WEEKLY REPORT

05/09/2026

BRAZIL FORMALIZES NATIONAL CLINICAL TRIAL PROGRAM THROUGH OFFICIAL GAZETTE PUBLICATION

The Ministry of Health officially instituted the National Clinical Trial Program (PPClin) through publication in the Federal Official Gazette (DOU), establishing a new framework to strengthen Brazil's clinical research ecosystem and expand the country's role in global health innovation. The initiative is designed to coordinate actions involving research institutions, healthcare services, regulatory agencies, and strategic partners within the Unified Health System (SUS). According to the ordinance, the program aims to promote scientific and technological development, increase national capacity for clinical trials and support the development of innovative therapies, vaccines, diagnostics, and healthcare products aligned with Brazil's public health priorities. This measure also seeks to improve governance, infrastructure, and integration among clinical research networks across the country. The Ministry of Health stated that the program is part of a broader strategy to reduce dependence on imported technologies, stimulate innovation and strengthen Brazil's participation in international research initiatives. The government also expects the initiative to contribute to faster patient access to new treatments and to attract investments in the life sciences sector. Read more.

BRAZIL'S EXPANDED NEWBORN SCREENING PROGRESSES SLOWLY FIVE YEARS AFTER FEDERAL LAW

Five years after Brazil approved legislation expanding the national newborn screening program, implementation of the so-called "expanded heel prick test" remains limited across the country. Federal Law No. 14,154/2021 established the gradual inclusion of additional diseases in neonatal screening under the Unified Health System (SUS), but only three states currently test newborns for Spinal Muscular Atrophy (SMA), according to a report by G1. Specialists and patient advocacy groups interviewed by the outlet warn that delays in implementation may compromise early diagnosis and treatment outcomes for children with rare diseases. The expansion of screening depends on laboratory capacity, logistics, trained personnel, and financing, while implementation timelines continue to vary among states. The report also highlights concerns over regional inequalities in access to neonatal screening and the pace of incorporation of new technologies into public healthcare services. Advocacy organizations defend a more coordinated national strategy to ensure broader and more uniform access to expanded newborn screening throughout Brazil. Read more.

BRAZIL PLANS CONFIDENTIAL PRICING MODEL FOR HIGH-COST DRUGS

The Ministry of Health is preparing a new model for purchasing high-cost drugs for Brazil's Unified Health System (SUS) based on confidential price agreements with pharmaceutical companies. Health Minister Alexandre Padilha said the government expects to carry out the first acquisition under the "silent pricing" model later in 2026, after advancing discussions with oversight bodies including the Federal Court of Accounts (TCU) and the Supreme Federal Court (STF). According to the ministry, confidential agreements could allow the government to negotiate larger discounts for innovative and high-cost therapies without publicly disclosing final prices, a practice already adopted in countries such as the United Kingdom. The proposal is part of broader efforts to expand access to advanced therapies while improving the sustainability of public healthcare spending and accelerating technology incorporation into SUS. Read more.

BRAZIL PREPARES ORDINANCE WITH TECHNICAL ADJUSTMENTS FOR DRUG PRICING POLICY

The Ministry of Health is preparing a new ordinance to establish technical adjustments for medicine pricing and reimbursement mechanisms within Brazil's Unified Health System (SUS). According to Futuro da Saúde, the measure is expected to define operational criteria related to price negotiations, procurement dynamics and the evaluation of high-cost therapies incorporated into the public healthcare system. The proposal is part of broader government efforts to improve predictability and efficiency in the acquisition of innovative medicines, especially therapies with significant budgetary impact. Discussions also involve coordination with oversight bodies and the pharmaceutical sector to refine the regulatory framework surrounding pricing practices and technology incorporation in SUS. Read more.

CONITEC OPENS PUBLIC CONSULTATION ON BUDGET IMPACT ANALYSIS GUIDELINES

The National Committee for Health Technology Incorporation (Conitec) opened a public consultation to receive contributions on new methodological guidelines for budget impact analysis in the evaluation of health technologies within Brazil's Unified Health System (SUS). The initiative aims to improve the standardization and transparency of economic assessments used in decisions regarding the incorporation of medicines, devices, and other healthcare technologies. According to Conitec, the proposed guidelines seek to strengthen technical criteria for estimating the financial impact of new technologies on public healthcare spending, supporting more sustainable and evidence-based decision-making processes. Contributions from healthcare professionals, industry representatives, researchers, and civil society may be submitted during the consultation period. Read more.

