WEEKLY REPORT

CONSULTORES
Relações Governamentais

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HEALTH MINISTRY DEFINES NEW SUPPLY MODELS FOR ONCOLOGY MEDICINES IN BRAZIL'S PUBLIC SYSTEM

The Ministry of Health has published Ordinance GM/MS No. 8,477 of October 20, 2025, creating the Oncology Pharmaceutical Assistance Component (AF-ONCO) within the Unified Health System (SUS). The regulation defines new funding, acquisition, and distribution mechanisms for oncology medicines, aiming to ensure comprehensive therapeutic access under the National Policy for Cancer Prevention and Control (PNPCC). The most anticipated section of the ordinance establishes how medicines will be purchased, distributed, and dispensed nationwide. The new framework introduces three supply modalities. The first involves centralized acquisition by the Ministry of Health, covering high-cost or strategic medicines purchased directly by the federal government and distributed to state and municipal health departments, as well as to federal hospitals such as the National Cancer Institute (INCA) and Grupo Hospitalar Conceição (GHC). This model will follow strict criteria including pre-authorization through the High-Complexity Outpatient Procedure Authorization (APAC) system, verification of existing inventories in hospitals and warehouses, and coordination with ongoing contracts and national stock levels. The second modality is national negotiation, in which the Ministry coordinates joint procurement with states and the Federal District through nationwide price-registry mechanisms. This model seeks to enhance SUS purchasing power, reduce regional disparities in access, and prevent shortages through coordinated logistics and shared responsibility for distribution. The third modality, decentralized acquisition, assigns the responsibility for procurement, storage and dispensing to state and municipal oncology centers (CACONs and UNACONs). These institutions will record dispensing and administration data in official SUS information systems to ensure full traceability and fiscal transparency. Read more.

BRAZIL'S HEALTH MINISTRY LAUNCHES TRANSPORT-AID SCHEME TO BROADEN RADIOTHERAPY ACCESS

The Ministry of Health has introduced a new aid package to cover transportation, lodging and meals for cancer patients undergoing radiotherapy far from home. Patients and one companion will each be eligible for daily allowances of up to BRL 300 for both travel and accommodation/food, given that many currently travel an average of 145 km for treatment. The measure is part of the "Agora Tem Especialistas" programme and accompanies an annual investment increase of BRL 156 million to expand radiotherapy services by up to 60 new patients per facility—representing a 20.7 % increase in funding and bringing the total annual radiotherapy budget to BRL 907 million. Under the new arrangement, funding shifts from a fixed monthly ceiling to a performance-based model via the Fund for Strategic Actions and Compensation (FAEC). Health networks will now receive financial incentives proportional to the number of procedures performed, aligning funding with treatment volume. With improved logistics for patient travel and new flow of resources linked to activity levels, the initiative aims to reduce geographical and socioeconomic barriers to cancer care in Brazil's public system. Read more.

NEW RULES FOR DRUG PRICING IN BRAZIL MAY BE PUBLISHED THIS YEAR BY CMED

The Drug Market Regulation Chamber (CMED) has submitted for legal review the draft of a new resolution that will redefine how medicine prices are established in Brazil. The proposal replaces the current Resolution No. 2/2004 and seeks to modernize the regulatory framework to reflect

market dynamics, international benchmarking, and transparency principles in price formation. According to the Ministry of Health, the new text updates the mechanisms for price setting, review, and monitoring, introducing clearer methodologies for classifying products, calculating ceiling prices and applying discounts or rebates. It also revises the rules for pricing innovative medicines, generics, and similar drugs, with the aim of improving predictability for manufacturers and expanding access for patients. The document's submission to legal analysis represents the final step before publication. Once reviewed and approved, the new regulation will be signed by CMED's Executive Secretariat and published in the Official Gazette. The measure is expected to bring greater regulatory stability to the pharmaceutical sector and ensure more balanced price control consistent with Brazil's economic and public-health objectives. Read more.

