

# WEEKLY REPORT



06/13/2026

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## **GLOBAL PHARMACEUTICAL COMPANIES EXPAND RARE DISEASE RESEARCH INVESTMENTS IN BRAZIL**

Global pharmaceutical companies are increasing investments in rare disease research in Brazil, attracted by the country's large patient population, growing research infrastructure and recent regulatory advances aimed at facilitating clinical studies. Industry executives and researchers report rising interest in conducting clinical trials for genetic, metabolic, and other rare conditions, a trend expected to improve access to innovative therapies and strengthen Brazil's role in global drug development. The movement coincides with the implementation of Brazil's new clinical research framework and growing efforts to expand patient identification and diagnosis. Experts note that rare disease studies often face recruitment challenges due to the low prevalence of individual conditions, making collaboration among research centers, patient organizations, and healthcare providers essential. Increased investment could accelerate the development of new treatments while providing Brazilian patients with earlier access to cutting-edge therapies through clinical trial participation. [Read more.](#)

## **BRAZIL NEEDS TO BETTER CONNECT PATIENTS AND VOLUNTEERS WITH CLINICAL RESEARCH CENTERS, EXPERTS SAY**

Brazil faces a significant challenge in linking patients and potential volunteers to clinical research centers, limiting participation in studies and delaying access to innovative treatments, according to specialists interviewed by Folha de S.Paulo. Experts argue that many eligible participants remain unaware of ongoing clinical trials, while researchers often struggle to recruit volunteers despite the country's large and diverse population. Researchers and patient advocacy groups defend the creation of more accessible information platforms and stronger collaboration among healthcare providers, research institutions, and patient organizations. They argue that improving awareness of clinical trial opportunities could accelerate scientific development, expand access to cutting-edge therapies and strengthen Brazil's position as a destination for global clinical research. The discussion gains relevance as the country seeks to increase investment in innovation and implement the new legal framework designed to streamline clinical research activities. [Read more.](#)

## **BRAZIL EXPANDS VACCINE SURVEILLANCE AFTER ADVERSE EVENTS LINKED TO DENGUE VACCINE**

Brazil has expanded its vaccine pharmacovigilance framework following the detection of rare adverse events associated with the Butantan-DV dengue vaccine. A new regulation published by the Ministry of Health broadens the responsibilities of the National Center for Drug Monitoring, updating rules that previously focused mainly on registered medicines and aligning vaccine monitoring practices with international standards. The measure strengthens the investigation, reporting and analysis of adverse events following immunization across the country. The decision follows the temporary suspension of the current vaccination strategy using the Butantan-DV vaccine after 42 cases with warning signs and three severe cases, including two deaths under investigation, were identified among approximately 500,000 administered doses. Health authorities emphasize that no causal relationship has yet been established and that the enhanced surveillance system demonstrates the effectiveness of Brazil's pharmacovigilance network in rapidly detecting and assessing potential safety signals. [Read more.](#)

## **ANVISA CREATES EXPERT PANEL TO DEEPEN INVESTIGATION INTO BUTANTAN-DV VACCINE SAFETY SIGNALS**

The Brazilian Health Regulatory Agency (Anvisa) will establish an expert panel to support the epidemiological investigation of adverse events reported following the administration of the Butantan-DV dengue vaccine. The initiative brings together independent specialists from fields such as epidemiology, infectious diseases, immunization, and pharmacovigilance to provide scientific assessments of the cases under review and strengthen the analysis of potential safety signals associated with the vaccine. The expert panel will assist Anvisa and the Ministry of Health in evaluating available evidence, reviewing clinical and epidemiological data, and determining whether any causal relationship exists between the reported events and the vaccine. The measure follows the temporary suspension of the current vaccination strategy involving Butantan-DV while investigations continue. According to Anvisa, the creation of the panel aims to ensure transparency, scientific rigor, and public confidence in the assessment process, while supporting future regulatory and public health decisions regarding the immunization program. [Read more.](#)

