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Life Sciences and Healthcare

Newsletter

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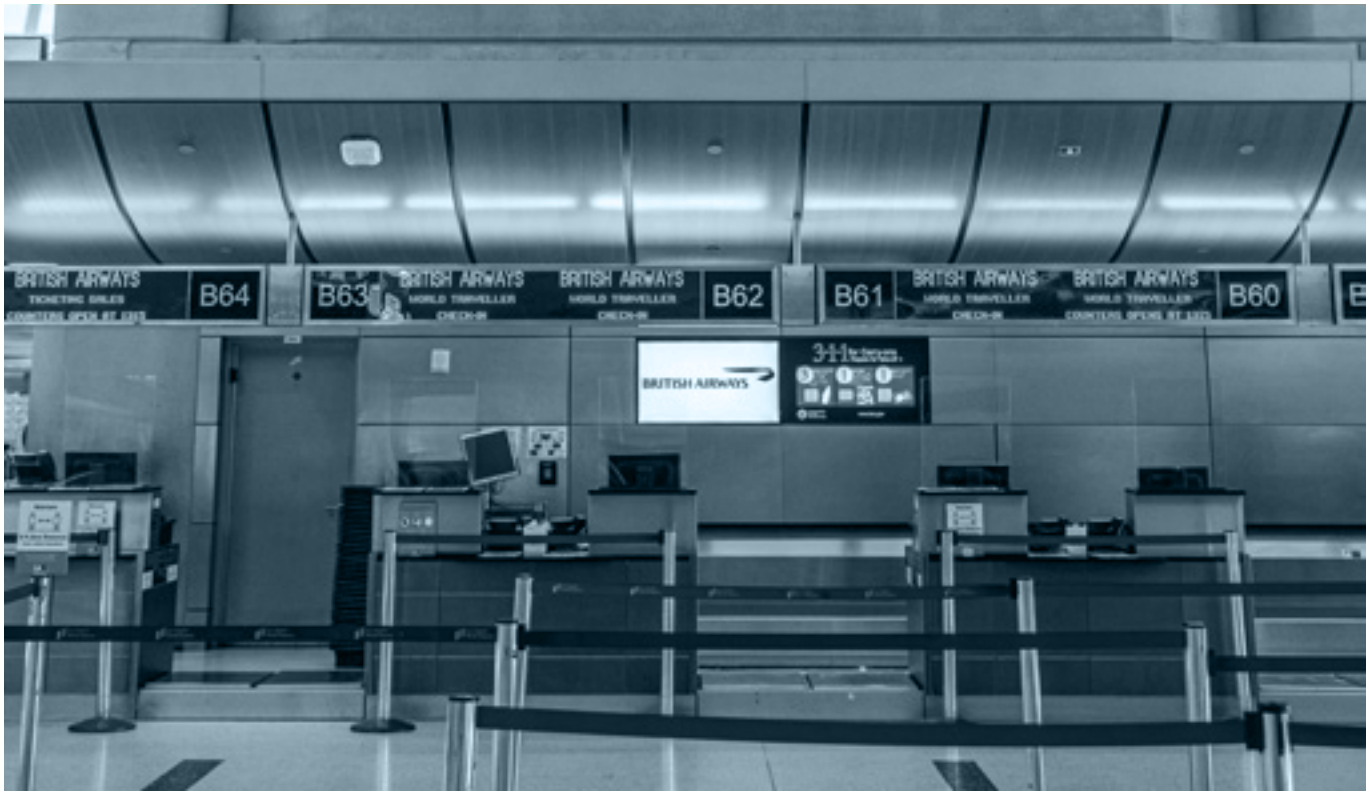


On June 13, 2025, the National Health Surveillance Agency (ANVISA in Portuguese) published the second version of the guide for establishing and maintaining a Contingency Plan for Ports and Airports. The update is meant to provide greater detail on certain parts of the plan and enhance the clarity of the guide as a whole.

Resolution RDC No. 932/2024 establishes the obligation for the regulated sector to create and maintain these programs, defining the contingency plan as a document indicating who is responsible and who participates in executing protocols and procedures in the event of public health issues or emergencies.

