WEEKLY REPORT

04/11/2026

BRAZIL SENATE COMMITTEE APPROVES PUBLIC HEARING ON GEOGRAPHIC ATROPHY CHALLENGES

The Senate Social Affairs Committee approved Request No. 23/2026 to hold a public hearing on geographic atrophy, focusing on barriers to early diagnosis and access to new therapies in both the Unified Health System (SUS) and private healthcare. The initiative, authored by Senator Dr. Hiran, aims to assess disease burden, discuss international treatment evidence and examine regulatory and policy pathways to enable future access in Brazil. Proposed participants include representatives from the Brazilian Council of Ophthalmology, the Brazilian Retina and Vitreous Society, the Retina Brasil patient association, the Ministry of Health, and the Brazilian Health Regulatory Agency, as well as retina specialist Mauricio Maia (UNIFESP). The hearing date will be defined at a later stage. Read more.

BRAZIL LAW GUARANTEES ACCESS TO IMMUNOTHERAPY FOR CANCER PATIENTS

A bill approved by the National Congress establishes that cancer patients treated in the Unified Health System (SUS) must have access to immunotherapy when the method proves more effective or safer than conventional treatments. The proposal (PL 2,371/2021) amends the Organic Health Law to incorporate immunotherapy into clinical protocols and therapeutic guidelines under defined criteria. The measure aims to accelerate access to innovative cancer therapies by reducing delays in the incorporation process, which can exceed 180 days. Immunotherapy, already used in several countries and in limited cases in Brazil, stimulates the immune system to identify and attack tumor cells and is expected to expand treatment options and improve outcomes within the public system. Read more.

BRAZIL BILL ON RISK-SHARING AGREEMENTS ADVANCES TO SENATE

The Constitution and Justice Committee of the Chamber of Deputies approved Bill No. 667/2021, which establishes a legal framework for risk-sharing agreements to support the incorporation of new health technologies in the Unified Health System (SUS). The proposal, already cleared by the Health Committee, now moves toward Senate consideration if no plenary appeal is filed. The measure allows the government to adopt managed entry agreements — including financial-based, performance-based, hybrid and risk-sharing models — for medicines, diagnostics, and other technologies. The objective is to expand access to innovative treatments, enable partnerships with the pharmaceutical industry and improve budget predictability through shared clinical and financial risk tied to real-world outcomes. Read more.

MINISTRY OF HEALTH LAUNCHES NEW PHARMACEUTICAL ASSISTANCE SYSTEM

The Ministry of Health presented the new e-SUS Pharmaceutical Assistance (e-SUS AF), a digital platform designed to modernize medicine management across the Unified Health System (SUS) and replace the current Hórus system. The tool integrates national databases and aims to improve planning, dispensing processes, and stock control, enabling decision-making based on more reliable and standardized data. The system connects with key national platforms, including the National Database of Pharmaceutical Services (BNAFAR), the National Health Data Network (RNDS), and the National SUS User Registry (CADSUS), and uses Gov.br authentication standards. The initiative seeks to increase interoperability, strengthen monitoring of medicines and enhance coordination among federal, state, and municipal managers. Read more.

BRAZIL DELAYS ONCOLOGY PHARMACEUTICAL POLICY REGULATION TO MAY AMID CRITICISM

The Ministry of Health plans to finalize and agree on all regulatory ordinances for the Oncology Pharmaceutical Assistance Component (AF-Onco) in May, postponing implementation timelines while stakeholders call for a clearer action plan. The initiative aims to organize access to cancer medicines within the Unified Health System (SUS), but concerns remain over lack of transparency regarding funding, integration across care levels and operational guidance. Entities also highlight the absence of a structured implementation roadmap and uncertainties about budget allocation for oncology policies. The discussion gains urgency as operational deadlines approach and leadership changes occur within the Department of Cancer Care, which is responsible for advancing AF-Onco implementation. Read more.

HEALTH MINISTRY TO REVISE CEIS RULES AND EXPAND MONITORING

The Ministry of Health is reviewing regulatory ordinances linked to the Health Economic-Industrial Complex (CEIS), with plans to simplify rules for Productive Development Partnerships (PDPs) and update the Local Development and Innovation Program. The initiative, led by the Secretariat of Science, Technology and Innovation in Health, aims to modernize industrial policy instruments and strengthen domestic production of strategic health technologies. The government also plans to expand monitoring of CEIS initiatives through a results dashboard to track implementation and performance. Officials indicate the review seeks to improve governance, reduce bureaucracy and align innovation and local production policies with broader goals of strengthening national manufacturing capacity and reducing external dependence. Read more.

