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Life Sciences and Healthcare

Newsletter

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

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RDC No. 1001 Defines Criteria, Hypotheses, and Procedures for Priority Classification of Petitions[1]

The National Health Surveillance Agency (Anvisa) published Collegiate Board Resolution No. 1,001 on December 11, 2025, which establishes the criteria and conditions for the priority classification of petitions submitted for the Agency's analysis. The regulation consolidates, in a single act, the hypotheses under which certain processes can be prioritized, covering applications for registration and post-registration of medications, certifications of Good Manufacturing Practices for medicines and active pharmaceutical ingredients, as well as requests for prior consent in clinical trials.

The text establishes that priority classification depends on meeting specific formal and material requirements, including properly supporting the petition, presenting complete information, and objectively demonstrating fulfillment of the criteria defined by Anvisa. The resolution also establishes the situations in which priority treatment may be requested, considering aspects related to health interest, the relevance of the product or technology, and the potential impact on public health.

Furthermore, the text clarifies that priority classification does not imply relaxing technical requirements or ensuring automatic approval of the request; all existing sanitary regulations remain fully applicable. Applicants are responsible for ensuring the information provided is true and for complying with all regulatory obligations throughout the analysis process.

[1] Available at: https://www.in.gov.br/web/dou/-/resolucao-da-diretoria-colegiada-anvisa-n-1.001-de-11-de-dezembro-de-2025-675494567

New Regulation Specifies Technical and Operational Requirements for Electronic Issuance of Prescriptions and Notices Subject to Special Control [2]

Collegiate Board Resolution No. 1,000, dated December 11, 2025, establishes the requirements applicable to the issuance, control, and validation of prescriptions and notices issued electronically. The new regulation covers prescriptions subject to special control, including Notifications of Prescription types A, B, and B2, as well as other prescriptions whose retention is required by sanitary legislation.

The text defines technical parameters related to the authenticity, integrity, traceability, and security of the information contained in electronic documents, regulating the identification of the prescriber, data protection, and the reliability of the systems used. The resolution aims to ensure that electronic prescriptions maintain a level of control equivalent to that required for documents issued as hard copies.

The document also addresses the responsibilities of healthcare professionals and establishments involved in prescribing, dispensing, and retaining prescriptions, establishing obligations related to storing information and making data available to health authorities whenever requested.

This normative act is part of the process of digitizing health services and modernizing the sanitary regulatory framework, aiming to align technological advancements with mechanisms for inspecting and controlling substances subject to special regimes.

[2] Available at: https://www.in.gov.br/web/dou/-/resolucao-da-diretoria-colegiada-anvisa-n-1.000-de-11-de-dezembro-de-2025-675167858

New Anvisa Resolution Consolidates Rules for Herbal Medicines[3]

Resolution No. 1,004, published by Anvisa on December 17, 2025, establishes updated criteria for the registration and notification of herbal medicines, organizing regulatory provisions that were previously spread across several regulations and complementing the guidelines already provided for in RDC No. 948/2024.

The regulation defines more precisely the categories of products that can be classified as herbal medicines, distinguishing those whose safety and efficacy are based on clinical evidence from traditional herbal medicines, whose effectiveness is supported by scientific technical data and history of use. It also establishes limits and regulatory protection, such as prohibiting the use of these products for treating diseases considered severe, preventing the use plant substances in concentrations with known toxic risks, and banning injectable and ophthalmic routes of administration.

Although the resolution provides for relevant procedural and conceptual adjustments, it does not alter the fundamental principles of health surveillance nor does it relax technical requirements that are already established in specific norms. The measure focuses on providing greater coherence among related regulations, ensuring uniformity in administrative interpretation, and reducing regulatory gaps that generated ambiguities for economic agents and professionals working in the sector.