NOVARTIS EXECUTIVE SAYS "EVERYONE WINS" WHEN NEW DRUG STUDIES ARE CONDUCTED IN BRAZIL

The president of international operations at Novartis, Patrick Horber, stated that conducting clinical trials in Brazil benefits patients, researchers, institutions, and the pharmaceutical industry alike. In an interview, Horber highlighted that Brazil's genetic diversity, qualified medical centers and improving regulatory environment make the country a strategic hub for global drug development. According to the executive, patients gain early access to innovative treatments while companies obtain more representative data and strengthen their scientific collaboration with local hospitals and universities. He also underscored that such studies generate investment, capacity building, and technology transfer, creating a virtuous cycle for innovation in health. Horber emphasized that Brazil has consolidated its role as one of the key emerging markets for clinical research, especially in oncology and rare diseases, but noted that continued regulatory agility and investment in infrastructure are essential for the country to remain competitive. Read more.

ANVISA PUBLISHES COMPOSITION OF NEW TECHNICAL CHAMBER FOR CLINICAL TRIALS OF DRUGS AND MEDICAL DEVICES

The National Health Surveillance Agency (Anvisa) has released the list of members of the new Technical Chamber for Clinical Trials on Drugs and Medical Devices (Catepec), which will serve a three-year term. The chamber will provide scientific and technical advice to Anvisa's directorate, supporting the development of regulatory standards and the monitoring of advances in clinical research involving medicines, vaccines, and medical devices. The creation of Catepec follows a public call issued in 2024 to select professionals with expertise in evaluating clinical trial protocols and methodologies. Members include representatives from academia, the public sector, research institutions, and clinical investigators, who will contribute to discussions on safety, efficacy, and innovation in clinical development. The group's mandate includes supporting Anvisa in harmonizing national rules with international standards, promoting regulatory convergence and improving transparency in the approval of clinical trials. Catepec will also help define agendas for studies of emerging technologies and propose improvements to simplify processes and accelerate research without compromising patient safety. Read more.

BRAZIL STILL FACES MAJOR BACKLOG AT ANVISA, WHILE INPI SHOWS PROGRESS

The regulatory backlog at the National Health Surveillance Agency (Anvisa) remains a critical issue for the pharmaceutical sector, with the average approval time for generic drugs estimated at around three years and active pharmaceutical ingredient (API) evaluations taking up to five years. In contrast, the National Institute of Industrial Property (INPI) has made measurable progress in reducing its patent analysis queue and improving processing times. As of mid-2025, the INPI reported 14,057 pending pharmaceutical patent applications—down from more than 18,000 in 2020. The average decision time has also improved, reaching approximately 4.9 years for drug patents and 5.7 years for biologics. These advances reflect process modernization efforts and the hiring of new patent examiners, which have increased productivity within the agency. Industry representatives and government officials point to human resource shortages and procedural bottlenecks as the main causes of delays at Anvisa.

To address these issues, the Ministry of Health has authorized the hiring of 129 new regulatory technicians through the "Agora Tem Especialistas" program, and 100 additional approved candidates from the last Anvisa recruitment have been called to serve. Experts agree that both agencies must maintain investment in staff and digital infrastructure to sustain efficiency gains and ensure timely evaluation of medicines and technologies. Read more.

BRAZIL'S ANVISA PRESIDENT OUTLINES AGENDA TO STREAMLINE APPROVALS AND STRENGTHEN DIALOGUE

The Director-President of Brazil's National Health Surveillance Agency (Anvisa), Leandro Pinheiro Safatle, announced that his administration will focus on expanding engagement with state and municipal health bodies, as well as with the Legislative and Judicial branches. His priorities include improving regulatory efficiency, accelerating decision-making, and reinforcing institutional coordination across agencies. Safatle highlighted plans to address long-standing backlogs in drug registration and product evaluation. He stated that Anvisa will hire additional staff, modernize its infrastructure, introduce artificial intelligence tools, and redesign internal workflows to shorten review times while maintaining scientific rigor. He also reaffirmed the agency's central role in Brazil's health-innovation ecosystem. According to Safatle, regulatory decisions must be closely aligned with the Drug Market Regulation Chamber (CMED), which oversees price evaluations, and the National Commission for the Incorporation of Technologies in the Unified Health System (Conitec), which assesses new technologies for public adoption. These collaborations, he said, are essential to ensure timely access to innovative therapies while preserving fiscal sustainability. Read more.