BRAZIL COMMITTEE REVIEWS PROGRESS IN RESTORING DOMESTIC DRUG PRODUCTION

The House of Representatives Health Committee held a public hearing to assess the status of Productive Development Partnerships (PDPs) aimed at restoring domestic pharmaceutical manufacturing and reducing external dependence of the Unified Health System (SUS). The debate focused on technology transfer policies and strengthening the Health Economic-Industrial Complex as part of Brazil's industrial strategy. Participants reported that the federal government resumed investments in public laboratories and selected 31 projects across oncology, vaccines, and rare diseases. Officials also highlighted the start of national production of insulin glargine and a respiratory syncytial virus (RSV) vaccine for pregnant women, alongside calls for legal certainty, infrastructure investment, and continuity of long-term PDP policies. Read more.

BRAZIL PUBLISHES INTERNAL RULES FOR NATIONAL RESEARCH ETHICS AUTHORITY (INAEP)

The Ministry of Health publishes Resolution No. 1/2026 establishing the Internal Rules of the National Research Ethics Authority (Inaep), a consultative and deliberative body with technical and decision-making autonomy. The regulation defines the authority's mandate to protect research participants' rights while promoting ethical scientific development, including responsibilities to issue research ethics standards, oversee the National Research Ethics System (Sinep), accredit and supervise Research Ethics Committees (CEPs), and act as an appellate body. The rules also define governance, quorum and decision-making procedures, including majority voting, electronic deliberation, and public consultations. Members must attend at least 75% of meetings and serve without remuneration, while a Secretariat-Executive provides administrative and technical support. The regulation further establishes transparency requirements, appeal procedures, and periodic review of the internal rules. Read more.

BRAZIL MEASURE ENCOURAGES RADIOPHARMACEUTICAL REGISTRATIONS

The Brazilian Health Regulatory Agency publishes Instruction Normative No. 433/2026 updating the list of established-use radiopharmaceuticals, expanding it to 57 medicines, and allowing

applicants to rely on scientific literature to demonstrate safety and efficacy for products with equivalent activities and indications. The measure aims to stimulate new registrations and expand availability of radiopharmaceuticals used in diagnosis and treatment, particularly in oncology. According to the agency, the updated list replaces the previous set of 33 items and reflects gradual market expansion with new companies and products. The regulatory framework continues to be supported by RDC 738/2022 and complementary rules governing documentation and registration pathways for these medicines. Read more.

ANVISA TIGHTENS OVERSIGHT OF WEIGHT-LOSS INJECTION IMPORTS AND COMPOUNDING

The Brazilian Health Regulatory Agency (Anvisa) announces new measures to combat irregularities in the import and compounding of GLP-1 injectable medicines, commonly known as weight-loss pens, including products containing semaglutide, tirzepatide and liraglutide. The initiative includes regulatory revisions, intensified inspections of importers and compounding pharmacies, and the possibility of suspending operating authorizations in cases of sanitary risk. The agency reports inconsistencies between imported active pharmaceutical ingredients and domestic demand, alongside quality-control failures identified in inspections that led to interdictions of establishments. The plan also foresees strengthened monitoring of adverse events, coordination with state and municipal surveillance authorities, and prioritization of registration analyses to expand access to regulated products. Read more.

AGENCY APPROVES NEW TREATMENT FOR GENERALIZED MYASTHENIA GRAVIS

The Brazilian Health Regulatory Agency (Anvisa) approved the registration of Rystiggo (rozanolixizumab) for the treatment of generalized myasthenia gravis, a rare autoimmune disease characterized by progressive muscle weakness and fatigue. The biologic therapy is indicated as an add-on to standard treatment for adult patients who test positive for anti-AChR or anti-MuSK antibodies. According to the agency, the monoclonal antibody acts by inhibiting the neonatal Fc receptor (FcRn), accelerating degradation of pathogenic IgG autoantibodies involved in the disease mechanism. The approval expands therapeutic options for patients with limited alternatives, particularly those with severe or refractory disease. Read more.

