WEEKLY REPORT

10/11/2025

BRAZIL ENACTS DECREE REGULATING THE CLINICAL TRIALS LAW

The federal government has published Decree No. 12,651 of October 7, 2025, which regulates Law No. 14,874/2024 on research involving human subjects and establishes the National System of Ethics in Research with Human Beings (SINEP). Originating from Senate Bill No. 200/2015, sponsored by former senators Ana Amélia, Waldemir Moka, and Walter Pinheiro, the law and its implementing decree seek to align Brazil's clinical research environment with international standards of Good Clinical Practice (GCP) while reducing bureaucracy and regulatory delays. Under the decree, SINEP will be coordinated by the Ministry of Health, through the Secretariat of Science, Technology, Innovation and the Health Economic-Industrial Complex (SECTICS). It is composed of two main instances: the National Instance of Ethics in Research (INAEP) — a consultative, deliberative, and supervisory body — and the Research Ethics Committees (CEPs), responsible for ethical evaluation at the institutional level. The decree introduces clear procedural deadlines to increase efficiency: - 30 working days for ethical review by CEPs; - 90 working days for Anvisa's sanitary authorization; and - 15 working days for trials considered strategic for the SUS or related to public health emergencies. It also establishes the National Platform for Research with Human Beings, which will replace Plataforma Brasil by late 2026. The new digital system will centralize registration, submission, and tracking of studies, enabling secure data exchange, compliance with Brazil's General Data Protection Law (LGPD), and full transparency in clinical trial oversight. The decree reinforces ethical obligations such as post-trial access to treatments showing proven benefit, special safeguards for vulnerable populations (including children, pregnant women, indigenous peoples, and prisoners), and ethical protocols tailored to social and behavioral sciences. A Temporary Working Group (GTT) coordinated by SECTICS will oversee implementation and propose complementary regulations. Read more.

BRAZIL CONSULTATION REVEALS REGULATORY AND FUNDING BOTTLENECKS IN CLINICAL RESEARCH

A public consultation carried out by the Secretariat of Science, Technology, Innovation and the Health Economic-Industrial Complex (SECTICS) of the Ministry of Health gathered 114 contributions between August and September 2025 to identify the main challenges for clinical research in Brazil. Participants pointed to excessive bureaucracy and lengthy regulatory timelines as the biggest obstacles, followed by limited funding, fragmented infrastructure, and difficulties in attracting international studies. The consultation also underscored the need to streamline ethical and regulatory processes, harmonize requirements across agencies, and expand financing mechanisms for both public and private institutions. Respondents emphasized the importance of improving professional training, integrating data systems, and fostering public-private partnerships to strengthen national capacity in health innovation. The findings will guide the revision of Brazil's Clinical Research Action Plan, coordinated by SECTICS, which seeks to align research policies with industrial development and access to innovation in the country's health system. The Ministry of Health expects the new plan to support a more agile, transparent, and competitive environment for conducting clinical trials in Brazil. Read more.

BRAZIL STILL LACKS REGULATORY FOCUS ON MENOPAUSE AND PERIMENOPAUSE

Despite increasing awareness of women's health, menopause and perimenopause remain neglected within Brazil's regulatory and public policy frameworks. Experts interviewed by JOTA

point out that, unlike reproductive or maternal health, this stage of women's lives still lacks structured evaluation and incorporation mechanisms in the health system. The absence of clear guidelines delays access to therapies capable of improving quality of life and preventing associated conditions such as osteoporosis and cardiovascular diseases. The article notes that Brazil's regulatory framework does not yet prioritize the inclusion of innovative therapies targeting menopause. There are no specific policies within the Ministry of Health or Anvisa that define criteria for assessing cost-effectiveness or accelerating the approval of such treatments. Specialists argue that this gap reinforces social and economic inequalities, as only women with private coverage or purchasing power can access the newest options. A recent example is fezolinetant, a non-hormonal therapy approved by Anvisa for vasomotor symptoms such as hot flashes. The drug is considered a scientific breakthrough for women unable or unwilling to use hormonal therapy. However, in the absence of a clear regulatory and pricing pathway, access to fezolinetant and similar products remains uncertain in the Brazilian context. According to experts, bridging this regulatory gap requires coordination between Anvisa, Conitec, and the Ministry of Health to establish a comprehensive policy for women's midlife health. This would include clinical guidance, access strategies in the public system, and coverage definitions in supplementary health — ensuring that menopause care becomes a national health priority. Read more.