The text was revised to address questions that arose during the Public Inquiry, which took place from November 25, 2024, to March 26, 2025.

The main changes include:

- Greater detail on the phases of the Contingency Plan;
- Greater clarity regarding the responsibilities of each type of port and airport; and
- Suggestion of a tool to assist in risk assessment.

The new version is available on ANVISA website.

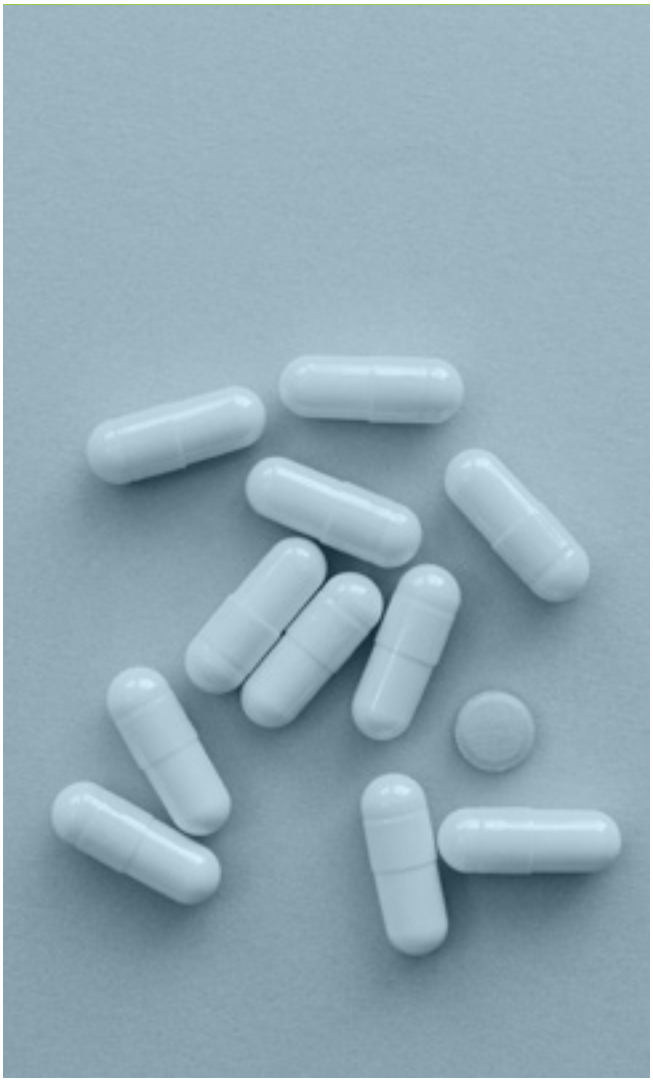
New Regulation of Self-Control Law

On June 12, 2025, Decree No. 12,502/2025 was published. It regulates the administrative process for farming and cattle raising inspection in Brazil. The norm regulates the implementation and procedures outlined in Law No. 14,515/2022, popularly known as "Self-Control Law," and establishes the procedure for investigating and judging violations applicable to all areas of inspection under the jurisdiction of the Ministry of Agriculture and Livestock (MAPA in Portuguese).

In addition to regulating the Self-Control Law, the Decree also created the Special Commission for Farming and Cattle Raising Defense Resources, a board that will work as final administrative instance. It will comprise representatives from MAPA, the Department of Justice and Public Security, the Confederation of Agriculture and Livestock of Brazil (CNA), and the Brazilian Confederation of Industry (CNI).

Another innovation introduced by the Decree is the possibility of signing a Consent Decree (TAC in Portuguese) between offenders and the Government, to convert more severe penalties, such as suspension or revocation of registrations, into less severe ones, such as fines.

The minister of Agriculture and Livestock, Carlos Fávaro, emphasized that the new regulation represents a significant advancement for the farming and cattle raising sector. He stated that, by unifying rules and procedures, they would strengthen MAPA's regulatory role, meet a long-standing demand from the sector, and reaffirm the government's commitment to a more modern and competitive agricultural sector that complies with sanitary requirements both in Brazil and in international markets.



