WEEKLY REPORT

08/15/2026

LULA AND FLÁVIO BOLSONARO PROPOSE HEALTH EXPANSION WITHOUT DETAILING FUNDING

The health platforms of presidential candidates Luiz Inácio Lula da Silva (PT) and Flávio Bolsonaro (PL) propose expanding healthcare services but share a key weakness: limited quantification of targets, costs, and funding sources. The issue is particularly relevant amid tight federal budgets, with a Senate technical note estimating R$105.5 billion in constraints on non-mandatory federal spending in 2026. Lula's plan largely builds on existing programs, including Mais Médicos, Farmácia Popular, Agora Tem Especialistas and SUS digitalization, while Flávio proposes a broader restructuring under a "Plano Real da Saúde," including correction of the SUS payment table, performance-based payments and interoperability between public and private health systems. Both candidates propose using idle capacity in private hospitals to reduce waiting lists, but with different approaches. Lula relies on the expansion of partnerships already used by Agora Tem Especialistas, while Flávio proposes contracting private-sector diagnostic services during off-peak hours. On electronic health records, Lula focuses on integrating UBSs, outpatient services, and hospitals within the SUS, whereas Flávio proposes interoperability with private providers. On Farmácia Popular, Lula proposes adding diagnostic and monitoring tests for chronic conditions; he also prioritizes vaccination, cancer control, and domestic production of health inputs. Flávio emphasizes telehealth, home delivery of medicines and expansion of long-term care for older adults, as well as national vaccine production. The candidates also differ on healthcare governance and the role of the private sector. Lula's proposals emphasize strengthening the SUS as the central coordinating system, expanding public-sector capacity, and using partnerships with private and philanthropic hospitals to address bottlenecks. Flávio's platform gives greater emphasis to integration between public and private networks, performance-based financing, and broader use of private providers. Both proposals include measures aimed at reducing waiting times and expanding access, but neither presents detailed estimates of the additional fiscal impact of these commitments or clearly identifies how the proposed expansion would be financed. The debate therefore places healthcare financing, efficiency, and the sustainability of public spending at the center of the 2026 electoral agenda. Read more.

CONITEC PREPARES NEW BUDGET IMPACT THRESHOLDS FOR SUS TECHNOLOGY INCORPORATION

Brazil's National Commission for the Incorporation of Technologies in the Unified Health System (Conitec) is finalizing new guidelines that will classify technologies with an estimated annual budget impact of R$37.8 million to R$75.6 million as high impact and those above R$75.6 million as very high impact. The assessment will consider eligible population, time horizon, current and future treatments, market share, alternative scenarios, treatment costs, health outcomes, and the impact on the SUS budget. The methodology is intended to bring greater transparency and predictability to economic assessments, but the threshold will not automatically determine whether a technology is incorporated. The new framework is expected to support additional incorporation pathways for high-impact technologies, including phased implementation, managed-access agreements, additional budget discussions, and price negotiations. These mechanisms are enabled by Ordinance No. 8,817/2025, while a Ministry of Health committee created in July may negotiate discounts, confidential-price agreements, and risk-sharing arrangements with manufacturers. Conitec will decide case by case whether a

technology exceeding the threshold should be referred for negotiation, considering budget impact alongside clinical, economic, and other factors. The Ministry also identifies the lack of alignment between incorporation decisions and the federal budget cycle as a major obstacle to meeting the legal 180-day deadline for making newly incorporated technologies available through SUS. Read more.

