WEEKLY REPORT

11/29/2025

MINISTRY OF HEALTH ANNOUNCES NEW PDPS AND PARTNERSHIPS TO STRENGTHEN THE HEALTH INDUSTRIAL COMPLEX

The Ministry of Health formalized new Productive Development Partnerships (PDPs) and strategic agreements during the November 24 meeting of the Executive Group of the Health Economic-Industrial Complex (GECEIS). The initiatives include cooperation with Anvisa for applying artificial intelligence in regulatory processes, partnerships with the National Institute of Industrial Property and Abifina to strengthen innovation, and a multi-institutional agreement to support startups and technology-based companies. Investments were also announced for equipment, ambulances, mobile units, incentivized debentures, and creation of binational regulatory committees. The Ministry confirmed new PDPs covering medicines and vaccines for oncology, HIV, immunological diseases, Covid-19, diabetes, and other strategic conditions. Proposals involve Bahiafarma, FUNED, FURP, Instituto Butantan, LAFEPE, LAQFA, LFM and TECPAR. Authorities emphasized the goal of expanding access to advanced therapies and reinforcing Brazil's sanitary sovereignty, with investments of R$ 5 billion in PDPs and R$ 15 billion in SUS infrastructure. Read more.

BRAZIL RESUMES NATIONAL INSULIN PRODUCTION AFTER 20 YEARS TO ADDRESS SUPPLY SHORTAGES

Brazil resumed domestic insulin production after a 20-year interruption. The first nationally manufactured batch was delivered to the Ministry of Health through a Productive Development Partnership focused on reducing dependence on imports. The initiative includes local manufacturing of regular and NPH insulin, with plans to expand to long-acting analogues. Patient groups have warned of recent shortages across several regions, reinforcing the need for local production to ensure stable supply for diabetic patients and strengthen pharmaceutical sovereignty. Read more.

STJ PATENT TRIAL CREATES UNCERTAINTY IN THE PHARMACEUTICAL MARKET

The Superior Court of Justice (STJ) intensified discussions around a high-impact patent case involving pipeline rules and protection terms. Ministers signaled conflicting interpretations about the duration and validity of certain pharmaceutical patents, creating significant market uncertainty. The outcome may influence drug pricing, competition timelines, and access to generics in Brazil. Industry experts note that the judgment could redefine boundaries of intellectual property protection in the pharmaceutical sector. Companies are closely monitoring the case due to its potential financial impact and implications for investments. Read more.

BRAZIL ESTABLISHES RULES FOR SUS-LINKED PROJECTS TO ISSUE INCENTIVIZED DEBENTURES

The Ministry of Health published regulations enabling projects linked to the public health system to raise private capital through incentivized debentures. The rules define criteria for hospitals, laboratories, primary-care units, and other SUS institutions to finance construction, expansion, or modernization of infrastructure. Only capital expenditure projects are eligible, and depending on the project's classification, debenture issuance may cover up to 100%, 90% or 50% of the investment. After validation by the Ministry's Executive Secretariat, project sponsors may proceed with issuance in the capital market. The measure seeks to stimulate private investment in public health infrastructure and accelerate improvements in SUS facilities. Read more.

TCU IDENTIFIES CRITICAL FLAWS IN MONITORING OF PRIMARY HEALTH-CARE CONSTRUCTION PROJECTS

The Federal Court of Accounts determined that the Ministry of Health must correct major flaws in the monitoring of construction and renovation works funded through the federal program to resume unfinished health facilities. An audit of 23 primary-care units across seven states revealed inconsistencies such as incorrect addresses, duplicated financing of existing structures, discrepancies between committed and paid amounts, and inaccurate completion dates. The Court recommended integrating monitoring systems with federal financial-management platforms to ensure data accuracy and transparency. It also suggested using QR codes on construction signboards to allow citizens to track progress and report issues. Read more.

BRASIL FACES CHALLENGES IN DEFINING PRICING MODELS FOR ADVANCED THERAPIES

Specialists in health economics and regulation highlighted the growing complexity of pricing and reimbursement for advanced therapies, including gene and cell therapies. Due to high development costs and small patient populations, these treatments challenge traditional pricing models and can exert financial pressure on health systems. The debate emphasizes the need for innovative payment mechanisms, such as outcomes-based agreements, long-term installments, and risk-sharing models. Experts argue that clear methodologies are essential to ensure both access and sustainability as more advanced therapies enter the market. Read more.

