



# Life Sciences and Healthcare


## Newsletter

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This is an informative newsletter  
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## New Resolution establishes the Internal Regulations of the National Instance for Ethics in Research

On April 6, 2026, Resolution No. 1 of the Collegiate of the National Instance for Ethics in Research (Inaep in Portuguese) was published, establishing its provisional Internal Regulations. The resolution was enacted in the context of Law No. 14,874/2024 and Decree No. 12,651/2025, which govern research involving human beings in Brazil.

The Internal Regulations outline the organization and operational rules of Inaep, including its composition, duties, responsibilities of the Coordination, Executive Secretariat, and members of the collegiate, as well as procedures for the distribution of matters, reports, meetings, in-person or electronic decisions, and the publication of acts.

The duties assigned to Inaep include the issuance of norms on ethics in research involving human beings, the accreditation, certification, and supervision of Research Ethics Committees (RECs), the evaluation of the effectiveness of the National System of Ethics in Research with Human Beings, and the analysis of appeals against decisions issued by the RECs.

The Resolution also regulates instruments for social participation and technical instruction, such as public consultations, public hearings, public calls for inputs, technical notes,

opinions, normative instructions, and resolutions. Furthermore, it provides that decisions contained in the opinions of the RECs may be subject to appeal to Inaep, as a second and final instance, within 30 working days.

The Internal Regulations are provisional and must be reviewed within 60 days from the appointment of the expert members provided for in Decree No. 12,651/2025.

The Resolution took effect on the date it was published.



## Anvisa announces preliminary analysis for regulatory Sandbox of customized cosmetics

On April 22, 2026, Anvisa (National Health Surveillance Agency) released the results of the preliminary stage of selection for the pilot project of the Experimental Regulatory Environment, known as the regulatory Sandbox, aimed at personal care products, cosmetics, and customized perfumes.

In total, four projects were deemed eligible to move to the next phase of the selection process after meeting the eligibility criteria outlined in the notice published in October 2025.

The initiative aims to allow, in a controlled environment and under the Agency's regulatory supervision, the testing of new business models and technologies related to the customization of cosmetics directly at points of sale, according to consumer demand and profiles.

Upon conclusion of the preliminary stage, eligible candidates will enter the phase of detailed technical analysis of the proposals, during which they must present technical documentation regarding the submitted projects.

The proposals will be evaluated by a working group responsible for the regulatory Sandbox, and meetings with the participants may be held for clarifications and possible adjustments.

The projects selected after this phase will have individualized protocols for experimental regulatory flexibility, which must define the conditions for operation, temporarily relaxed rules, scope of activities, deadlines, monitoring requirements, and risk mitigation measures.

At the end of the process, approved companies may receive temporary authorization from Anvisa's Collegiate Board to implement the proposed business models, under the conditions established in the respective protocols.



