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Newsletter

2nd Edition | 2025

This is an informative newsletter produced by the **Life Sciences and Healthcare** practice of TozziniFreire Advogados.

INDEX

Click at the topic of your interest and browse through the content

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Anvisa Opens Public Inquiry for Review of RDC on Cannabis Products

On March 26, 2025, Anvisa published Public Inquiry No. 1,316/2025. This inquiry aims to gather opinions and suggestions regarding the proposed update of resolution RDC No. 327/2019, which addresses the regulation of cannabis-based products for medicinal purposes in Brazil.

When it was published, RDC No. 327/2019 aimed to regularize cannabis-based products to enable public access to such products, which is particularly relevant when patients do not respond to the treatments available in the Brazilian market.

The resolution then created the sanitary category of Cannabis Products, which can be regularized by means of a Sanitary Authorization—valid for five years, during which Anvisa would re-evaluate the scenario and possibly propose new regulatory solutions applicable to the topic.

Anvisa claims that the five-year period proved insufficient for completing studies and submitting the products for registration as medications, the reason why it maintained the Sanitary Authorization.

Among the main changes proposed in the inquiry, the following stand out:

- **Validity and Extension:** authorization remains at five years; possibility of extending for another five years, provided there are ongoing clinical studies;
- **New Routes of Administration:** inclusion of oral, sublingual, inhalation, and dermatological routes. Smoking or injectable forms remain prohibited;
- **Good Manufacturing Practices:** requirement for Good Manufacturing Practices Certificate for the finished product; the active ingredient must be obtained from a line that complies with Good Manufacturing Practices, but without the need of formal certification;
- **THC Concentration:** limit of 0.2% THC for products requiring a Special Prescription in two copies, replacing the "B" Prescription Notification. For products with concentrations above 0.2% THC, the prescription must be made via "A" Prescription Notification and intended for patients with serious illnesses;
- **Compounding in Pharmacies:** dispensing of industrialized cannabis products is authorized in compounding pharmacies; compounding of magistral preparations containing exclusively isolated cannabidiol (CBD), with a minimum purity of 98%, is permitted;

- **Prescription and Dispensing:** possibility of prescription by qualified doctors and dental surgeons; mandatory dispensing by pharmacists in pharmacies and drugstores;
- **Advertising:** allowed only if targeted at prescribers, with content limited to the information approved in the package insert and labeling;
- **Transition to Drug Registration:** companies must, by the expiration of the authorization, request that the product be registered as medication.

The proposed changes reflect the evolution of the topic in Brazil and the growing demand from the public for access to Cannabis Products. Therefore, a clear and effective regulation to ensure the safe and appropriate use of these products is essential.

In view of this, those interested in contributing to the Public Inquiry should fill out the electronic form available on Anvisa's portal by June 2, 2025.

CFF and CFM in Legal Dispute Over Prescription of Medications

On March 31, 2025, the Regional Federal Appellate Court of the 1st Region (TRF-1) suspended Resolution No. 5/2025 of the Federal Pharmacy Council (CFF in Portuguese), approved on February 20, which allowed pharmacists to prescribe medications, including those subject to prescription. This suspension results from a public-interest civil action filed by the Federal Council of Medicine (CFM in Portuguese).

The broad-scope resolution addressed the act of establishing the pharmacotherapeutic profile upon the systematic supervision of patients by pharmacists, which would involve "defining, establishing, determining, creating, constituting, founding, developing, putting into effect, putting into action, or formalizing pharmacotherapeutic plans dynamically and continuously, according to the needs and variations in the patient's health condition, ensuring the application of the best practices based on scientific evidence."[1]

To establish the pharmacotherapeutic profile of patients, the Resolution authorized pharmacists to:

- Prescribe medications, including those requiring a prescription (only pharmacists with a Specialist Qualification Registration (RQE in Portuguese) in Clinical Pharmacy, except if the medication was covered by government programs and regulations within the scope of SUS (Brazil's Unified Health System) or specific CFF resolutions);
- Renew prescriptions previously issued by other legally qualified health professionals; and
- Prescribe medications for individuals at imminent risk of death.

CFF appealed against the preliminary decision, clarifying that "although there are state and municipal laws that have long recognized pharmaceutical prescription, the judge of the 17th Civil Court concluded that there is a need for a federal law, upon presentation of a bill to the National Congress."[2]

The judge argues that the CFF resolution exceeds the limits of pharmacists' competencies and encroaches on the exclusive duties of physicians, as defined by the Medical Act Law (Law No. 12,842/2013).

Therefore, for now, CFF Resolution No. 5/2025 remains suspended.