## **ANVISA RECOGNIZES INTERCHANGEABILITY OF BIOSIMILARS AND UPDATES REGULATORY GUIDANCE**

The Brazilian Health Regulatory Agency (Anvisa) has updated its regulatory understanding of biosimilar interchangeability, recognizing that approved biosimilars can be exchanged with their reference biologic products when used according to the conditions established in their approved labeling. The agency formalized the position through Technical Note No. 60/2026, aligning Brazil with recommendations from the World Health Organization (WHO) and other leading international regulatory authorities. The update is intended to increase confidence in biosimilars and support broader access to biological therapies. According to Anvisa, more than 90 biosimilar products have been approved in Brazil since 2015, with registrations accelerating in recent years. The agency emphasized that biosimilars undergo rigorous comparability assessments to demonstrate quality, safety, and efficacy equivalent to those of their reference products. The new guidance is expected to provide greater regulatory predictability for the sector while fostering competition and expanding treatment options for patients within both the public and private healthcare systems. Anvisa is also preparing a review of the regulatory framework governing biological products, currently established under Resolution RDC 55/2010. [Read more.](#)

## **BRAZIL IMPORT SECTOR ADAPTS TO NEW CUSTOMS MODEL AS ANVISA EXPANDS SUPPORT MEASURES**

The Brazilian Health Regulatory Agency (Anvisa) has reinforced support actions and operational improvements to facilitate the transition to Brazil's new import process based on the Single Import Declaration (DUIMP). Since April 27, 2026, DUIMP has become mandatory for several import operations subject to Anvisa clearance, replacing the previous Import License (LI) and Import Declaration (DI) systems and centralizing customs, tax, commercial and logistics information within the Foreign Trade Single Window platform. According to Anvisa, the transition has revealed recurring issues in the submission of import data, including incomplete product catalog information, incorrect DUIMP records and inadequate completion of the "Import Purpose – Anvisa" field. These inconsistencies affect the agency's risk assessment process and can delay clearance decisions. To address the challenges, Anvisa has implemented a series of measures, including mandatory completion of key import fields, webinars, technical meetings with stakeholders, regular updates to guidance manuals and greater transparency through a public dashboard tracking DUIMP review queues. The agency stressed that accurate and complete information submitted by importers remains critical to ensuring faster processing and reducing bottlenecks. [Read more.](#)

## **BRAZIL EVALUATES DIGITAL PACKAGE LEAFLET ROLLOUT THROUGH TARGETED CONSULTATIONS**

The Brazilian Health Regulatory Agency (Anvisa) has launched two targeted consultations to assess the implementation of digital package leaflets and gather evidence for the Regulatory Outcome Assessment of Resolution RDC 885/2024, which established the country's digital leaflet pilot program. The initiative seeks feedback from pharmaceutical companies on both participation barriers and operational challenges associated with the transition from printed to digital information systems. Targeted Consultation 4/2026 aims to identify the technical, financial, logistical, and regulatory factors that prevented some companies from joining the Digital Package Leaflet and Electronic Product Information Repository (RIEP) pilot project. Targeted Consultation 5/2026 focuses on the operational feasibility of implementing digital leaflets, including the adaptation of production lines for QR code printing and the logistics required to ensure access to printed leaflets when requested by patients. The information collected will support Anvisa's evaluation of the pilot program, which runs through the end of 2026, and help determine the future regulatory framework for digital package leaflets in Brazil. [Read more.](#)

## **BRAZIL LAUNCHES ACTIVE MONITORING PROGRAM FOR GLP-1 DRUGS IN HOSPITALS**

The Brazilian Health Regulatory Agency (Anvisa) has held its first meeting with hospitals participating in a new active pharmacovigilance program focused on GLP-1 receptor agonists and tirzepatide. The initiative brings together 20 hospitals from different regions of Brazil and marks the start of the operational phase of a nationwide effort to strengthen the monitoring of adverse events associated with these medicines under real-world conditions. The project is led by Anvisa's Pharmacovigilance Office and aims to improve the quality and consistency of safety data collected from healthcare institutions. During the meeting, Anvisa presented the medicines and adverse events of interest, case identification criteria, reporting procedures through the VigiMed system, and the next implementation steps, including staff training and regular follow-up meetings. The program is part of a broader regulatory strategy launched earlier this year in response to the rapid growth in the use of GLP-1 therapies, including semaglutide, liraglutide, dulaglutide and tirzepatide. The agency expects the initiative to enhance early detection of safety signals and support evidence-based regulatory decision-making. [Read more.](#)