## New ordinance from MAPA restricts the use of antimicrobials in animals

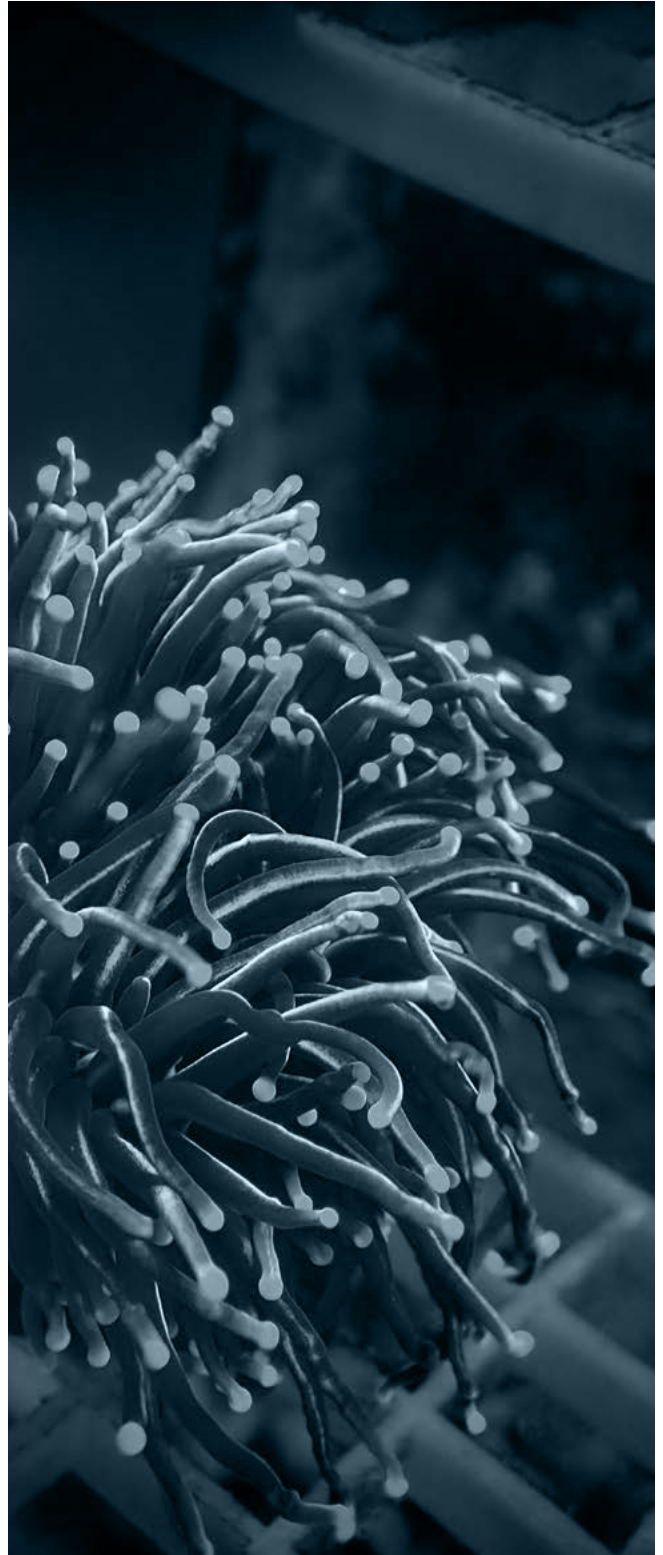
On April 14, 2026, Ordinance No. 1,600/2026 from the Department of Inspection (SDA) of the Ministry of Agriculture, Livestock and Supply (MAPA) was published, prohibiting the registration, import, and use of products containing active pharmaceutical ingredients classified as antimicrobials reserved for human use, according to the classification of the World Health Organization (WHO), in animal species used for human consumption.

The regulation establishes that the prohibition applies to the antimicrobials listed in its Annex, including classes such as carbapenems, glycopeptides, lipopeptides, monobactams, oxazolidinones, and medications used exclusively for the treatment of tuberculosis or other mycobacterial diseases, among others.

The ordinance also stipulates that the off-label prescription of critically important antimicrobials of highest priority must be limited to situations in which no alternatives are available, supported by a technical justification from the prescribing veterinarian.

Furthermore, MAPA must publish and keep updated the list of classification of antimicrobials on its website.

The ordinance took effect on the date it was published.



## Anvisa establishes Technical Chamber of Cosmetovigilance

On April 17, 2026, Anvisa announced the establishment of the Technical Chamber of Cosmetovigilance (CTEC), created by Ordinance No. 471/2026. The new structure is linked to the General Management for Monitoring of Products Subject to Sanitary Surveillance (GGMON) and has an advisory nature.

CTEC's purpose is to provide technical advice to Anvisa on issues related to the post-market monitoring of personal care products, cosmetics, and perfumes.

Its responsibilities include the analysis and evaluation of safety signals, the proposal of regulatory and preventive measures, the development of methodologies and technical criteria applied to cosmetovigilance, and the qualification of data obtained from notification systems and other sources of information.