1 Avaliable at: https://www.in.gov.br/en/web/dou/-/resolucao-n-5-de-20-de-fevereiro-de-2025-617962146. Access on May 13, 2025.

2 Avaliable at: https://site.cff.org.br/noticia/Noticias-gerais/31/03/2025/nota-cff-contesta-liminar-e-reafirma-luta-pela-prescricao-farmaceutica. Access on May 13, 2025.

Anvisa Opens Public Inquiry on Over-the-Counter Medicines

On April 14, 2025, Anvisa published Public Inquiry No. 1,320/2025. The inquiry seeks inputs and suggestions for the proposed update of the List of Over-the-Counter Medicines (LMIP in Portuguese), currently established by Normative Instruction No. 285/2024.

Over-the-Counter Medicines (OTCs) are regulated by RDC No. 882/2024, which sets the requirements and procedures for classifying medications as OTCs. Some of these include the minimum time for marketing the medication, safety, indications for non-serious diseases, short-term use, etc.

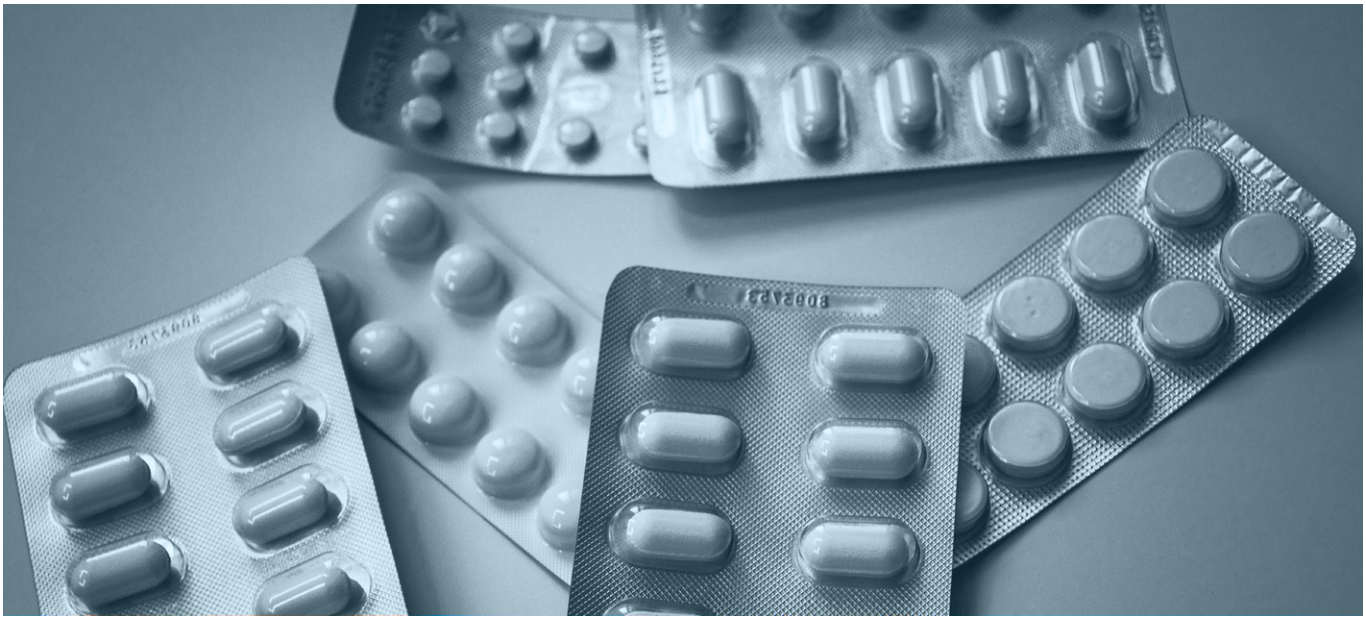
According to the rapporteur of the proposal, Director Daniel Meirelles Fernandes Pereira, OTCs are a way to expand public access to safe and effective medications, reduce healthcare costs, decrease visits to doctor's offices, and enhance patients' autonomy and perception of self-care.[3]

The proposal under the inquiry aims to update the LMIP by proposing inclusions and exclusions of medications, as well as formalizing refusals of classification.

This measure seeks to comply with the provisions of RDC No. 882/2024 and adjust the list to the current scientific and social context of the country.

The deadline for inputs is May 21, 2025. Interested parties must fill out the specific form available on Anvisa Legis website.