[3] Available at: https://www.in.gov.br/web/dou/-/resolucao-n-1.004-de-17-de-dezembro-de-2025-676938378

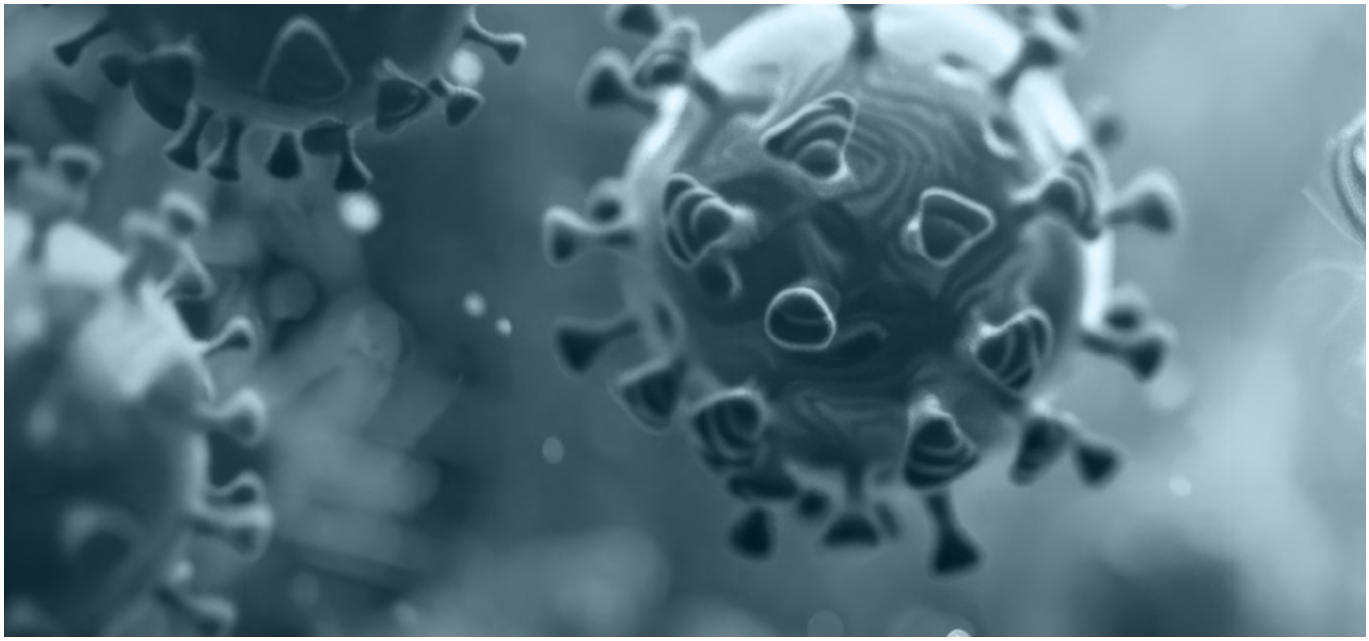
Public Inquiry Discusses Regulatory Proposal on the Prevention and Control of Healthcare-Associated Infections[4]

Anvisa has launched a public inquiry to receive inputs on a regulatory proposal aimed preventing and controlling healthcare-associated infections. This initiative seeks to review and update technical and organizational requirements applicable to health services, considering care practices, risk management, and patient safety.

The proposal addresses aspects related to the organization of services, training of professionals, implementation of infection control protocols, and monitoring of adverse events. The goal is to consolidate guidelines that reflect the evolution of care practices and the scientific evidence available.

The text subject to public inquiry also considers the need for integrating health surveillance actions and the operational routines of healthcare services, aiming to strengthen the prevention of infections associated with care at different levels of complexity.

Inputs will be submitted via an electronic form and should contribute to the development of a regulation that updates the regulatory framework on the subject, potentially impacting the organization, functioning, and oversight of healthcare services.



[4] Available at: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2025/consulta-publica-discute-requisitos-para-prevenir-e-controlar-infec-coes-em-servicos-de-saude

Public Inquiries Launched on Proposals for Requirements Applicable to Cosmetic and Perfume Packaging[5]

Anvisa announced the launch of Public Inquiries No. 1,380/2026 and No. 1,381/2026, both focused on updating regulatory requirements applicable to the packaging and repackaging of personal hygiene products, cosmetics, and perfumes. The proposals were published on January 20, 2026, and individually address technical, operational, and safety aspects related to repackaging and the reuse of packaging, as well as defining the categories of products that may be subjected to these activities.