SENATOR MARA GABRILLI CRITICIZES ANVISA FOR DELAY IN APPROVING POLYLAMININ

Senator Mara Gabrilli, who has been tetraplegic since a car accident in 1994, expressed concern over the delay by the National Health Surveillance Agency (Anvisa) in authorizing the use of polylaminin, a compound developed in Brazil as a potential therapy for spinal cord injuries. The senator said that the long evaluation process has frustrated patients and researchers who see promise in the treatment. Gabrilli acknowledged the importance of scientific rigor but stated that the regulatory pace must also consider the urgency of patients living with severe disabilities. She emphasized that years of waiting for decisions discourage innovation and limit access to experimental therapies that could restore functions or improve quality of life. The case, she argued, reflects broader systemic challenges in Brazil's health regulatory framework, including the need for clearer pathways for advanced therapies and better coordination between research institutions and the agency. Gabrilli called for Anvisa to implement prioritization mechanisms for high-impact therapies and greater transparency in approval timelines. Read more.

PROPOSED CONSTITUTIONAL AMENDMENT GIVES HOUSE OF REPRESENTATIVES OVERSIGHT OF REGULATORY AGENCIES IN BRAZIL

The Constitution, Justice and Citizenship Committee (CCJ) of the House of Representatives approved the admissibility of Constitutional Amendment Proposal (PEC) No. 42/2024, which grants the lower chamber exclusive authority to oversee Brazil's regulatory agencies. The measure, approved by 33 votes to 13, now proceeds to a special committee before being considered by the full House. The proposal, sponsored by Representative Danilo Forte (União–CE), gathered 208 signatures—well above the minimum required. It stipulates that if parliamentary committees identify irregularities, omissions, or misconduct within regulatory agencies, they must forward the findings to the Federal Public Prosecutor's Office (MPF), the Office of the Attorney General (AGU), or the Federal Court of Accounts (TCU) for accountability actions. Supporters argue that the amendment strengthens the legislative branch's institutional oversight role, increasing transparency and balance among powers. Critics, however, warn that it could politicize agencies that depend on technical autonomy—such as Anvisa, ANS and ANEEL—potentially undermining regulatory stability in key sectors like health, energy, and telecommunications. Read more.

44% OF BRAZILIAN WOMEN WITH MENOPAUSE SYMPTOMS DO NOT SEEK TREATMENT, STUDY SHOWS

Nearly half of Brazilian women experiencing menopause symptoms are not undergoing any form of treatment, according to data highlighted by Medicina S/A. The article points out that 44% of women report suffering from hot flashes, insomnia, irritability, and other hormonal-transition symptoms without medical support, revealing a persistent gap in women's health care. Specialists emphasize that hormone replacement therapy (HRT) remains the most effective treatment for symptom relief and long-term protection against complications such as osteoporosis. However, barriers such as misinformation, fear of side effects, limited access to specialized care and social stigma continue to deter many from seeking medical help. Experts recommend greater investment in awareness campaigns, improved training for primary-care professionals and expansion of non-hormonal treatment options through the Unified Health System (SUS). The findings underscore the need for a national strategy to ensure comprehensive and evidence-based care for women during menopause. Read more.

BRAZIL'S ANS CHIEF SAYS HEALTH-PLAN REFORM BILL WILL NOT BE VOTED THIS YEAR

The president of the National Supplementary Health Agency (ANS) announced that the draft bill to reform Brazil's private health-plan sector will not be voted on this year, emphasizing that "there is no reason for haste." He stated that the agency prefers a technically consistent proposal developed through broad consultation, rather than a rushed process that could undermine regulatory stability and consumer protection. According to the ANS, the legislative debate should focus on structural issues such as the definition of coverage, financial sustainability of plans, and transparency in the relationship between insurers, providers, and consumers. The agency has argued that a premature vote could generate uncertainty and distort the ongoing effort to modernize supplementary health regulation. The decision aligns with the agency's strategy to strengthen technical dialogue with Congress and market stakeholders before the bill moves forward. By postponing the vote, the ANS aims to consolidate a framework that balances access, affordability and predictability for beneficiaries and the health-insurance industry alike. Read more.