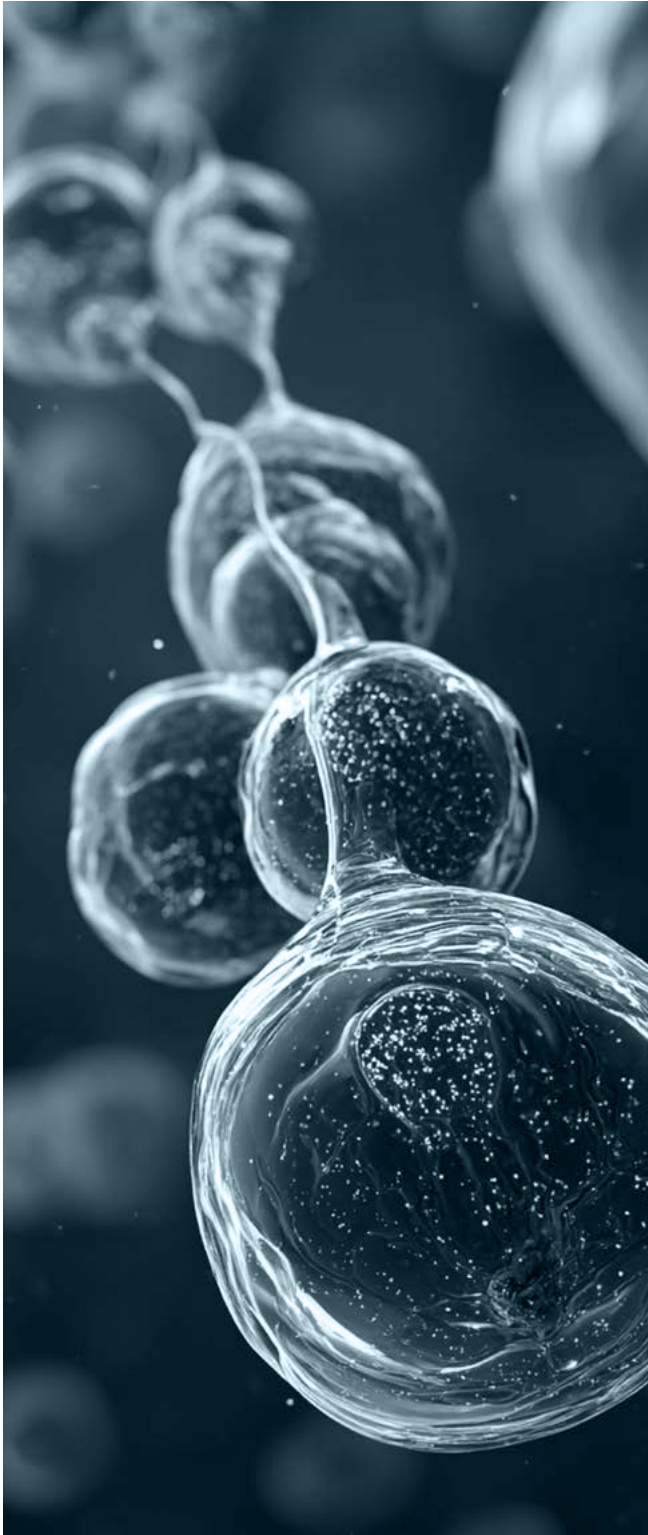
The Chamber will consist of five full members and five substitutes, affiliated with higher education and research institutions from different regions of the country, in addition to representatives from the Health Surveillance and Environment Department of the Ministry of Health.

The terms will last up to three years, with the possibility of reappointment, and ordinary meetings will occur every six months, without prejudice to extraordinary meetings when necessary.

The creation of CTEC takes place in the context of Collegiate Board Resolution (RDC) No. 894/2024, which addresses Good Practices for Cosmetovigilance and establishes requirements for the operation of safety monitoring systems by companies holding cosmetic products.



## Anvisa and professional councils establish partnership on GLP-1 agonists



On April 15, Anvisa announced the signing of a letter of intent with the Federal Council of Medicine (CFM), the Federal Council of Dentistry (CFO), and the Federal Council of Pharmacy (CFF), aimed at promoting the rational and safe use of glucagon-like peptide-1 (GLP-1) receptors in Brazil.

The initiative encompasses medications commonly known as “weight loss injections” and seeks to strengthen the combined actions of the Agency and professional councils, focusing on information exchange, technical alignment, and educational actions directed at healthcare professionals and the public.

The planned actions include encouraging responsible prescribing, strengthening adverse event reporting, and explaining health risks associated with irregular products and practices, including situations related to the import, manipulation, prescription, and dispensing of these medications.