BRAZIL'S PARANÁ ASSEMBLY DEBATES WOMEN'S HEALTH IN MENOPAUSE, HIGHLIGHTING DELAYS IN FEZOLINETANT APPROVAL

The Legislative Assembly of Paraná held a public hearing on Women's Health in Menopause, gathering specialists, health officials and state representatives to discuss challenges, advances, and priorities in women's health policies during this life stage. The event was promoted by the state's women's caucus, composed of ten female representatives from multiple parties, alongside other legislators engaged in the theme. Gynecologist Alexandra Ongarato, technical director at Instituto Gris Curitiba, called attention to the lack of access to non-hormonal therapies for menopausal symptoms. She cited fezolinetant — the first non-hormonal medication approved by the U.S. FDA — which has awaited Anvisa's approval for more than a year. Ongarato criticized the lack of regulatory prioritization, stressing that while the treatment is already available in the United States, Brazilian women remain without access. She underscored the need to treat menopause as a public-health issue grounded in science and empathy, and presented the concept of "duopause," emphasizing the role of partners in supporting women through this transition. Participants also discussed the stigmas surrounding menopause, the need for individualized and evidence-based care, and the integration of lifestyle medicine, psychological support, and non-hormonal alternatives. Speakers warned against unproven hormonal implants and aesthetic infusions, calling for policies that promote informed and comprehensive care. Representatives from the Paraná State Health Secretariat reinforced the central role of the SUS in ensuring equitable care for women in all life stages. Read more.

BRAZIL FACES LANDMARK PATENT EXTENSION DISPUTE OVER OZEMPIC THAT COULD SET PRECEDENT

A legal dispute in Brazil over a patent extension for Ozempic (semaglutide) could establish a precedent with major implications for the pharmaceutical industry. The case, currently before the Superior Court of Justice (STJ), will determine whether delays by the Brazilian Patent Office (INPI) justify an extension of exclusivity for Novo Nordisk's drug, whose protection is set to expire in 2026. Novo Nordisk argues that administrative backlogs at INPI have unfairly shortened its period of patent protection and seeks "recomposition" of the lost time. Legal experts, however, point out that the Supreme Federal Court (STF) ruled in 2021 against automatic patent extensions under Article 40 of the Industrial Property Law, which may restrict the company's chances of success. According to specialists, if the court grants the extension, it could open the door for similar claims from other pharmaceutical companies and delay the entry of generics or biosimilars into the Brazilian market. Conversely, a decision upholding the original expiration date would reinforce the precedent that patent terms cannot be prolonged due to bureaucratic inefficiencies. The outcome of this case is expected to shape future

discussions on innovation, competition, and access to medicines in Brazil, particularly for chronic conditions like obesity and diabetes, for which semaglutide is widely prescribed. Read more.

