Collegiate Board Resolution #327/2019

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This Resolution provides the procedures to grant Sanitary Authorization for manufacturing and importation, as well as the requirements for marketing, prescribing, dispensing, monitoring and supervising cannabis-based products for medicinal purposes, among other provisions.

SUMMARY

Provides the procedures to grant Sanitary Authorization for manufacturing and importation, as well as the requirements for marketing, prescribing, dispensing, monitoring and supervising cannabis-based products for medicinal purposes, and other provisions.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 15, items III and IV, combined with Article 7, items III and IV of Law no. 9782 dated 26 January 1999, and article 53, V, §§ 1 and 3 of the Internal Regulations approved by the Collegiate Board Resolution - RDC No. 255, of December 10, 2018, adopts the following Collegiate Board Resolution, as decided upon in a meeting held on December 3rd 2019, the Director-President, determines its publication:

CHAPTER I.
INITIAL PROVISIONS

SECTION I. OBJECTIVE

Article 1 This Resolution provides for the conditions and procedures to grant a Sanitary Authorization for manufacturing and importation, as well as the requirements for marketing, prescribing, dispensing, monitoring and supervising cannabis-based products for human medicinal purposes and establishes other provisions.

SECTION II. SCOPE

Article 2 The procedure provided in this Resolution applies to the manufacture, importation, marketing, monitoring, inspection, prescribing and dispensing of industrialized products containing as active substances plant derivatives or *Cannabis sativa* herbal derivatives, herein referred to as Cannabis-based products.

SECTION III. DEFINITIONS

Article 3 For the purposes of this Resolution, in addition to the definitions already provided in the sanitary legislation for herbal medicines and phytochemicals, specifically Collegiate Board Resolution - RDC #26, of May 13, 2014, and the Collegiate Board Resolution - RDC #24 of June 14, 2011 and its updates, the following definitions are adopted:

I - Sanitary Authorization (AS): act authorizing the exercise of the activities defined in this Resolution, issued by the Brazilian Health Regulatory Agency and published in the Official Gazette (DOU), after the grant of a company's request to manufacture, import or sell cannabis-based products for medicinal purposes;

II - Sanitary Authority of a foreign country recognized by Anvisa: international authorities that are members of PIC/S - Pharmaceutical Inspection Co-operation Scheme;

III - Cannabidiol (CBD): phytocannabinoid chemical name: 2 - [(1R,6R)-3-methyl-6-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-Benzenediol, CAS: 13956-29-1 and molecular formula: C21H30O2;

IV - Palliative care: active and comprehensive care for patients whose disease no longer responds to curative treatment, aiming to improve the quality of life of patients and their families;

V - Excipient: substance added to the product as a vehicle or for the purpose of preventing changes, correcting and/or improving organoleptic and technological characteristics;

VI - Package leaflet: printed material included in cannabis-based products, containing information on product composition and use, among others, to instruct the user;

VII - Assistant Physician: a medical professional who is committed to the patient, whose performance aims to restore health, well-being or to prevent a disease;

VIII - Simplified procedure: administrative procedure rite that requires the submission of documents regarding a company's quality and other information provided in this Regulation;

IX – Cannabis-based Product: industrialized product, object of Sanitary Authorization by Anvisa, for medical purposes, containing as active substances exclusively plant derivatives or phytopharmaceuticals from Cannabis sativa; and

X - Tetrahydrocannabinol (THC): chemical name phytocannabinoid: (6AR, 10aR)-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydro-6H-benzo[c]chromen-1-ol, CAS: 1972-08-3 and molecular formula: C21H30O20.

CHAPTER II.
GENERAL PROVISIONS

Article 4 Cannabis-based products, containing as active substances exclusively those derived from Cannabis sativa plant or phytopharmaceuticals, shall have predominantly cannabidiol (CBD) and no more than 0.2% of tetrahydrocannabinol (THC).

Sole Paragraph. Cannabis-based products may contain THC content above 0.2%, as long as they are intended for palliative care exclusively for patients without other therapeutic alternatives and in irreversible or terminal clinical situations.

Article 5 Cannabis-based products may be prescribed when other therapeutic options available in the Brazilian market are exhausted.

Article 6 The registration of Cannabis spp. medicinal products and its derivatives and phytopharmaceuticals must follow the special legislation in force.