3 Avaliable at: https://anexosportal.datalegis.net/arquivos/1889457.pdf. Access on May 13, 2025.



Anvisa Approves New Measures for Control of GLP-1 Agonists

On April 24, 2025, RDC No. 973/2025 was published. It will come into effect on June 23, 2025, and will amend RDC No. 471/2021, aiming to establish more robust controls regarding the prescription and dispensing of glucagon-like peptide-1 receptor agonists (GLP-1), used in the treatment of type 2 diabetes and for weight loss. The main medications in this class include semaglutide, liraglutide, and tirzepatide.

This measure arises in response to the increase in reports of misuse of these medications, which have resulted in more adverse effects than anticipated. Anvisa intends to collect information on the distribution of these products for monitoring purposes. To this end, the National System for the Management of Controlled Products (SNGPC in Portuguese) was chosen as the monitoring tool, through the retention of prescriptions, which will support the adoption of inspection measures regarding these medications.

Rômison Rodrigues Mota, interim president of the Agency, highlighted the justifications for supporting the measure:

a) the "infodemic" generated by constant publications encouraging the use of these products for aesthetic purposes;

b) the considerable increase in reports of adverse events, received over the last two years, related mainly to off-label use;

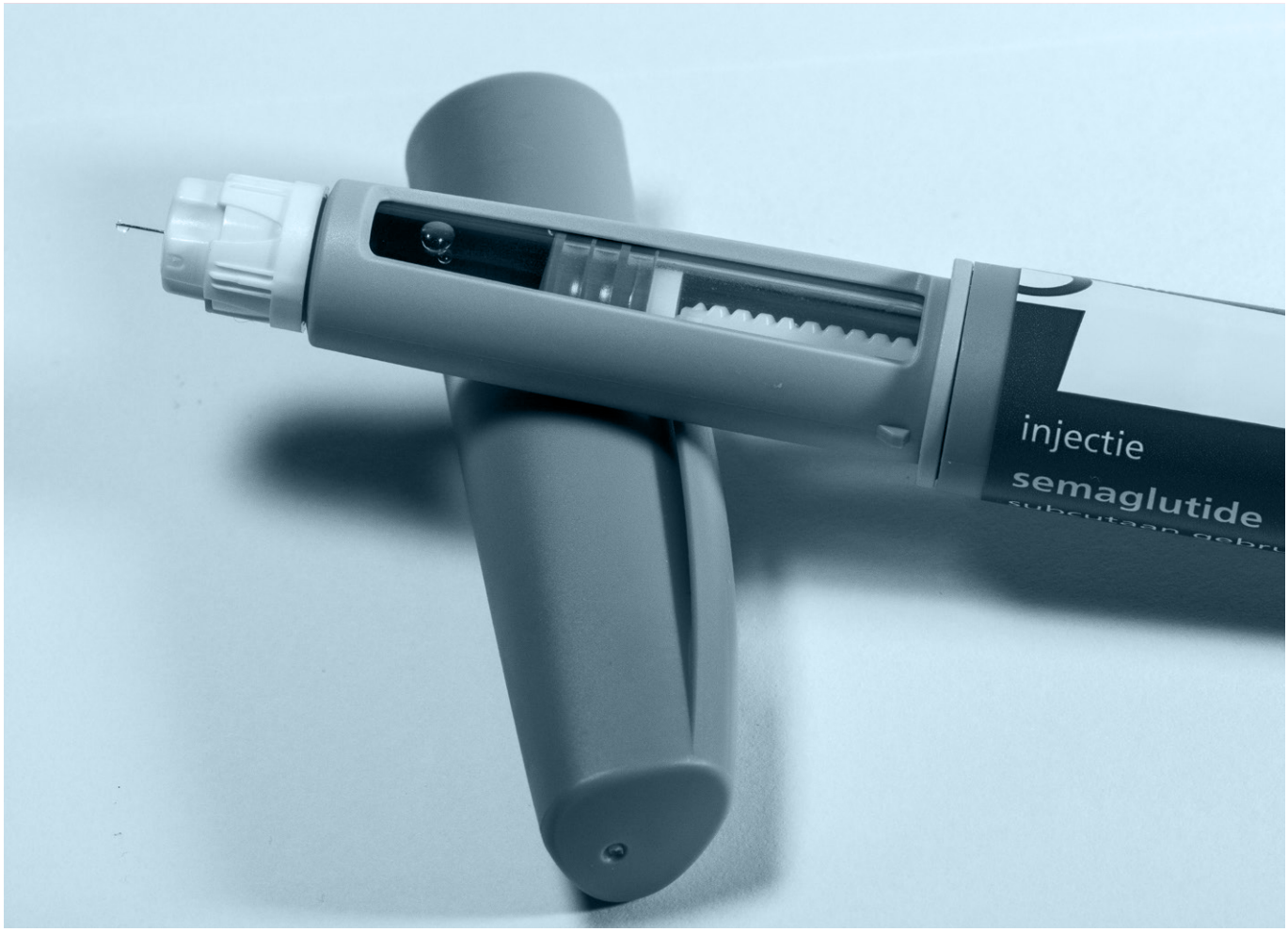
c) communications, especially from the Federal Council of Medicine (CFM) and medical organizations, regarding the need for greater control over dispensing by means of prescription retention.

