WEEKLY REPORT

02/28/2026

BRAZIL EXPANDS RARE DISEASE STRATEGY WITH HIGH-TECH DIAGNOSIS AND EXPANDED SERVICES

The Ministry of Health announces a comprehensive expansion of public policies for rare diseases, centering on the inclusion of Whole Exome Sequencing (WES) in the Unified Health System (SUS) to drastically reduce diagnostic delays and improve patient care. The sequencing test — a high-complexity genetic exam that can cost up to R$ 5,000 in the private sector — will be offered free of charge through SUS, with an estimated 20,000 diagnoses per year and a reduction in average diagnostic time from seven years to six months. This expansion is supported by an annual investment of about R$ 26 million and aims to serve families across Brazil. Health Minister Alexandre Padilha underscores the initiative as part of a broader strategy to expand specialized care and integrate advanced diagnostics into the public network. Two public laboratories in Rio de Janeiro (the National Institute of Cardiology (INC) and Fiocruz) will lead the rollout, with plans to scale services nationwide. The government also commits R$ 44 million to enable 11 additional specialized services, potentially bringing the total to 51 reference centers in public and philanthropic hospitals, strengthening SUS's capacity for rare disease treatment. Beyond diagnostic innovation, the ministry is partnering with Fiocruz under the Advanced Therapies Platform within the Health Economic-Industrial Complex program, allocating R$ 122 million to build domestic capacity for gene therapy and viral vector production. Stakeholders say the comprehensive package positions Brazil to become a reference in rare disease diagnostics and care while addressing longstanding gaps in access to early detection, clinical research, and long-term management of these conditions. Read more.

BRAZIL FACES DIAGNOSTIC ODYSSEY AND TREATMENT GAPS FOR RARE DISEASES

Patients living with rare diseases in Brazil endure protracted and uncertain diagnostic journeys — commonly referred to as a diagnostic odyssey — that can span several years before reaching an accurate diagnosis. This challenge reflects deep structural limitations in clinical knowledge, access to specialists and genetic testing across the country, leaving many families navigating long sequences of misdiagnoses, repeated consultations, and fragmented care. Rare diseases are statistically defined as conditions affecting up to 65 people per 100,000 population, yet an estimated 13 million Brazilians live with these conditions, underscoring that although each disease is individually uncommon, collectively they constitute a significant public health concern. Brazil's Unified Health System (SUS) has made strides through the National Policy for Comprehensive Care for People with Rare Diseases, which has expanded reference centers and integrated advanced diagnostics such as whole exome sequencing. However, persistent barriers remain, including insufficient specialist personnel, geographical inequities in service availability and limited data infrastructure for tracking rare disease cases, impairing policy planning, and continuity of care. Additionally, only a small fraction of rare diseases has approved drug therapies, and treatments that are available often entail prohibitively high costs, leaving many patients reliant on supportive care or judicial action to access essential medicines. Experts and patient advocates emphasize that resolving the diagnostic odyssey requires not only broader deployment of genetic and genomic tools but also investment in clinician training, real-world data systems and coordinated research networks. Improving timely diagnosis is seen as foundational to enabling early interventions, access to specialized care and reducing the emotional and financial toll that prolonged uncertainty imposes on patients and families. Read more.

BRAZIL LAWMAKER PUSHES PATENT OVERRIDE STRATEGY TO LOWER MOUNJARO PRICES

A federal lawmaker moves forward with a proposal to classify Mounjaro as a medicine of public interest, a legal mechanism that could open the way for compulsory licensing and potential patent override under Brazil's intellectual property framework. The initiative aims to reduce the price of the drug, currently indicated for type 2 diabetes, and widely used off-label for obesity, amid growing political pressure over the affordability of high-cost therapies in the country. The bill is under analysis in the House of Representatives, where the author seeks to appoint a physician as rapporteur to strengthen the technical legitimacy of the debate and counter expected resistance from the pharmaceutical sector. The strategy also includes securing backing from the center bloc, whose support is considered decisive for accelerating committee review and ensuring favorable positioning in the legislative agenda. If advanced, the proposal could reignite broader discussions on the use of compulsory licensing as a public health tool in Brazil, particularly in cases involving innovative medicines with significant budgetary impact. The debate reflects the tension between intellectual property protection, market exclusivity, and public health access policies, especially as demand for metabolic and anti-obesity treatments continues to expand. Read more.