Article 7 Anvisa shall grant the Sanitary Authorization for the manufacture and import of Cannabis products.

Article 8 The Sanitary Authorization of Cannabis-based products will have an unextendible period of 5 (five) years, counted after the date of publication of the authorization in the Official Gazette (DOU).

Paragraph 1. The company responsible for the product for which the Sanitary Authorization was granted may, within the period of validity of the authorization, request the regularization of the product through the registration of medicines and drugs, following the specific legislation in force.

Paragraph 2. Until the expiration of the Sanitary Authorization, the company wishing to manufacture, import and sell Cannabis-based products in Brazil must request regularization through the registration of medicines and drugs.

Article 9 Cannabis products may not bear commercial names and must be designated by the name of the plant derivative or phytopharmaceutical followed by the name of the responsible company.

Sole Paragraph. When the company intends to request Sanitary Authorization for more than one Cannabis-based product with similar qualitative composition, varying only the concentrations of THC and CBD, the concentration of these cannabinoids should be part of the product name.

Article 10 Cannabis-based products will be allowed for oral or nasal use only.

Paragraph 1. Cannabis-based products must have pharmaceutical quality for human use.

Paragraph 2. Isolated substances of synthetic or semisynthetic origin cannot be added to cannabis-based products, except those with excipient function.

Paragraph 3. Cannabis-based products may not contain substances that are potentially toxic at the prescribed dosages.

Paragraph 4. Cannabis-based products cannot be of modified release, nanotechnological and pegylated.

Paragraph 5. Cosmetics, smoking products, health products or cannabis-based foods and their derivatives are not considered as Cannabis-based products for medicinal purposes.

Paragraph 6. Cannabis-based products cannot be marketed in the form of Cannabis spp. plant or its parts, even after the stabilization and drying process, or in its crushed, shredded or pulverized form, even if made available in any pharmaceutical form.

Article 11 Imported Cannabis-based products shall be properly regularized by the competent authorities in their countries of origin.

Article 12 Any advertising of Cannabis-based products is prohibited.

Article 13 The prescription of Cannabis-based products is restricted to medical professionals legally qualified by the Federal Council of Medicine.

Article 14 "*Free Sample*" is not allowed for Cannabis-based products.

Article 15 The manipulation of master formulas containing derivatives or phytopharmaceuticals based on Cannabis spp is prohibited.

CHAPTER III.
SANITARY AUTHORIZATION

SECTION I. GENERAL REQUIREMENTS

Article 16 The procedure for granting the Sanitary Authorization of Cannabis-based products will have simplified rite, based on a specific application filed by the interested company, prior to the manufacture, import or marketing of the product, with the documents required in this Resolution.

Paragraph 1. Sanitary Authorization number will be granted for each commercial presentation of Cannabis-based products, through publication in the Official Gazette provided that all requirements requested in this Resolution are fulfilled.

Paragraph 2. The marketing of the Cannabis-based product is only authorized after the publication of the Sanitary Authorization grant.

Paragraph 3. After the Sanitary Authorization expiration period, the product may not be manufactured and imported for marketing purposes in Brazil.

Paragraph 4. The Cannabis-based products commercialized must comply with what was submitted in the Authorization Procedure filed before Anvisa.

Paragraph 5. The company requesting the Sanitary Authorization is responsible for the quality and safety of the Cannabis products.

Paragraph 6. The technical documentation regarding quality that grounds the authorization application shall be maintained for one year after the expiration date of the batch to which it refers or for at least five years, after released for sale, whichever is longer.

Paragraph 7. If the documentation requested

in the Resolution is not properly presented, Anvisa can make requirements, even after the granting of the Sanitary Authorization, to the responsible for the Cannabis-based product, in accordance with Anvisa's submission procedure.

Article 17 The administrative procedure to the granting of the Sanitary Authorization for Cannabis-based products will follow the submission and publication procedure from Anvisa's drugs and medicines registration area.

Paragraph 1. For the purposes of granting the Sanitary Authorization, prior evaluation of the documentation submitted by the company is not necessary.

Paragraph 2. Sanitary Authorizations granted under this Resolution may be reviewed by Anvisa at any time or be locally verified, which may result in changes on the decision, request for additional evidence, collection of batches, suspension of manufacture and/or commercialization and cancellation of the Sanitary Authorization for the Cannabis-based product, without prejudice to other appropriate legal measures.