TCU FLAGS PERSISTENT GAPS IN ANVISA'S POST-REGISTRATION MEDICINE OVERSIGHT

The Federal Court of Accounts (TCU) has identified persistent weaknesses in the Brazilian Health Regulatory Agency's (Anvisa) post-registration monitoring of medicines, a decade after an initial audit raised similar concerns. In a review approved on July 29, the TCU found that four recommendations had not been implemented by 2025, seven were only partially addressed and eight remained under implementation. The audit points to reactive rather than preventive surveillance, fragmented data, weak coordination between registration, inspection and pharmacovigilance teams, and insufficient use of post-market safety information in regulatory decisions. The TCU ordered Anvisa to present a plan within 120 days to integrate national medicine complaint data and issued 10 additional recommendations. The audit also highlighted a sharp reduction in quality testing: public laboratories analyzed an average of 329 medicine samples annually between 2020 and 2024, compared with more than 1,583 in 2014, after the National Medicine Quality Verification Program (Proveme) was replaced by risk-based projects. The TCU also criticized the extension of registration validity from five to 10 years, arguing that the change was not accompanied by sufficient post-market capacity; analysis of Periodic Benefit-Risk Assessment Reports is reportedly stalled because of staff shortages, including for 40 priority active ingredients selected by Anvisa in 2025. The Tribunal further cited the lack of regulation of the medicine traceability system established by Law No. 14,338/2022, gaps in notification systems and the weakening of the Sentinel Network after changes to RDC No. 872/2024. Read more.

ANVISA APPROVES NEW MEDICINE FOR DUCHENNE MUSCULAR DYSTROPHY

Brazil's Health Regulatory Agency (Anvisa) has approved the registration of Duvyzat (givinostat) for Duchenne muscular dystrophy (DMD), a rare genetic disease characterized by progressive loss of muscle strength. The oral medicine is indicated for children aged six and older, in combination with corticosteroids, and is the first non-steroidal treatment for DMD approved in Brazil. Clinical studies showed that givinostat can slow functional decline, with patients experiencing significantly less deterioration in motor function than those receiving corticosteroids alone. The approval adds a new therapeutic option for a disease with no cure, while targeting mechanisms associated with muscle inflammation and deterioration. Duvyzat has already been approved in the United States and Europe. In Brazil, however, registration does not automatically guarantee access through the Unified Health System (SUS): the medicine must still undergo price definition by CMED and, if public incorporation is sought, assessment by Conitec. The Anvisa approval also includes post-registration monitoring of the medicine's efficacy and safety. Read more.

ANVISA EXPANDS TRANSPARENCY ON MEDICINES PENDING REGISTRATION

The Brazilian Health Regulatory Agency (Anvisa) has expanded the information available on its Panel of Medicines Pending Registration Analysis, adding the pharmaceutical form and active ingredient concentration to data already provided on active ingredients, regulatory categories and the number of applications awaiting review. Launched in 2024, the panel is designed to increase transparency and allow the pharmaceutical sector to monitor registration applications under analysis. The new information may help companies assess whether their applications meet applicable prioritization criteria and provides greater predictability regarding medicines awaiting publication after registration decisions. Anvisa stressed that the data are based on information submitted by applicants and may be corrected following technical and regulatory analysis. Read more.

ANVISA INTRODUCES NEW FORM FOR ADVANCED THERAPY MANUFACTURING CERTIFICATION

The Brazilian Health Regulatory Agency (Anvisa) has introduced a new Petition Form for Good Manufacturing Practices (GMP) Certification (CBPF) for advanced therapy products, standardizing the information required for initial and renewal certification applications submitted by Brazilian and international manufacturers. The new form covers both GMP certification of the active component, corresponding to the Active Pharmaceutical Ingredient (API), and the manufacturing line for the advanced therapy product, consolidating the information into a single model. The measure also simplifies the petition codes, reducing them to two for initial certification (11821 for active components and 11822 for sterile products) and two for renewals (11836 and 11837, respectively). The revised checklist aligns requirements more closely with medicine GMP certification while maintaining the specificities of advanced therapies, including information on manufacturing chains, production stages, regulatory history, and product types such as in vivo and ex vivo gene therapies, advanced cell therapies, tissue-engineered products, and combined products. Anvisa says the changes should facilitate submissions, reduce classification uncertainties, and improve the screening and distribution of regulatory applications. Read more.