BRAZIL UPDATES HEALTH TECHNOLOGY ASSESSMENT GUIDELINES AMID METHODOLOGICAL GAPS

The Ministry of Health, through the Brazilian Network for Health Technology Assessment (Rebrats) and the Department of Management and Incorporation of Health Technologies (DGITS), is updating the Methodological Guidelines for Economic Evaluation in Health, which guide the assessment of technologies proposed for incorporation into the Unified Health System (SUS). The current version, published in 2014, is considered outdated given the growing complexity of health technologies and new analytical methods available. The new draft introduces several key innovations, including the establishment of a cost-effectiveness threshold, improved modeling of long-term patient costs, and clearer methodologies for evaluating medical devices, covering logistics, maintenance, and consumables. It also proposes differentiated parameters for orphan and ultra-rare disease technologies and seeks to enhance transparency, standardization, and reproducibility in economic evaluations submitted to Conitec. Despite progress, experts point to persistent gaps — such as the absence of explicit guidance on risk-sharing agreements, judicialization costs, and the integration of real-world evidence and observational data into decision-making frameworks. The text also grants flexibility for assessing advanced therapies and high-cost technologies but lacks full alignment with international reference models. The updated guidelines are expected to strengthen technical rigor, reduce political influence in incorporation decisions, and provide more predictable criteria for industry and policymakers. The final version will be published after analysis of contributions received during the public consultation period. Read more.

BRAZIL SEES GROWTH IN PRIVATE HEALTH COVERAGE, BUT REGULATORY STRAIN LOOMS

The Brazilian supplementary health sector reached 53.0 million beneficiaries in August, marking a 2.5% increase compared with August 2024, according to data from the National Regulatory Agency for Private Health Insurance and Plans (ANS). The rise reflects an addition of 189,200 users month over month and 1.29 million year over year. Among these, 38.5 million are enrolled in employer-sponsored plans, 5.87 million under collective adhesion plans, and 8.58 million in individual or family plans. In the exclusively dental segment, the number climbed to 34.6 million users, a 2.9% year-on-year increase, with a net gain of 326,000 just in August. Over the past 12 months, nearly 987,500 new dental beneficiaries were added, reflecting both a post-pandemic demand for preventive oral care and expanding employer benefits. While the upward trend signals sector resilience and sustained demand, experts warn that regulatory challenges may intensify. The growing beneficiary base puts pressure on pricing models, reimbursement rules, and the sustainability of operators. Coordination between ANS, the Ministry of Health, and market stakeholders will be essential to maintain service quality, cost control, and equitable access across regions. Read more.

BRAZIL'S ANS SIGNALS IT MAY IMPOSE REGULATION ON HEALTH PLANS IF NEEDED

In a recent interview, ANS President Wadih Damous affirmed that the agency is ready to impose regulation on private health plans if negotiation fails to ensure balance in the sector. He emphasized that regulation does not inherently mean imposition, but signaled that the regulatory agency will act decisively if required. Damous pointed out structural imbalances in the health-plan market, especially in collective contracts, and called for reviving the individual/family product segment. He indicated that ANS aims to convene stakeholders to discuss pricing, coverage, and risk sharing. If consensus is not reached in these dialogues, the agency will use its regulatory powers to correct distortions. Read more.

BRAZIL SEES CHANGE IN HEALTH-PLAN REFORM LEADERSHIP AS HOUSE OF REPRESENTATIVES' PRESIDENT REPLACES PRO-CONSUMER RAPPORTEUR

In a move that reshapes the debate over Brazil's health-plan reform, House of Representatives' President Hugo Motta removed representative Duarte Jr. (PSB–MA) from the rapporteur position of Bill No. 7.419/2006, which updates the country's private health insurance legislation. Motta appointed representative Domingos Neto (PSD–CE), a member of the Centrão bloc, with the stated goal of unblocking the long-delayed proposal. The decision follows months of tension between consumer-rights advocates and industry representatives. Duarte Jr., known for his pro-consumer stance and for calling for a parliamentary inquiry into unilateral cancellations by health plans, had proposed stricter rules on contract transparency and coverage denials. His replacement signals a shift in the political balance toward sectors seeking greater flexibility in the regulatory framework. Motta's strategy is to rebuild consensus among operators, regulators, and legislators to advance the bill, which has been under discussion for nearly two decades. The new rapporteur is expected to deliver a revised draft that may soften some consumer protection measures in an effort to secure broader support within the House of Representatives. Read more.