BRAZIL'S ANS EVALUATES PRICE-BASED AGREEMENTS FOR INCLUSION OF HIGH-COST DRUGS IN MANDATORY COVERAGE LIST

The National Supplementary Health Agency (ANS) is evaluating a new mechanism to incorporate high-cost medicines into the mandatory coverage list for private health plans in Brazil through negotiated price reductions with pharmaceutical companies. The initiative involves responsibility agreements in which manufacturers commit to maintaining discounted prices as a condition for inclusion in the agency's coverage list. The model was first applied to dupilumab, marketed by Sanofi, for severe chronic obstructive pulmonary disease (COPD). According to reports, the agreement included discounts linked to the price ceiling established by the Drug Market Regulation Chamber (CMED), as well as additional commercial discounts for all indications already covered by ANS. Agency officials say the strategy aims to balance patient access to innovative therapies with the financial sustainability of Brazil's supplementary health sector. ANS representatives also indicated that the agency is discussing broader economic evaluation tools, including possible cost-effectiveness thresholds for future incorporation decisions. Industry associations and private healthcare stakeholders have generally viewed the initiative positively, while emphasizing the need for regulatory predictability and transparent negotiation criteria. Read more.

BRAZIL'S ANS SAYS GAP IN HEALTH PLAN INCREASES REINFORCES NEED FOR REGULATORY REVIEW

The National Supplementary Health Agency (ANS) stated that the significant difference between premium increases applied to small-group health plans and large corporate contracts reinforces the need to review current regulatory rules in Brazil's supplementary health sector. According to the agency, collective plans with up to 29 beneficiaries remain subject to pooled risk adjustment mechanisms that can result in substantially higher annual increases compared to contracts negotiated by large companies. The debate comes amid broader discussions on the sustainability and transparency of Brazil's private healthcare market. ANS officials have signaled that the agency is evaluating possible regulatory changes involving the methodology for readjustments, risk-sharing arrangements and contractual balance between insurers and

beneficiaries. Industry representatives argue that rising healthcare costs, judicialization and incorporation of new technologies continue to pressure premiums across the sector. Read more.

BRAZILIAN CONGRESSMAN PROPOSES SPECIAL COMMITTEE ON SUPPLEMENTARY HEALTHCARE

Federal Congressman Dr. Luizinho (Progressistas-RJ) proposed the creation of a special committee in the Chamber of Deputies to discuss structural challenges in Brazil's supplementary healthcare sector. According to Futuro da Saúde, the initiative aims to bring together lawmakers, regulators, healthcare providers, insurers, and patient representatives to debate issues such as rising healthcare costs, judicialization, regulatory modernization and the sustainability of private health insurance plans. The proposal comes amid growing pressure on the supplementary health market due to increasing medical expenses, demographic aging and the incorporation of new technologies and therapies. Discussions are expected to involve the National Supplementary Health Agency (ANS) and industry representatives, with a focus on identifying legislative and regulatory measures capable of improving predictability and expanding access within the sector. Read more.

BRAZILIAN HEALTH REGULATORY AGENCY FOCUSES ON INNOVATION AND FASTER APPROVALS, SAYS SAFATLE

The Director-President of the Brazilian Health Regulatory Agency (Anvisa), Leandro Safatle, said the agency is prioritizing technological innovation and measures to reduce regulatory backlogs amid growing demand for new therapies and healthcare technologies in Brazil. In an interview with Futuro Talks, Safatle stated that "technological innovation is the agency's future agenda" and highlighted efforts to optimize review timelines for medicines, biosimilars, and advanced therapies. Safatle said one of ANVISA's main current challenges is addressing regulatory queues that directly affect the pharmaceutical and healthcare sectors. According to him, the agency has reduced waiting times in areas such as clinical trial authorizations and radioisotope-related petitions, while also seeking greater efficiency in drug registration reviews. He noted that improving predictability and shortening approval timelines are essential to expand patient access to innovative therapies and to strengthen Brazil's competitiveness in life sciences. The ANVISA chief also pointed to emerging regulatory challenges involving GLP-1 drugs and the expansion of biosimilars in the Brazilian market. He defended a regulatory model capable of balancing agility, innovation, and patient safety, while reinforcing dialogue with the productive sector and the scientific community. Read more.

ANVISA APPROVES NEW DRUG FOR RARE CARDIAC DISEASE

The Brazilian Health Regulatory Agency (Anvisa) approved the registration of Beyonttra® (acoramidis hydrochloride), a new treatment for transthyretin amyloid cardiomyopathy (ATTR-CM), a rare and progressive cardiac disease that can lead to heart failure and death. The therapy is indicated for patients with both wild-type and hereditary forms of the disease. According to ANVISA, the drug works by stabilizing the transthyretin (TTR) protein, reducing cardiovascular mortality risk associated with amyloid deposits in the heart muscle. In a Phase 3 clinical trial, patients treated with acoramidis showed a statistically significant benefit compared to placebo, with a 77.2% higher likelihood of achieving treatment benefit. Estimates from the Brazilian Society of Cardiology indicate that nearly 13,000 people in Brazil may be affected by the condition, particularly men over 60 years old. Read more.