Paragraph 3. The administrative measures listed in the preceding paragraph will be applied unilaterally by Anvisa.

Article 18 For the purposes of the manufacture and commercialization of Cannabis-based product in national territory, the company must import the pharmaceutical input in the form of plant derivative, phytopharmaceuticals, in bulk or as an industrialized product.

Sole Paragraph. The import of the plant or parts of the Cannabis spp. plant is not allowed.

Article 19 The company responsible for requesting the Sanitary Authorization of the Cannabis-based product must present the following documents:

I - information presented in the request of the Sanitary Authorization on the product, as well as the content of all technical documentation on the quality, elaborated during the manufacturing or the import of these products;

II - list of manufactured or imported batches during the year, intended exclusively for commercialization in the Brazilian market, including manufacture date, number and batch size (mass/volume and units);

III - technical rationality of all changes made to the product after the granting of the Sanitary Authorization for immediate implementation, with or without filing in Anvisa;

IV - latest version of the document(s) containing tests, specification limits and analytical methods of product quality control, as approved by the company;

V - stability studies reports;

VI - technical and scientific rationality justifying the formulation of the Cannabis-based product and route of administration; and

VII - Periodic Benefit-Risk Assessment Report for the Cannabis-based product.

Article 20 The documents described in Article 19 will be the subject of sanitary control by Anvisa, including sanitary inspections.

SECTION II. PRIOR SANITARY AUTHORIZATION SUBMISSION MEASURES

Article 21 The company responsible for submitting the Sanitary Authorization of the Cannabis-base product must have:

I - Company Operation Authorization (AFE) issued by ANVISA with activity of

manufacturing or importing medicine;

II - Special Authorization (EA);

III - ANVISA's Certificate of Good Manufacturing Practices (CBPF) of Medicines for the manufacturer of the product;

IV - Good drug distribution and storage practices;

V - Technical and scientific rationale that justifies the formulation of the cannabis-based product and the route of administration;

VI - Technical documentation of product quality;

VII - Operational conditions to perform quality control analyzes in Brazilian territory;

VIII - Ability to receive and deal with notifications of adverse effects and technical complaints about the product; and

IX - Knowledge of the concentration of the main cannabinoids present in the formulation, among them, minimally, CBD and THC and be able to justify the development of the cannabis product, whether phytotherapeutic or phytopharmaceutical.

Sole Paragraph. For the technical and scientific rationale, the company must consider the formulation, the dose, the duration of use and the target population

Article 22 Only manufacturers that have the Certificate of Good Manufacturing Practices, of drugs and medicines, issued by Anvisa, or importing companies that comply with Good Practices for Distribution and Storage of drugs and medicines, may apply for the Sanitary Authorization to manufacture Cannabis-based products.

Paragraph 1. Within three (3) years from the date of publication of this Resolution, an equivalent document, issued by sanitary authority of a foreign country recognized by Anvisa, will be accepted, regarding the measures and controls applied for the verification of Good Manufacturing Practices of medicines.

Paragraph 2. During a period of three (3) years from the date of publication of this Resolution, the company shall file an application for Certificate of Good Manufacturing Practices for drugs and medicines before Anvisa, as established by specific legislation in force.

Paragraph 3. The absence of submission of the Certificate of Good Manufacturing Practices request for drugs and medicines within the established period will result in the cancellation of the Sanitary Authorization.

SECTION III. MEASURES FOR SANITARY AUTHORIZATION SUBMISSION

Article 23 The application for the Sanitary Authorization of Cannabis-based products should be individualized by each pharmaceutical form.

Article 24 All Sanitary Authorization of Cannabis-based products submissions must be filed with the following documents:

I - Application form of Cannabis-based products, available at Anvisa's website;

II - Application form of Sanitary Authorization of Cannabis-based products properly completed, according to the template of Annex I;

III - Justification of the technical and scientific rationality, explaining the formulation of the Cannabis-based product and administration mode;

IV - Justification containing the summary of the rational development of the phytotherapeutic or phytopharmaceutical Cannabis-based product and the

concentrations of the main cannabinoids, among them, minimally, the CBD and the THC;

V - Packaging and labelling layout;

VI - Leaflet's layout;

VII - Declaration of conformity, according to the template of Annex II;

VIII - Quality report of raw materials and manufactured products;

IX - Latest version of the document(s) containing the specification limits and analytical methods of quality control;

X - Stability studies report;

XI - Informed Consent Term (TCLE) that will be signed by the patient, according to the template of Annex III, which must be completed with the specific data of Cannabis-based products to be authorized; and

XII - Cannabis-based products use monitoring plan.