MINISTRY OF HEALTH HIGHLIGHTS IMPORTANCE OF CLINICAL TRIALS TO EXPAND ACCESS AND INNOVATION IN BRAZIL'S HEALTH SYSTEM

The Ministry of Health emphasized the strategic role of clinical trials in expanding access to innovative therapies and strengthening technological development in the country. The announcement detailed efforts to expand Brazil's participation in international research, attract new studies and reduce regulatory barriers that delay development of treatments. The Ministry stated that clinical trials help accelerate patient access to new therapies, improve scientific capacity, and strengthen public–private collaboration. Investments are being directed toward infrastructure, regulatory modernization and training of professionals involved in research oversight. The government also stressed that clinical trials support the national production of medicines and contribute to the sustainability of the health system. Read more.

ANVISA AUTHORIZES FIOCRUZ CLINICAL TRIAL USING GENE THERAPY FOR A RARE DISEASE

Anvisa authorized a clinical trial developed by Fiocruz involving a gene-therapy approach for treating a rare condition. The study represents a milestone for Brazilian biomedical research, marking the country's first authorization for a gene-therapy clinical investigation conducted by a national public institution. According to the agency, the authorization reflects advances in domestic capacity for developing cutting-edge therapies and reinforces Brazil's role in the global landscape of advanced research. The trial aims to assess safety and therapeutic potential in patients with the targeted rare disease. Read more.

ANVISA UPDATES Q&A ON RDC 359/2020 TO CLARIFY API DOSSIER REQUIREMENTS

Anvisa released a new edition of its questions-and-answers document on RDC 359/2020, the regulation that governs the submission of the Active Pharmaceutical Ingredient Dossier (DIFA) and the Letter of Adequacy (CADIFA). The updated material compiles new recurrent questions, clarifies procedures for DIFA submission, documentation structure, reference numbering, and conditions under which the agency may request additional data. According to the agency, the update strengthens transparency and supports quality, safety, and traceability of active ingredients. Read more.

A.C. CAMARGO EXPANDS RISK-SHARING AGREEMENTS TO BROADEN ACCESS TO INNOVATIVE CANCER THERAPIES

The A.C. Camargo Cancer Center expanded its portfolio of risk-sharing partnerships in 2025 by formalizing agreements with companies such as Roche, AbbVie, Johnson & Johnson, and Pfizer. The institution now maintains seven active agreements linking payment for high-cost oncology treatments to real-world clinical outcomes. Under the model, if a therapy does not deliver the expected benefit, the manufacturer reimburses the cost, reducing financial exposure for the hospital and for patients. Hospital leadership states that the approach helps maintain access to innovative therapies while ensuring sustainability in oncology care, an increasingly important consideration as the cost of innovative treatments rises in Brazil. Read more.

BRAZIL OPENS NATIONAL 'SUPER CENTER' TO ACCELERATE CANCER DIAGNOSIS

The A.C. Camargo Cancer Center and the Ministry of Health launched a new national "Super Center for Cancer Diagnosis", created to shorten waiting times for pathology results across the country. The unit began operating in September and has already issued more than 1,500 biopsy and surgical pathology reports, 97% delivered within five business days. Samples have arrived from multiple states, including Pará, Minas Gerais, Alagoas, Acre, Amazonas, and Pernambuco, with further expansion expected. The initiative responds to a nationwide shortage of pathologists and uses digital workflows and telepathology to expand equitable access to cancer diagnostics. According to the Ministry, the center is expected to reach a capacity of up to 1,000 daily reports, supporting earlier treatment decisions and improving outcomes for patients nationwide. Read more.

ANS INCORPORATES FOUR NEW TECHNOLOGIES INTO THE COVERAGE LIST

The National Regulatory Agency for Private Health Insurance Plans approved the incorporation of four new technologies into the mandatory coverage list. The updates, which take effect on December 1, 2025, include a test for detection of NTRK gene fusions in pediatric cancer, an immunoenzymatic urine test for detection of Histoplasma antigen used in the diagnosis of systemic fungal infection, and expanded use of the immunoprophylactic therapy nirsevimab for the prevention of lower respiratory tract infections associated with respiratory syncytial virus (RSV) in infants. A fourth technology was also incorporated with specific clinical indications defined by the agency. Read more.