ANVISA APPROVES EXPANDED USE OF THERAPY FOR ATYPICAL HEMOLYTIC UREMIC SYNDROME

The Brazilian Health Regulatory Agency (Anvisa) approved an expanded indication for Ultomiris (ravulizumab) for the treatment of atypical hemolytic uremic syndrome (aHUS), extending use to pediatric patients weighing at least 5 kg. The decision also removes the requirement for prior treatment with eculizumab before initiating or switching to ravulizumab, potentially enabling earlier access to therapy. The rare, life-threatening condition is characterized by thrombotic microangiopathy that can lead to organ failure, particularly affecting the kidneys. According to the agency, the monoclonal antibody blocks complement protein C5, preventing formation of the membrane attack complex and reducing disease-related damage. The request received priority review due to the severity of the condition and its impact on pediatric patients. Read more.

ANS MANDATES COVERAGE OF QUANTITATIVE RT-PCR TEST FOR LEUKEMIA

The National Supplementary Health Agency (ANS) approves the inclusion of a quantitative RT-PCR test for leukemia in the mandatory coverage list for private health plans. The decision was taken unanimously during a board meeting and incorporates the procedure into the Roll of Procedures and Health Events, making coverage compulsory when clinically indicated. The agency's technical area estimates the measure will generate an average annual cost of approximately R$3 million for the sector. The exam is used to diagnose and monitor leukemias, particularly through molecular detection and quantification of disease markers, supporting treatment follow-up in clinical practice. Read more.

BRAZIL ANS HIGHLIGHTS PREVENTION AND HEALTH PROMOTION AS ESSENTIAL PARAMETERS

The president of the National Supplementary Health Agency (ANS), Wadih Damous, states that prevention and health promotion should guide a new care model in Brazil's private health insurance sector, replacing the current reactive approach focused on treating established diseases. In an interview, he argues that preventive strategies can reduce costs, improve outcomes and support sustainability for operators and beneficiaries. Damous also defends health literacy initiatives and broader dialogue with insurers, providers, and government to advance value-based care and earlier diagnosis of chronic conditions such as diabetes, hypertension, and obesity. He notes that cancer is expected to become the leading disease burden in Brazil in coming years, reinforcing the need for prevention-oriented policies. Read more.

BRAZIL ELI LILLY CHALLENGES MUNICIPAL OBESITY PROGRAM USING COMPOUNDED TIRZEPATIDE

U.S. pharmaceutical company Eli Lilly is seeking to block a municipal obesity treatment program that relies on compounded tirzepatide, arguing the model is illegal and could undermine regulatory safeguards. The initiative, implemented at the local level, offers treatment using manipulated versions of the GLP-1/GIP therapy, prompting concerns over quality, safety, and intellectual property. The Brazilian Health Regulatory Agency reports it has opened an administrative process to investigate the case. The dispute highlights growing regulatory tension around compounded weight-loss injections and may influence broader rules on the use of manipulated GLP-1 therapies in public programs. Read more.

BRAZIL HOSPITAL DRUG PRICES RISE IN FEBRUARY AFTER NINE MONTHS OF DECLINE

Prices of medicines negotiated between suppliers and hospitals in Brazil increased 0.12% in February, according to the Hospital Drug Price Index (IPM-H) calculated by Fundação Instituto de Pesquisas Econômicas (FIPE) and Bionexo. The result interrupts a sequence of nine consecutive months of declines, although the variation remains close to the historical average for the month. Despite the monthly increase, the indicator still shows a 1.96% decline over 12 months, with reductions in nine of the twelve therapeutic groups monitored. The index also accumulates a 0.58% drop in the first two months of 2026, suggesting continued price accommodation influenced mainly by exchange-rate dynamics. Read more.

BRAZIL HEALTH MINISTRY DOUBLES EARMARK COMMITMENTS FROM PARLIAMENTARY AMENDMENTS IN Q1

The Ministry of Health committed R$76.7 million in parliamentary amendments by March 23, 2026, more than double the amount recorded in the same period of 2025, according to an analysis based on federal transparency data. The increase represents a 121% rise and reflects an accelerated budget execution strategy at the beginning of the year. The ministry states the early commitments are driven by the electoral calendar, as transfers of these resources cannot occur after July 4. Most of the amount (about 93%) refers to outstanding payments from previous years, while roughly R$5 million correspond to the 2026 budget. The commitment phase reserves funds prior to contracting and signals government intent to execute projects financed by lawmakers. Read more.