Public Inquiry No. 1,380/2026 presents a proposed Resolution aimed at regulating technical requirements and good practices for the repackaging of products and for the reuse of packaging sold directly to consumers. The text seeks to update the existing regulation, which currently restricts repackaging to a limited number of categories and expressly prohibits the reuse of packaging, a scenario that no longer aligns with the innovations and contemporary models of risk control and sustainability in the sector. The proposal includes guidelines on documentation, personnel qualification, facilities, equipment, maintenance, and sanitation, as well as procedures for handling complaints, returns, recalls, and cosmetic surveillance activities, reinforcing the need for traceability and safety across all stages of the process.

On the other hand, Public Inquiry No. 1,381/2026 addresses the proposed Normative Instruction that will define the categories of personal hygiene products, cosmetics, and perfumes that may undergo repackaging, with or without reuse of packaging. The initiative aims to overcome gaps in the current regulation, recognized by the Agency as outdated in terms of technological advancements and current market practices. The objectives include the expansion of categories authorized for repackaging, enabling new business models and greater product diversity in retail, without compromising the quality and safety parameters required by the National Health Surveillance System.

The two inquiries reflect a broader regulatory movement to review the normative framework applicable to the cosmetics sector, considering technological evolution, international practices, and the need to adapt packaging to product characteristics. By addressing issues such as material safety, functional adequacy of packaging, and clarity of information provided to consumers, Anvisa aims to strengthen health protection, ensure product reliability, and promote greater regulatory predictability.

The deadline for submitting inputs to Public Inquiries No. 1,380/2026 and No. 1,381/2026 ends on March 21, 2026, and responses must be submitted via the electronic forms provided by the Agency.

[5] Available at: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2026/abertas-consultas-publicas-sobre-embalagens-de-cosmeticos-e-perfumes

New Special Control Regime for Substances of Veterinary Use[6]

MAPA (Ministry of Agriculture, Livestock and Food Supply) Ordinance No. 837, dated September 23, 2025, establishes the Special Control Regime and comprehensively regulates the procedures for the acquisition, record-keeping, prescription, dispensing, and labeling of substances subject to special control when intended for veterinary use, as well as the veterinary products containing them. The regulation addresses establishments that manufacture, store, handle, distribute, sell, import, or export these products, while also regulating the actions of veterinarians responsible for prescribing and using these substances.

The text presents precise definitions that guide the application of the regime, including the concepts of anabolic steroids, narcotics, record books, and registered veterinarians. According to the Ordinance, anabolic steroids are substances capable of increasing protein and non-protein nitrogen retention, resulting in muscular growth; narcotics are substances with the potential to cause physical or psychological dependence, as per applicable international lists. The record book becomes a mandatory tool for chronologically recording the entry, exit, and loss of controlled substances or products containing them, reinforcing the need for traceability in the lifecycle of these substances.

The Ordinance also details the requirements for prescribing, acquiring, and handling controlled substances. Veterinarians wishing to prescribe or acquire products subject to special control must have prior registration approved in a specific electronic system of the Ministry, a condition that enables the issuance of numbered and standardized prescription and acquisition notifications. These notifications, mandatory for the movement and acquisition of certain products, constitute a fundamental control tool for monitoring the flow of inputs and preventing deviations.

[6] Available at: https://www.in.gov.br/web/dou/-/portaria-mapa-n-837-de-23-de-setembro-de-2025-679029448

In operational terms, the regulation outlines record-keeping procedures, imposing the chronological recording of all movements and defining responsibilities for technical representatives in charge when it comes to maintaining the record book and keeping related documentation. It also establishes labeling and dispensing rules, indicating that products subject to the Special Control Regime must contain specific information for them to be unequivocally identified, including warnings and guidelines specific to high-risk sanitary control.

Additionally, the Ordinance defines differentiated obligations for establishments that manufacture, handle, or import and export products containing controlled substances. These establishments must meet additional requirements for document organization, security, and tracking, ensuring each operation is recorded and can be audited by supervisory bodies. The specifics of these regulatory requirements reinforce compliance with the decrees underpinning the legal regime of the Ordinance, including Decree No. 11,332/2023 and Decree No. 24,548/1934, which address the control and inspection of veterinary products.