The partnership is part of the action plan announced by Anvisa on April 6, 2026, to address irregularities involving injectable GLP-1 agonist medications. According to the Agency, the plan encompasses areas aimed at regulatory improvement, monitoring and enforcement, institutional coordination, and communication with society.

## CFN approves updates on the Nutrition Code of Ethics

On April 28, 2026, Resolution CFN No. 856/2026 was published, approving the new Code of Ethics and Conduct for Nutritionists. The regulation was issued by the Federal Council of Nutrition (CFN) based on Law No. 6,583/1978, Decree No. 84,444/1980, and Law No. 8,234/1991, considering the need to update the ethical principles and conduct applicable to the professional practice of the category.

The new Code outlines fundamental principles, professional responsibilities, rights, duties, and prohibitions applicable to nutritionists' activities. Key topics addressed include the duty of scientific and technical justification for professional conduct, the need to provide adequate information to patients, adherence to informed consent, and the protection of confidentiality, privacy, and security of personal and sensitive data obtained during professional practice.

The Resolution also includes specific provisions regarding the use of technologies in professional practice. The text allows the use of technological tools and automated systems to support nutritionists' work, provided this is

done ethically, responsibly, transparently, and based on scientific evidence. Furthermore, the regulation establishes that the use of artificial intelligence cannot replace direct interaction, technical analysis, or the professional autonomy of nutritionists.

Another point discussed in the Code is professional practice in face-to-face settings, telehealth for nutrition, and social media. The regulation outlines rules for sharing technical information, professional advertising, communication of prices and fees, association with products, brands, services, companies, or industries, as well as the reporting of conflicts of interest in specific situations.

The Code also addresses professional training activities, research, and technical-scientific production, including rules for supervising internships, preceptorship, publication of studies, statement on the use of artificial intelligence or automation, and identification of potential conflicts of interest. The Resolution revokes CFN Resolution No. 599/2018 and will come into effect 90 days after it is published in the Federal Register.



## ANS initiates process for regulation of discount cards

On April 29, 2026, Ordinance PRESI No. 8/2026 was published, establishing an Internal Committee within ANS (Brazil's National Supplementary Health Agency) to analyze discount cards, prepaid services, and related services in the healthcare sector.

This initiative follows a decision by the Superior Court of Justice (STJ) at the end of 2025, which recognized ANS's authority to regulate and supervise discount cards in health services.

The Committee will have 90 days, extendable for an equal period, to examine technical, healthcare, legal, economic, social, and regulatory aspects related to the topic. The Committee will be formed by representatives from the boards of the Agency and ANS Presidency.

The points to be evaluated include the operational and economic models used in the market, the legal nature of the offering companies, methods of access to services, mediation with networks of providers, and the informational and assistance-related impacts on users.

The Ordinance also provides for guidelines for possible regulation, including restrictions on the use of names, brands, advertising, or visual identity that may mislead consumers into confusing them with health plans. The need for operational segregation is also expected between companies offering discount cards or related services and health plan operators belonging to the same economic group.