BRAZIL'S PATENT OVERRIDE BILL FOR MOUNJARO FACES PROCEDURAL DELAY IN HOUSE OF REPRESENTATIVES

Even after the House of Representatives approved an urgent processing request for the bill proposing to break the patents on Mounjaro and Zepbound, the legislative text is unlikely to reach plenary debate until after the second half of March as priority shifts to other agenda items. The proposal, which seeks a compulsory licensing mechanism for the tirzepatide-based drugs on public-interest grounds, had been fast-tracked in early February following broad support for urgent consideration. The procedural delay comes amid political negotiations and competing legislative priorities in the House leadership, led by Hugo Motta, who is expected to defer floor time for the bill despite its urgency status. If the postponement materializes, the postponement could extend deliberations beyond the earliest procedural estimates, slowing momentum for a high-profile measure that has attracted industry scrutiny and public debate over intellectual property, drug pricing, and access. Read more.

BRAZIL CITY LAUNCHES TIRZEPATIDE PROGRAM FOR OBESITY THROUGH SUS

The municipality of Urupês, in the state of São Paulo, has announced a local public health initiative to offer tirzepatide free of charge through the Unified Health System (SUS) to treat obesity, in a pilot project expected to serve up to 200 eligible residents. The program, disclosed by the city's mayor, Beto Cacciari (PL), will provide the medication alongside comprehensive multidisciplinary support including endocrinology, nutrition, psychology, physical education, and social services for patients who meet clinical criteria related to age, body mass index, and prior non-pharmacological treatment attempts. While local authorities characterize the measure as a responsible effort to improve quality of life and prevent chronic complications of obesity, the manufacturer Eli Lilly has raised concerns, noting that the product distributed is a manipulated version of tirzepatide and not the approved Mounjaro formulation, which could lead to patient confusion and potential safety issues. Separately, similar initiatives have been observed in other municipalities, but broad inclusion of tirzepatide-based therapies in SUS remains contingent on health technology assessment and cost-effectiveness evaluation by national bodies such as Conitec. Read more.

BRAZIL INDUSTRY DENOUNCES ILLEGAL PARAGUAYAN WEIGHT-LOSS PENS SOLD ON MARKETPLACES

The Brazilian pharmaceutical industry, represented by Sindusfarma, lodges formal complaints against the sale of Paraguayan weight-loss pens marketed on online marketplaces and social media platforms, warning that these products are unregistered, unregulated, and potentially

unsafe for consumers. The devices — often promoted as slimming aids and sourced from Paraguayan suppliers — have proliferated across digital marketplaces, raising concerns about quality assurance and regulatory compliance. Industry stakeholders argue that the clandestine sale of these pens not only undermines legitimate regulated markets but also poses serious public health risks, as the products lack registration with the National Health Surveillance Agency (ANVISA) and have not undergone evaluation for safety, efficacy, or content verification. ANVISA has already issued resolutions banning and ordering the seizure of unregistered tirzepatide and retatrutide pens, popularly known as "Paraguayan slimming pens," emphasizing that such products cannot be sold, imported, advertised, or used in Brazil due to unknown composition and lack of regulatory authorization. Consumer safety advocates and industry representatives call for strengthened enforcement and monitoring to curb the influx of unregulated weight-loss devices, noting that marketplace platforms and social networks can facilitate rapid distribution of prohibited items. The complaints underscore the ongoing challenge of safeguarding public health in digital commerce and the need for robust cooperation between regulators, industry, and enforcement agencies. Read more.

BRAZILIAN DRUGMAKERS PURSUE INDIAN TECHNOLOGY FOR WEIGHT-LOSS PEN MANUFACTURING

Brazilian pharmaceutical companies intensify efforts to secure technology transfer agreements with Indian manufacturers for the local production of weight-loss pens, a move aimed at reducing dependency on imports and addressing unmet demand for anti-obesity therapies. According to industry sources, firms have engaged in technical dialogues with Indian partners to evaluate production capabilities and regulatory compliance requirements for injectable devices that deliver peptides such as tirzepatide or related compounds. Representatives of Brazilian manufacturers indicate that leveraging established Indian expertise — where biologics and complex injectables are widely produced — could accelerate domestic capacity to manufacture weight-loss pens that meet regulatory standards. The strategy is framed against a backdrop of ongoing industry complaints about the proliferation of unregistered devices sourced from Paraguay and concerns over product safety and quality assurance. Collaboration with Indian firms, proponents argue, would help ensure local output of regulated, quality-assured weight-loss pens compatible with Brazil's technical and safety frameworks. Read more.