MINISTRY OF HEALTH INVESTS R$2.3 BILLION TO PROVIDE ZOLGENSMA IN BRAZIL

The federal government has allocated R$2.3 billion to acquire and distribute 385 doses of Zolgensma, a gene therapy indicated for spinal muscular atrophy (SMA), through Brazil's Unified Health System (SUS). Known in the country as the world's most expensive medicine, each dose is priced at about R$6.2 million—below its global market average of R$7 million. The agreement between the Ministry of Health and Novartis Biociências S.A. runs until 2030 and introduces a results-based payment model: the government will release funds as patients show clinical improvement. The treatment, approved by Anvisa in 2020, is indicated for babies under six months diagnosed with type I SMA, a severe and progressive neuromuscular disease. Read more.

WOMEN WITH BREAST CANCER WAIT MORE THAN TWICE AS LONG IN BRAZIL'S PUBLIC SYSTEM COMPARED TO PRIVATE SECTOR

A study conducted by 14 cancer-treatment centers across Brazil reveals that women diagnosed with early-stage estrogen-receptor-positive (ER+) breast cancer wait on average 93 days in the Unified Health System (SUS) to begin treatment, compared with 41 days in the private network. The delay is especially concerning given that timely treatment initiation is key to improving survival and reducing recurrence risk in this subtype of breast cancer. Although Brazilian law (Law No. 12.732/2012) guarantees patients with cancer the right to start therapy within 60 days after diagnosis, the study indicates that the legal timeframe is rarely met in the public system. According to lead researcher Romualdo Barroso de Sousa, delays are caused by structural inefficiencies, including multiple referral stages, limited diagnostic capacity, and fragmentation in care coordination across the SUS oncology network. Researchers also found

that longer waiting periods affect even patients with subtypes that have well-established treatment pathways, such as ER+ breast cancer, which responds effectively to endocrine-adjuvant therapy. Experts warn that postponing therapy not only worsens individual outcomes but also increases system costs due to disease progression and higher treatment complexity. Read more.

FEDERAL GOVERNMENT LAUNCHES NEW DIGITAL PLATFORM FOR SOCIAL PARTICIPATION

The federal government has launched a new digital platform called Brasil Participativo, designed to centralize all official tools for public engagement, including consultations, contribution forms and participatory processes related to health policy. The initiative was presented by the National Committee for Health Technology Incorporation (Conitec) and aims to expand transparency and facilitate dialogue between the government, patients, professionals, and civil society. Through Brasil Participativo, users can submit comments, attach supporting documents, and track public consultations in progress. The platform is integrated with the national gov.br authentication system, allowing secure participation using individual taxpayer identification (CPF) credentials. According to Conitec, all new public consultations and calls for input on health technology assessments will now be hosted through this unified system. Officials highlighted that the new tool represents a milestone in participatory governance, offering a more accessible, transparent, and data-driven process for incorporating technologies into Brazil's Unified Health System (SUS). The platform reinforces the government's strategy to modernize digital participation and ensure that decisions on public health policies increasingly reflect social and scientific contributions. Read more.

BRAZILIAN TOWN SEES SURGE IN FRIEDREICH'S ATAXIA CASES TREATED WITH HIGH-COST DRUG

A municipality in Piauí is witnessing a growing number of cases of Friedreich's ataxia, a rare hereditary neurodegenerative disease that impairs coordination, balance, and muscle strength. The condition, linked to genetic mutations and often associated with consanguinity, has appeared with unusual frequency in local families, prompting concern among public-health authorities. Patients have been treated with omaveloxolone, a medication developed by Reata Pharmaceuticals, a U.S.-based company acquired by Biogen in 2023. The drug, marketed under the name Skyclarys, costs about R$ 199,000 per package and is one of the few therapies approved to slow the progression of Friedreich's ataxia. Approved by the U.S. Food and Drug Administration (FDA) in 2023 and by Anvisa in 2024, the treatment acts by reducing oxidative stress in nerve cells and improving mitochondrial function. Read more.

