

WEEKLY REPORT



11/08/2025

ANVISA APPROVES EXCEPTIONAL MEASURES TO REDUCE BACKLOG IN DRUG AND CLINICAL TRIAL ANALYSES

The Brazilian Health Regulatory Agency (Anvisa) approved, by unanimous vote, a resolution establishing exceptional and temporary measures to accelerate the review of drug registrations, post-registration changes, and clinical trial authorizations. Proposed by Director Daniel Pereira, the regulation aims to cut the agency's backlog and improve efficiency "without compromising technical rigor," according to the rapporteur. The resolution creates a 15-day window for companies to withdraw outdated applications and replace them with new ones of the same priority category, maintaining their place in the queue. This replacement mechanism is expected to reduce inactive petitions by up to 15%. Anvisa will publish a transparent report listing all substitutions made, ensuring fairness and traceability. It also establishes a dedicated queue for applications already approved by trusted foreign authorities, such as the U.S. FDA and European Medicines Agency (EMA), under the reliance principle. This change could shorten total review times by up to 45%, according to Anvisa's director. The rule further allows the use of Evaluation Management Plans (PGAs) to assess similar dossiers simultaneously (an approach projected to boost technical productivity by 20% and reduce review times by nearly two years, based on pilot programs with radiopharmaceuticals and biologics). The regulation will remain in force until December 2026, and Anvisa must present a Regulatory Results Report by January 2027 measuring its impact. Director-President Leandro Safatle said the measure "is part of a broader strategy to modernize processes, expand staff, and integrate artificial intelligence systems," citing the Anvisa AI project, with an investment of R\$ 25 million. [Read more.](#)

BRAZIL PHARMACEUTICAL SECTOR VOICES SUPPORT AND CAUTION ON ANVISA'S NEW MEASURES

Representatives from leading pharmaceutical associations expressed support and caution during the Anvisa Collegiate Board meeting, on Friday (7), that approved a resolution establishing exceptional and temporary measures to reduce the agency's backlog. The sector praised the initiative as a necessary response to a long-standing problem but called for transparency, technical rigor, and balance in its implementation. Renato Porto, president of Interfarma, warned that the effort to reduce the queue should not "create sanitary or competitive distortions" and urged that decisions be based on objective, risk-based technical criteria. Porto also defended equal treatment for all product categories, cautioning that excessive prioritizations could harm predictability and fairness. Reginaldo Arcuri, president of Grupo FarmaBrasil, described the current backlog as "the main challenge faced by Brazil's pharmaceutical industry," estimating that pending dossiers represent around R\$ 23 billion in products awaiting approval. Representing Sindusfarma, Nelson Mussolini acknowledged the agency's proactive stance but raised concerns about transparency and legal certainty. He warned that the mechanism allowing substitution or reordering of applications must be applied with strict oversight to prevent unequal treatment and preserve fair competition. Mussolini called on Anvisa to ensure that "exceptional measures remain exceptional," to avoid undermining credibility or generating judicial disputes. Tiago de Moraes Vicente, from PróGenéricos, endorsed the new resolution, calling it "a balanced and responsible response to a complex regulatory scenario." He stressed that the initiative does not relax sanitary standards but rather modernizes management to "restore predictability and ensure timely access to innovation." [Read more.](#)

BRAZIL ANVISA JOINS EXECUTIVE COMMITTEE OF THE PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME (PIC/S)

The Brazilian Health Regulatory Agency (Anvisa) was elected to the Executive Committee of the Pharmaceutical Inspection Co-operation Scheme (PIC/S), joining 56 other regulatory authorities that collaborate to harmonize international standards for good manufacturing practices (GMP). The election took place during the 2025 annual meeting in Kuala Lumpur, marking an important milestone for Brazil's participation in the global regulatory network. According to Anvisa, the new position will allow Brazil to contribute more actively to the development of international inspection guidelines and training programs. Director Daniela Marreco Cerqueira emphasized that the appointment "strengthens Brazil's voice in international regulatory convergence" and reflects the agency's progress in inspection quality and transparency. [Read more.](#)

BRAZIL SUPREME COURT SCHEDULES HEARINGS ON DRUG PRICING AND NATIONAL HEALTH PLATFORM

The Supreme Federal Court (STF) will hold two public hearings, convened by Justice Gilmar Mendes, to monitor the implementation of rulings related to Theme 1,234, which concerns the supply of medicines registered by Anvisa but not standardized within the Unified Health System (SUS). The first hearing, set for November 10, 2025, will discuss drug pricing procedures managed by Anvisa and the Drug Market Regulation Chamber (CMED). Among the invited speakers are Ludhmila Abrahão Hajjar, Congressman Dr. Luizinho, Denizar Vianna, Marcos Pinto (Ministry of Finance), Daniel Wei Liang Wang, Anvisa President Leandro Safatle, CMED Executive Secretary Mateus Amâncio, and Fernanda De Negri (Ministry of Health). The second hearing, scheduled for December 1, 2025, will address the development of Brazil's national health platform, aimed at integrating data on medicine dispensing across the SUS network. [Read more.](#)