ANVISA APPROVES UPDATED DOSING SCHEDULE FOR WEGOVY

The Brazilian Health Regulatory Agency (Anvisa) approved an update to the dosing schedule of Wegovy® (semaglutide), expanding flexibility in dose escalation for obesity treatment in Brazil. The change allows physicians to adjust the interval for dose increases according to individual patient response and tolerability, aiming to improve adherence and treatment management. Wegovy is indicated for chronic weight management in adults with obesity or overweight associated with at least one comorbidity. According to ANVISA, the updated label provides greater flexibility for healthcare professionals to delay dose escalation when patients experience

gastrointestinal adverse events, one of the main causes of treatment discontinuation with GLP-1 therapies. The decision comes amid growing demand for GLP-1-based medications in Brazil and globally, driven by rising obesity rates and increasing interest in metabolic disease treatments. Semaglutide-based therapies have gained prominence not only for weight management but also for their potential cardiovascular and metabolic benefits observed in recent clinical studies. Read more.

ANVISA DELAYS DECISION ON COMPOUNDED GLP-1 REGULATION

The Brazilian Health Regulatory Agency (Anvisa) postponed a decision on a proposed regulation for the importation and manipulation of active pharmaceutical ingredients used in compounded GLP-1 medicines, including semaglutide and tirzepatide. According to Futuro da Saúde, the draft rule was discussed by the agency's board, but director Thiago Campos requested additional review of the proposal before a final vote. The proposed regulation is part of ANVISA's broader effort to strengthen oversight of compounded weight-loss drugs amid rising demand and concerns over counterfeit products, quality control, and traceability. The agency has intensified inspections of compounding pharmacies and importers in 2026 and is reviewing technical requirements related to supplier qualification, sanitary controls, and testing standards for GLP-1 ingredients. Read more.

ANVISA AND FEDERAL POLICE INTENSIFY CRACKDOWN ON ILLEGAL WEIGHT-LOSS DRUGS

The Brazilian Health Regulatory Agency (Anvisa) and the Federal Police announced plans to strengthen joint actions against the illegal sale of weight-loss medications, particularly injectable drugs based on semaglutide and tirzepatide used in obesity treatment. The cooperation agreement aims to expand investigations and enforcement efforts targeting the irregular production, importation, and commercialization of products without proper sanitary authorization. According to ANVISA director Daniel Pereira, authorities are increasingly concerned about the rise in adverse events linked to the use of counterfeit or unauthorized weight-loss drugs, many of them sold online without medical prescription or quality control guarantees. The initiative builds on previous joint operations conducted by ANVISA and the Federal Police against illegal pharmaceutical networks operating across several Brazilian states. Read more.

INTERFARMA DEFENDS PATENTS AS KEY INFRASTRUCTURE FOR INNOVATION IN BRAZIL

The president of the Pharmaceutical Research Industry Association (Interfarma), Renato Porto, defended intellectual property protections as essential infrastructure for technological development and healthcare innovation in Brazil. Speaking at the "Intellectual Property in the Public Agenda" summit hosted by Correio Braziliense, Porto argued that patents should not be viewed as privileges, but rather as mechanisms that encourage investment, research, and the development of new therapies. Porto warned that regulatory uncertainty, chronic delays, and recurring debates over compulsory licensing may discourage innovation and reduce Brazil's attractiveness for investments in life sciences. He also linked weak intellectual property protection to higher risks of piracy and counterfeit products, arguing that the issue directly affects patient safety and the country's long-term healthcare development strategy. According to Porto, countries with stronger innovation ecosystems generally combine regulatory predictability, legal certainty, and effective patent protection. He argued that Brazil needs to improve coordination between industrial, healthcare, and innovation policies in order to strengthen domestic research capacity and attract global pharmaceutical investments. Read more.

INTERFARMA EXECUTIVE LINKS PIRACY TO LOWER INCENTIVES FOR INNOVATION IN BRAZIL

An executive from the Pharmaceutical Research Industry Association (Interfarma) warned that product piracy and illegal commercialization practices may discourage innovation and

investments in Brazil's pharmaceutical sector. Speaking to Correio Braziliense, Interfarma's institutional relations director, Marina Gadelha, said intellectual property protection is essential to maintain incentives for research, development, and the introduction of innovative therapies in the Brazilian market. According to the association, counterfeit and irregular products not only create economic losses for the industry but also represent risks to patient safety and public health. Interfarma argued that stronger enforcement actions and greater regulatory oversight are necessary to combat piracy and ensure a safer and more predictable environment for pharmaceutical innovation in Brazil. Read more.