UNREGISTERED INSULIN DOMINATES SUS SUPPLY AS GOVERNMENT BLAMES WEIGHT-LOSS DRUG BOOM

Nearly 70% of the insulin distributed through Brazil's Unified Health System (SUS) in 2025 comes from batches not registered with the National Health Surveillance Agency (Anvisa), according to data from the Ministry of Health. The government attributes the situation to global production shortages linked to the surge in demand for weight-loss medications such as semaglutide and tirzepatide. Officials argue that pharmaceutical companies have redirected production capacity toward higher-value obesity drugs, reducing the availability of traditional insulin formulations. As a result, Brazil has been importing emergency supplies approved only by foreign regulators to avoid treatment interruptions for diabetic patients. Experts warn that the growing dependence on unregistered imports exposes vulnerabilities in public procurement and regulatory oversight. To mitigate the shortage, the Ministry of Health is negotiating technology-transfer agreements with manufacturers from India and China to expand local production and restore supply stability. Read more.

JUDICIAL ACTIONS FOR OZEMPIC CONCENTRATE ON BRAZIL'S SUS AMID HIGH COST AND PATENT BARRIERS

Legal claims seeking access to Ozempic (active ingredient semaglutide) in Brazil are increasingly filed against the Unified Health System (SUS), driven by the drug's high cost and patent-protected status. Patients with obesity or type 2 diabetes view the medication as essential, but the requirement of judicial enforcement underscores the absence of broad public coverage and affordability. Industry and legal analysts point to two major obstacles: the patent exclusivity held by the manufacturer, which delays generics entry and keeps public procurement limited, and the budgetary implications for SUS should coverage at scale be mandated. These pressures are causing courts, health agencies, and policymakers to revisit how high-cost therapies are incorporated into the public system. Read more.

BRAZILIANS TURN TO PARAGUAYAN-SOURCED MOUNJARO PENS AMID ACCESS GAPS IN BRAZIL

An increasing number of Brazilians are resorting to importing or purchasing through informal channels pens of Mounjaro (tirzepatide) from neighboring Paraguay, driven by limited access and high demand for anti-obesity and metabolic therapies in Brazil. The surge in cross-border acquisition highlights regulatory, supply and affordability challenges in the country's pharmaceutical market. Authorities report that many of the imported units bypass formal distribution and regulatory oversight, posing risks of counterfeit products, improper storage, and lack of medical supervision. Customs seizures of large quantities of the medication reflect concern among enforcement agencies about patient safety and market integrity. Experts warn that while self-importation and parallel channels may appear as short-term workarounds for patients, they undermine drug safety, compromise public-health oversight and may distort accessible treatment pathways within the regulated system. Read more.

MORE HIGHLIGHTS

Brazil's Senate debate calls for stronger integration of health innovation and national industry

Senate approves creation of the National Palliative Care Program

Senate's committee passes bill on annual comprehensive women's health assessment

Brazil's Health Ministry launches national training to support Implanon rollout in SUS

Brazil's Anvisa opens public consultation on adaptive-design clinical trial guidelines

Anvisa prohibits falsified lots of cancer drugs in Brazil

Brazil's Anvisa suspends manipulated medicines and hormonal implants from Elmeco

Experts urge enforcement of laws ensuring full treatment for neurodivergent people in Brazil

Government forecasts widespread use of artificial intelligence in Brazil's health and education sectors by 2028

Medicinal cannabis market matures in Brazil with falling prices and new regulation

BRAZIL NEWS

Brazil's Lula says he will seek re-election in 2026

Brazil government to resubmit part of fiscal measures to Congress after setback

Brazil posts wider-than-expected current account deficit in September

Brazil's Lula open to discussing tariffs, Venezuela with Trump

Trump says he's willing to reduce tariffs on Brazil in right circumstances

China to buy Brazil's deforestation-free beef, says NGO

Brazil forest loss linked to coffee hit 737,000 hectares between 2002 and 2023, report says

How Brazil’s climate talks in the Amazon can deliver a fairer, safer future

Brazil's Petrobras gets green light to drill near mouth of Amazon river

Brazil's Petrobras reports record oil exports in third quarter as output rises

MercadoLibre to sell products of Brazil rival Casas Bahia under new partnership

Ambipar bankruptcy filing in Brazil cites 'irregularities'

Brazil's bar, restaurant sales fall amid beverage poisoning cases, survey finds