CMED Updates Criteria and Procedures Applicable to Drug Price Regulation[7]

CMED Resolution No. 3, dated December 29, 2025, published by the Drug Market Regulation Chamber, establishes new criteria and procedures for defining prices of new products and new presentations of medications in Brazil, also governing the presentation of the Price Information Document (DIP in Portuguese). The regulation was enacted based on Article 7 of Law No. 10,742/2003 and reorganizes the regulatory framework applied to pricing in the pharmaceutical sector.

The text elaborately defines essential technical concepts for the pricing process, including notions of therapeutic alternatives, innovative activities, additional clinical benefits, groupable pharmaceutical forms, and types of scientific evidence accepted to justify price requests. These definitions guide the classification of medicines into specific categories and underpin CMED's evaluation regarding therapeutic value and declared innovation, which are determining factors for calculating the initial Factory Price (PF in Portuguese).

The regulation systematically reorganizes the categories of medicine classification, expanding the number of categories to eight, with distinctions considering the level of innovation, the existence of therapeutic comparators, and the product profile. They include medications with new active pharmaceutical ingredients, products resulting from incremental innovation, non-new biological products, and generic medicines. Each category has its own criteria for price determination, aligning the regulatory methodology with the degree of technological novelty and the competitive landscape relevant to the product.

Furthermore, the Resolution regulates the procedure for presenting the Price Information Document, establishing that the DIP must be submitted after the protocol of the sanitary registration request with Anvisa and before publication of the respective approval. The absence or inadequacy of the DIP authorizes CMED to initiate a procedure on its own initiative to define the price, reinforcing the need for predictability and documentary compliance on the part of companies. The mandatory technical content of the DIP has also been expanded, now requiring regulatory justifications, robust scientific evidence, and, when applicable, pharmacoeconomic elements, with the possibility of simplified modalities in specific cases.

[7] Available at: https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/legislacao/RESOLUOCM_CMEDN3DE29DEDEZEMBRODE2025DOU.pdf

The Resolution also updates the international benchmarking parameters used to determine the Factory Price, increasing the number of reference countries from nine to fourteen. The proposed price cannot exceed the lowest price practiced in these countries, considering the applicable taxes. For a final price to be adopted, the product must be marketed in at least four countries from the established list; otherwise, a temporary price will be applied until the criterion is met.

Anvisa Establishes New Regulatory Provisions Applicable to Products Subject to Health Surveillance[8]

Collegiate Board Resolution (RDC) No. 1,009, dated January 5, 2026, published by Anvisa, introduces changes to the Agency's Internal Regulations by modifying provisions of Annex I of RDC No. 585/2021. The regulation adjusts the organizational structure and internal competencies, directly impacting the administrative organization, decision-making flow, and the activities of the technical-regulatory units.

The text modifies provisions related to the Sanitary Surveillance and Inspection Management of Health Products, which will now have new coordination areas responsible for supervising health products, certifying manufacturers, and executing the Unified Audit Program for Health Products. The reorganization of these areas aims to improve the distribution of activities and the definition of internal responsibilities.

There is also a review of the structure of the General Management of Technology in Health Services, which will now include the Coordination of Services of Interest for Health, the Health Control and Regulation Management in Health Services, and the Health Services Surveillance and Monitoring Management. These changes adjust the operations of the area responsible for health services and related activities, redefining internal arrangements outlined in the regulations.

Within the competencies of the Collegiate Board, the Resolution updates provisions on personnel management, such as the appointment and dismissal of servants for commission-paid positions, the assignment and leave for training activities, as well as assignments related to the analysis of reports by the ombudsman and to accusatory corrective procedures. These modifications update the decision-making roles of the Board, aligning them with the exercise of administrative and corrective supervision.

Another relevant change pertains to the rules related to Decision-Making Circuits, an instrument used by the Board for remote decision-making. The regulation introduces provisions that require repeating the circuit when quorum is not met, and if there is still no sufficient number of people, the matter is automatically included in the agenda of the next ordinary public meeting. This adjustment enhances the decision-making flow outlined in the Regulations, ensuring continuity in the decision-making process.

