

WEEKLY REPORT



11/01/2025

BRAZIL'S CMED HEAD SAYS NEW DRUG PRICING RULES ARE MODERN AND WILL SUPPORT INNOVATION

The new Executive Secretary of the Drug Market Regulation Chamber (CMED), Mateus Amâncio, stated that the forthcoming drug pricing resolution is "modern, balanced, and not a barrier to innovation." The proposal, which received more than 1,400 contributions during public consultation, aims to replace rules in place since 2004 and adapt the regulatory framework to Brazil's current pharmaceutical and biotechnology market. Amâncio explained that the new text maintains CMED's role in controlling medicine prices but incorporates technical and transparent criteria for evaluating innovative and high-cost products. The resolution seeks to increase predictability for the industry while ensuring equitable access for patients and fiscal sustainability for the Unified Health System (SUS). He underscored that his administration will prioritize data-based regulation and continuous dialogue with all stakeholders, including the pharmaceutical industry, patient groups, and government bodies. Amâncio noted that CMED's goal is to foster a regulatory environment that encourages innovation without compromising affordability. [Read more.](#)

BRAZILIAN PHARMA PROJECTS 11.5% GROWTH AMID REGULATORY AND TAX HURDLES

Brazil's pharmaceutical industry projects an 11.5% expansion for 2025, driven by demographic growth, the increasing prevalence of chronic diseases, and continued investments in research and production capacity. Despite this positive outlook, the sector faces ongoing challenges related to regulatory bottlenecks and uncertainty surrounding the country's tax reform. According to the Brazilian Pharmaceutical Industry Association (Sindusfarma), regulatory efficiency and predictable pricing policies remain essential for sustaining innovation and competitiveness. The industry also calls for faster decision-making by Anvisa and greater alignment between pricing, incorporation, and reimbursement policies to ensure patient access and encourage long-term investment. [Read more.](#)

BRAZIL STUDY EVALUATES DIGITAL ENGAGEMENT OF PHARMACEUTICAL INDUSTRY

A new study conducted by Interfarma analyzed how pharmaceutical companies in Brazil use digital platforms to engage with health professionals, patients, and policymakers. The research found that most companies maintain an institutional presence on social networks, but few adopt strategies that promote dialogue, education, and scientific dissemination. The report highlights that only 20% of the evaluated companies use digital channels to provide reliable and accessible health information to the public. Interfarma emphasized the need for clear ethical and regulatory parameters for digital communication in the health sector, as well as capacity-building initiatives to strengthen compliance with advertising and transparency standards. [Read more.](#)

BRAZIL SEES 7% DROP IN PUBLIC-HEALTH JUDICIALIZATION BUT SLIGHT RISE IN HEALTH-PLAN LAWSUITS

New data from the National Justice Council (CNJ) indicate a 7% decrease in lawsuits against the Unified Health System (SUS) in 2024, while actions involving private health plans rose slightly. Analysts credit the drop in public-sector cases to expanded access policies and negotiation platforms, but stress persistent regional disparities. According to the report, states

such as São Paulo and Minas Gerais recorded the sharpest declines, while northern regions still face difficulties in implementing mediation structures. The CNJ highlighted that the creation of technical support centers in the judiciary has reduced repetitive litigation and improved the qualification of health-related decisions. [Read more](#).

BRAZIL'S MINISTER ANNOUNCES SUPPORT FOR HEMOPHILIA DRUG BEFORE CONITEC DECISION

Health Minister Nísia Trindade announced institutional support for a hemophilia treatment still under evaluation by the National Commission for the Incorporation of Technologies in the Unified Health System (Conitec). The statement, made before the commission's final recommendation, reinforces the ministry's alignment with patient groups advocating for wider access to rare-disease treatments. The medicine under review has shown significant results in clinical practice abroad. Patient associations have called for faster regulatory and reimbursement decisions, emphasizing the impact of treatment delays on quality of life. [Read more](#).

BRAZIL UPDATES PATIENT-PERSPECTIVE CRITERIA FOR HEALTH-TECHNOLOGY ASSESSMENTS IN THE SUS

The Ministry of Health published new guidelines reinforcing patient-experience and quality-of-life indicators in health-technology assessment (HTA) processes. The changes, applicable to submissions to Conitec, aim to improve evidence integration and make evaluations more inclusive of social and individual outcomes. The update details how patient organizations can contribute with structured evidence on lived experiences, treatment adherence, and impact on daily activities. The ministry also announced new training initiatives for civil society groups interested in participating in HTA processes. [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 the conflict-of-interest safeguards applicable to this new position. 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 and advocacy groups have expressed concern about the delay in implementing the rule. [Read more](#).