ANVISA UPDATES GUIDANCE ON CLINICAL TRIAL RULES

The Brazilian Health Regulatory Agency (Anvisa) has updated its Questions and Answers document on RDC No. 945/2024 and IN No. 338/2024, which regulate clinical trials conducted in Brazil for the registration of medicines. The fourth edition, released after 18 months of the rules coming into force, incorporates clarifications on recurring regulatory requirements and the submission of clinical research processes. The update places particular emphasis on fixed-dose combination (FDC) medicines, addressing regulatory and scientific aspects of their clinical development based on questions identified during the review of clinical trials and registration applications. The document also includes guidance on the use of Reliance procedures, risk- and complexity-based assessments, recurring technical requirements and the SOLICITA system for clinical research submissions. Read more.

BRAZIL'S NATIONAL HEALTH COUNCIL CREATES NEW RESEARCH ETHICS COMMISSION

Brazil's National Health Council (CNS) has established a new Intersectoral Commission of Ethics in Research (Conep/CNS), preserving the institution's role in social participation and protection of people involved in research. Approved during the CNS's 381st Ordinary Meeting, the new commission will operate alongside the National Institute of Ethics in Research (Inaep), created under Law No. 14,874/2024 and regulated by Decree No. 12,651/2025, with responsibilities divided between the two bodies and the network of Research Ethics Committees (CEPs). The restructuring follows the changes introduced by the new clinical research framework, which transferred the former National Commission of Ethics in Research from the CNS structure to Inaep. The new Conep/CNS was developed through a Working Group established by CNS Resolution No. 803/2026, with discussions held between April and June. The Brazilian ethics system has registered more than 1.1 million research projects and 1.3 million participants, involving approximately 42,000 institutions, while more than 900 CEPs operate nationwide. The CNS says the new structure is intended to preserve effective social control and ethical oversight of research involving human beings. Read more.

BRAZIL PREPARES FIRST NATIONAL NEGOTIATION FOR ONCOLOGY MEDICINES

Brazil's Ministry of Health has launched the first national negotiation for the purchase of nine oncology medicines under the new Oncology Pharmaceutical Assistance Component (AF-Onco). States must report by September 4 the number of eligible patients and quantities required, while oncology services have until August 24 to complete the demand survey. The first round includes asciminib, betadinutuximab, brentuximab vedotin, durvalumab, erlotinib, ponatinib, larotrectinib, lenalidomide and arsenic trioxide, covering indications for leukemias, lymphomas, lung cancer, neuroblastoma, and pediatric solid tumors. The initiative adopts an exceptional

procurement flow to accelerate acquisition and is the first practical application of the national negotiation model established under the AF-Onco framework. The Ministry will be responsible for negotiating and establishing price registration agreements, while state health departments and the Federal District will execute purchases and distribution. Read more.

BRAZIL'S NATIONAL DIGITAL HEALTH POLICY APPROVED BY HEALTH COUNCIL

Brazil's National Health Council (CNS) has unanimously approved the National Information and Digital Health Policy, establishing guidelines for the digital transformation of the Unified Health System (SUS). Presented by Ana Estela Haddad, Secretary of Information and Digital Health at the Ministry of Health, the policy prioritizes the integration and strategic use of health data, strengthening of the National Health Data Network (RNDS), expansion of telehealth and adoption of new technologies. It also establishes guidelines for data protection, information security, workforce training, and digital governance. The policy is expected to strengthen interoperability among health information systems, improve the use of data for healthcare management and expand integration across Brazil. The initiative builds on the Ministry's efforts to expand the RNDS and advance digital health infrastructure, including discussions with the private sector to integrate hospitals, laboratories, and health insurers into the national data ecosystem. With CNS approval, the policy becomes a key institutional framework for expanding digital health in the SUS, with potential implications for telehealth, data governance, artificial intelligence, and health technology adoption. Read more.