Article 25 For the Sanitary Authorization submission as well as its modifications, the requesting company must submit the documents by electronic means.

SECTION IV. THE QUALITY CONTROL OF CANNABIS-BASED PRODUCTS

Article 26 The quality control of Cannabis-based products containing phytopharmaceutical as an active substance must carried out in accordance with specific drug standards.

Article 27 The quality control of Cannabis-based products containing plant derivatives as an active substance must be carried out in accordance with the provisions of the standards for phytopharmaceuticals.

Article 28 All excipients used in the Cannabis-based product shall be approved for pharmaceutical use.

Article 29 If exists a monograph in the Brazilian Pharmacopoeia or in another official pharmacopoeia, as provided in the Collegiate Board Resolution No. 37, of July 6, 2009, about the admissibility of foreign pharmacopoeias, for the raw material or the finished product, this monograph becomes mandatory.

Article 30 The quality control of the finished product must be carried out in national territory for all imported lots.

Paragraph 1 Total or partial outsourcing is permitted, in the national territory, of the quality control of the finished product and stability studies with a laboratory accredited by the Brazilian Network of Analytical Health Laboratories (REBLAS) or with manufacturing companies that have Certificate of Good Manufacturing Practices to manufacture medicines.

Paragraph 2 The control tests of raw materials can be outsourced according to the precepts provided in the Collegiate Board Resolution No. 234, of June 20, 2018.

Article 31 If the Cannabis-based product, or the raw materials derived from it, are manufactured in more than one place, the documentation shall be submitted for each place of manufacture.

SECTION V. LABELLING, PACKAGING AND INFORMATION LEAFLET FOR CANNABIS PRODUCTS

Article 32 It is prohibited to appear on the labeling, packaging and package leaflet of Cannabis-based products:

I - designations, geographical names, symbols, figures, drawings or any indications that allow false interpretation, error or confusion about its origin, provenance, nature, composition or quality, which assign to the products purposes or different

characteristics from those they possess;

II - the terms medicine, drug, phytotherapeutic, supplement, natural, or any other like these;

III - any indication of the intended use, including therapeutic or medicinal claims directly or indirectly;

IV - images of people using the Cannabis-based product;

V - stamps, nominative, figurative or mixed marks of government institutions, philanthropic entities, foundations, associations and medical societies, non-governmental organizations, associations representing the interests of consumers or health professionals and quality certification seals, except if required in specific standards;

VI - images or figures that refer to the indication of the flavor of the product;

VII - expressions or images that may suggest that a person's health may be affected by not using the product;

VIII - labels with a similar layout to that of a medicinal product registered by Anvisa or another international sanitary authority; and

IX - colors that may cause confusion or error in the identification of the black stripe.

Article 33 The following may appear in the labelling, packaging and package leaflet of Cannabis products:

I – anatomical figures in order to guide the health professional or the patient on the correct use of the product; and

II – the flavor of the product.

Article 34 Packaging and labelling of Cannabis-based products shall have characteristics that inhibit errors of dispensation and administration, exchanges or misuse.

Article 35 Packaging, labelling and package leaflets must be written in Portuguese.

Article 36 The following information must be available on the packaging of Cannabis-based products:

I - the name of the product;

II - information on whether the product consists of vegetable derivative or cannabis-derived phytopharmaceuticals;

III - the qualitative and quantitative composition of the markers or phytopharmaceuticals established for the product;

IV - the phrase: "Cannabis-based product";

V - the phrase in bold: "This product has no efficacy and safety evaluated by Anvisa";

VI - the phrase: "This product should be used only according to medical prescription";

VII - the physical and organoleptic characteristics of the product, including after the reconstitution and/or dilution;

VIII - the mode of use;

IX - the route of administration;

X - warnings regarding the use of the product, which should include adverse effects, potential dietary, drug or laboratory interactions, when known;