WIPO OFFICIAL DEFENDS PRESERVATION OF GLOBAL INTELLECTUAL PROPERTY FRAMEWORK

Anjam Aziz, assistant director general of the World Intellectual Property Organization (Wipo), defended the preservation of the global intellectual property framework as essential for innovation, technological development, and international cooperation. Speaking during the "Intellectual Property in the Public Agenda" summit hosted by Correio Braziliense, Aziz argued that predictable and harmonized international rules are critical to encourage investments in research and development across strategic sectors, including healthcare and pharmaceuticals. According to Aziz, weakening global intellectual property protections could create legal uncertainty and reduce incentives for innovation, particularly in emerging economies seeking to expand their technological capabilities. He also emphasized the importance of balancing access policies with mechanisms that preserve incentives for scientific advancement and the development of new products and technologies. Read more.

HEALTHCARE EXPERT POINTS TO PATENT BOTTLENECKS AND CALLS FOR INNOVATION ADVANCES IN BRAZIL

Raquel Sorza, director of health policy at the Latin American Federation of the Pharmaceutical Industry (Fifarma), warned that Brazil still faces important structural barriers in intellectual property and innovation policy. Speaking during the "Intellectual Property in the Public Agenda" summit hosted by Correio Braziliense, Sorza highlighted patent examination delays, regulatory uncertainty, and limitations in data protection as factors that reduce the country's competitiveness in the bio-pharmaceutical sector. According to Sorza, Brazil has an opportunity to strengthen its innovation ecosystem and attract more investment if it advances regulatory adjustments and improves predictability for companies and researchers. She noted that countries with stable innovation policies and stronger intellectual property frameworks tend to perform better in regional competitiveness rankings, regardless of market size. Read more.

FIFARMA STUDY POINTS TO PERSISTENT ACCESS GAPS FOR INNOVATIVE MEDICINES IN LATIN AMERICA

A study released by the Latin American Federation of the Pharmaceutical Industry (Fifarma) highlights significant delays and inequalities in access to innovative medicines across Latin America, including Brazil. According to the survey, patients in the region continue to face long waiting periods between regulatory approval and the effective availability of new therapies in healthcare systems. The analysis indicates that barriers involving incorporation processes, reimbursement decisions, healthcare infrastructure, and funding constraints continue to limit access to innovative treatments, particularly for patients with rare, chronic, and high-complexity diseases. The report also argues that improving regulatory efficiency and strengthening coordination between governments, healthcare systems and the pharmaceutical industry are essential to reduce disparities in access. According to Fifarma, the study reinforces concerns about the growing gap between scientific innovation and the capacity of health systems in Latin America to rapidly offer new therapies to patients. The entity also defended policies aimed at accelerating health technology assessment and expanding sustainable access mechanisms. Read more.

FARMABRASIL PROJECTS BRL 30 BILLION INVESTMENT TO MODERNIZE BRAZIL'S PHARMACEUTICAL INDUSTRY

The Brazilian Pharmaceutical Industry Association (Farmabrasil) projects investments of approximately BRL 30 billion aimed at modernizing Brazil's domestic pharmaceutical industry over the coming years. According to the entity, the resources are expected to support the expansion of manufacturing capacity, digital transformation, research infrastructure, and technological innovation within the national healthcare production chain. Industry representatives said the investment agenda is aligned with federal initiatives focused on strengthening the Health Economic-Industrial Complex and reducing Brazil's external dependence on strategic healthcare products. The association also highlighted the importance of regulatory predictability, industrial policies, and innovation incentives to improve the competitiveness of Brazil's pharmaceutical sector and attract new investments. Read more.

BRAZILIAN AUDIT COURT SAYS DELAYS IN CORONAVAC PURCHASE LED TO BRL 260 MILLION WASTE

An audit by Brazil's Federal Court of Accounts (TCU) concluded that delays by the Ministry of Health in finalizing the purchase of CoronaVac doses contributed to the waste of at least BRL 260 million in Covid-19 vaccines. According to the investigation, negotiations for the acquisition in 2023 lasted more than seven months, and a significant share of the doses expired before being distributed or administered. The audit found that around 8 million of the 10 million doses acquired were eventually incinerated after expiration. TCU auditors argued that the ministry accepted vaccines with a short shelf life despite signs of low demand for the immunizer within the Unified Health System (SUS) at the time. The Ministry of Health said the process followed existing public administration rules and cited uncertainties related to Covid-19 variants and vaccine supply during the period. Read more.

