) reliability, which should prompt questions about the regularity of its importation.

The use of *Cannabis*-derived products with higher THC concentration relative to CBD entails risks due to THC's known psychoactive profile, which may lead to adverse effects such as anxiety, paranoia, the development of tolerance, or even dependence[19,20]. Recently, *Cannabis* use has been associated with cardiovascular effects and other adverse events[21,22].

Under medical supervision, some studies indicate the use of products with higher THC concentrations for the treatment of chronic pain—particularly neuropathic pain—and cancer-related pain[23], as well as for helping control nausea and stimulate appetite in patients with HIV/AIDS or undergoing chemotherapy[24].

The presence of prohibited information on the label of a *Cannabis* product constitutes noncompliance and a risk to patients. A study conducted in the United States found that the terms 'pain' and 'pain relief' are the most common medicinal claims, followed by 'inflammation' and 'anxiety'. Moreover, wellness-related health claims and associations with flavors or pleasant sensations were frequent[25].

In the Brazilian context, when such situations are identified in any other product intended for medicinal use, they could result in suspension, seizure, or sale prohibition[26]. For products falling within the category authorized for manufacture and marketing in Brazil, the responsible company could be fined and subjected to administrative sanctions, including revocation of the marketing authorization[8]. However, because the products analyzed fall under the 'imported' category, they end up receiving different treatment and, even when irregularities are identified, there appear to be no consequences foreseen. It is even open to question whether such irregularities are known to ANVISA, which would partly explain its apparent passivity.

The lack of documentation attesting to product quality is another matter of concern. Without a certificate of analysis, there is no

assurance that the product contains the correct concentrations of CBD, THC, and other cannabinoids. Divergent phytocannabinoid doses create the possibility of subclinical, harmful, or toxic concentrations, or levels outside the specifications of what would constitute the 'medicinal use' of *Cannabis*—particularly for THC and nabiximols[12,27]. A study of *Cannabis*-derived products sold in the United States identified discrepancies between the actual phytocannabinoid concentrations present in the products and the information stated on their labels[28]. This situation is especially worrisome given the possibility that these are the very products reaching the Brazilian market via importation.

The absence of a stability report, in turn, precludes verification of the product's actual shelf life and its optimal storage conditions over time[29]. In addition, the high cost of analytical equipment and the need for mastery of specific analytical methodologies mean that chemical analyses are not widely available or routinely used[30].

The analysis of product origin revealed that the United States is the country concentrating the largest exporters of *Cannabis*-derived products to Brazil. This is possibly due to factors such as the large producer and consumer market for these products[31]. Notwithstanding the issue of social acceptance of *Cannabis* use in the United States—where heterogeneous situations exist within the same country due to state-by-state differences in what is or is not permitted[32]—the FDA's position, like ANVISA's, is not to classify *Cannabis*-derived products as medicines[33].

The trade relationship between Brazil and the United States may also be cited as a factor favoring importation, since shipping logistics from the U.S. are better developed than those of other producing countries, such as Colombia or Canada[31].

The review of products vis-à-vis the FDA uncovered instances of irregularity occurring either before or after ANVISA issued import authorizations. There is no indication that such cases were taken into account either at the time of authorization or in any subsequent review. This situation reinforces questions about how import authorizations are granted and about the scope and rigor of the analyses conducted to issue this documentation.

It is important to emphasize that, because data collection relied on websites and not on direct access to physical products, we cannot assert, in cases where information was not found, that it was nonexistent. However, these are precisely the same information sources available (or not) to users, prescribers, and to the Agency itself before they may ultimately obtain access to the physical product. Although they are not medicines, these are products intended for the so-called 'medicinal' use and are subject to Brazilian sanitary regulation[34]. As such, they are required to provide clarity and adequacy in labeling, packaging, and other technical information. It should also be noted that companies in good regulatory standing, even without a legal mandate, ought to ensure clear access to information attesting to the quality of their products. Another limitation concerns the analysis of phytocannabinoid concentrations. Because it was not conducted on an individual-product basis, it is not possible, in the case of products with higher THC concentrations, to affirm that they are being used for the purposes contemplated for such cases, or in palliative care, nor whether the concentrations of the products analyzed are appropriate for those purposes. Despite these limitations, it is important to note that the study has engaged with the current regulations in an unprecedented way, offering a critical analysis of their practical implications. In this sense, we hope that it may contribute to the much-needed regulatory progress related to *Cannabis*-derived products in Brazil.

Conclusions

The analysis of ANVISA's lists revealed an exponential increase in the number of

Cannabis-derived products authorized for importation in Brazil in less than ten years. This growth reflects the rising use of these products by the Brazilian population. However, in parallel, there was a substantial absence of essential information related to product safety. It must be borne in mind that these are products used for medicinal purposes and are being widely consumed.

The *Cannabis* market in the country is expanding rapidly. The number of patient-consumers and of companies interested in operating in the national market is increasing. The present moment is therefore seen as crucial for ANVISA to adopt a clear stance.

Finally, in light of the ongoing development of Brazil's regulatory framework and the maturity of the national regulatory agency, regardless of product origin, safeguarding patients' health must lie at the core of sanitary oversight—something that should be reflected in more assertive and safer regulation for *Cannabis*-derived products in Brazil.

Collaborators

Clemente GG (0009-0001-7620-1808)* and Miranda ES (0000-0002-6204-5023)* contributed to the design of the study, data analysis and interpretation, writing and revision, and approval of the final version. Oliveira CVS (0000-0002-0464-1476)*, Osorio-de-Castro CGS (0000-0003-4875-7216)*, Moritz ÂFE (0000-0002-7473-8636)* and Santos-Pinto CDB (0000-0002-5478-4977)* contributed to the design of the project and the study, analysis and interpretation of the data, drafting and revision, and approval of the final version. Hora MFVMP (0009-0005-9907-0619)* contributed to the project's conception, data analysis and interpretation, drafting, and approval of the final version. ■

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