It is worth noting that the new regulation does not change physicians' autonomy to prescribe medications for off-label use. The decision for off-label prescription must be responsibly evaluated by the physician, weighing the benefits and risks associated with the treatment choice.

The main changes include:

- **Creation of a future Normative Instruction:** to specify the medications subject to the new rules;
- **Prescription in two copies:** the prescription must be issued in two copies, with detailed information about the patient, the prescribed medication, and the healthcare professional in charge;

- **Retention of the prescription:** as with antimicrobials, the sale of GLP-1 agonists will require the pharmacy or drugstore to keep one copy of the prescription;
- **Registration in the SNGPC:** pharmacies must register the purchase and sale of these medications in the SNGPC;
- **Label alteration:** package inserts and labels of the medications must contain the phrase "SALE UNDER MEDICAL PRESCRIPTION - CAN ONLY BE SOLD WITH RETENTION OF PRESCRIPTION," with a compliance period to be defined by the future Normative Instruction—medications manufactured before the measure becomes effective may be dispensed until the end of their validity period.



Anvisa Opens Public Inquiry on Sanitary Control of Airports and Aircraft

On April 16, 2025, Anvisa published Public Inquiry No. 1,323/2025. The goal is to collect information from society about the proposed amendment to RDC No. 2/2003, which addresses sanitary inspection and control in airports and aircraft.

RDC No. 2/2003 is the main regulatory framework of the sector and has been in effect for over two decades. The purpose of the update is to incorporate technological advancements and respond to recent changes in epidemiological and socioeconomic scenarios.

Main topics of the proposal:

- **Quality Management System (QMS):** mandatory establishment of a QMS by airlines and airport administrators, focusing on ensuring good sanitary practices;
- **Differentiated requirements:** establishment of specific sanitary requirements according to the type of airport (national, international, designated) and the volume of passengers served;
- **Internationalization of airports:** definition of rules for the internationalization process, aiming to standardize and ensure sanitary compliance.

Interested parties must provide their inputs by July 21, 2025, by filing out the electronic form available on Anvisa Legis Portal.

The proposal aligns with Anvisa's Regulatory Agenda for 2024-2025, reflecting the agency's commitment to improving the regulatory framework for ports, airports, borders, and customs facilities.

CMED Opens Public Inquiry on Pricing of New Products and Presentations

On May 5, 2025, the Executive Technical Committee of the Drug Market Regulation Chamber (CMED in Portuguese) published Public Inquiry No. 1,330/2025, with a period for providing inputs from May 12, 2025, to July 10, 2025.

The proposal aims to fully revoke CMED Ordinance No. 2/2004, among others, and update the criteria for defining prices for new products and new presentations, as well as improve the procedure for submitting the Price Information Document (DIP in Portuguese).

The main proposed innovations are:

- **New list of categories:** changing the 6 former categories to 8 categories, with updated classification criteria and the creation of new categories such as non-new biological medications or biosimilars and medications resulting from transfers of ownership;
- **Patent validity for category I:** it aims to clarify that molecules with denied or expired patent applications are not considered patented;

- **More robust DIP:**
    - Setting a deadline of 60 days after sanitary approval to submit the DIP via electronic system, under the risk of CMED initiating a procedure for defining the Factory Price (PF in Portuguese) on its own initiative;
    - New requirements: scientific evidence, pharmaco-economic studies, and proof of performance of innovative activities in Brazil, etc.;
    - A simplified DIP is expected for medications that already have an approved Factory Price.
- **Meetings:** explicit provision for interested companies to request meetings for DIP pre-submission and during the CMED review process, to present and support the submitted scientific evidence;
- **Language:** explicit possibility to present documents in English and Spanish, which may require simple or sworn translation depending on the case;
- **New reference countries:** inclusion of Germany, Norway, Japan, Mexico, South Africa, and the United Kingdom in the list and exclusion of New Zealand;
    - **Higher minimum number:** increasing the minimum number of reference countries where the product must be marketed from three to five countries—otherwise, a provisional price will be established (except if the products are developed and manufactured in Brazil);
- **Appeal and mandatory re-examination:** detailing the hypotheses of appeal and its processing; creating mandatory re-examination.

Interested parties should provide their inputs by filling out the electronic form available on Participa + Brasil Portal.

Partner responsible for the newsletter

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