BRAZIL ESTABLISHES FIRST REGULATION FOR ARTIFICIAL INTELLIGENCE IN MEDICAL PRACTICE

Brazil establishes its first specific regulation governing the use of artificial intelligence in medicine, determining that AI systems may function only as clinical support tools and cannot issue automated diagnoses directly to patients. The Federal Council of Medicine published a resolution stating that diagnoses, prognoses, and therapeutic decisions remain the exclusive responsibility of licensed physicians. Under the new rule, doctors must inform patients when AI tools are used in their care, and patients have the right to refuse the use of such technologies. The measure seeks to balance technological innovation with patient safety, ethical standards, and professional accountability. The resolution enters into force 180 days after its publication. Read more.

BRAZIL MINISTRY OF HEALTH PLANS SUPPORT PROGRAM TO BOOST CLINICAL RESEARCH

The Ministry of Health, through the Secretariat of Science, Technology and Innovation in Health, is developing a dedicated support program for clinical research aimed at fostering the execution of clinical studies within Brazil. The initiative, currently in its early stages of design and expected to launch by the end of this year, is intended to complement the federal government's radical innovation strategy for new drug development by bridging a key gap between scientific discovery and clinical testing. According to the secretariat's leadership, the program may include training components, the creation of accredited research center networks and regulatory support services to reduce critical bottlenecks that limit the conduct of trials nationally. The program is also being considered in the broader context of strengthening the

country's ability to carry out clinical research and attract multicenter studies, which remains a priority given Brazil's sizeable scientific capacity and demographic diversity. The ministry has concurrently advanced steps to implement the National System of Research Ethics, including establishing the National Research Ethics Instance (Inaep) to work alongside Research Ethics Committees (CEPs), as part of efforts to modernize the regulatory environment for human studies. Read more.

BRAZIL'S SANTAS CASAS JOIN FORCES TO EXPAND CLINICAL RESEARCH NETWORK

Philanthropic hospitals known as Santas Casas are coordinating a joint strategy to expand their participation in clinical research, aiming to strengthen scientific capacity, attract investment and improve financial sustainability. The initiative seeks to integrate multiple institutions into structured research networks capable of conducting multicenter trials and partnering with pharmaceutical companies and academic centers. Nelson Teich, former Minister of Health, is cited in the discussion as a supporter of expanding clinical research within hospital networks as a way to enhance efficiency, generate evidence and diversify revenue streams. According to stakeholders involved in the initiative, scaling research activities across Santas Casas could position the network as a relevant player in Brazil's innovation ecosystem while contributing to improved standards of care. The movement comes amid ongoing financial pressures on philanthropic hospitals, which play a central role in delivering services within Brazil's public health system. Expanding research capacity is seen as a strategic pathway to modernization, technological incorporation, and long-term sustainability. Read more.

BRAZIL DEBATE OVER POLYLAMININ HIGHLIGHTS IMPORTANCE OF CONTROL GROUPS IN CLINICAL TRIALS

The debate surrounding the experimental therapy polylaminin brings renewed attention to the role of control groups in clinical research. A control group consists of participants who do not receive the investigational treatment and serves as a benchmark to determine whether observed outcomes are truly attributable to the intervention rather than to natural disease progression, placebo effects, or external variables. Specialists emphasize that without a properly designed control group, it is not possible to establish causal relationships or reliably measure efficacy and safety. Randomized controlled trials, considered the gold standard in clinical research, depend on comparison between treated and untreated or standard-care groups to ensure scientific validity and regulatory credibility. The discussion gains relevance as preliminary findings related to polylaminin generate public interest while still lacking the methodological robustness required for definitive conclusions. Read more.

BRAZIL SCIENTIFIC SOCIETIES CALL FOR PRECISION IN POLYLAMININ DEBATE

Leading Brazilian medical and scientific societies urge caution and rigorous evidence assessment in discussions about polylaminin, an experimental therapy proposed for spinal cord injuries. In a joint statement, associations of neurologists, rehabilitation specialists and clinical researchers highlight that current data are preliminary and insufficient to support definitive clinical benefit claims, emphasizing the importance of adhering to evidence-based standards before public endorsement or widespread clinical application. The societies call for robust clinical research — including well-designed controlled trials with clear primary endpoints — to establish safety, efficacy, and reproducibility of results. They caution that anecdotal reports and early-stage findings should not be interpreted as conclusive evidence, and warn against premature expectations that could mislead patients and caregivers. The statement also underscores the need for transparent communication about uncertainty in emerging therapies, urging health authorities and policymakers to base public discourse and resource decisions on validated evidence. Read more.