BRAZIL'S FIOCRUZ TO PAY R\$ 23 MILLION TO TERMINATE CONTRACT FOR NEW VACCINE FACTORY

The Oswaldo Cruz Foundation (Fiocruz) will pay R\$ 23 million to terminate a contract for the construction of a new vaccine production facility after technical and financial disputes with suppliers. The project, part of Brazil's effort to expand national manufacturing capacity, is expected to be redesigned under a new public-private partnership. Fiocruz stated that the decision to terminate the contract was based on financial efficiency and legal compliance criteria, with the aim of avoiding additional expenses. The foundation reaffirmed its commitment to strengthening domestic production of immunobiologicals to meet growing demand in the country. [Read more](#).

BRAZIL'S ANVISA TO EXPAND RELIANCE MODEL WITH NEW INTERNATIONAL REGULATORY PARTNERS

The Brazilian Health Regulatory Agency (Anvisa) plans to broaden its international reliance framework, allowing faster evaluation of products already assessed by reference authorities. The initiative will include new bilateral agreements with agencies in Europe and Asia, aiming to shorten timelines and promote convergence of standards. According to Anvisa, the expansion will prioritize products in strategic areas such as advanced therapies and vaccines. The measure

aligns with Brazil's broader goal of strengthening regulatory cooperation and positioning itself as a reference in Latin America for health product evaluation. [Read more.](#)

BRAZIL'S ANVISA UPDATES STATUS OF GENE THERAPY FOR DUCHENNE MUSCULAR DYSTROPHY

The Brazilian Health Regulatory Agency (Anvisa) released an update on the evaluation of a gene therapy for Duchenne muscular dystrophy, confirming that additional data have been requested from the manufacturer. The agency emphasized its commitment to balancing scientific rigor with timely access to innovative treatments for rare diseases. The therapy, already approved in other markets, is under technical review within Anvisa's Third Directorate, responsible for medicines and biological products. [Read more.](#)

BRAZIL'S ANVISA STEPS UP RESPONSE TO COUNTERFEIT SEMAGLUTIDE AND UNREGISTERED ANABOLIC DRUGS

The Brazilian Health Regulatory Agency (Anvisa) announced intensified inspection and enforcement actions against counterfeit semaglutide products and unregistered anabolic steroids circulating in the market. According to the agency, the coordinated operation involves federal police, health departments, and laboratories, aiming to trace distribution chains and prevent illegal sales. Anvisa also reinforced alerts to consumers and professionals to check packaging authenticity and report suspicious products. [Read more.](#)

BRAZIL'S HYPERA TO LAUNCH OWN-BRAND INJECTABLE PEN, AVOIDING GENERIC SEGMENT

Hypera Pharma will introduce an injectable pen under its own brand, bypassing the generic market segment. The company expects the product to strengthen its presence in diabetes care and self-administration technologies. The launch, part of Hypera's strategy to focus on innovation and branding, follows a broader movement in the Brazilian pharmaceutical industry to invest in devices that combine practicality, technology, and adherence for patients. [Read more.](#)

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BRAZIL STUDY SHOWS LATE BREAST-CANCER DIAGNOSIS TRIPLES TREATMENT COSTS

A new analysis by Brazilian researchers found that breast-cancer treatment costs triple when the disease is diagnosed in advanced stages. The study underscores the importance of timely screening programs and equitable access to diagnostic services across regions. Researchers from the Oncoguia Institute and partner universities highlighted that late diagnosis leads to more aggressive treatment, longer hospital stays, and lower survival rates. The findings reinforce the economic and public-health benefits of investing in early detection policies and continuous awareness campaigns. [Read more.](#)

BRAZIL STUDY SHOWS R\$ 3 MILLION THERAPY MAY BE MORE EFFICIENT AND COST-EFFECTIVE IN CANCER CARE

A new Brazilian study evaluated the lifetime costs and outcomes of an advanced cancer therapy priced at around R\$ 3 million per patient. Researchers found that when the treatment is used earlier in the disease course, rather than as a last-resort option, it may lead to better survival outcomes and lower cost per life-year gained compared to traditional care. The analysis indicated that earlier intervention significantly reduces downstream expenses such as hospital admissions, intensive-care use, and complications related to late-stage cancer. According to the study, this approach could transform high-cost therapies from being viewed solely as expensive options into economically sustainable innovations within the public-health system. [Read more.](#)