## **MOUNJARO PRICE CUT EXPANDS ACCESS TO OBESITY AND DIABETES TREATMENT IN BRAZIL**

Eli Lilly has reduced the prices of Mounjaro (tirzepatide) in Brazil, lowering the cost of one of the country's most sought-after treatments for obesity and type 2 diabetes. The company announced discounts of up to 19.6% through its Lilly patient support program, bringing monthly treatment costs closer to those of competing GLP-1 therapies. The move comes amid growing demand for incretin-based medicines and increasing competition in the Brazilian market. According to the company, patients enrolled in the support program can now access lower prices across different dosage strengths, with the reductions applying to purchases made through participating pharmacies. Industry analysts view the price adjustment as a strategic effort to expand patient access and strengthen Mounjaro's position in the rapidly growing obesity treatment segment, where demand has surged following the success of GLP-1 and dual-action therapies. The price cut may also intensify competition among manufacturers as more treatments become available in Brazil. [Read more.](#)

## **BRAZILIAN PHARMACEUTICAL INDUSTRY SEEKS R\$15 BILLION CREDIT PROGRAM EXTENSION**

FarmaBrasil is urging lawmakers to approve a provisional measure that would unlock R\$15 billion in credit for strategic sectors under the federal government's Brasil Soberano program. Managed by the Brazilian Development Bank (BNDES), the initiative was designed to support industries affected by international trade tensions and geopolitical disruptions, but the funding has yet to be released because the measure still awaits congressional approval and is set to

expire in July. According to FarmaBrasil Executive President Reginaldo Arcuri, maintaining the program is essential to strengthen Brazil's pharmaceutical industry, reduce dependence on imported active pharmaceutical ingredients and expand domestic production capacity. The sector currently imports roughly 80% of its pharmaceutical inputs, largely from Asian suppliers. FarmaBrasil argues that failure to approve the measure could undermine competitiveness and delay investments at a time when major economies are expanding industrial policies aimed at securing strategic supply chains. [Read more.](#)

### **BRAZIL VICE PRESIDENT BACKS PATENT LIMITS AND WARNS AGAINST EXTENSIONS**

Vice President and Minister of Development, Industry, Trade and Services, Geraldo Alckmin, publicly defended the Brazilian Supreme Court's decision preventing patent terms from being extended beyond 20 years and warned lawmakers against legislative proposals that could expand exclusivity periods for pharmaceutical products. Speaking during an event marking the 15th anniversary of FarmaBrasil, Alckmin said extending patent protection would reduce competitiveness and increase costs for consumers. Alckmin's remarks come amid ongoing efforts by multinational pharmaceutical companies to revisit the patent debate in the National Congress (CN) and through court actions seeking patent-term extensions. The vice president reiterated the government's position that both patent extensions and compulsory licensing measures create distortions, arguing instead for stable intellectual property rules and faster patent examination processes through the National Institute of Industrial Property (INPI). [Read more.](#)

### **BRAZILIAN HEALTH INSURERS REPORT 22% DROP IN OPERATING PROFIT IN FIRST QUARTER**

Brazil's private health insurance sector recorded a 22% decline in operating profit during the first quarter of 2026, according to data released by the National Supplementary Health Agency (ANS). Operating earnings fell to approximately R\$3.5 billion, reflecting rising healthcare costs, increased utilization of medical services and continued pressure on insurers' margins despite ongoing premium adjustments. The ANS noted that the sector remains financially stable overall, but profitability has been affected by higher spending on hospital care, medical procedures, and new technologies. Industry analysts point to the growing demand for healthcare services following the pandemic years and the incorporation of innovative treatments as key factors driving costs. The results highlight the challenges facing health plan operators as they seek to balance financial sustainability with access to care for more than 50 million beneficiaries in Brazil. [Read more.](#)

### **BRAZILIAN CAR-T THERAPY FOR BLOOD CANCERS COULD REACH PUBLIC HEALTH SYSTEM WITHIN A YEAR**

A Brazilian-developed CAR-T cell therapy for blood cancers could be incorporated into Brazil's Unified Health System (SUS) within the next year, according to Health Minister Alexandre Padilha. The treatment, developed through a partnership involving the University of São Paulo (USP), the Ribeirão Preto Blood Center and other research institutions, has shown promising results against leukemia and lymphoma while costing approximately one-fifth of comparable commercial therapies currently available on the market. Recent clinical data indicate an efficacy rate of 87.5% among patients with hematologic cancers treated through the national research program. The federal government has invested R\$100 million in the project and is supporting efforts to accelerate regulatory review and future incorporation into SUS. If approved by the Brazilian Health Regulatory Agency (Anvisa) and subsequently evaluated by the National Commission for the Incorporation of Technologies in the Unified Health System (Conitec), the therapy could significantly expand access to advanced cancer treatment while reducing dependence on imported technologies. Researchers also see potential future applications for other cancers and autoimmune diseases. [Read more.](#)