BRAZIL LAUNCHES ELECTRONIC FORM TO ASSIST FOREIGN USERS

As part of its digital transformation strategy, Anvisa has introduced a new electronic form called Contact US, designed to facilitate communication with foreign users — individuals and companies abroad seeking regulatory information or assistance. The new tool aims to reduce language and procedural barriers for international stakeholders, offering a direct channel distinct from the existing domestic services such as the 0800 hotline, webchat, and the "Fale Conosco" portal. Through the form, users can request information on regulatory requirements, product registration, health surveillance procedures, and other matters related to sanitary control in Brazil. By creating a dedicated point of contact for foreign stakeholders, Anvisa strengthens its commitment to transparency, international cooperation, and efficiency in handling cross-border regulatory issues. The initiative also reflects the agency's effort to modernize its communication systems and align with global standards of regulatory governance. Read more.

BRAZIL SEEKS HEALTH-SECTOR PARTNERSHIPS WITH UK, CHINA AND INDIA AFTER U.S. TARIFFS

In response to recent tariff surcharges imposed by the Trump administration, Brazil is actively pursuing strategic partnerships with the United Kingdom, China and India in the health sector. The Brazilian government sees this as a move to diversify supply chains for medicines, vaccines and health technologies, reducing dependency on the U.S. market and mitigating the impact of protectionist measures. Brazilian health and trade officials intend to explore shared production, technology transfer, and joint regulatory pathways with these countries, hoping to streamline imports and enhance resilience in the domestic pharmaceutical ecosystem. The strategy may also bolster Brazil's negotiating power in global health diplomacy, especially amid growing geopolitical tensions over access to medical goods. Read more.

BRAZIL RECORDS OVER A THOUSAND OCULAR CANCER CASES ANNUALLY, INCA DATA SHOW

Brazil registers more than 1,000 new cases of ocular cancer each year, according to data from the National Cancer Institute (INCA). Among children, retinoblastoma is the most frequent form, with an estimated 230 new cases annually, representing the majority of pediatric eye tumors. In adults, the most common intraocular malignancy is choroidal melanoma, a condition that often progresses silently and can lead to vision loss if not detected early. Worldwide, ocular cancer affects roughly one person in every 20,000, and about 90% of pediatric cases occur before the age of five, half of them before age two. Specialists highlight that early diagnosis is critical to preserving vision and preventing more invasive treatments such as enucleation. In Brazil, the main challenge lies in expanding access to advanced therapeutic modalities, including intra-arterial chemotherapy, brachytherapy, external radiotherapy, and topical chemotherapy for surface lesions. Experts also call for greater investment in public awareness

campaigns, early screening initiatives, and improved regional referral networks to ensure equitable access to specialized care. Read more.

BRAZIL DEBATES NEED FOR STRONGER INVESTMENT IN CANCER THERAPIES DURING SENATE HEARING

The Senate's Temporary Subcommittee on Cancer Prevention and Treatment held a public hearing on October 7 to discuss the urgent need for increased federal investment in research, innovation, and access to therapies against cancer. Lawmakers and experts warned that Brazil risks falling behind global standards in oncology if it fails to expand funding and foster local production of high-cost medicines. Participants from the Ministry of Health, the Ministry of Science, Technology and Innovation, and the National Cancer Institute (INCA) emphasized the need to strengthen the national research ecosystem and attract new clinical trials to the country. The discussion also highlighted the importance of implementing the Law of Clinical Trials (Law No. 14,874/2024) to streamline approvals, reduce bureaucracy, and align Brazil's industrial and health-innovation policies. Speakers noted that cancer is on track to become the leading cause of death in Brazil in the coming decades, underscoring the importance of early detection, prevention, and equitable access to modern treatments through the SUS. Representatives from the pharmaceutical industry reinforced the urgency of removing regulatory bottlenecks, arguing that each delay in incorporating therapies can cost lives. Read more.