BRAZIL'S HOUSE OF REPRESENTATIVES DEBATES CREATION OF ASSISTED-THERAPY CENTERS IN THE SUS

Lawmakers in the House of Representatives are discussing a bill to establish assisted-therapy centers within Brazil's public health system. The proposal aims to expand rehabilitation and psychological support services for patients with chronic and developmental conditions. If approved, the policy would strengthen access to multidisciplinary care across regions, benefiting children, adults, and the elderly who depend on continued therapy to maintain or recover functionality. [Read more.](#)

BRAZIL REGULATOR VOWS TOUGHER OVERSIGHT OF HEALTH-INSURANCE OPERATORS

The National Supplementary Health Agency (ANS) announced new measures to strengthen oversight of health-plan operators, including stricter financial and service-quality criteria. The initiative follows a series of complaints from consumers about denied coverage and delayed authorizations. According to the agency, the new approach will prioritize recurrent infractions and include performance monitoring based on indicators of user satisfaction and regulatory compliance. ANS also stated that it will intensify on-site inspections and enhance cooperation with consumer-protection agencies to ensure that beneficiaries' rights are respected across the sector. [Read more.](#)

BRAZIL REGULATOR QUESTIONS HEALTH-PLAN PROFITS DESPITE COMPLAINTS

The National Supplementary Health Agency (ANS) expressed concern over record profits reported by major health-plan companies amid growing dissatisfaction and complaint volumes. According to data from the regulatory agency, the sector accumulated strong financial results in the first half of 2025, surpassing pre-pandemic levels. At the same time, the number of formal complaints about denied procedures and reimbursement issues increased by double digits compared to the previous year. ANS officials said the agency will review transparency and service-quality requirements and evaluate the need for new rules to balance corporate profitability with consumer protection and service efficiency. [Read more.](#)

BRAZIL SURVEY FINDS COST-SHARING MAKES SIX IN TEN WORKERS THINK TWICE BEFORE USING HEALTH PLANS

A new national survey revealed that 60% of Brazilian employees hesitate to use their corporate health plans due to copayments and other cost-sharing mechanisms. The study, conducted by the Institute of Supplementary Health Studies (IESS), found that high out-of-pocket expenses discourage preventive care and may increase long-term costs for both companies and the health system. The report also showed that 54% of workers consider cost-sharing a barrier to regular check-ups and routine tests. Experts suggest that employers review benefit design and invest in preventive programs to promote healthier habits and reduce absenteeism. [Read more.](#)

BRAZIL STROKE SURVIVAL RATES SHAPED BY RESPONSE TIME AND REGIONAL INEQUALITIES

Researchers highlight that stroke survival in Brazil remains heavily dependent on emergency response time and regional access to specialized care. The study indicates that states with well-structured stroke networks achieve significantly better outcomes, while under-resourced regions continue to face preventable fatalities. Experts call for investment in telemedicine, ambulance coordination, and public awareness campaigns to recognize early symptoms and reduce delays in treatment. They also emphasize the need for national policies to ensure equitable access to neurological care and rehabilitation services. [Read more.](#)

BRAZIL STUDY FINDS ONLY 17% OF DOCTORS USE ARTIFICIAL INTELLIGENCE IN DAILY PRACTICE

A new national survey shows that only 17% of Brazilian physicians currently use artificial intelligence tools in their daily professional activities. Respondents cited lack of training, regulatory uncertainty, and cost barriers as the main challenges, though most expressed optimism about AI's potential to improve diagnostics and efficiency. According to the research, doctors in radiology, oncology, and cardiology are among the most frequent adopters of AI-based technologies. The study also found that 78% of respondents expect AI use to expand within five years, provided that ethical guidelines and reimbursement models evolve accordingly. [Read more.](#)

BRAZIL NEWS

[Health Committee schedules public hearing on bill creating the National Day for Climacteric and Menopause Awareness](#)

[Deputy Moses Rodrigues appointed floor rapporteur for bill on tax exemption for medicine donations](#)

[Ministry of Health provides information on the National Neonatal Screening Program](#)

[Public hearing to discuss biosimilar medicines in Brazil](#)

[Ministry of Health responds on absence of a clinical protocol for Huntington's disease](#)

[Brazil launches plan to adapt health system to climate change](#)

[Brazilian researchers develop blood test capable of detecting Alzheimer's](#)

[Brazil Senate debates awareness initiative for Phelan-McDermid syndrome](#)

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