BRAZIL CLARIFIES PATENT STATUS OF POLYLAMININ AMID DEBATE OVER INNOVATION PROTECTION

Recent reporting highlights that polylaminin — an experimental substance under investigation for spinal cord injury treatment — is covered by intellectual property protection for up to 20

years, with Brazilian patent rights valid until 2042 and related international patent protection extending until 2043, based on patent applications filed by laboratory Cristália covering extraction, purification and polymerization processes. This exclusivity enables the holder to block third parties from making, using, selling, or importing the patented technology while the rights remain in force. The patent system grants territorial rights based on individual filings in each jurisdiction, meaning there is no single "international patent" that automatically applies worldwide — instead, rights must be obtained and maintained separately in each country. In the case of polylaminin, the laboratory asserts that patent protection was pursued both domestically in Brazil and in key foreign markets following partnership arrangements, securing exclusivity that could support future development and commercialization if clinical trials and regulatory approvals are successful. Read more.

BRAZIL MOVES TO USE TECHNOLOGICAL PROCUREMENT FOR MEDICAL DEVICES, VACCINES AND HEALTH SUPPLIES

The federal government is structuring the use of technological procurement as a targeted instrument to acquire health technologies and strategic inputs, with initial contracts planned for this year to test the viability of the mechanism. This initiative, led by the Ministry of Health together with the Secretariat of Science, Technology and Innovation in Health, aims to identify priority demands of SUS including medical devices, vaccines and essential health supplies and to leverage public purchasing power to stimulate research, development and innovation (R&D&I) in sectors where solutions are not readily available on the market. Technological procurement is a special type of public acquisition designed to contract R&D and innovation services involving technological risk — meaning the State commissions the development of solutions that may not yet exist commercially, with the objective of meeting a clearly defined public health need. In this context, an initial, smaller-scale technological order will be executed to assess operational viability, while future rounds could address vaccines, diagnostic tools, therapeutic devices, and other strategic inputs for the Unified Health System (SUS). Officials involved in the rollout also indicate plans to complement procurement efforts by strengthening Brazil's clinical research infrastructure, including training personnel, building accredited research centers, and providing regulatory support — a response to long-standing calls for an integrated innovation ecosystem in health. The strategy is being developed in coordination with stakeholders from industry and science as part of broader efforts to reinforce the Health Industrial Complex and reduce dependence on imported technologies. Read more.

BRAZIL INDUSTRY COALITION MOBILIZES AROUND HEALTH ECONOMIC-INDUSTRIAL COMPLEX AGENDA

A coalition formed by representatives of the health industry is organizing to strengthen participation in the Health Economic-Industrial Complex (CEIS) agenda, positioning the sector as a strategic partner in Brazil's industrial and innovation policy. The group aims to coordinate proposals related to local production, technological development, and regulatory modernization, seeking alignment with federal initiatives designed to expand domestic capacity in pharmaceuticals, vaccines, medical devices, and strategic health inputs. Industry leaders argue that structured engagement with the federal government can accelerate investment, reduce external dependency, and reinforce supply chain resilience, particularly in light of vulnerabilities exposed during the COVID-19 pandemic. The coalition intends to contribute to policy discussions involving technological procurement, research incentives and financing mechanisms tied to the Unified Health System (SUS), advocating for a long-term strategy that integrates industrial competitiveness with public health priorities. Read more.

BRAZIL SPECIAL COMMITTEE ON CANCER URGES FASTER IMPLEMENTATION OF NATIONAL CANCER POLICY

Members of the Special Committee on Combating Cancer, Stroke and Heart Disease and health specialists press for accelerated implementation of the National Policy for Cancer Prevention and Control, emphasizing the urgency of translating law into improved patient access to early diagnosis and timely treatment across the Unified Health System (SUS). The debate, held on

February 24, focused on closing the gap between legal frameworks and frontline care delivery, noting that current delays in operationalization reduce opportunities for effective prevention and lifesaving interventions. Congressman Weliton Prado, author of the debate request, welcomed the policy's regulatory approval but highlighted ongoing challenges, including insufficient workforce capacity and persistent inequities in access to diagnostic services such as radiotherapy and HPV screening. Specialists called for an urgent public tender to strengthen the National Cancer Institute (INCA) workforce, which has lacked a recruitment process for nearly a decade, and underscored the need for stable, adequate funding to support oncology services, research, and professional training. Speakers also raised concerns about misinformation in screening practices and emphasized the expansion of validated molecular diagnostics and mobile health units as promising steps. Plans for a dedicated hearing on workforce shortages at INCA and proposals for a national cancer fund to prioritize federal budget allocations were outlined as next steps by committee members. Read more.