The decree came into effect on June 12, 2025.

ANVISA Publishes Report on the Process for Reviewing RDC on Good Practices in Compounding Pharmacies

On June 30, 2025, the 10th Public Ordinary Meeting of the Collective Board of the National Health Surveillance Agency (Dicol – ANVISA in Portuguese) was held. The topics in the agenda included the review of Annex IV of the Collective Board Resolution - RDC No. 67, dated October 8, 2007, which addresses Good Practices for Compounds and Extemporaneous Preparations for Human Use in pharmacies.

Data from the Sterile Compounding Inspection Program conducted by the Agency in 2024 show that sixteen of the nineteen pharmacies analyzed were totally or partially closed.

The main non-conformities identified were:

- Structural deficiencies;
- Absence of monitoring for non-viable particles; and
- Failures in proving the sterility of products before dispensing to patients.

Additionally, some factors would delay regulatory responses in cases of health risk: the sale of these products through digital means; deficiencies in post-market monitoring; lack of stability testing to define the shelf life of injectable products; and the inadequacy of medium-scale production in view of the regulatory concept of individualized compounding.

Considering this, the review of Annex IV of RDC No. 67/2007 has the following main objectives:

1. Update the minimum technical requirements, incorporating modern standards for environment qualification, environmental monitoring, and technological barriers;
2. Align the normative text with established international references;
3. Establish objective criteria to support inspection actions;
4. Reduce health risks and adverse events associated with compounded sterile products;
5. Ensure alignment with international standards;
6. Strengthen the legal certainty of the sector; and
7. Define a feasible transition timeline in line with pharmacies' operational capabilities.

The update should involve broad participation from the regulated sector and ensure a reasonable timeline for the sector to adjust to the new rules, especially micro and small pharmacies.

Proposal to Review Regulatory Framework for Medical Devices

During the 10th Public Ordinary Meeting of the Collective Board of the National Health Surveillance Agency, the proposal to start the review of RDC No. 478/2021 and Normative Instructions No. 84/2021 and No. 119/2022 was approved.

The proposal aims to improve the monitoring of prices of medical devices, correcting regulatory distortions and ensuring the credibility of information published by the agency while preserving public funds.

The Regulatory Outcome Assessment Report (ARR in Portuguese) concluded that, despite achieving expected results in some areas, there was operational overload and inability to expand monitoring. Furthermore, according to the document, the productive sector did not adhere to the project as expected and failed to submit information in a timely manner, while the dissemination and updates of monitoring panels did not achieve the desired results either.

In light of this situation, several recommendations have been made:

I. Strengthen the technical team and the infrastructure to expand the scope of economic monitoring.

II. Use channels in addition to the portal (email, social media, newsletters) to reach public buyers and prescribers.

III. Create an indicator to assess the quality of technical information submitted by registration holders.

IV. If the scope is expanded, extend the internal deadline of 90 days for publishing the monitoring panels.

The responsibilities for economic monitoring of medical devices were transferred to the Coordination of Price Evolution Monitoring of SCMED (CMEPS/SCMED) to optimize and make this process more efficient. The new coordination, upon diagnosing the existing model, identified difficulties in tracking price evolution and thus proposed a review of the regulatory framework to establish a more transparent price monitoring system, with structured data to assist in detecting and investigating potential irregularities in the market.

The Regulation Administrative Process was approved during the ROP (Standard Operational Routine) and should be included in the next Regulatory Agenda.

ANVISA Begins Process for Reviewing Regulation on Nutritional Labeling of Packaged Foods

The National Health Surveillance Agency (ANVISA) approved, during the 10th Public Ordinary Meeting of the Collective Board of ANVISA, the process to start the review of the regulation on nutritional labeling of packaged foods.

The proposal establishes the review of two regulations:

- Collective Board Resolution - RDC No. 429, dated October 8, 2020, which addresses the nutritional labeling of packaged foods;
- Normative Instruction - IN No. 75, dated October 8, 2020, which establishes the technical requirements for declaring the nutritional labeling of packaged foods;

With the publication of RDC No. 429/2020 and IN No. 75/2020, the sanitary norms on labeling that internalized the Technical Regulations of Mercosur (RTMs in Portuguese) were revoked.