XI - the phrase in bold: "Keep out of the reach of children";

XII - the phrase: "Do not exceed the use indicated by the prescriber";

XIII - the name and the address of the company holding the Sanitary Authorization in Brazil;

XIV - the name of the professional responsible technician, the registration number and the acronym of the professional's class council;

XV - the telephone number of the customer service of the company that owns the Sanitary Authorization;

XVI - the health clearance number as published

in the Official Gazette;

XVII - the date of manufacture, the batch number and the shelf life;

XVIII - conservation care, indicating the temperature range and storage conditions, according to a stability study;

XIX - the total amount of net weight, the volume and the units, according to the case; and

XX - the expression "Brazilian Industry", when applicable.

Paragraph 1. The information described in Article 36 shall be written in easy-to-read format and should be easy to understand.

Paragraph 2. When all the information described in Article 36 does not fit in the internal packaging of the product, at least the provisions of items I to VI, IX, XI, XIII, XV to XVII and XIX shall be observed.

Paragraph 3. Where the space in the internal packaging is not enough, other information provided in Article 36 shall be available in the external packaging.

Paragraph 4. The package leaflet for Cannabis-based product must contain at least the following warnings in bold:

I - "Sale under Medical Prescription";

II - "Can only be Sold with Retention of the Medical Prescription";

III - "The Use of this product may cause physical or psychic dependence";

IV - "This product should not be used in children under 2 (two) years of age";

V - "This product does not replace the use of registered medicines";

VI - "This product does not have complete clinical studies that prove its efficacy and safety";

VII - "There are uncertainties about the long-term safety of the use of Cannabis-based products as a medical therapy";

VIII - "The use of the Cannabis product is admitted when there is a defined clinical condition in which other treatment options are exhausted and that scientific data suggest that Cannabis may be effective";

IX - "During the use of the product, the patient should not drive vehicles or operate machines or perform activities that involve risks to himself and third parties, because their skills and attention may be impaired";

X - "Attention: Risk for Pregnant and Lactating Women"; and

XI - "This product is for individual use and transfer to third parties is prohibited".

Paragraph 5. The package leaflet for the Cannabis-based product must contain information about:

I – the use conditions; and

II – the safe disposal, according to the procedures defined in a sectoral agreement or term of commitment for the implementation of reverse logistics systems, predicted in Law #12.305 of August 2, 2010.

Article 37 The packaging labels of Cannabis products must have a horizontal stripe in black color, covering all sides, in the height of its middle third and with width not less than a third of the width of the larger side of the larger face.

Paragraph 1. Inside the black stripe of Cannabis products containing up to 0.2% THC only two sentences must be included, in capital letters, "SALE UNDER MEDICAL PRESCRIPTION" and "CAN ONLY BE SOLD WITH RETENTION OF THE MEDICAL PRESCRIPTION".

Paragraph 2. Inside the black stripe of Cannabis products containing above 0.2% THC only two sentences must be included, in

capital letters, " SALE UNDER MEDICAL PRESCRIPTION" and "WARNING: THE USE OF THIS PRODUCT MAY CAUSE PHYSICAL OR PSYCHIC DEPENDENCE".

Article 38 The same reference of black color used for drugs' black stripe should be used in Cannabis-based products.

SECTION VI. INFORMATION AND DEVICES FOR TRACEABILITY OF THE CANNABIS PRODUCT

Article 39 The batch number, manufacturing date (month/year) and expiration date (month/year), must be printed on the product packaging so that it is easy to understand, readable and indelible, using letters with the biggest size possible, for its easy reading and identification.

Paragraph 1. The readability of this information must be guaranteed without the use of optical instruments, except in case of people who require visual correction.

Paragraph 2. In secondary packaging it is forbidden to use exclusively negative or positive relief, without color or with color that does not keep clear and permanent the contrast with the color of the support for printing the information required in this article.

Article 40. Secondary packaging must contain seal or safety seal that is unrecoverable after its disruption and allows to detect any attempt of disruption, in order to ensure their inviolability.

Paragraph 1. When flap bonding is used, the company must ensure the requirements described in the caput of this article to be considered a safety seal.

Paragraph 2. When using safety seals, in addition to the characteristics described in the caput of this article, it cannot be allowed its recovery and must contain custom laboratory identification.