BRAZIL STUDIES NEW PROCUREMENT MODELS FOR HIGH-COST MEDICINES

The Brazilian government is studying new models to improve the procurement and financing of high-cost medicines within the Unified Health System (SUS). According to the Ministry of Health, the initiative seeks to make access to innovative treatments more sustainable by linking payment to treatment outcomes and establishing long-term supply contracts. Among the proposed mechanisms are performance-based agreements, volume guarantees, and shared-risk contracts with manufacturers. Technical teams from the Secretariat of Science, Technology, and Strategic Inputs (SCTIE) and Conitec are also analyzing international experiences from countries such as Italy and Canada. The ministry highlighted that the new procurement models are expected to be tested in pilot projects beginning in 2026, focusing on rare and oncology diseases. [Read more.](#)

BRAZIL PUBLISHES POLICY TO STRENGTHEN EVIDENCE-BASED HEALTH DECISIONS

The Ministry of Health has published a new policy aimed at strengthening evidence-based decision-making in the Brazilian public health system. The initiative establishes principles and guidelines to ensure that public policies and health-technology assessments incorporate the best available scientific evidence. It reinforces transparency in decision-making and promotes collaboration between technical bodies such as Conitec, Anvisa, and the National Supplementary Health Agency (ANS). According to the ministry, the policy also includes capacity-building programs for managers and technical staff to improve the interpretation and application of scientific data in policy formulation. [Read more.](#)

BRAZIL HOUSE PASSES TAX EXEMPTION FOR DONATION OF MEDICINES; BILL HEADS TO PRESIDENTIAL APPROVAL

The House of Representatives passed Bill 4719/2020, which establishes a federal tax exemption on donations of medicines destined for public administration bodies and entities recognized as being of public utility. Authored by former Congressman General Peternelli, the proposal defines

as public-utility entities certified as beneficent under Complementary Law No. 187/2021, as well as social organizations and civil-society entities covered by existing federal laws. The exemption applies to three federal taxes: PIS/Pasep, Cofins, and IPI, covering donations to the Union, states, municipalities, and charitable institutions. The measure aims to encourage pharmaceutical companies to donate medicines to the public health network and philanthropic hospitals. The bill now awaits presidential approval. [Read more.](#)

BRAZIL YET TO REGULATE CIVIL SOCIETY REPRESENTATION IN CONITEC'S DECISION-MAKING BODY

Although a recent law guarantees a voting seat for a civil-society or patient representative on the National Commission for the Incorporation of Technologies in the Unified Health System (Conitec), the measure still awaits formal regulation by the Ministry of Health. The forthcoming decree will define how the representative will be selected, the term of office, and conflict-of-interest safeguards. Under the law, only organizations with at least two years of formal existence and proven activity related to the health condition under evaluation will be eligible. Patient associations have expressed concern about the delay, noting that inclusion of civil-society voices is key to making the technology assessment process more transparent and participatory. [Read more.](#)

BRAZIL ASSOCIATIONS DISCUSS STRATEGIES TO COMBAT MEDICINE COUNTERFEITING

Brazilian pharmaceutical associations, including Interfarma, Sindusfarma, PróGenéricos, and Grupo FarmaBrasil, met in São Paulo to discuss joint actions to combat the rise of counterfeit and illegal medicines in the country. The meeting focused on expanding cooperation with the Brazilian Health Regulatory Agency (Anvisa) and law enforcement authorities, as well as improving public awareness and traceability mechanisms. According to participants, the rapid growth of online drug sales and the use of social media platforms for illegal distribution pose increasing risks to patient safety. The sector defends stricter penalties for counterfeiters, greater inspection of e-commerce platforms, and investments in digital verification technologies. [Read more.](#)

BRAZIL PHARMACEUTICAL INDUSTRY RAMPS UP INVESTMENT IN INNOVATION

Brazil's pharmaceutical industry is accelerating investments in research, development, and digital transformation, signaling renewed confidence in the country's regulatory and economic environment. According to industry representatives, companies are prioritizing areas such as gene therapy, artificial intelligence in clinical trials, and digital health technologies. Data from the Brazilian Pharmaceutical Industry Association (Sindusfarma) show that R&D spending grew by 18% in the first half of 2025 compared to the same period in 2024. Executives highlighted that recent regulatory improvements, including Anvisa's reliance mechanisms and faster approval pathways, are key to fostering innovation and international competitiveness. [Read more.](#)