BRAZIL PROPER MEDICINE DISPOSAL SURPASSES 1,000 TONS IN 2025

The correct disposal of expired or unused household medicines in Brazil exceeded 1,000 tons in 2025, reaching about 1,011 tons collected by 29 major pharmacy chains, according to data from the Brazilian Association of Pharmacy and Drugstore Chains (Abrafarma). The volume represents a 30% increase compared to 2024 and is roughly 18 times higher than the amount recorded in 2021, when the reverse logistics system began implementation. Collection infrastructure also expanded significantly, with disposal points rising from 3,634 to 7,780 in five years across 775 municipalities, covering nearly 199 million people. Most of the collected

material was incinerated, while a smaller portion was sent to sanitary landfills, reflecting growth in environmentally appropriate disposal practices. Read more.

BRAZIL TO TRAIN 11,000 PROFESSIONALS TO EXPAND CONTRACEPTIVE IMPLANT

The Ministry of Health has launched a second phase of training workshops to qualify more than 11,000 physicians and nurses to provide the etonogestrel subdermal contraceptive implant (Implanon) in the Unified Health System (SUS). The initiative includes 32 in-person trainings across all states, prioritizing municipalities with fewer than 50,000 inhabitants to expand access to long-acting reversible contraception. The sessions combine theoretical and practical instruction using anatomical simulators and expanded workloads of 12 hours for nurses and six hours for physicians. The program is part of a broader strategy to increase availability of the method nationwide, following distribution of 500,000 implants in 2025 and planned delivery of 1.3 million additional units in 2026. Read more.

BRAZIL SENATE TO VOTE ON ANNUAL WOMEN'S HEALTH ASSESSMENT IN SUS

A bill requiring the Unified Health System (SUS) to provide a comprehensive annual health assessment for women advances to the Senate plenary after approval by the Social Affairs Committee. The proposal (PL 1,799/2023) mandates periodic exams and follow-up based on factors such as age, socioeconomic conditions, residence, and disability status, aiming to strengthen prevention and early diagnosis. The measure also foresees public awareness campaigns addressing physical activity, nutrition, mental health, vaccination, and preventive screenings. Authored by Deputy Nely Aquino and reported by Senator Mara Gabrilli, the initiative seeks to expand primary care and reduce the incidence of diseases frequently detected at advanced stages among women. Read more.

BRAZIL BREAST CANCER LEADS LAWSUITS FOR ACCESS TO TREATMENT

Breast cancer leads judicial claims for access to treatment in Brazil, accounting for 20.3% of oncology-related lawsuits, according to an analysis of 9,599 cases filed between 2023 and May 2025. Blood cancers (11.1%), prostate cancer (10.1%), gynecologic tumors (9.7%), and lung cancer (8.9%) follow in the ranking. The study indicates that patients often resort to courts due to difficulties accessing prescribed therapies, particularly medicines. Requests for drug supply represent 66.7% of lawsuits, while other demands include hospital treatment and follow-up (9.7%), chemotherapy, immunotherapy or radiotherapy (8.8%), diagnostic tests (4.3%), and surgeries (4.1%). Nearly half of the cases target the Unified Health System (SUS), with 37.3% involving private health plans, highlighting gaps between legal guarantees and real-world availability of oncology care. Read more.

MORE HIGHLIGHTS

Brazil patient rights statute enters into force nationwide

Brazil law requires companies to promote HPV and cancer awareness campaigns

Brazil law regulates doula profession nationwide

Brazil Nortec plans on-demand API development strategy

Survey finds 33% of Brazilian households used weight-loss injections

Brazil Federal Police targets illegal weight-loss injection sales in multi-state operation

Brazil updates composition of Conitec committees

Brazil opens public consultation on biobank and human biological material rules

BRAZIL NEWS

Lula and Flavio Bolsonaro even in Brazil election second-round, Datafolha poll shows

Brazil annual inflation accelerates in March on fuel price pressures

Brazil eyes strict budget curbs and tax-break limits in 2027, Mello says

Brazil to release $1.37 billion from severance fund for 10 million workers

Brazil eyes new debt relief with federal guarantees for consumers

Brazil court exempts some oil firms from export tax

Brazil ethanol sector ready to fill demand from higher blends

Brazil weighs fast-tracking biodiesel tests as diesel prices spike

Brazil natural gas distributors see Petrobras raising prices by some 20% in May

Brazil seizes over 1,100 weapons and 1.5 tons of drugs from US, says official

Brazil and US launch joint action to fight organized crime

Brazil to appeal court ruling suspending oil export tax, says minister

Brazil puts China's BYD on list of shame for workers' past slavery-like conditions

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