

WEEKLY REPORT



12/06/2025

BRAZIL TO LAUNCH NATIONAL MEDICATION PLATFORM TO STRENGTHEN JUDICIAL AND ADMINISTRATIVE DECISION-MAKING

The Supreme Federal Court announces the creation of the National Medication Platform, a system designed to centralize and standardize information used in judicial and administrative decisions related to access to medicines within the public health system. The tool aims to improve transparency, support evidence-based rulings and strengthen alignment between individual demands and national health policy. The platform will consolidate data such as regulatory status, incorporation decisions, clinical evidence, therapeutic indications, price information, and availability of generics or biosimilars. Authorities expect the initiative to reduce regional disparities, improve budget planning, and mitigate the fiscal and operational impact of health-related litigation. [Read more.](#)

ANVISA PUBLISHES LIST OF WITHDRAWN AND SUBSTITUTED APPLICATIONS UNDER RDC 997/2025

Anvisa releases the first official list of regulatory applications that were formally withdrawn and those that replaced them in the agency's evaluation queue, as provided for under Resolution RDC 997/2025. The mechanism allows companies to withdraw pending dossiers (such as drug registrations, post-registration changes, and clinical-trial authorization) and replace them with updated or higher-priority submissions. According to the agency, the measure aims to reorganize the queue, reduce backlog and ensure that ongoing analyses reflect companies' most current regulatory strategies. The list will be updated periodically during the validity period of the resolution. [Read more.](#)

MINISTRY OF HEALTH APPOINTS FORMER ANVISA'S DIRECTOR TO LEAD NEW NATIONAL ETHICS-IN-RESEARCH BODY (INAEP)

The Ministry of Health appoints Meiruze Sousa Freitas, Director of the Department of Science and Technology, to coordinate the newly created National Authority for Ethics in Research (INAEP). Meiruze previously served as director of Anvisa's 2nd Directorate and has been a sanitary surveillance specialist at the agency since 2007. Eight months ago, she assumed the leadership of the department linked to the Ministry of Health's Secretariat for Science, Technology and Innovation and the Health Economic-Industrial Complex. The ordinance formalizes the structure and mandates of the institution. INAEP will standardize ethical procedures for human-subject research, accredit and supervise local ethics committees and act as an appeal body. The creation of the authority aims to strengthen governance, improve oversight and streamline ethics review processes across Brazil. [Read more.](#)

BRAZIL'S SUPREME COURT TIGHTENS CRITERIA FOR COVERAGE OUTSIDE ANS LIST

The Supreme Federal Court publishes its full ruling on coverage of treatments not listed in the ANS's mandatory procedures roster, establishing cumulative requirements for when private plans must cover therapies outside the list. The decision aims to reinforce technical parameters and reduce legal uncertainty. Under the decision, coverage is mandatory only when all conditions are met: qualified prescription; no explicit refusal or pending review by ANS; no adequate alternative therapy within the list; strong scientific evidence of efficacy and safety; and valid registration with Anvisa. The ruling strengthens the role of ANS as the technical reference for coverage decisions. [Read more.](#)

BRAZIL'S COLLECTIVE HEALTH PLANS SHOW HIGHER AVERAGE PREMIUM INCREASES THAN INDIVIDUAL CONTRACTS

New data from the regulatory agency indicate that collective medical-hospital plans register significantly higher premium adjustments in 2025. Between January and August, collective plans show an average increase of 11.15%, with small-group contracts experiencing the steepest rises. For individual and family plans, the maximum adjustment authorized for the 2025–2026 cycle is 6.06%. The disparity between contract types reinforces concerns about affordability, especially for beneficiaries of small corporate groups. [Read more.](#)

CIVIL SOCIETY URGES STRONGER OVERSIGHT OF ABUSIVE PRACTICES BY HEALTH PLANS IN BRAZIL

Consumer advocacy groups and patient-rights organizations called for stronger regulatory action from the National Supplementary Health Agency (ANS) to address abusive practices by private health plans. Reported problems include automated coverage denials, restrictive care packages, expenditure caps, and refusals of medically indicated treatments. ANS representatives noted that fines begin at R\$ 80,000 per infraction and total approximately R\$ 2.7 billion over the past four years, with 80% of complaints resolved in preliminary mediation. [Read more.](#)

BRAZILIAN PUBLIC HEARING IN THE HOUSE OF REPRESENTATIVES HIGHLIGHTS RISING FISCAL IMPACT OF HEALTH JUDICIALIZATION

Data presented in the House of Representatives show that the federal government spent R\$ 1.84 billion until August 2025 on court-ordered purchases of the ten most expensive medicines demanded through lawsuits. The figures illustrate the growing budgetary strain caused by judicialization. During the hearing, specialists and officials call for stronger evidence-based decision-making and improved administrative pathways for access to high-cost treatments. Participants warn that current patterns create inequities, favor those who litigate and challenge long-term financial sustainability. [Read more.](#)

BRAZILIAN PUBLIC HEARING URGES ENFORCEMENT OF THE 60-DAY LAW TO REDUCE SKIN-CANCER MORTALITY

Specialists and lawmakers call for strict compliance with the 60-day law, which guarantees cancer patients the start of treatment within 60 days after diagnosis in the public health system. They warn that delays severely worsen outcomes for skin-cancer patients, many of whom could be cured with timely surgery. Participants highlight insufficient documentation of care timelines and fragmentation across facilities, contributing to patient “peregrination” and preventable complications, including advanced disease and mutilating procedures. [Read more.](#)