In this regard, the proposed review aims to restore the harmonization of nutritional labeling requirements for packaged foods among the Mercosur Member States, ensuring the effectiveness of nutritional labeling as a tool for protecting public health and ensuring the right to adequate, clear, and precise information for consumers.

Additionally, the approved proposal for review includes conducting a Public Inquiry with a 90-day deadline for submitting inputs.

ANVISA Publishes Normative Instruction Defining Technological Functions, Limits, and Conditions of Use for Food Additives

On July 7, 2025, the National Health Surveillance Agency (ANVISA) published Normative Instruction No. 380/2025, which amends Normative Instruction No. 211/2023 and establishes the technological functions, maximum limits, and conditions of use for food additives and processing aids authorized for use in food.

The main changes included:

- Decrease in the maximum limit of preservatives, such as pimaricin and natamycin (INS 235) for the category "01.8 Milk Caramel Spread;"
- Reduction in the maximum limit and changes in the conditions of stabilizers for the categories "09.1.1 Fresh, refrigerated, or

frozen fish, except mollusks, crustaceans, and echinoderms" and "09.1.2 Fresh, refrigerated, or frozen mollusks, crustaceans, and echinoderms;"

- Changes in the "Notes" regarding hydrogen peroxide as an enzymatic inhibition agent before the bleaching stage;
- Changes in the "Notes" regarding carbon dioxide and nitrogen as propellant gases and packaging gases; and
- Inclusion of the additive spirulina extract (INS 134) as a colorant for the categories "04.9 Fruit and/or seed preparations (including coverings and fillings) for use in other food products (except fruit pulp)," "14.1 Liquid dietary supplements (including suspensions, solutions, syrups, emulsions, and liquid content of gelatin capsules)," "14.2 Solid and semi-solid dietary supplements (including tablets, gummies, pills, lozenges, capsules, gelatin capsules, gels, creams, powders, granules, tablets and chewable forms)," and "21.1 Non-alcoholic beverages based on soy."

Normative Instruction No. 380/2025 came into effect on July 7, 2025.

MAPA Extends Deadline for Compliance with Ordinance SDA/MAPA No. 1,170/2025

On July 7, 2025, Ordinance SDA/MAPA No. 1,327/2025 was published in the Federal Register (DOU in Portuguese), extending the deadline set forth in Article 15 of Ordinance SDA/MAPA No. 1,170/2025 to December 1, 2026.

Ordinance SDA/MAPA No. 1,170/2025 approved the Technical Regulation of Identity and Quality for dairy composite products, intended for human consumption, and previously required compliance from the sector until August this year. With the new ordinance, the regulated sector will have just over a year to comply with the provisions of Ordinance SDA/MAPA No. 1,170/2025.

Ordinance SDA/MAPA No. 1,327/2025 came into effect on July 7, 2025.

Decree Establishes National Program for Pesticide Reduction[1]

On June 30, 2025, Decree No. 12,538/2025 was enacted, establishing the National Program for Pesticide Reduction (Pronara in Portuguese). The program creates mechanisms to progressively reduce the use of pesticides, particularly those considered highly dangerous to the environment and human health, while promoting sustainable production models.

The new program is linked to the National Policy on Agroecology and Organic Production (Pnapo in Portuguese), regulated by Decree No. 7,794/2012. In addition to the gradual reduction of pesticide use, it aims to encourage agroecological transition through technical and financial support; strengthen the monitoring of residues in food, water, and soil; promote sustainable alternatives and bioinputs; and train farmers and healthcare professionals.

According to the minister of the Environment and Climate Change, Marina Silva, "Pronara is a fundamental step in establishing sustainable agriculture in Brazil. We are fulfilling our commitment to the population's health and the protection of ecosystems while supporting our producers, family farmers, and traditional peoples and communities in this necessary transition. The program demonstrates that it is possible to produce food in harmony with the environment and drive agricultural development toward a new cycle of prosperity where no one is left behind."