BRAZIL'S SENATE MARKS PINK OCTOBER WITH CALLS FOR STRONGER BREAST CANCER PREVENTION AND TREATMENT

The Federal Senate held a special session on October 9 to commemorate Pink October (Outubro Rosa) and to call for greater investment in breast cancer prevention, early detection, and access to treatment. Lawmakers, health professionals, and civil-society representatives highlighted that Brazil is expected to register around 74,000 new breast cancer cases in 2025, reaffirming that early diagnosis can lead to cure rates of up to 95%. Senator Leila Barros (PDT–DF), who presided over the session, stressed that the campaign must go beyond awareness and serve as a platform for social justice and health equity. She emphasized the need to ensure that all women, regardless of region or socioeconomic status, have access to mammography, timely diagnosis, and adequate treatment. Participants also called for stronger public policies and greater budget allocations for women's health, particularly to expand diagnostic capacity and therapeutic infrastructure within the SUS. Senator Damares Alves (Republicanos–DF) shared her personal experience as a breast cancer survivor, reinforcing that early screening and continuous follow-up can save lives. Read more.

BRAZIL'S PHARMACY ASSOCIATION REAFFIRMS OPPOSITION TO DRUG SALES VIA MARKETPLACE

The Brazilian Association of Pharmacies and Drugstores (Abrafarma) has reiterated its opposition to the sale of medicines through marketplace platforms, warning that such practices may compromise consumer safety and undermine public health regulations. The statement comes amid growing debate following Mercado Livre's acquisition of Cuidamos Farma, signaling its entry into the pharmaceutical retail sector. According to Abrafarma, the marketplace model poses legal and operational challenges, including risks of horizontal concentration in the drug retail market and vertical integration between pharmacies and e-commerce conglomerates. The association argues that medication sales require strict compliance with sanitary regulations and must involve direct oversight by qualified pharmacists, conditions that are not guaranteed in open online platforms. Abrafarma also called on health authorities to strengthen surveillance and maintain the integrity of the regulatory framework that governs medicine distribution in Brazil. The entity defends that any modernization of the pharmaceutical retail environment must occur within existing safety and ethical parameters established by the National Health Surveillance Agency (Anvisa). Read more.

MORE HIGHLIGHTS

Ministry of Health provides information on the expansion of the neonatal screening test in all Brazilian states

Ministry of Health clarifies criteria for applying Elevidys gene therapy to children with Duchenne Muscular Dystrophy

Brazil reports up to 58% drop in cervical cancer cases after HPV vaccination

Bill aims to guarantee access to oral medications that modify the course of immune-mediated diseases and rare diseases

Public hearing held on funding for research and development of vaccines, drugs and therapies against câncer

House of Representatives debates public policies and awareness about Huntington's Disease

Measles-free status in jeopardy in the Americas as outbreaks continue

BRAZIL NEWS

Brazil's Lula and Trump agree to meet in person after friendly call

Brazil, US officials agree to meet in Washington to discuss trade

Brazil's beef exports to China jump 38% in September amid US tariffs

Brazil's soybean exports to hit record as US out of market, Chinese demand strong

Michelle Bolsonaro tamps down talk of 2026 Brazil run as husband awaits prison

Brazil Justice Barroso to leave Supreme Court, opening new appointment for Lula

Brazil weighs budget options after investment tax setback, Haddad says

Brazil's cenbank director says tightening pause means longer hold on rate levels

Brazil inflation rebounds in September despite falling food prices

Brazil unveils new housing credit model, freeing up $6.7 billion for new loans

Brazil not planning free public transport soon, presidential chief of staff says

Construction still in progress in Belem as Brazil readies to host COP30

Hotel prices lead countries to consider skipping COP30 climate summit

Brazil to begin construction on TikTok data center in six months, minister says