## **HEALTH TECHNOLOGY ASSESSMENT EXPANDS BEYOND CONITEC AND GAINS GROUND IN STATES AND MUNICIPALITIES**

Health Technology Assessment (HTA) is becoming increasingly decentralized in Brazil, with states and municipalities developing their own structures to evaluate and incorporate medicines, medical devices and healthcare technologies alongside the federal process led by the National Commission for the Incorporation of Technologies in the Unified Health System (Conitec). Experts argue that expanding HTA education and technical capacity across the healthcare system is essential to support evidence-based decisions at all levels of government. According to specialists, several local health authorities have strengthened their ability to assess clinical benefits, budget impact, and cost-effectiveness before adopting new technologies. The movement reflects growing demand for more efficient resource allocation and greater transparency in healthcare decision-making. Advocates believe that expanding HTA training throughout Brazil's Unified Health System (SUS) can improve the quality of incorporation decisions, support regional health priorities, and contribute to the long-term sustainability of public healthcare spending. [Read more.](#)

## **BRAZIL ESTABLISHES NATIONAL POLICY ON QUALITY AND PATIENT SAFETY IN THE PUBLIC HEALTH SYSTEM**

The Ministry of Health has established a new National Policy on Quality and Patient Safety for Brazil's Unified Health System (SUS), creating a framework to improve healthcare quality, reduce preventable harm and strengthen safety practices across public health services. The initiative seeks to standardize patient safety measures nationwide, promote continuous quality improvement and reinforce a culture of risk management throughout the healthcare network. The policy introduces guidelines for monitoring healthcare outcomes, preventing adverse events, improving care processes, and encouraging the adoption of evidence-based practices. It also aims to strengthen coordination among federal, state, and municipal health authorities while supporting healthcare professionals through training, performance indicators, and quality assessment tools. According to the government, the measure is part of broader efforts to enhance the efficiency, safety, and sustainability of healthcare delivery within SUS. [Read more.](#)

## **EXPANDED NEWBORN SCREENING REMAINS A CHALLENGE 25 YEARS AFTER BRAZIL'S HEEL PRICK TEST LAUNCH**

Brazil marks 25 years of its national newborn screening program, commonly known as the heel prick test, but access to expanded screening panels remains uneven across the country. While the public health system universally offers testing for a core group of diseases, the gradual implementation of legislation enacted in 2021 to expand screening to more than 50 conditions continues to face operational, financial and infrastructure challenges. As a result, many families still rely on private laboratories to access broader diagnostic panels. Experts emphasize that early diagnosis through newborn screening is critical for preventing severe complications, disabilities and deaths associated with rare genetic, metabolic, and endocrine disorders. Although progress has been made in expanding testing capacity and integrating new diseases into the public system, specialists argue that regional disparities, laboratory limitations, and workforce training requirements continue to slow implementation. The debate highlights the importance of strengthening neonatal care policies and ensuring equitable access to early diagnosis across Brazil. [Read more.](#)

## **DRUGSTORES EXPAND HEALTHCARE SERVICES AND RECORD 10 MILLION CONSULTATIONS IN 2025**

Pharmacies in Brazil continue to expand their role in healthcare delivery, performing approximately 10 million clinical services in 2025, according to sector data. The services include vaccinations, blood pressure monitoring, blood glucose testing, medication reviews, and other patient care activities, reflecting the growing integration of pharmacies into primary healthcare and disease prevention efforts. Industry representatives argue that the expansion of pharmacy-based services has improved access to care, particularly in areas with limited healthcare infrastructure, while helping reduce pressure on hospitals and primary care facilities. The trend

also reflects broader changes in the pharmacy sector, which is increasingly positioning itself as a healthcare destination rather than solely a retail channel for medicines and consumer products. Specialists note that regulatory developments and advances in pharmacist training have supported the growth of these services, although discussions continue regarding reimbursement models and integration with the broader healthcare system. [Read more.](#)