MINISTRY OF HEALTH CLARIFIES APAC COVERAGE FOR CYCLIN INHIBITORS IN BRAZIL

The Secretary for Specialized Health Care, Mozart Sales, and the General Coordinator of the National Cancer Policy, José Barreto, stated that the APAC reimbursement value of R\$ 2,200.00 for cyclin inhibitors used in breast cancer treatment is sufficient to cover both drug acquisition and clinical administration. They noted that some oncology centers have acquired the medicines at approximately R\$ 1,700.00, indicating that the reimbursement amount remains above actual purchase costs. The Ministry emphasized that institutional cost structures and payment conditions vary, and centralized purchasing may be considered in the future to improve efficiency. [Read more.](#)

BRAZIL LAUNCHES NATIONAL CENSUS OF ONCOLOGY CENTERS TO STRENGTHEN CANCER-CARE PLANNING

The Ministry of Health launches the 2025 Census of CACONs and UNACONs to map the structure and capacity of high-complexity oncology services. The survey aims to improve planning within the SUS and guide policy and investment decisions. The data will support resource allocation,

identification of gaps and strategies to reduce disparities in cancer care across regions. [Read more.](#)

FEDERAL GOVERNMENT ENACTS TAX EXEMPTION FOR MEDICINE DONATIONS IN BRAZIL

Law 15.279/2025 exempts federal taxes on donations of medicines to public agencies and certified nonprofit institutions. The measure applies to donations made to health authorities at federal, state, municipal and district levels, as well as philanthropic and social-assistance entities. Donated medicines must have at least six months of remaining shelf life and be used exclusively for non-commercial purposes. The exemption covers taxes such as PIS/Pasep, Cofins and IPI, aiming to encourage donations and expand access to treatments within public and nonprofit networks. [Read more.](#)

TELECONSULTATIONS SURGE AS A CONSOLIDATED MODALITY IN BRAZIL'S HEALTH SYSTEM

Brazil records an exponential increase in teleconsultations between 2020 and 2025, reflecting a structural shift in healthcare delivery. Remote care becomes routine in both public and private systems, supported by legal regulation and expanding digital infrastructure. According to the study, the number of teleconsultations grows from roughly 200,000 in 2020 to 3.1 million in 2025. Video consultations represent most interactions, and over 70% of appointments are resolved during the virtual encounter, highlighting patient acceptance and operational efficiency. [Read more.](#)

BRAZIL ESTABLISHES NATIONAL RESIDENCY-IN-HEALTH POLICY TO EXPAND SPECIALIST TRAINING IN THE SUS

The federal government institutes the National Policy on Health Residencies to standardize and expand residency programs across Brazil. The policy focuses on underserved regions and strategic specialties for the public health system. The framework introduces structured curricula, improved supervision and incentives such as increased bursaries and housing support. Authorities expect the policy to reduce regional disparities and strengthen specialist formation. [Read more.](#)

BRAZILIAN MEDICAL ENTITIES CALL FOR IMMEDIATE BAN ON COMPOUNDED WEIGHT-LOSS PENS

Medical associations urge Anvisa to immediately ban the production and sale of unregistered weight-loss injection pens by compounding pharmacies, following a police investigation that exposed large-scale illegal manufacturing. The entities warn of imminent sanitary risk, pointing to inadequate storage, lack of regulatory oversight and incorrect dosages. The request is endorsed by major medical societies, which emphasize the growing circulation of unregulated GLP-1 products. Anvisa reiterates that commercialization and importation of non-registered weight-loss pens are already prohibited in Brazil. [Read more.](#)

NOVO NORDISK'S BILLION-REAL INVESTMENT POSITIONS BRAZIL AS HUB FOR NEXT-GEN SEMAGLUTIDE PRODUCTION

Novo Nordisk announces a multibillion-real investment to expand its industrial complex in Montes Claros, enabling production of next-generation semaglutide-based medicines. The project aims to strengthen domestic supply capacity amid rising demand for diabetes and obesity treatments. The expansion consolidates Brazil as a strategic manufacturing base in Latin America and aligns with federal and state agendas to attract high-value pharmaceutical production. [Read more.](#)

MORE HIGHLIGHTS

[Brazilian experts highlight prioritization and data integration as key challenges for expanding health-care access](#)

[Brazil's pharmacy retail sector grows above 10% as regional expansion accelerates](#)

[Brazilian drugstores consider adopting South Korean experiential retail model](#)

[Brazil study reveals barriers to hemophilia treatment adherence](#)

BRAZIL NEWS

[Bolsonaro's senator son touts father's backing for 2026 Brazil presidential run](#)

[Brazil's Lula and Trump discuss trade, sanctions in phone call](#)

[Brazil's Lula expects more US tariff cuts after call with Trump](#)

[Brazil soy exports jump 64% in November ahead of Chinese shift to US](#)

[Brazil Amazonian state postpones cattle tracking key to preventing deforestation](#)

[Terra Brasil draws US, UK, Chinese interest in \\$1 billion rare earths project](#)

[Brazil's 2025 chicken exports to rise despite bird flu trade bans](#)

Relações Governamentais