ANS DEFINES NEW REGULATION FOR SELF-MANAGED HEALTH PLAN OPERATORS

The National Regulatory Agency for Private Health Insurance Plans approved a new regulatory framework for self-managed health plan operators with the publication of Normative Resolution No. 649/2025. The rule modernizes governance requirements, revises eligibility criteria, and updates financial oversight mechanisms for non-profit plans serving employees, retirees and dependents of institutions or companies. The regulation establishes mandatory corporate bodies, strengthens transparency obligations, and clarifies responsibilities for administrators. Operators must adapt statutes and internal procedures by July 2026. According to the agency, the new framework aims to reinforce accountability and ensure long-term sustainability for self-managed plans. Read more.

ANS PRESIDENT STATES THAT DISCOUNT CARDS MUST BE REGULATED AS HEALTH PRODUCTS

The president of the National Regulatory Agency for Private Health Insurance stated that discount cards marketed as health services will be regulated as health products due to recurring consumer abuses and confusion over their scope. According to the agency, many companies promote discount cards as if they were health plans, despite not offering guaranteed coverage or regulated protections. The agency is developing new rules to ensure transparency on what discount cards can and cannot offer, and to prevent misleading advertising practices. The objective is to protect consumers from financial and health risks arising from products that mimic regulated health plans without providing the same guarantees. Read more.

ANS PRESIDENT DEFENDS PROHIBITING CANCELLATION OF HEALTH PLANS FOR ELDERLY BENEFICIARIES

The president of the National Regulatory Agency for Private Health Insurance defended prohibiting the cancellation of health plans for elderly beneficiaries, citing recurring cases in which older adults lose coverage due to non-payment or disputes with operators. According to the agency, losing access to healthcare at advanced age creates severe risks and violates the principles of consumer protection and continuity of care. The proposal being evaluated would prevent operators from discontinuing coverage for elderly individuals except in cases of proven fraud. The agency argues that stronger safeguards are needed to protect a population that depends more heavily on medical care. Read more.

MINISTRY OF HEALTH WARNS THAT MEDICAL SCHOOL EXPANSION MUST MEET QUALITY STANDARDS

The Ministry of Health, through the Secretary of Workforce and Health Education, Felipe Proenço, expressed concern about the rapid expansion of medical schools in Brazil. The number of seats rose from 13,820 in 2004 to 48,491 in 2024. According to the most recent national evaluation, 20% of medical courses did not achieve satisfactory performance, and only six received the highest score. To address quality gaps, the government introduced a national medical training assessment (ENAMED), which becomes mandatory in 2025 and will guide decisions regarding reduction of admissions or suspension of entrance exams for underperforming programs. The Ministry also reinstated the accreditation process for teaching hospitals to improve practical training environments. The plan is to expand accreditation from 202 institutions to approximately 1,300, strengthening supervision and improving distribution of health professionals across the country. Read more.

UNREGULATED USE OF ZOLPIDEM BECOMES A PUBLIC HEALTH PROBLEM, PROMPTING CALLS FOR NEW GUIDELINES

Medical specialists warned that irregular and excessive use of zolpidem has become a significant public health challenge, driven by widespread off-label consumption, uncontrolled access, and dependence risks. Physicians have reported rising cases of adverse events, including cognitive difficulties, behavioral changes, and withdrawal symptoms. Experts argue that updated national guidelines are necessary to limit inappropriate prescriptions, improve monitoring and increase public awareness of the risks associated with chronic use. They emphasize that zolpidem should be reserved for short-term treatment and accompanied by non-pharmacological approaches to insomnia. Read more.

HEALTH COMMITTEE DEBATES RISE IN COUNTERFEIT MEDICINES AND PUBLIC-HEALTH RISKS IN BRAZIL

The Health Committee of the House of Representatives held a public hearing to discuss the rapid expansion of counterfeit and adulterated medicines, medical products, and other critical-use items in Brazil. Lawmakers, regulatory authorities, industry representatives, scientific institutions, and federal law-enforcement agencies warned that the country faces escalating risks due to gaps in surveillance, online commerce, and weak supply-chain controls. The debate was requested by Congresswoman Rosângela Moro, who cited Anvisa data showing growth in falsification cases over the past decade, with particular concern for high-cost therapies and controlled substances. She also highlighted that 36% of counterfeit products circulate through digital platforms and referenced WHO estimates that one in ten medicines sold in low and middle-income countries is falsified. Read more.

FEDERAL POLICE DISMANTLE ILLEGAL FACTORY PRODUCING TIRZEPATIDE SLIMMING PENS

The Federal Police executed an operation to dismantle an illegal manufacturing scheme producing and distributing tirzepatide-filled slimming pens without sanitary authorization.