### **LACK OF MENOPAUSE TRAINING AMONG PHYSICIANS AFFECTS DIAGNOSIS AND TREATMENT, EXPERTS WARN**

A growing number of specialists are warning that insufficient medical training on menopause is contributing to delayed diagnoses and inadequate treatment for millions of Brazilian women. According to experts interviewed by Medicina S/A, menopause remains underrepresented in medical education and continuing professional development programs, leaving many healthcare professionals unprepared to recognize symptoms, discuss treatment options and provide comprehensive care during the transition. The issue gains relevance as Brazil's population ages and more women seek medical support for symptoms such as hot flashes, sleep disturbances, mood changes and increased cardiovascular and bone health risks. Specialists argue that improving physician education could help reduce stigma, promote evidence-based use of menopausal hormone therapy when appropriate, and enhance quality of life for patients. The discussion also highlights broader efforts to strengthen women's health policies and expand awareness of menopause as a significant public health issue rather than a natural condition that should simply be endured. [Read more.](#)

### **BRAZIL ALLOCATES R\$60 MILLION TO EXPAND WOMEN'S HEALTH RESEARCH**

The federal government has announced R\$60 million in funding for scientific research focused on women's health, aiming to strengthen knowledge and innovation in areas that have historically received limited attention in medical research. The investment will support studies on maternal health, gynecological conditions, reproductive health, chronic diseases, mental health, and other issues that disproportionately affect women. According to the Ministry of Health and partnering research agencies, the initiative seeks to reduce knowledge gaps, improve public health policies and foster the development of new technologies, treatments and care strategies tailored to women's health needs. The program also aims to encourage greater participation of Brazilian research institutions and scientists in projects addressing gender-related health challenges, reinforcing the government's broader agenda of promoting equity in healthcare and scientific development. [Read more.](#)

### **BRAZIL RELEASES R\$577.2 MILLION THROUGH 'HEALTH PIX' PROGRAM TO ACCELERATE SUS INFRASTRUCTURE PROJECTS**

The federal government has authorized the transfer of R\$577.2 million through the Health Pix program to accelerate construction, renovation, and expansion projects across Brazil's Unified Health System (SUS). The initiative allows resources to be transferred directly to states and municipalities, reducing administrative delays and enabling local governments to advance healthcare infrastructure projects more quickly. According to the Ministry of Health, the funding will support works at hospitals, primary healthcare units, specialty centers, and other public health facilities throughout the country. The government expects the measure to speed up project execution, improve access to healthcare services and strengthen the capacity of SUS to meet growing demand. The Health Pix mechanism is part of a broader strategy to modernize federal health transfers and increase efficiency in the use of public resources. Officials argue that faster execution of healthcare infrastructure investments can help reduce regional disparities in access to care while improving the quality and availability of services. The latest funding release adds to ongoing federal efforts to expand healthcare capacity and support municipalities in completing stalled or delayed projects. [Read more.](#)

## **SENATE ADVANCES HEALTHCARE SPENDING MEASURES WITH SIGNIFICANT FISCAL IMPACT**

The Brazilian Senate advanced two healthcare-related proposals on June 10 that could substantially increase public spending in the coming years. [The Constitution and Justice Committee \(CCJ\) approved a constitutional amendment granting special retirement rules to community health workers and endemic disease control agents](#), while [the Social Affairs Committee \(CAS\) approved legislation establishing a new national salary floor for physicians and dentists](#). Both measures are supported by healthcare professionals but have raised concerns within the economic team and among fiscal policy analysts over their long-term budgetary impact. The proposed salary floor would raise the minimum monthly pay for physicians and dentists working 20-hour weeks from R\$3,636 to R\$13,662, with annual inflation adjustments. Estimates discussed during the Senate debate indicate the measure could add R\$8.1 billion to federal expenditures as early as 2026 and generate a cumulative fiscal impact of approximately R\$25 billion through 2029. The proposal now moves to the Chamber of Deputies. Meanwhile, the special retirement proposal for community health workers and endemic disease control agents would establish differentiated retirement conditions and strengthen pension guarantees for the category. Municipal governments have warned that the measure could create significant long-term pension liabilities and increase personnel-related expenditures across the public sector, although official federal cost estimates have not yet been finalized.

### **MORE HIGHLIGHTS**

[Anvisa approves new treatment for myelofibrosis in Brazil](#)

[Anvisa launches national consultation on risk-based inspection model for health services](#)

[Anvisa expands reliance pathway for medical cannabis products to accelerate access in Brazil](#)

[ANS trains consumer protection agencies nationwide to improve health plan oversight](#)

[CFM launches AI system to strengthen medical oversight across Brazil](#)

[Experts highlight technology that could improve cancer surgery outcomes in Brazil](#)

[Brazilian cancer center advocates risk-sharing agreements to expand access to CAR-T therapies](#)

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