HEALTHCARE JUDICIALIZATION IN PRIVATE SECTOR SURPASSES SUS IN 2026

For the first time, Brazil's private healthcare sector has recorded more new lawsuits than the Unified Health System (SUS), according to the National Council of Justice (CNJ). In the first half of 2026, more than 181,000 new cases involving health plans were filed, 10.4% above the 164,000 cases related to the public system. Medical and hospital treatments accounted for 43% of private-sector lawsuits, followed by disputes over adjustments and contracts, while medicines represented 15% of cases. São Paulo, Bahia, Rio de Janeiro, Pernambuco and Minas Gerais accounted for 72% of the cases. The CNJ and the National Supplementary Health Agency (ANS) point to the need for better classification of lawsuits, stronger administrative dispute resolution and closer coordination between regulators and the judiciary. The increase comes after the Supreme Federal Court (STF) established stricter criteria for judicial requests involving treatments not incorporated by ANS. Read more.

PRIVATE HEALTHCARE SLOWS MEDICINE INCORPORATION, INTERFARMA STUDY FINDS

The pace of new medicine incorporation into Brazil's private healthcare system has slowed significantly, according to a study by the Research-Based Pharmaceutical Industry Association (Interfarma). Annual additions to the National Health Agency's (ANS) coverage list fell from an average of 18.5 medicines to seven. While 37 medicines were incorporated between 2019 and 2020, only 28 were added between 2021 and 2024, and just 25% of medicines incorporated by the National Commission for the Incorporation of Health Technologies (Conitec) subsequently entered the private system. The study also points to the lack of predictability and standardized criteria in the ANS' Committee for the Update of the Health Procedures and Events List (Cosaúde), as well as the growing weight of budget impact in incorporation decisions. Restrictions on coverage of outpatient medicines are another barrier: 79% of medicines evaluated between 2022 and 2026 were denied incorporation for this reason, including 47 oral medicines for rare diseases and 18 for chronic immune-mediated conditions. Interfarma estimates that medicines account for only 7% of private healthcare expenditures, compared with approximately R$52.5 billion in losses from fraud, waste, and overuse in 2024. Read more.

PHARMACEUTICAL RETAIL SALES REACH R$3.9 BILLION IN FIRST HALF

Brazil's pharmaceutical retail sector generated R$3.9 billion in revenue in the first half of 2026, according to a Zetti Brasil study based on approximately 56 million purchases at 1,600 pharmacies. The monitored market grew 8.2% in revenue and 6.1% in sales volume,

outperforming overall retail, with an average ticket of R$70.04. Digital channels continued to gain ground, with online sales revenue increasing 14.7% and the number of transactions rising 12.3% year-on-year. The average online ticket reached R$82.37, 17.6% above physical-store purchases. Delivery revenue also grew 13.2%, while purchases by customers enrolled in loyalty programs accounted for 62.4% of the transactions analyzed. Read more.

FARMÁCIA POPULAR PROJECTED TO REACH R$6.8 BILLION IN GOVERNMENT TRANSFERS IN 2026

Brazil's Farmácia Popular program is projected to receive R$6.8 billion in government transfers to accredited pharmacies in 2026, a 13.1% increase from the R$6.01 billion distributed in 2025. Between January and May, the program had already transferred R$2.83 billion, averaging R$567 million per month. Independent pharmacies and pharmacy associations accounted for 54% of transfers in the period, or R$1.53 billion, while major chains represented R$1.3 billion. Despite the program's growth, its share of total pharmaceutical sales declined from 2.61% to 2.45%, as the broader market expanded faster, driven in part by GLP-1 medicines, whose sales increased 88.3% year-on-year. Read more.

BRAZIL MODERNIZES FARMÁCIA POPULAR AND CONSIDERS ADDING DIAGNOSTIC TESTS

Brazil's Ministry of Health has updated the regulation of the Farmácia Popular program, introducing technological modernization, stronger monitoring, and a Working Group to assess the addition of services such as blood and urine tests, rapid tests, telehealth, and therapeutic monitoring. The government will also study expanding the network in vulnerable areas and using mobile or advanced units in regions with limited access. The new rules strengthen risk-based oversight of accredited pharmacies, including automated sanctions and suspension in high- or very high-risk cases. The Sales Authorization System (SAV) will also be upgraded to improve security, traceability, and data integration. The program currently has 28,000 accredited pharmacies across more than 4,900 municipalities and provides 41 health products free of charge. Read more.