EXPERTS WARN HEALTHCARE SYSTEM FRAGMENTATION STILL LIMITS EFFICIENCY IN BRAZIL'S SUS

Fragmentation among healthcare information systems continues to be one of the main barriers to efficiency and care coordination within Brazil's Unified Health System (SUS), according to experts interviewed by Medicina S/A. Specialists argue that the lack of interoperability between platforms compromises patient monitoring, increases operational costs and limits the use of data for healthcare management and public policy planning. According to the report, integrating clinical and administrative systems is considered essential to improve continuity of care, optimize resource allocation and expand the use of digital health solutions in Brazil. Experts also highlighted that advances in interoperability and data governance could strengthen preventive care strategies and support broader adoption of technologies such as artificial intelligence and precision medicine within the public healthcare network. Read more.

BRAZIL WARNS AGING POPULATION MAY PRESSURE HEALTHCARE AND PENSION SYSTEMS

The Brazilian government warned that the country's accelerated demographic transition is expected to increase pressure on both the public healthcare and pension systems over the coming decades. According to projections presented by the Ministry of Planning and Budget, population aging could significantly raise public spending on healthcare, social security, and long-term care, requiring structural adjustments in fiscal planning and public policies. Officials highlighted that Brazil is aging at a faster pace than many developed countries did, reducing the time available for economic adaptation. The debate has gained relevance amid discussions over fiscal sustainability and the future financing of the Unified Health System (SUS), with experts warning that chronic diseases, higher demand for specialized care and increased pharmaceutical expenditures are likely to intensify pressure on healthcare budgets. Read more.

BRAZIL LAUNCHES PUBLIC NOTICES TO CONNECT PRIMARY CARE UNITS IN REMOTE REGIONS

The Ministries of Communications and Health launched new public notices aimed at expanding internet connectivity for healthcare services in remote areas of Brazil, including up to 2,700 Basic Health Units (UBS). The initiative seeks to strengthen telehealth capacity within the Unified Health System (SUS) and improve access to specialized medical services in underserved regions. According to the government, the program is part of broader digital health and connectivity policies financed through the Universal Telecommunications Service Fund (Fust). The project includes broadband or satellite connections and internal Wi-Fi infrastructure for health units, enabling teleconsultations, electronic medical records, and real-time exchange of clinical information. Authorities say the measure is intended to reduce diagnostic delays and expand healthcare access for vulnerable populations living far from major urban centers. Read more.

GLAUCOMA CARE RISES IN BRAZIL'S PUBLIC HEALTH SYSTEM, BUT LATE DIAGNOSIS REMAINS A CHALLENGE

The number of glaucoma-related procedures performed through Brazil's Unified Health System (SUS) has increased in recent years, reflecting broader access to ophthalmologic care and treatment. However, the Brazilian Council of Ophthalmology – CBO warned that late diagnosis continues to be one of the main obstacles in preventing blindness associated with the disease. According to specialists cited by Folha de S.Paulo, glaucoma often progresses without symptoms in its early stages, leading many patients to seek medical attention only after significant and irreversible vision loss. The entity defended expanded screening policies, awareness campaigns and improved access to ophthalmologic consultations in order to reduce preventable blindness in Brazil. Read more.

MORE HIGHLIGHTS

Brazilian Health Committee approves ophthalmologic treatment for diabetes patients in SUS

Brazil's ANS adds thrombophilia diagnostic test to mandatory coverage list

Brazil authorizes domestic production of chikungunya vaccine

Brazilian public university inaugurates molecular diagnostics laboratory for SUS patients

Brazil and Ecuador advance sanitary cooperation to expand access to medicines

Anvisa bans sale of unregistered cannabis-based products

Brazil opens enrollment to train healthcare professionals on insulin transition

Brazilian government announces measures to strengthen integrative health practices in SUS

Brazil mobilizes civil society to prepare proposals for UN 2030 Agenda

BRAZIL NEWS

Brazil Supreme Court justice suspends bill that ordered early release of ex-president Bolsonaro

Brazil senator targeted with search warrant as Banco Master probe widens

Brazil's Lula says Trump unlikely to sway upcoming election

Brazil's Lula reports progress in relations with US after talks with Trump

Brazil's April trade surplus jumps nearly 38% on rise in soy, oil exports

Brazil revives consumer debt relief program ahead of Lula's re-election bid

How China's evolving consumer habits may protect the Amazon rainforest

Greece is interested in purchasing C-390 military planes, says minister