Investigators found that the group operated a clandestine facility that fractionated, filled, and labeled the substance on an industrial scale, bypassing all regulatory requirements for quality, sterility, and traceability. Search and seizure warrants were carried out across four states, targeting clinics, laboratories, commercial establishments, and residences. Authorities noted that the irregular formulations were sold online with aggressive marketing aimed at individuals seeking rapid weight loss. The Federal Police and sanitary authorities emphasized that the products posed serious health risks due to lack of verified dosage, purity, and safety controls. Read more.

NOVO NORDISK SEEKS APPROVAL FOR HIGHER-DOSE WEGOVY FORMULATION IN BRAZIL

Novo Nordisk submitted a request to Anvisa to approve a 7.2 mg formulation of Wegovy, a semaglutide-based drug used for obesity treatment. The new dose is three times higher than the version currently available in Brazil and is aimed at adults with a body mass index of 30 or above. According to clinical trial data, the higher dose achieved greater weight loss compared with the 2.4 mg dose, with a safety profile consistent with previous findings. Novo Nordisk reports that adverse events were mostly gastrointestinal, mild to moderate, and decreased over time, with a small share of patients discontinuing treatment. The company has also submitted similar applications to regulatory authorities in other countries. Read more.

FARMÁCIA POPULAR GROWS IN SALES AND ATTRACTS EVEN PREMIUM RETAIL CHAINS

The Farmácia Popular program has become one of the main drivers of growth in the pharmaceutical retail sector, attracting even premium networks that traditionally focus on higher-income consumers. Expanded coverage, increased reimbursement values and the inclusion of new therapeutic categories contributed to rising demand. Retail chains report significant increases in foot traffic and prescription volume associated with the program. Analysts note that participation in Farmácia Popular strengthens commercial performance while expanding access to essential medicines for chronic conditions such as hypertension and diabetes. Read more.

BRAZIL RECORDS LOW UPTAKE OF THE "AGORA TEM ESPECIALISTAS" PROGRAM AMONG PRIVATE HEALTH PLANS

The Ministry of Health reported that the "Agora Tem Especialistas" program has seen limited adherence from private health-plan operators since the credit-swap mechanism opened in July 2025. By late October, only one operator, Hapvida, had formally joined and begun providing services to SUS patients, while Amil is expected to enter the program in January 2026. On the hospital side, about 180 institutions submitted applications, with 85 validated, a modest result compared with the more than 3,700 private hospitals and 1,800 philanthropic facilities nationwide. Analysts attribute the low uptake to regulatory delays, uncertainties regarding debt-swap rules and insufficient financial incentives. The Ministry plans to issue complementary regulation soon and to launch a monitoring panel by March 2026 to provide transparency on contracted services, production volumes, and reimbursement flows. Read more.

BRAZIL APPROVES NEW NATIONAL POLICY TO STRENGTHEN HEALTH RESIDENCIES ACROSS COUNTRY

Federal authorities approved the National Policy for Health Residencies, aimed at expanding and improving medical and multiprofessional training programs throughout Brazil. The policy establishes new incentives for teaching hospitals, strengthens accreditation processes, and seeks to ensure a more equitable distribution of health professionals. The initiative is expected to reinforce the SUS workforce, improve training quality and support regional development in areas facing shortages of specialized professionals. Read more.

MORE HIGHLIGHTS

RSV vaccine to arrive in SUS in December with 1.8 million doses

Brazil and OPAS sign agreement to purchase updated vaccines at reduced prices

Brazil launches new therapeutic consensus for leprosy to strengthen treatment guidelines

Advance of Chagas disease reveals failures in diagnosis and treatment in Brazil

New guidelines for cancer technologies advance to House of Representatives

Half of brazilians have never been to a dermatologist, study shows

Mammography for women from age 40 under sus advances to presidential sanction

Brazil study reveals how some breast cancer tumors evade treatment

BRAZIL NEWS

Ex-President Bolsonaro starts serving 27-year sentence for Brazil coup plot

Bolsonaro says medications made him tamper with tracking device, triggering detention

Brazil creates fewer formal jobs than expected in October

Brazil's annual inflation back within target range for first time since January

Brazil central bank still uneasy on inflation outlook, governor says

COP30: Big pledges on renewables and industry, but ambition falters on ending fossil fuels

No roadmap to end deforestation, but Brazil’s COP in the Amazon delivered for forests

Brazil to issue carbon market rules by end-2026, finance official says

Brazil environment minister, climate summit star, faces political struggle at home

Brazil seeks US cooperation in money-laundering probe

Brazil sees issues related to import of US biofuels 'practically resolved'

Brazil's foreign direct investment through October surpasses 2024 total