Paragraph 3. In the case of packages allowing access to primary packaging by more than one end, both must meet the requirements contained in this article.

Paragraph 4. When the product is available exclusively in primary packaging and is openable, it shall contain seal or safety seal, according the characteristics described in this article.

Article 41 Packaging of Cannabis products shall contain identification and safety mechanisms that enable product tracking from its manufacturing or importation to the time of dispensation, as provided in specific standards.

Article 42 Secondary packaging or, in its absence, primary packaging must have the GTIN identification and safety barcode that allows product tracking from manufacturing or importation to the time of dispensation.

Sole Paragraph. It is allowed to place the GTIN Barcode on the lateral side of the package, on the prescription restriction stripe, structuring a gap in it.

Article 43 It is optional to include in the secondary packaging of the product or, in its absence, in the primary packaging, the reactive ink and under the same word "Quality" and the logo of the company holding the Sanitary Authorization, if they contain mechanisms of identification and safety that enable the tracking of the product from manufacturing or importation to the time of dispensation.

Paragraph 1. Reactive ink must be placed on one lateral side at the same level of the black stripe, and for this, it is allowed to place a gap in these stripes in order to allow the fixing of the ink.

Paragraph 2. Any other place on the outer face of the packaging can be used if it does not affect any other legal requirements and if there is an indication to the consumer of the place where to scrape.

SECTION VII. INFORMATION FOR TRANSPORTS BOXES

Article 44 Transports box labels for Cannabis-based products shall contain, printed or tagged, the following information:

I - the name of the holder of the Sanitary Authorization or its logo, if it contains the name of the company;

II - conservation conditions, indicating the temperature range and storage conditions, according to the stability study of the product.

CHAPTER IV. CHANGES IN THE SANITARY AUTHORIZATION

Article 45 Any changes made in the Cannabis-based product after the granting of the Sanitary Authorization are the responsibility of the company holding the authorization.

Paragraph 1. The company must ensure the quality, stability and safety of the cannabis product after the post-Sanitary Authorization change.

Paragraph 2. The company holding the Sanitary Authorization must file a new form, as shown in Annex I, updating only the information that has been modified, among those allowed in this standard, attaching justification, describing the modification and the updated documents.

Paragraph 3. In the case of method change, a full report containing the modified method and information on the pharmacopoeic reference or analytical validation report shall be sent.

Article 46 The changes in the Cannabis-based product to be made after the granting of the Sanitary Authorization for immediate implementation, after prior file before Anvisa, are as following:

I - change in the layout of labelling and packaging;

II - change in the manufacturing site of the plant or phytopharmaceutical derivative;

III - change in the site of one or more manufacturing steps of the finished product;

IV - those related to tests, specification limits and analytical methods of quality control of the finished product;

V - expiration date and conservation conditions;

VI - inactive ingredient; and

VII - manufacturing suspension.

Sole Paragraph. Changes in Cannabis-based products made after the grant of the Sanitary Authorization, filed before Anvisa and in accordance to the items from I to VI, do not require publication in the Official Gazette.

Article 47 The following changes in the Cannabis-based products, made after the grant of the Sanitary Authorization, require Anvisa's authorization and previous filing:

I - inclusion of a new commercial presentation;

II - inclusion of new packaging of primary packaging;

III - inclusion of concentration;

IV - cancellation of the Sanitary Authorization for the presentation; and

V - cancellation of the Sanitary Authorization for the product.

Sole Paragraph. All changes made after Sanitary Authorization listed in this article require publication in the Official Gazette (DOU).

CHAPTER V.
CONTROLS

SECTION I. PRESCRIPTION OF CANNABIS PRODUCTS

Article 48 Cannabis-based products may be prescribed in clinical conditions of absence of therapeutic alternatives, in accordance with the principles of medical ethics.

Paragraph 1. The prescription requirements for Cannabis-based products must not include reasons related to cost, convenience or operational needs.

Paragraph 2. Cannabis-based products can be prescribed when the prescribing physician is directly responsible for the patient.

Paragraph 3. The prescribing physician should rely on technical data capable of suggesting that this alternative can be effective and safe.

Article 49 The indication and use of Cannabis-based products are the responsibility of the attending physician.