BRAZIL GENE THERAPY GAINS GROUND WITH STUDIES ON SICKLE CELL DISEASE AND MPS

Gene therapy is gaining momentum in Brazil, with new clinical studies focusing on sickle cell disease and mucopolysaccharidosis (MPS). Researchers from Fiocruz, USP, and private biotech companies are advancing preclinical and early-phase trials using viral vectors to correct defective genes responsible for the diseases. According to Anvisa, Brazil currently has eight ongoing studies involving gene therapy, with more expected to be submitted in 2026. Experts believe these advances could place Brazil among the regional leaders in advanced therapies. The government's recent investments in national biomanufacturing and the creation of regulatory fast-track pathways have also supported the sector's expansion. [Read more.](#)

BRAZIL OFFICE OF THE COMPTROLLER GENERAL ESTIMATES SUS LOST R\$ 7.3 BILLION IN VACCINES AND SUPPLIES FROM 2021–2023

The Office of the Comptroller General (CGU) reported that the Ministry of Health may have incurred losses of approximately R\$ 7.3 billion between 2021 and 2023 in the purchase and distribution of vaccines and medical supplies for the Unified Health System (SUS). The CGU's audit identified failures in inventory control, purchasing schedules, and logistics management. According to the report, part of the losses resulted from expired or unused vaccines, delayed deliveries, and inefficient allocation of health inputs, revealing weaknesses in monitoring and coordination within the national immunization and supply networks. The Ministry of Health stated that it is implementing new digital tracking systems and updated inventory protocols to address the shortcomings identified. [Read more](#).

BRAZIL COURT CONFIRMS ANS OVERSIGHT OF HEALTH-DISCOUNT CARDS

The Brazilian Federal Regional Court of the 1st Region (TRF-1) upheld the authority of the National Supplementary Health Agency (ANS) to regulate and oversee the operation of health-discount cards in the country. The decision reinforces the agency's role in ensuring consumer protection and service transparency in products that, although not health plans, offer medical and dental discounts. According to the court, the ANS has the power to act when these products create confusion for consumers or operate similarly to regulated health plans. The ruling was celebrated by consumer-rights advocates, who argue that stronger supervision is necessary to prevent abusive practices and misleading marketing in the sector. [Read more](#).

BRAZIL PUBLIC PROSECUTORS OFFICE RECOMMENDS CHANGES TO HEALTH INSURANCE PLAN PRICING POLICY

The Federal Public Prosecutor's Office (MPF) issued a recommendation to the National Supplementary Health Agency (ANS) suggesting changes to the rules governing the pricing of private health insurance plans. The MPF argues that the current adjustment model disproportionately affects older consumers and lacks sufficient transparency regarding cost-composition criteria. The recommendation proposes that the ANS review actuarial parameters, enhance communication with policyholders, and establish clearer criteria for annual adjustments. According to the MPF, the goal is to ensure a balance between financial sustainability for operators and affordability for users. The ANS stated it will analyze the proposal before any regulatory revision. [Read more](#).

BRAZIL STATES DEFINE STRATEGIC PRIORITIES FOR HEALTH CARE IN 2026

State health secretariats gathered in Brasília under the Chamber of Technical Care of the National Council of Health Secretaries (CTAS/Conass) to outline priorities for 2026. The discussions included topics such as cancer prevention, health system regulation, urgent and emergency networks, and chronic kidney therapy. The meeting also addressed proposals to improve coordination between states and the Ministry of Health, focusing on strengthening regional care networks. Representatives from the ministry presented updates on national policies and ongoing programs to improve access and efficiency in the Unified Health System (SUS). [Read more](#).

MORE HIGHLIGHTS

[Bill proposes creation of the National Registry of Rare Diseases](#)

[Brazil STJ extends deadline for medicinal cannabis regulation](#)

[Ministry of Health may present budget planning details for 2026, with focus on projected spending on court-ordered medicines](#)

[Hearing to debate bill creating the Regulatory Framework for Vaccines and High-Cost Cancer Medicines in Brazil](#)

BRAZIL NEWS

[Brazil top-court panel unanimously rejects Bolsonaro's prison sentence appeal](#)

[Brazil's Lula says he will call Trump again if negotiations do not progress soon](#)

[US sold sniper rifles to Brazil police unit tied to deadly raid](#)

[Brazil's deadliest police raid puts Lula in a political bind](#)

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