ANVISA EXPECTS TO REVIEW 13 SYNTHETIC GLP-1 APPLICATIONS BY DECEMBER

The Brazilian Health Regulatory Agency (Anvisa) expects to complete by December the analysis of 13 registration applications for synthetic GLP-1 analogues, potentially paving the way for more generic versions of injectable weight-loss medicines in Brazil. The arrival of these products is seen as a potential mechanism to reduce the use of medicines sold without sanitary registration. The agency concluded 261 pending applications for synthetic medicines in the first half of 2026, as part of efforts to reduce its regulatory backlog. The expansion of registered GLP-1 alternatives could increase competition and access while strengthening regulatory oversight of a market that has seen growing demand and concerns over unauthorized products. Read more.

IMPORTS OF WEIGHT-LOSS INJECTABLES RISE 85% IN BRAZIL

Brazilian imports of medicines containing semaglutide and tirzepatide, including injectable weight-loss products, rose 85% in the first seven months of 2026, reaching US$1.51 billion, according to Comex Stat data from the Ministry of Development, Industry, Foreign Trade and Services (MDIC). The figure compares with US$813 million in the same period of 2025. In July alone, imports surged to US$257.1 million, nearly three times the US$95.7 million recorded in June. The United States, Germany and Denmark were the main sources of these products. The rapid expansion is also increasing demand for specialized logistics, including temperature-controlled transportation and greater traceability. At the same time, the Brazilian Health Regulatory Agency (Anvisa) has strengthened oversight of imports and products involving semaglutide and tirzepatide amid growing demand for GLP-1 medicines. Read more.

WEIGHT-LOSS INJECTIONS GENERATE R$2.3 BILLION IN BRAZIL IN SIX MONTHS

Weight-loss injectable medicines have become a major consumer market in Brazil, with 13 million orders generating approximately R$2.3 billion in sales in the first six months of 2026, according to data cited by G1. The surge reflects the rapid expansion of demand for GLP-1 medicines, particularly products containing semaglutide and tirzepatide, which have gained prominence in the treatment of obesity and diabetes. The growth is also reshaping the pharmaceutical retail market, increasing demand for specialized distribution and temperature-controlled logistics while intensifying regulatory concerns over unauthorized products. The Brazilian Health Regulatory Agency (Anvisa) has expanded oversight of GLP-1 medicines amid the growing circulation of imported and irregular products, while the agency expects to analyze 13 applications for synthetic GLP-1 analogues by December, potentially increasing competition and access to registered alternatives. Read more.

BRAZILIAN HOUSE TO DEBATE ANVISA RESTRICTIONS ON PARAGUAYAN GLP-1 INJECTIONS

Brazil's House of Representatives will hold a public hearing to discuss the Brazilian Health Regulatory Agency's (Anvisa) restrictions on weight-loss injections containing tirzepatide produced and marketed in Paraguay. The hearing, requested by Representatives Fausto Pinato (União-SP) and Diego Garcia (União-PR) and to be held jointly by the Health and Science, Technology and Innovation Committees, will bring together Anvisa, physicians, researchers, lawyers, and patient representatives. The date has not yet been set, but the meeting is expected to take place within the next two weeks. The debate comes amid growing demand for lower-cost alternatives to Mounjaro, the only tirzepatide product currently authorized for commercialization in Brazil. The lawmakers question Anvisa's restrictions and the technical evidence supporting the measures, citing a Unicamp analysis that identified tirzepatide in samples of five Paraguayan products, although the study did not assess sterility, stability, or clinical safety. The discussion is also expected to address sanitary regulation, patient access, and the possibility of legislative measures, including a potential debate on patent-related alternatives. Pinato has also proposed an official mission to Paraguay to examine manufacturing, quality-control, and pharmacovigilance procedures. Read more.