[8] Available at: https://www.in.gov.br/web/dou/-/resolucao-da-diretoria-colegiada-anvisa-n-1.009-de-5-de-janeiro-de-2026-679340398

MAPA Issues Complementary Ordinance on Inspection and Agricultural Administrative Measures[9]

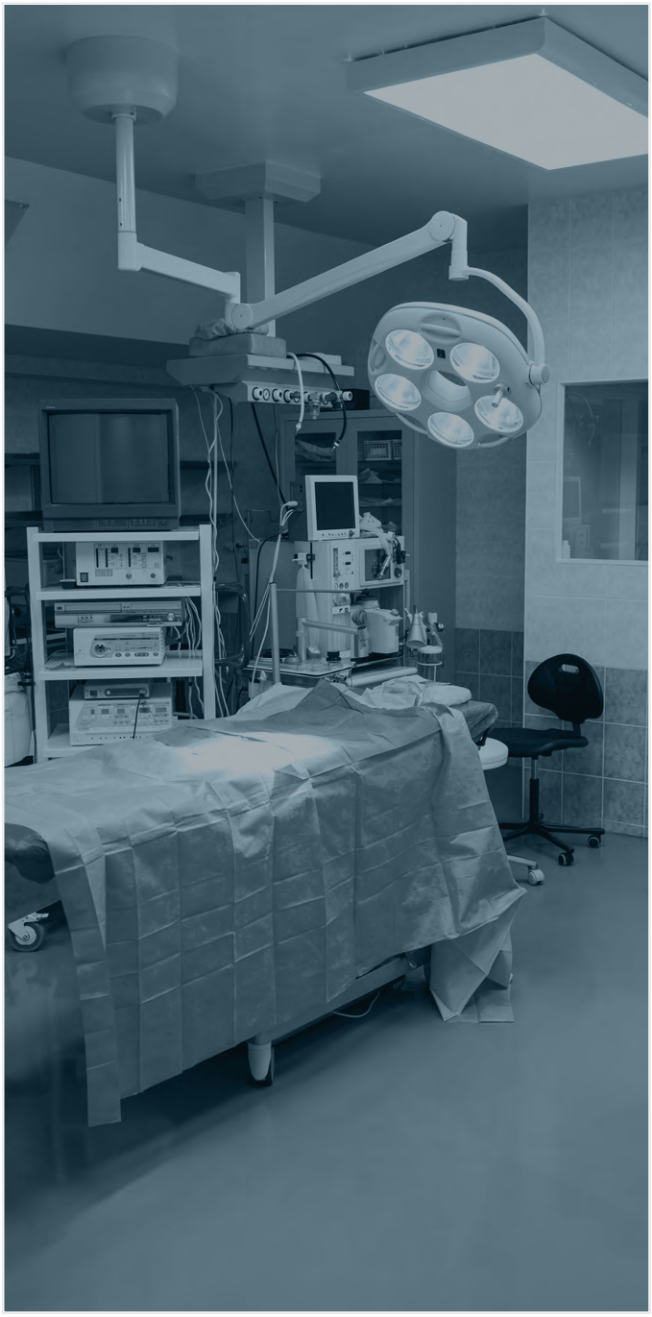
MAPA Ordinance No. 854, dated November 6, 2025, updates the penalty amounts provided for in the Exhibit of Law No. 14,515/2022 based on the accumulated variation of the INPC (Brazilian Consumer Price Index) for the period from January to December 2024, applying an index of 4.87%. The update covers all penalty ranges and economic sizes, including individuals, individual micro-entrepreneurs, microenterprises, small businesses, medium-sized companies, and other establishments.

The table attached to the ordinance presents the new minimum and maximum values applicable to offenses classified as minor, moderate, serious, and very serious, adjusting the amounts according to the infringing agent's size. These values will be observed by the competent authority according to the date of the administrative order, in accordance with Decree No. 12,502/2025.

The Ordinance took effect on the date it was published, i.e. January 2, 2026, and officially updates the sanctioning regime intended for activities subject to self-control within the Ministry of Agriculture and Livestock.

[9] Available at: https://in.gov.br/web/dou/-/portaria-mapa-n-854-de-6-de-novembro-de-2025-679031273

Update of the Manual for Regulating Medical Equipment and Software as a Medical Device[10]



Anvisa has made version 1.3 of the Manual for Regulating Medical Equipment and Software as Medical Device available. The document consolidates technical and procedural guidelines aimed at supporting manufacturers, importers, and other stakeholders in the regulatory process for these products with the Agency.