Article 50 Patients should be informed about the use of cannabis products and should be provided, at the same time, the following information:

I - the involved health hazard;

II - regulatory condition of the product regarding proof of safety and efficacy, stating that the Cannabis product is not a drug or medicine;

III - possible adverse effects, taking as an example, but not restricted to: sedation and cognitive impairment, which may impact work, drive, operate machines or other activities that pose risks to you or third parties; and

IV - use conditions.

Paragraph 1. The patient or, in its impossibility, its legal representative, must sign the Informed Consent Term (TCLE), which should be completed with Cannabis-based product specific data.

Paragraph 2. The TCLE shall be completed according to the template in Annex III of this Resolution or another established by the respective Class Councils.

Paragraph 3. The TCLE must be signed in two copies, one retained by the patient or his legal representative and another filed by the attending physician.

Article 51 The prescription of the Cannabis-based product with THC up to 0.2% should be accompanied by the "Type B" Prescription Notification, in accordance with the Ordinance SVS/MS nº 344, of May 12, 1998 and its updates.

Article 52 The prescription of the Cannabis product with THC above 0.2% should be accompanied by the "Type A" Prescription Notification, in accordance with the Ordinance SVS/MS nº 344, of May 12, 1998 and its updates.

SECTION II. DISPENSATION OF CANNABIS PRODUCTS

Article 53 Cannabis-based products must be dispensed exclusively by pharmacies without manipulation or drugstores, upon presentation of a prescription by a medical professional, legally qualified.

Paragraph 1. The dispensation of Cannabis-based products must be done exclusively by a pharmaceutical professional.

Paragraph 2. The dispensation of Cannabis-based products must be carried out upon the presentation of specific Prescription Notification, issued exclusively by a medical professional, following the other determinations of Ordinance SVS/MS nº 344, of May 12, 1998 and its updates.

Article 54 The bookkeeping activities related to the movement of Cannabis-based products in pharmacies and drugstores should be carried out through the National Controlled Products Management System (SNGPC), in accordance with the Collegiate Board Resolution - RDC nº 22, of April 29, 2014 and its updates.

SECTION III. IMPORTATION OF CANNABIS PRODUCTS

Article 55 The importation and exportation of Cannabis-based products must follow the provisions of the Collegiate Board Resolution No. 11, of March 6, 2013, in the Collegiate Board Resolution No. 99, of December 24, 2008, in the Collegiate Board Resolution No. 81, of November 5, 2008, in the Collegiate Board Resolution No. 201 , of July 18, 2002, and in the Collegiate Board Resolution No. 62, of February 11, 2016, and its updates.

Article 56 The procedures of importation of Cannabis-based products must follow the provided in the Collegiate Board Resolution No. 81, of November 5, 2008 and its updates, specially the procedure I to "Goods and Products Subject to Special Control", which refers the Ordinate SVS/MS n.º 344, of 1998 and its updates and its lists"A1", "A2", "A3", "B1", "B2" and "D1".

SECTION IV. CANNABIS PRODUCT MONITORING

Article 57 All regulations related to drug monitoring actions are applicable to Cannabis-based products.

Article 58 The professionals legally qualified to prescribe, other healthcare professionals and companies responsible for the authorization must notify adverse events related to the use of the Cannabis-based products, on the terms of the Anvisa's Resolution No. 36, of July 26 , 2013, and its updates.

Article 59 The holder of the Sanitary Authorization shall carry out post-marketing actions of the Cannabis-based products, allowing for the adoption, when necessary, of measures concerning the products under its responsibility.

Article 60 The holder of the Sanitary Authorization and the manufacturer must submit any requested information for post-marketing surveillance purposes of Cannabis-based products at the time limit set by the sanitary authority.

Article 61 The holding company of the Sanitary Authorization must have a database for the systematic, updated and routine record of activities and information related to notifications of adverse events and quality issues.

Paragraph 1. The holding company of the Sanitary Authorization must prepare an annual Periodic Benefit-Risk Assessment Report for the Cannabis-based product.

Paragraph 2. The Periodic Benefit-Risk Assessment Report may be requested by Anvisa, at any time, intending to evaluate the benefits of Cannabis products in relation to risks.

Article 62 Any relevant information related to the safety of Cannabis-based products must be communicated to Anvisa.

Sole Paragraph. Urgent situations related to the use of these products that affect user's safety must be reported to Anvisa within

seventy-two (72) hours.