Additionally, the Program for the Valuation of Sociobiodiversity and Extractivism (Sociobio Mais) was established by means of Decree No. 12,539/2025, replacing the Policy for the Guarantee of Minimum Prices for Sociobiodiversity Products (PGPM-Bio). Sociobio Mais aims to promote fair remuneration for rural producers by encouraging sustainable use and the permanence of traditional communities in their territories.

Decree No. 12,539/2025 also provides for the regulation of the first three articles of Law No. 8,427/1992, which covers the granting of economic subsidies in rural credit operations.

Both decrees were signed and published in the Federal Register on June 30 and are already in effect.

1 Available at: https://www.gov.br/mma/pt-br/noticias/lula-institui-programa-nacional-de-reducao-de-agrotoxicos. Accessed on: July 29, 2025.

ANVISA Conducts Reassessment of PMMA Indications in Brazil

In recent months, the National Health Surveillance Agency (ANVISA) has reevaluated the risk profile and benefits of Polymethylmethacrylate (PMMA) and the approved indications for this product in Brazil. Based on the data obtained by the Agency, it was concluded that the risk-benefit profile of the product is acceptable when used within the limits of the approved indications and under appropriate conditions. Given this, ANVISA did not identify any need to change the current indications.

The analysis conducted by the areas of registration of products for health, inspection and surveillance, and adverse event monitoring involved evaluating products approved in the country and the services and establishments involved in the production and healthcare chain that use PMMA as a medical device. Additionally, the Agency inspected the two manufacturers with approved products in Brazil and conducted a review of the available scientific literature and international regulatory experiences.

The review process began following a request from the Federal Council of Medicine (CFM in Portuguese), which called for suspending the production and commercialization of PMMA-based fillers in Brazil.

Finally, the Agency explained that the notifications it received indicated cases of application in volumes exceeding those approved by the institution. The off-label use of these products is not regulated by ANVISA, and according to the agency, use in disagreement with the indications on the label is the responsibility of the councils that regulate the activities and conduct of their professionals.

International Public Inquiry on Good Manufacturing Practices for the Pharmaceutical Sector

On July 14, 2025, the National Health Surveillance Agency (ANVISA) informed the pharmaceutical sector on its website about an international public inquiry regarding revised documents under the alignment between the European Union (EU) and the Pharmaceutical Inspection Cooperation Scheme (PIC/S).

As a participant in PIC/S, ANVISA was invited to disseminate the inquiry to the sector, particularly the pharmaceutical industry, encouraging the submission of inputs about the documents under review.

The documents submitted for the inquiry are:

- Chapter 4 of GMP – Documentation (revised)
- Annex 11 – Computerized Systems (revised)
- New Annex 22 – Artificial Intelligence

Brazil's participation in the inquiry is essential to ensure that the specificities of national regulation are considered in the process of international harmonization of Good Manufacturing Practices requirements.

For companies associated with entities representing the pharmaceutical sector, comments should be sent directly to these entities, which will be responsible for consolidating and providing inputs. For other interested parties, comments should be submitted through the EU Survey platform.

The deadline for providing inputs began on July 7 and will run until October 7, 2025. More information can be obtained on ANVISA website.

Ban on Animal Testing for Cosmetics Comes into Effect in Brazil

On July 31, 2025, Law No. 15,183/2025 was published in the Federal Register, prohibiting the use of live vertebrate animals in safety, efficacy, or toxicity testing for personal hygiene products, cosmetics, and perfumes. This regulation is a milestone in animal protection and in the alignment of Brazil with international ethical testing practices.

The new legislation also prohibits the use of data obtained from animal tests conducted after its entry into force for the marketing of these products. Exceptions will only be allowed when tests are required by non-cosmetic regulations, either national or foreign, upon provision of documentary evidence.

Health authorities, such as ANVISA, will have up to two years to implement measures ensuring the application of the law, including recognizing internationally validated alternative methods, defining labeling rules, and publishing biennial reports on the use of documentary evidence by companies.

Partner responsible for the newsletter

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