BRAZIL EXPANDS ONCOLOGY TREATMENT OPTIONS WITH NEW CANCER DRUG INDICATIONS FROM ANVISA

The National Health Surveillance Agency (ANVISA) has approved expanded therapeutic indications for two immunotherapy drugs used in cancer care, broadening their clinical applications for patients in Brazil. Keytruda (pembrolizumab), previously registered in the country for melanoma, is now approved for use in combination with standard chemotherapy — with or without bevacizumab — to treat patients with platinum-resistant epithelial ovarian carcinoma, offering a new treatment option for a subgroup with limited alternatives. The updated indications were published in the Official Gazette on February 23. Imfinzi (durvalumab) also received a new indication, enabling its use in combination with FLOT chemotherapy for patients with resectable gastric or gastroesophageal junction adenocarcinoma. The drug's previous approvals included treatment of locally advanced or metastatic urothelial carcinoma following progression after platinum-based chemotherapy. The expanded labels reflect growing evidence supporting the use of immunotherapy agents in earlier disease settings and in combination regimens across solid tumors. Read more.

BRAZIL COMPANIES NEGOTIATE COST-SHARING OF HEALTH PLANS AMID RISING EXPENSES

Amid escalating health plan costs, Brazilian employers and labor representatives are increasingly negotiating shared cost arrangements for private health insurance to ease financial pressure on both companies and employees. The trend reflects broader economic challenges facing the corporate sector as health care premiums continue to rise above general inflation, prompting businesses to seek collaborative strategies that maintain coverage while balancing operational budgets. Under these arrangements, firms agree to share a portion of the monthly health plan premiums with employees, contrasting with traditional models where employers absorb the full cost. Advocates argue that cost-sharing can sustain plan viability and prevent wholesale benefit cuts, while critics warn that increased out-of-pocket expenses may reduce access to care and place disproportionate burdens on lower-income workers. The negotiations are occurring against a backdrop of intense debate about the structure and regulation of collective health benefits in Brazil's private insurance market, where stakeholders continue to call for measures that promote affordability and equitable access. Read more.

BRAZIL HEALTH SECTOR EMPLOYMENT REMAINS RESILIENT, REACHING 5.28 MILLION JOBS IN 2025, IESS REPORTS

According to the Instituto de Estudos de Saúde Suplementar (IESS), formal employment within Brazil's health industry — including providers, suppliers, and health plan operators — reached 5.28 million jobs in December 2025, reflecting sustained growth despite a broader contraction in the Brazilian job market. Between September and December 2025, the sector added approximately 7.5 thousand new formal positions even as total formal employment nationwide declined, highlighting the structural demand for health services. The health sector accounted for 10.9% of all formal employment in Brazil at year-end, underscoring its economic

importance. The period also saw the private health segment drive much of the expansion, with nearly 162 thousand formal jobs created over the past 12 months. Growth was most pronounced in service provision, which remains highly labor-intensive, while the public sector experienced slight employment contraction. Regionally, the Centro-Oeste, Sul and Nordeste reported employment gains, whereas the North and Southeast registered modest declines. Analysts attribute this resilience to sustained demand for health care, demographic shifts and expanded service delivery across both public and private networks. Read more.

MORE HIGHLIGHTS

Congressman presents favorable opinion on bill to transform ANS into broader health technology agency

Brazil's National Congress lit up to mark World Rare Disease Day

Brazil Senate committee approves public hearing on rare disease policies

Brazil lawmaker seeks Health Minister's testimony on civil society voting rights in Conitec

Brazil House health committee invites Health Minister to present 2026 agenda

Brazil lawmaker proposes debate on evidence-based medicine amid health judicialization

Brazil lawmaker proposes technical visit to USP menopause education project

Brazil House health committee to debate women's health and oncology policies

BRAZIL NEWS

Lula, Flavio Bolsonaro tied in Brazil run-off, poll shows

Brazil January tax revenue climbs to record level after Lula income tax overhaul

Brazil's inflation overshoots forecasts in mid-February

Brazil hails zero US tariff on aircraft exports

Brazil's monetary council expands airlines' access to public aviation fund

Brazil lower house approves EU-Mercosur free trade deal

South Korea and Brazil agree to expand cooperation in key minerals, trade

Brazilian government condemns strikes on Iran

Brazil doesn't want 'new Cold War', Lula says before Trump meeting

Trump administration taps far-right official for key Brazil post

Brazil partially rolls back import tax hike

Brazil Supreme Court panel convicts plotters of Marielle Franco's assassination