Article 63 The holding companies of the Sanitary Authorization, the manufacturers or the importers may receive, at any time, inspections focused on post-market monitoring of this products, conducted by the National Health Surveillance System (SNVS), previously announced or not, whenever there is a need to evaluate the compliance of the current legislation.

Sole Paragraph. The holding companies of the Sanitary Authorization, manufacturing or importation must promptly present all the documentation requested by the agents of the National Health Surveillance System (SNVS), as well as allow the employees to be interviewed and allow the access to the database with the purpose of verifying the compliance of the legal requirements.

SECTION V. ANALYTICAL MONITORING OF CANNABIS PRODUCTS

Article 64 Anvisa Public Health Laboratory Management (GELAS) will establish and coordinate a special program for monitoring Cannabis-based products.

Article 65 Analytical testing in monitoring programs shall be conducted in the modalities of guidance or fiscal analysis by official or accredited laboratories.

Article 66 The results of analytical testing obtained from market monitoring programs and in monitoring routine surveillance routine activities shall be made public by the responsible sanitary authority.

Sole Paragraph. Unsatisfactory analytical results shall be published after the investigation of suspected illicit acts has been completed, without prejudice to other preventive and precautionary measures provided for by law.

Article 67 Analytical laboratories of the importers, manufacturers or companies responsible for securing and ensuring the quality maintenance of cannabis products to the final consumer, who perform quality control tests on the finished products must be enabled in the Brazilian Testing Laboratories Network (REBLAS) and must provide their analytical data to Anvisa.

SECTION VI. SURVEILLANCE OF CANNABIS PRODUCTS

Article 68 All regulations related to inspection actions for the purposes of certification of good manufacturing practices, control, storage, distribution, transportation and health surveillance applicable to drugs and medicines must be observed for the Cannabis-based products.

Article 69 Sanitary Surveillance may, at any time, inspect all establishments in the production, distribution and marketing chain, as well as take samples for tax analysis of Cannabis-based products.

Article 70 When requested by the health surveillance entities, product managers should provide the information or deliver documents within the deadlines.

Article 71 The proof or evidence that a particular Cannabis-based product is harmful to health or does not fulfil the requirements set forth in the health regulations can imply the modification of the product, the cancellation of the Sanitary Authorization and/or its withdrawal by the responsible company throughout the national territory and other penalties under Law #6.437 of August 20, 1977 and its updates, without prejudice to other penalties provided for by Law.

CHAPTER VI.
FINAL AND TRANSITORY PROVISIONS

Article 72 Anvisa's entities responsible for drug authorization, inspection, supervision and monitoring will establish a post-market follow-up program for Cannabis-based products.

Article 73 Cannabis-based products authorized in accordance with the criteria of this Resolution shall have up to 365 (three hundred and sixty-five) days to be sold, counted from the date of publication of the granted authorization.

Sole Paragraph. Failure to comply with the provisions of this Article will result in the cancelation of the Sanitary Authorization.

Article 74 Cannabis-based products that do not fit into the drug or medicine category within the time period stipulated in this Resolution will have its Sanitary Authorization canceled.

Paragraph 1. The cancellation of the Sanitary Authorization for Cannabis-based products may be issued in the same time of the Anvisa's decision regarding its adequation as a drug or medicine.

Paragraph 2. Companies should follow their research strategies to prove the effectiveness and safety of their formulations.

Article 75 All the places that exercise any activities with Cannabis-based products must accomplish all the provided requirements applied at the Ordinance SVS/MS no.344, of 1998, and, of the Ordinance SVS/MS no. 6, of January 29, 1999, or others that might replace them.

Sole Paragraph. The establishments referred in this main section must realize the control and keep the records of all the distribution channels, and they must propose clear, quick and easy-access information to the sanitary authorities when required.

Article 76 The non-compliance of the provisions of this Resolution is considered a sanitary infraction, on the terms of the Law #6.437 of August 20, 1977, without prejudice of the civil, regulatory and criminal responsibilities.

Article 77 The guidelines established in this Resolution to the Sanitary Authorization are transitory.

Sole Paragraph. This Resolution must be reviewed up to three (3) years after its publication.

Article 78 This Resolution is effective ninety (90) days from the date of its publication.

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