CFM WARNS OF PENALTIES FOR PRESCRIBING UNREGISTERED TIRZEPATIDE

The Federal Council of Medicine (CFM) has warned that physicians who prescribe, indicate, administer or facilitate access to tirzepatide products without valid registration with the Brazilian Health Regulatory Agency (Anvisa), including the so-called "Mounjaro from Paraguay," may face ethical, administrative, civil and criminal proceedings. The council also prohibits the use of prescriptions to facilitate the acquisition of medicines imported without proper authorization, documentation, traceability, or invoice. The CFM reinforced that only Mounjaro, manufactured by Eli Lilly, is currently approved by Anvisa in Brazil and also raised concerns about compounded tirzepatide produced outside applicable sanitary rules. Read more.

BRAZIL OPENS PROCESS TO CONSIDER RECIPROCITY MEASURES AGAINST U.S. TARIFFS

Brazil's government has formally initiated the process for applying the Economic Reciprocity Law in response to new U.S. tariffs on Brazilian exports. The Chamber of Foreign Trade (Camex) will assess the American measures, while the Ministry of Foreign Affairs (MRE) will formally notify Washington and seek diplomatic consultations before any countermeasures are adopted. The tariffs affect approximately US$7.4 billion in Brazilian exports, with combined rates reaching up to 37.5% for some products. The process does not represent an immediate decision to retaliate. Under the law, Brazil could adopt measures including tariffs, import restrictions and suspension of commercial concessions, provided they are proportional to the economic damage identified. The government has emphasized that negotiations remain the priority and that any response will be evaluated cautiously, including its potential impact on Brazilian companies, supply chains, and access to imported inputs. The development is relevant to the

pharmaceutical sector given its exposure to international supply chains and imported inputs, particularly active pharmaceutical ingredients, and medical technologies. Read more.

U.S. TARIFF ON GENERIC DRUGS EXPECTED TO HAVE LIMITED IMPACT ON BRAZIL

The U.S. decision to impose tariffs on imported generic medicines is expected to have a limited direct impact on Brazil but is intensifying discussions over pharmaceutical sovereignty and domestic production. Brazil has a diversified generic medicines market and relies heavily on local manufacturing, reducing its exposure to potential disruptions in U.S. trade flows. The measure, however, could reinforce efforts to strengthen Brazil's pharmaceutical production capacity and reduce dependence on imported active pharmaceutical ingredients (APIs), particularly from Asia. The debate also highlights the strategic importance of expanding domestic capabilities in medicines considered essential to public health and strengthening supply-chain resilience. Read more.

MORE HIGHLIGHTS

House committee approves broader coverage of medicines for rare diseases

House committee approves rules for switching between biologics and biosimilars

Pharmaceutical sector asks Anvisa to clarify medicine sales on Shopee

Anvisa launches search tool for registered biosimilars

Anvisa moves international medical device manufacturer registration online

Anvisa may take up to nine months to review food advertising rules

Public consultation evaluates adding hypertension medicine to SUS

Brazil begins migration of SUS data to sovereign cloud

Health Ministry expands outcome evaluation to improve public policies

SUS to implement more effective test for colorectal cancer screening

Brazilian movement seeks to establish health literacy as permanent public policy

More than half of breast cancer patients delay treatment in SUS

Technology and ai expand sus partnerships with private hospitals

Brazilian study highlights neonatal screening for spinal muscular atrophy

One in three women is uncertain whether she is in perimenopause

Study warns of underdiagnosis of chronic kidney disease in Brazil

Senate debate calls for new sus treatments for rare blood disorder

Senate debate highlights access gaps for adrenal insufficiency patients

Doctors and patients call for national endometriosis policy

BRAZIL NEWS

Lula's lead over Bolsonaro narrows ahead of Brazil election, poll shows

Brazil's Lula launches reelection bid, aims to win back workers to his Workers Party

Bolsonaro campaign drafts debt-linked fiscal rule to replace Brazil framework

Brazil presidential race ramps up with catchy campaign earworms

Brazil Congress approves spending curbs as debt concerns mount

Brazil inflation slows in July, returns to central bank target range

Brazil central bank says inflation remains demand-driven despite growing impact of rate hikes

BRICS nations discuss linking payment systems and CBDCs, RBI chief says

Brazil central bank eyes expansion for Pix payment system as US trade scrutiny intensifies