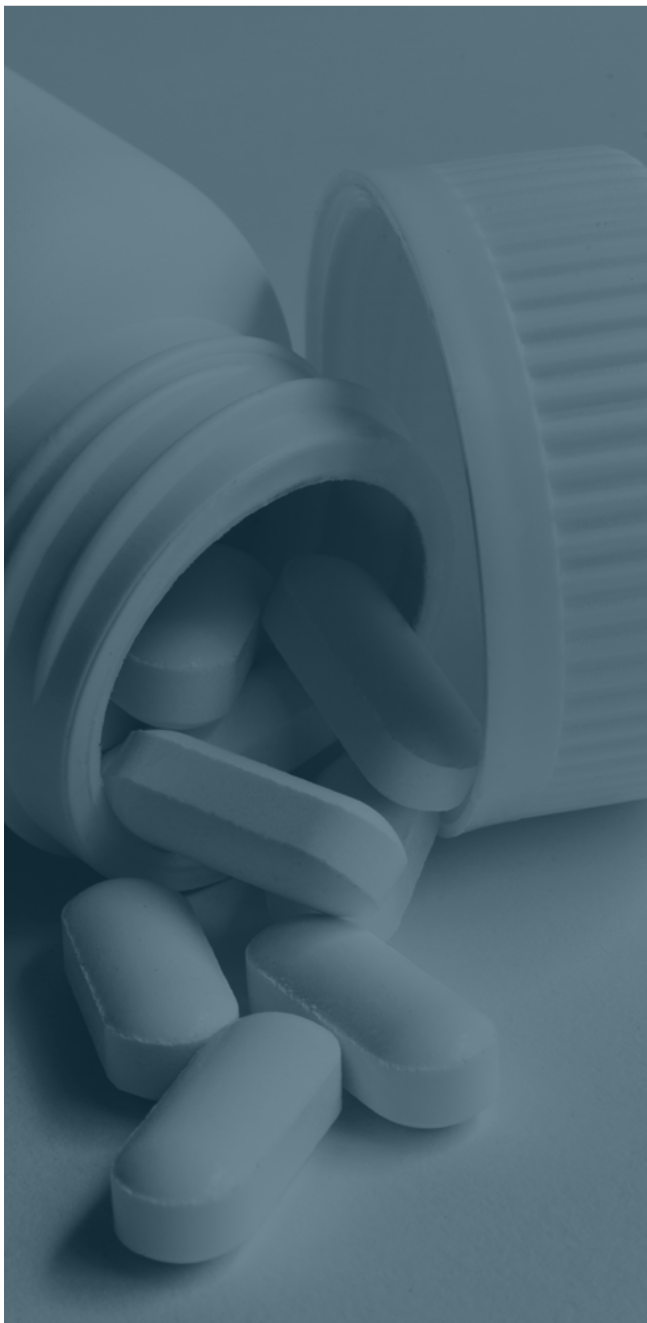
## CMED extends the validity of regulation on drug pricing

On April 29, 2026, Resolution CM/CMED No. 6/2026 was published, extending the effective date of Resolution CM-CMED No. 3/2025, which establishes criteria for defining prices of new products and new presentations of medications.

Resolution CM-CMED No. 3/2025 was republished on December 30, 2025, addressing the update of the drug pricing model in Brazil, including rules on product classification, presentation of the Drug Price Information Document (DIP), international comparison criteria, therapeutic gain analysis, and definition of the Factory Price.

With the new amendment, the *vacatio legis* period for Resolution CM-CMED No. 3/2025 has been extended from 120 to 150 days from its publication. In practice, the regulation's effective date, initially set for April 29, 2026, has been postponed to May 29, 2026.

The extension delays the implementation of the new pricing rules, including criteria applicable to new products, new presentations, medications with incremental innovation, biologicals, generic drugs, and cases of provisional pricing.



## Anvisa approves new regulatory proposals during the 7th Public Ordinary Meeting

On May 6, 2026, the Collegiate Board of Anvisa held the 7<sup>th</sup> Public Ordinary Meeting of 2026, during which it approved regulatory proposals related to procedures for analysis of medicines, biological products, vaccines, active pharmaceutical ingredients, and pesticides.

The approved items include the amendment of Normative Instruction No. 289/2024, which addresses the optimized analysis procedure based on the use of assessments conducted by an Equivalent Foreign Regulatory Authority (AREE), a mechanism known as reliance. The proposal aims to adjust the criteria applicable to registration and post-registration petitions, as well as to provide greater predictability to documentation instructions and analysis flows by the Agency.

A proposal to amend RDC No. 997/2025 was also approved, establishing exceptional and temporary measures for optimizing the

analysis queue for approval in clinical research and for registration and post-registration applications for medicines and biological products. The amendment reduces the deadline for meeting requirements set by Anvisa in the processes covered by the regulation to 60 days.

The Collegiate Board also approved a proposal for Normative Instruction to amend IN No. 103/2021, which provides for the list of active ingredients of pesticides, disinfectant sanitizers, and wood preservatives. The update includes the monograph of the active ingredient I35, corresponding to Icafolin-methyl.

The proposals were unanimously approved by the Collegiate Board. The approved changes must comply with the respective final regulatory acts and their effectiveness rules after official publication.





## Partner responsible for the newsletter

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