The manual covers risk classification criteria, documentary requirements, petitioning flows, and aspects related to regulatory evaluation. The update incorporates recent regulatory adjustments and answers recurring questions identified in the regulatory process.

The document does not replace the existing legislation but works as a support tool for regulatory compliance, assisting regulated agents in correctly supporting their processes.

This initiative contributes to greater transparency and predictability in the procedures for regulating medical equipment and software as a medical device.

[10] Available at: https://www.gov.br/anvisa/pt-br/centraisdeconteudo/publicacoes/produtos-para-a-saude/manuais/manual-regularizacao-gquip/view

Anvisa Releases Regulatory Agenda for the 2026–2027 Biennium[11] [12]

The Regulatory Agenda for 2026–2027, approved by Anvisa by means of Ordinance No. 1,484/2025, consolidates 161 priority topics distributed across several regulated segments, including medications, food, medical devices, cosmetics, healthcare services, ports and airports, sanitizers, agrochemicals, and cross-cutting issues. The document includes 97 topics migrated from the previous agenda, 26 topics for periodic updates, and 38 new subjects, many of which were suggested by the Agency's technical areas and by society during the public inquiry held from August to September 2025.

The Agenda's cross-cutting topics include issues impacting the entire regulatory scope, including rules for authorizing stock depletion of products subject to health surveillance, guidelines for sharing productive areas, a review of SVS/MS Ordinance No. 344/1998 on substances under special control, procedures for judging Sanitary Administrative Proceedings, regulations on Consent Decrees within the Agency, the definition of the regulatory sandbox model, criteria for classifying border products, and regulations on the cultivation of Cannabis sativa L. with THC content equal to or lower than 0.3%, as per the Superior Court of Justice's decision.

In the medicines sector, which contains the largest number of topics (38), the agenda includes reviewing safety and efficacy requirements, improving clinical trial rules, updating pharmacovigilance provisions, reviewing Good Manufacturing Practices for medicines and active pharmaceutical ingredients, enhancing regulations applicable to biologics and biosimilars, and specific rules for advanced therapy products still pending complete regulation. This group also covers topics associated with price and economic monitoring of the pharmaceutical market, aligned with CMED's tasks.

The food sector, comprising approximately 35 topics, addresses updates to nutritional labeling rules, regulations on additives, contaminants and residues, regulation of plant-based food, guidelines for dietary supplements, assessment of new ingredients, and updates to packaging and materials in contact with food, as well as adjustments resulting from international practices and sector innovations.

The medical devices field, with 14 priority topics, addresses updates on Good Manufacturing Practices, rules for software as a medical device, clinical and performance evaluation criteria, harmonization with

[11] Available at: https://www.gov.br/anvisa/pt-br/assuntos/regulamentacao/agenda-regulatoria/agenda-2026-2027

[12] Available at: https://www.gov.br/anvisa/pt-br/assuntos/regulamentacao/agenda-regulatoria/agenda-2026-2027/arquivos/portal_lista_final_ar_2026-2027.pdf

international IMDRF standards, and review of standards applicable to implantable technologies and traceability systems.

Issues related to cosmetics and sanitizers involve requirements for the regulation of products used in aesthetic procedures with dermal action, review of lists of permitted or restricted substances, Good Manufacturing Practices, and accessibility guidelines for information on packaging, specifically aimed at individuals with visual impairments.

As regards agrochemicals and agricultural inputs, the agenda includes topics related to the toxicological reevaluation of active ingredients, maximum residue limits, toxicological classification, and updated criteria for the registration and post-registration of these products, in alignment with contemporary scientific and regulatory demands.

In the health services sector, topics encompass the review of requirements applicable to vaccination services, dialysis units, hemodynamics, and other healthcare structures, as well as standards focused on sanitary surveillance and monitoring of services and food services associated with health.

Finally, the ports, airports, and border segment covers the review of rules applicable to health control of travelers, procedures for the import and export of products subject to health surveillance, and standards for monitoring cargo, passengers, and entry points, aiming to strengthen sanitary protection in border operations.

The Regulatory Agenda for 2026–2027 serves as a planning and transparency tool by organizing topics by area and establishing priorities, guiding the regulatory processes that will be conducted by Anvisa throughout these two years.

Partner responsible for the newsletter

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